FROM FREE ENTRY TO PATENT PROTECTION: WELFARE IMPLICATIONS FOR THE INDIAN PHARMACEUTICAL INDUSTRY

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Abstract—There has been fierce debate over the imposition of stronger intellectual property rights laws for pharmaceutical products in developing countries. This paper uses data from the Indian pharmaceutical industry to develop a structural model of demand, supply and entry. The estimation yields demand and supply parameters that indicate significant heterogeneity among firms both within and across different therapeutic segments. The estimated parameters are used to simulate patent enforcement and price deregulation for 43 drugs, which predicts large losses for consumers and relatively small gains in profits for the global patent holders.

I. Introduction

PHARMACEUTICAL industries in the developed world are typically associated with high entry barriers in the form of stringent patent laws. In contrast, patent laws for pharmaceutical products in many developing countries have historically been weak, often enabling local firms in these countries to market drugs that were still under patent protection in the West. This disparity in standards for intellectual property rights (IPR) protection has meant that the high costs of innovation have mostly been borne by the world's developed nations.

The heightened pace of globalization over the past two decades has led to the formalization of a more uniform legal framework for all fields of trade, including the important area of IPR protection. One of the most notable developments on this front was the formation of the World Trade Organization (WTO) in 1994. As a condition of its membership in the WTO, developing countries were expected to provide legal protection to all trade-related intellectual property rights (TRIPs), including pharmaceuticals. Because the new IPR regime involved a fairly dramatic overhaul of existing institutions, many countries were granted transitional periods to implement the new policy.

The TRIPs agreement fueled intense debate in developing signatory countries, especially over the imposition of stronger IPR protection in pharmaceuticals. Proponents of TRIPs cited the familiar arguments in favor of stronger IPR protection, contending that TRIPs would benefit developing countries in the long run by spurring the development of new drugs that are more relevant for local health conditions and providing incentives for innovation to local producers. Its opponents countered that the purchasing power of developing country consumers was too low to significantly affect the level and direction of global research and development (R&D), even in the presence of strong local patent protection for drugs. According to such critics, the large gap in purchasing power between the developing and the developed world, in conjunction with the fact that most existing patents were held by giant multinationals from the world's most developed nations, meant that the primary effect of TRIPs in developing countries would be higher prices for local consumers and a transfer of rents from local firms to foreign patent holders (Lanjouw, 1998a; McCalman, 2001).

TRIPs had far-reaching implications for the industrially more advanced developing countries such as India, which had been very successful in building an indigenous generic pharmaceutical industry with the help of its lax patents laws. This paper studies the welfare implications of weak patent laws in the Indian pharmaceutical industry and adds to a growing literature that focuses on the transition by developing countries to the stronger IPR regimes traditionally favored by the developed world. Most relevant to this paper is previous work by Chaudhuri, Goldberg, and Jia (2006), who study the quinolones family of antibacterial drugs in India. In their study, demand and cost estimates that are recovered from a multistage budgeting model are used to perform counterfactual policy simulations of stronger patent enforcement for the selected drugs. The simulations suggest that the losses to the Indian economy of withdrawing the four domestic product groups from this subsegment would be on the order of $450 million, an overwhelming portion of which results from the reduction in consumer surplus. The gain in profits for the foreign patent holders is estimated to be only approximately $53 million.

In this paper, I use retail sales data on pharmaceutical products sold in India before the TRIPs agreement was to be implemented. Using three years of such data, I develop a structural model of demand, supply, and entry for 155 pharmaceutical products in India. The estimation of the model recovers demand- and supply-side parameters, which are used to simulate the changes in consumer surplus, profits, market prices, and market quantities that would result from patent enforcement (and price deregulation, whenever applicable) for 43 drugs in which foreign firms were present. The paper adds to the existing work on the topic, particularly that by Chaudhuri et al., in several ways. First, the sample covers a significantly larger number of drugs than has previously been studied. Second, the free entry setting that existed during the sample period is used to recover firms' fixed costs. And finally, the model allows a substantial amount of differentiation among firms and across drugs, which proves to be an important factor in the estimation.

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For the 43 drugs for which I simulate patent enforcement, the total loss in consumer welfare from patent enforcement and price deregulation is estimated to be $378.5 million, which amounts to an average loss of $9 million per drug and an overall decrease in consumer surplus of 48% from the free entry scenario. In addition, patent enforcement and price deregulation are together estimated to result in a total loss of almost 8.5 million patients, representing a decrease of over 50% from the free entry scenario. In contrast, the average annual gain to the foreign patent holder from this policy simulation exercise is estimated to be $1.4 million per drug.[1] Firm and drug characteristics are found to play a large role in predicting demand and supply patterns across different pharmaceuticals products markets and in the counterfactual policy simulations

In the two sections that follow, I review the relevant literature and provide a brief background of the Indian pharmaceutical industry. In section IV, I discuss the data and some basic descriptive statistics. In sections V to VII, I develop the model of demand, supply, and entry. In section VIII, I discuss the results of the estimation of this model. In section IX, the parameter estimates from the model are used to perform counterfactual simulations that assess the effect of patent enforcement on welfare indicators. Section X concludes.

II. Literature Review

This paper is related to three broad strands in the literature: previous work on demand and competition in pharmaceuticals markets, the literature on entry into markets, and related literature on the value of strong IPR protection, particularly in developing countries.

Demand estimation for pharmaceutical products has been of interest to economists because of the importance of the products in question and the somewhat unique nature of the purchasing process, where the consumer—in this case, the patient—is restricted in range of possible purchases by a prescription from a doctor. In addition, the choice of the consumer is often influenced by other factors at the dispensing stage, such as insurance policies or recommendations by pharmacists.

Models of demand estimation for the pharmaceutical industry typically incorporate the highly differentiated nature of the industry, where a variety of product choices are often available to patients to treat a particular indication.[2] Ellison et al. (1997) model demand as a multistage budgeting problem for four drugs in the cephalosporins segment of antibacterial drugs and compute own and cross-price elasticities of demand between branded and generic drugs. Stern (1996) uses a discrete-choice framework to estimate demand for four categories of drugs and evaluates patterns of substitutability between branded and generic versions of these drugs. Cleanthous (2003) uses a random-coefficients logit specification to study the antidepressants market in the United States and estimates large patient welfare gains from innovation in this market.

The literature on the pharmaceutical industry in the United States has also focused on price competition between branded and generic products and on the role of quality in the demand for pharmaceuticals products. For example, some models predict that if some quality-conscious consumers place a very high premium on pioneer or other branded products, then entry by generics could allow the branded firms to increase prices for this loyal group of price inelastic consumers. While Frank and Salkever (1997), Caves, Whinston, and Hurwitz (1991), and Grabowski and Vernon (1992) find theoretical and empirical support for such a market segmentation story, Wiggins and Maness (2004) find that brand loyalty or quality consciousness might not be such a significant aspect of demand for pharmaceuticals products.

Several papers have developed rigorous econometric techniques to assess the competitive effects of entry on markets. Entry can be modeled in a number of ways, but because of computational complexities, most entry models make restrictive assumptions on either the demand or the supply side.[3] Notable work in the empirical entry literature includes the pioneering work of Bresnahan and Reiss (1990, 1991), who formalize the idea that with free entry competition and U-shaped average costs, a demand entry threshold relates the market size to the number of firms in the market. Berry and Waldfogel (1999) use the same principle to compute fixed costs in the market for radio broadcasting and relate the free entry number of firms to the social optimum. Seim (2006) jointly estimates the location and entry decisions of firms in the video rental industry and finds high returns to differentiation in this industry. Ishii (2008) studies interconnected markets in ATM networks by estimating a structural model of consumer and firm behavior and confirms that network effects are important in this industry.

Entry in the context of the pharmaceutical industry in the United States has been studied by Scott Morton (1999), who finds that generic drug manufacturers tend to enter markets with supply and demands characteristics similar to those of the firm's existing drugs. The study concludes that heterogeneity among potential entrants is an important factor in predicting entry into markets because of both the technical and demand side characteristics of drugs.

Finally, this paper adds to the literature on the implications of stronger patent protection, particularly in developing countries. Patents create short-term monopolies but are typically

[1] In its ultimate form, TRIPs compliance in India did not involve strict patent enforcement for any drug that was already being sold in the country by generic manufacturers before India's transition deadline of 2005. For this reason, the results of these patent simulations cannot be tested against real post-2005 prices.

[2] See Anderson, de Palma, & Thisse (1992), for an excellent general discussion of discrete choice models for differentiated goods industries.

[3] Because my primary interest is recovering substitution patterns among different firms and molecules, I use a static model of entry. This assumes that all fixed costs are per-period costs such as marketing and distribution and that one-time sunk costs of entry are zero.

credited for providing dynamic incentives for future innovation. While the study by Chaudhuri et al. (2006) focuses on the demand-side implications of stronger patent protection, other studies have considered its supply-side effects, such as the ability of stronger IPR protection to stimulate local innovation. An examination of this literature suggests a nuanced role for IPR protection in this context: strong IPR protection appears to be most effective in industries where the fixed costs of innovation are high and imitation of an existing product is easy (such as in chemicals and pharmaceuticals) and in countries that display some threshold level of absorptive capacity, measured by factors such as the country's stock of human capital and its degree of economic freedom.[4]

III. Industry Background

Following its independence from British rule in 1947, India retained its patent laws from its British colonial days, and the country was home to some of the highest drug prices in the world. However, in 1970, a major legislative change, the Indian Patent Act, was enacted with a view to lowering the prices of essential products and developing the infant domestic industry. In a departure from the customary practice in most developed countries, this new legislation provided official recognition to process rather than product patents for pharmaceuticals. Process patents allowed a small modification in the synthesis of a known chemical entity to yield a new patent and enabled several firms to produce essentially the same drug. As a result, drugs that were still protected by patent rights in much of the developed world were marketed locally by Indian firms at a fraction of the R&D cost. While domestic firms thrived under the opportunity provided by the 1970 Patent Act, the act's controversial provisions caused the exit of many multinational drug manufacturers from India. Consequently, between 1970 and 1993, the market share of multinational pharmaceutical companies in India fell from 80% to 39%.

After 1994, the TRIPs-catalyzed transformation of India's patent laws led to the introduction of three amendments to the original 1970 Patent Act. The last of these amendments occurred in early 2005 and brought patents of pharmaceutical products into effect in India. Due to criticism and concern about the effect of pharmaceutical patents on domestic drug prices, the Indian government retained legitimate means for balancing innovation incentives against the social costs of pharmaceutical products patents. For example, the Indian Patent Office holds a great deal of discretion in setting the terms for government-compelled compulsory licenses that would allow generic producers to market under-patent drugs in India alongside the primary patent holder.

[4] For cross-industry studies on the role of IPR, see Mansfield (1986), Levin et al. (1987), and Lanjouw (1998b). For cross-country studies on the same issue, see Chen and Puttitanun (2005) and Qian (2007). For supply-side effects of TRIPs in India, see Lanjouw and Cockburn (2000), Cockburn (2008), and Dutta and Sharma (2009).

IV. Data

A. Data Sources

The primary sources of data for this paper are the retail pharmacy audits of ORG-IMS, India's best-known market research firm for pharmaceuticals. The audit provides detailed product-level information—estimates of retail sales, price, dosage form, launch dates, brand name, active pharmaceutical ingredient, therapeutic categorization—on all pharmaceutical products sold in India by 300 of the largest firms in India. The sample covers approximately 90% of all pharmaceutical sales in India during the years 2001 to 2003, before product patents began to be enforced in the industry. A secondary data source is the ORG-IMS Prescription Audit, which tracks prescriptions by doctors of different specializations in a large cross-section of towns and cities in India. The data on prescriptions are used to construct an exogenous measure of market size, which is described in this section 4.[5]

Because drugs can be grouped into separate "markets" on the basis of the indications that they treat as well as their chemical composition, I collect additional data on the pharmacological properties of the molecules in my sample, the indications treated by these molecules, and their dosage and length of treatment from a variety of pharmacological sources.[6]

Sample: I restrict attention to only oral systemic forms of presentation for single-ingredient products. I focus on these products because the firms in my sample are found to launch multiple-ingredient products only after having entered the market for each of its individual constituents, whenever such entry is possible. This could make the pool of potential entrants for such products—and the entry decision—very different from that for single-ingredient products.[7] I leave out injectable dosage forms because oral systemic forms are likely to have been purchased in different settings from injectables, which are usually administered in hospitals. I also drop from my sample all nonprescription drugs because my measure of market size is least likely to be consistent with the real market size for such products. The final sample consists of 155 molecules spread across five broad therapeutic categories and fourteen groups of indications, described in table 1. I collapse the quarterly data for the years 2001 to 2003 to the yearly level in the empirical analysis that follows.[8]

The 155 molecules together account for almost Rs 58 billion in revenue ($1.28 billion) in 2003, the final year of the

[5] The data suggests that on average, approximately 73% of the prescribed doses are not filled. But perhaps this is not surprising given that even in the United States, the outside good share for some drug categories has been estimated to be over 50%.

[6] For example, the medical handbook *Drug Facts and Comparisons* (2004).

[7] In addition, I found that the retail audit data do not provide clear dosage information about the active chemical ingredients in products with multiple ingredients. This makes it difficult to extend the empirical analysis to such products.

[8] This is done to minimize problems caused by serial correlation between the error terms across time.

TABLE 1.—FIRMS AND MARKETS, BY THERAPEUTIC CATEGORIES

Therapeutic Group	Group Code	Indication Group	Pharmacological Market	Number of Molecules	Number of Firms
Alimentary & metabolism system	A	Gastroprokinetic	Gastroprokinetic drugs	4	50
		Antiemetic	Antiemetic drugs	7	60
		Antidiabetic	Meglitinides	2	9
			Sulfonyureas	4	55
			Thiazolidinediones	2	34
		Antiulcerant	H2 antagonists	5	69
			Proton pump inhibitors	3	104
Cardiovascular system	C	Antihypertensive	Ace inhibitors	5	51
			Alphablockers	4	18
			Angiotensin II receptor blockers (ARBs)	5	33
			Beta blockers	5	51
			Calcium channel blockers	7	64
			Diuretics	4	17
Systemic anti-infectives	J	Antibacterial	Cephalosporins	7	110
			Lincosamides	2	5
			Macrolides	4	88
			Penicillins	4	117
			Quinolones	10	127
			Tetracyclines	4	71
		Antiviral	Antiviral Drugs	2	12
Musculoskeletal system	M	Antirheumatic	Coxibs	3	85
			Nonsteroidal anti-inflammatory drugs (NSAIDs)	7	132
Nervous system	N	Anti-Parkinson's	Anticholinergic	3	13
			Dopaminergic	2	11
		Antipsychotic	Novel	6	26
			Typical	7	22
		Antianxiety	Antianxiety drugs	6	72
		Antidepressant	Serotonin reuptake inhibitors (SRI's)	7	37
			Tricyclic	9	30
		Antiepileptic	Antiepilepsy drugs	11	32
		Antiinsomnia	Antiinsomnia drugs	4	23

The group codes are used in the balance of tables in this paper.

TABLE 2.—TOTAL MOLECULE AND FIRM REVENUES, BY THERAPEUTIC GROUP

	Molecule Revenue			Big Domestic Firm Revenue			Foreign Firm Revenue			Small Domestic Firm Revenue		
Therapeutic Group	Observations	Mean	s.d.	Observations	Mean	s.d.	Observations	Mean	s.d.	Observations	Mean	s.d.
A	26	402.4	407.0	8	513.2	271.5	10	182.7	259.3	127	35.7	86.8
C	30	285.6	368.4	8	467.2	276.1	12	163.4	216.3	67	42.8	87.1
J	33	735.1	769.8	8	940.5	1126.3	15	204.2	413.1	158	86.5	243.2
M	10	563.9	523.9	8	219.0	186.9	9	144.0	254.5	126	20.6	42.8
N	53	164.7	226.7	8	518.6	524.0	12	179.6	210.0	71	34.2	90.7

All revenues are for 2003 and in Rs. million. Rs 45 = $1.

sample. Over the three years between 2001 and 2003, the total revenue for these drugs increased by 26%, amounting to an additional Rs 12 billion ($267 million) in revenue over the three-year period. There is variation in both the size and growth rates of revenue across the different therapeutic categories during this time. The anti-infectives segment is the biggest category in terms of revenue, commanding Rs 24 billion ($0.5 billion) in revenue in 2003. This is approximately 2.5 times the revenue of the next largest category and reflects the preponderance of bacterial diseases in India. Drugs that treat the alimentary and metabolism, cardiovascular, and nervous systems are reasonably close to each other in terms of revenue in all three years. Finally, drugs for the musculoskeletal system bring in the lowest total revenue in all three years. In terms of rates of growth, the highest rates of growth are seen in drugs of the nervous system, followed by cardiovascular drugs and drugs of the alimentary and metabolism system. This is consistent with industry reports about the increasing popularity of "lifestyle drugs" in India—drugs that treat depression, anxiety, heart disease, and diabetes and are associated with India's hectic urbanization during the past decade.

Table 2 presents more detailed data on revenues in the Indian pharmaceutical industry. The revenue earned by a typical molecule ranges from Rs 735 million ($16 million) in the anti-infectives segment to Rs 165 million ($4 million) for drugs of the nervous system.[9]

[9] The latter category contains the largest number of molecules at 53.

V. Demand

A "market" is defined as group of molecules that treat the same set of indications and share common pharmacological properties. There is some variation in the number of markets that can be assigned to an indication group across the fourteen such groups in the sample. Some indications, such as insomnia and anxiety, are treated by a relatively small number of molecules that are all close substitutes for each other. For other indications such as hypertension, available therapies can be broken into a number of subsets, whose chemical composition differs by group and makes the molecules in two distinct groups unlikely substitutes for each other. The framework for demand incorporates two distinct tiers of differentiation: the first tier comprises chemically similar molecules that compete to treat the same set of indications. The second tier of product differentiation occurs at the level of the molecule, where products are differentiated in terms of physical characteristics such as strength, pack size, and dosage form, as well as in terms of the characteristics of the product manufacturer.

A. *The Two-Level Nested Logit Model of Demand*

The two tiers of differentiation are accommodated by a two-level nested logit framework of demand.[10] Formally, let a market L be a group of chemically similar single-ingredient molecules. Each market comprises several molecules $L_1, \ldots, L_N$, where L_i is a unique molecule. Let S_k be the set of all products for the molecule L_k. Consumer $i's$ utility from consuming firm j's product in molecule m is given by

$$u_{ijm} = \delta_{jm} + \zeta_{im} + (1 - \sigma)\epsilon_{ijm}, \tag{1}$$

where δ_{jm} is the mean utility for the product defined as

$$\delta_{jm} = x_{jm}\beta + \alpha p_{jm} + \xi_{jm}. \tag{2}$$

In equation (1), each ϵ_{ijm} is or independent and identically distributed (i.i.d.) extreme value. The term σ captures the degree of correlation between the alternatives in the nest. As the parameter σ approaches 1, the within-group correlation of utility levels goes to 1, and as σ approaches 0, the within-group correlation of utilities goes to 0. Equation (2) defines the mean utility for a product jm to depend on x_{jm}, a vector of product characteristics, p_{jm}, the product price, and ξ_{jm}, a product-level shock that includes unobservable firm-specific variables that could affect utility.

In this framework, the well-known formulas for market shares are given by

$$s_{j/m} = \frac{e^{\delta_{jm}/(1-\sigma)}}{D_m},$$

where $s_{j/m}$ is the probability of choosing product j, given the choice of group m and

$$D_m = \left[\sum_{h \in S_m} e^{\delta_{hm}/(1-\sigma)}\right],$$

The probability of choosing group m is given by

$$s_m = \frac{D_m^{1-\sigma}}{\left[1 + \sum_k D_k^{1-\sigma}\right]}.$$

Then the market share of product jm is given by

$$s_{jm} = s_m s_{j/m}.$$

The share of the outside good in this framework is

$$s_o = \frac{1}{\left[1 + \sum_k D_k^{1-\sigma}\right]}.$$

Berry (1994) shows that this can be worked out to be the following simple linear regression:

$$ln(s_{jm}) - ln(s_o) = x_{jm}\beta - \alpha p_{jm} + \sigma ln(s_{j/m}) + \xi_{jm}. \tag{3}$$

The expression on the right side of equation (3) is the sum of the mean utility defined in equation (2) and the term $\sigma ln(s_{j/m})$. This means that the estimated coefficients of the product characteristics from the demand estimation capture the effect of each of these characteristics on the mean utility. The term $ln(s_{j/m})$ helps to identify the within-group correlation σ. Because p_{jm} and $s_{j/m}$ are both potentially correlated with the firm-specific unobservable in equation (3), I describe instruments that are used to correct this endogeneity.

B. *Market Shares, Quantities, and Market Size*

Equation (3) is formulated in terms of market shares as opposed to quantities. Market size is assumed to be exogenous in that every patient diagnosed with an indication in the sample has the option of not purchasing any of the options. In this case, he is said to purchase the outside good, which is computed to be the difference between the size of the market and the total quantity sold of the inside goods in the market.

In order to be able to make comparisons across different molecules, I consult the pharmacological literature to assign a patient-day dose measure to each product in the sample. The patient-day measure also aids in approximating the market size. For each of the fourteen indication groups, the ORG-IMS Prescription Audit provides an estimate of the total number of people who were diagnosed with an indication from the group during the year 2003. The market size for an indication is the number of prescriptions for the indication multiplied by the average length of drug therapy. When an indication group comprises multiple indications—as, for

[10] While the Independence of Irrelevant Alternatives (IIA) property does not hold in general in the nested logit specification, defining the nests proves to be critical to minimize the IIA implications of the standard logit model.

TABLE 3.—AVERAGE MOLECULE PRICE AND REVENUE, BY FIRM TYPE

Therapeutic Group	A. All Molecules (152)						B. Molecules with Foreign Firms (85)					
	Big Domestic		Foreign		Small Domestic		Big Domestic		Foreign		Small Domestic	
	Price	Revenue	Price	Revenue	Price	Revenue	Price	Revenue	Price	Revenue	Price	Revenue
A	5.3	42.8	8.7	79.4	4.8	10.5	5.8	48.8	8.7	79.4	4.6	10.6
C	8.0	49.8	13.5	78.4	7.0	13.7	9.1	64.3	13.5	78.4	7.3	16.1
J	21.8	63.2	38.5	60.0	18.8	18.8	25.0	71.4	38.5	60.0	20.7	20.1
M	3.0	36.5	2.7	108.0	2.4	9.5	2.3	45.7	2.7	108.0	2.1	9.5
N	9.0	29.6	18.8	82.9	7.0	6.9	10.4	37.7	18.8	82.9	8.4	8.2

All revenues are for 2003 and in Rs. Million. Rs 45 = $1.

example, is the case for infectious diseases—the market size is the sum of the market sizes of each indication that belongs to the group.

Because the prescriptions data are by indication rather than by the drug prescribed, I do not have data on the size of each market when multiple markets exist for the treatment of the same indication. For such cases, I use sales data from the primary data set to construct weights that divide the composite market size for the whole indication into separate market sizes for each distinct pharmacological group.

The unit of observation in the estimation of demand is at the firm-molecule-year level. It is customary for firms to sell each molecule in multiple dosage forms and pack sizes. I aggregate across all presentations of a molecule sold by a firm to arrive at the measure of the total number of patient-day doses sold for a molecule by a firm. The market share of the firm then is the total doses sold divided by the market size. As shown in equation (3), the dependent variable in the demand estimation is *LnShareDiff,* the difference between the log of firm share and the log of the outside good share.

Finally, the variable *LnCondShare* is the log of a firm's within-group share, which is the market share of the firm when conditioned on the choice of the molecule. The conditional market share is equal to the number of doses a firm sells of the molecule divided by the total number of patient-day doses sold of the molecule.

C. *Product Characteristics and Instruments*

In addition to reporting the price and quantity sold of each product, the retail audit data contains other information about the products, which makes it possible to construct a number of variables that could play a role in explaining the choice of product.

The conversion of each product in the data into a patient-day measure allows us to create a measure of price that makes comparison across different molecules possible. The variable *Price* is calculated as the average price at which a firm sells one daily dose of a molecule.[11] *FormNo* is a variable that equals the number of presentation forms a firm has for that particular molecule. The variable *Branded*, which takes the value 0 if the firm produces only generic versions of the molecule and 1 otherwise, is used to capture the effect of brand differentiation by a firm. *FirmExp* refers to the number of years since the firm launched a molecule in that market. *MolAge* is the number of years since the molecule was launched in India. *MktPres* is a measure of the firm's market presence and the ratio of the number of molecules the firm produces in the market to the total number of molecules currently being produced in that market. The expected effect of *Price* in the demand estimation is negative, whereas *FormNo*, *Branded*, *MktPres*, and *FirmExp* would be expected to affect utility positively. The effect of *MolAge* on utility is theoretically ambiguous. On the one hand, it is possible to imagine that older drugs tend to be valued less than newer drugs. However, if new varieties of drugs are only minor improvements on existing therapies or if older therapies have established strong loyalty or trust among consumers, they will command a higher market share, and *MolAge* may have a positive effect on demand.

I also create two other firm-level variables that are significant in explaining demand and in the estimation of fixed costs, described in the sections that follow. The variable *BigDom* refers to eight big domestic firms that are prominent not only for the size of their overall portfolio across all therapeutic categories but also for their presence in international markets. *Foreign* takes the value 1 for the twenty firms of foreign origin and 0 otherwise.

Table 2 presents the total firm-level revenues in each broad therapeutic category. This data are broken up by firm type and reveal at least two striking facts. First, big domestic firms earn the higher total revenue in every single therapeutic category, while small domestic firms have the lower total revenue. Second, both big and small domestic firms tend to earn disproportionately higher revenue from the anti-infectives segment, while foreign firms' revenues are more evenly distributed across the different therapeutic categories.

Table 3 considers the per molecule price and revenue of each firm type. A salient observation from this table is that on average, foreign firms are typically able to charge higher prices but still maintain higher revenues than both categories of domestic firms in three of the five broad therapeutic categories. When the same analysis is restricted to molecules in which there is some foreign firm presence, this result can also be extended to a fourth category. In the remaining fifth category, systemic anti-infectives, the foreign firm's price is,

[11] *Price* is the simple, rather than a weighted, average of the daily dose price of each product sold by a firm within a molecule category. The difference between the simple average and the sales-weighted average is negligible.

on average, 54% higher than that of a big domestic firm, and its revenue is 19% lower. Tables 2 and 3 together indicate that foreign firms enter fewer molecules than big domestic firms but have dominant positions when they do enter.

Table 4 presents additional characteristics of each firm type, focusing on their average experience and product portfolio. Foreign and small domestic firms are present in all 31 markets whereas big domestic firms are present in 30 of the 31 markets. However, the average product portfolio of a big domestic firm consists of 66 molecules and is spread across 25 markets. The corresponding figures for foreign and small domestic firms are much lower. Each foreign firm on average produces approximately 7 molecules and has a portfolio that is spread across 6 markets. Small domestic firms on average produce close to 11 molecules and are spread across 7 markets. Finally, table 4 shows that the average experience of a big domestic firm in a market is 9.6 years, which is greater than that of foreign firms, at 7.5 years, and small firms, at 4.8 years.

Both price and the within-group share are potentially endogenous in equation (3), which necessitates the use of instruments. Berry, Levinsohn, and Pakes (1995) and Berry (1994) show that valid instruments in this framework for price and within-group shares are functions of the characteristics of other firms. These are correlated with the price and within-group shares of an individual firm through the markup conditions but uncorrelated with the product-specific error term. Following this principle, I construct instruments for a firm's price and its within-group share using the sums and the sums of squares of its rivals' characteristics.[12]

VI. Supply

In this section, I formalize the supply side of the market with the goal of recovering the marginal costs of production. For most drugs in the sample, marginal costs are recovered by drawing inference about costs from the profit-maximization conditions of each firm. However, 14 of the 155 molecules in the sample are under price control, for which a specified margin is allowed over the marginal costs of production. For these drugs, I use the allowed margins on these products to back out the marginal cost.

A. *Drugs Free of Price Control*

Since a large number of firms in any given market are multiproduct firms, I incorporate this feature in the supply-side model. In a differentiated goods market, a multiproduct firm sets prices for each of its products after taking into account the effect of these prices on the demand for all of its other products in the market. I assume that prices in the industry are set in a Bertrand-Nash equilibrium.

Let product s_{jm} be the share of firm j's product in molecule m. Let ϑ_j denote the set of products produced by firm j in the market. Firm j's profit function can be written as

$$\Pi_j = \Sigma_{h\in\vartheta_j}(p_{jh} - c_{jh})s_{jh}M.$$

The first-order condition of firm j with respect to the price of any particular molecule m is given by

$$\partial\Pi_j/\partial p_{jm} = s_{jm} + \Sigma_{h\in\vartheta j}(p_{jh} - c_{jh})\partial s_{jh}/\partial p_{jm} = 0. \quad (4)$$

For the two-level nested logit model, the following conditions can be derived for the response of market shares to own and other prices:

$$\partial s_{jm}/\partial p_{jm} = -\alpha s_m s_{j/m}\left[\frac{(1 - s_{j/m})}{(1 - \sigma)} + s_{j/m}(1 - s_m)\right] \quad (5)$$

$$\partial s_{jh}/\partial p_{jm} = \alpha s_h s_m s_{j/m}. \quad (6)$$

Following Berry et al., (1995), a matrix Δ of dimension J X J can be created, where J is the total number of firm-molecule-year-level observations:

$$\begin{aligned}\Delta &= -\partial s_r/\partial p_j, \text{ if } r \text{ and } j \text{ are produced by the same firm}\\ &\quad \text{in the same market and year}\\ &= 0, \text{ otherwise.}\end{aligned}$$

In vector notation, equation (4) can then be written as

$$\begin{aligned}&s(p, x, \xi) - \Delta(p, x, \xi)(p - c) = 0\\ &p = c + \Delta(p, x, \xi)^{-1}s(p, x, \xi).\end{aligned} \quad (7)$$

The matrix Δ is constructed by using the observed values for the market shares in the data and the estimated coefficients for α and σ from the demand side. $\Delta(p, x, \xi)^{-1}s(p, x, \xi)$ is a measure of the predicted markup for a multiproduct firm in this industry. Let the marginal cost of firm j of producing molecule m be defined as

$$\ln c_{jm} = c_m + \omega_{jm}, \quad (8)$$

where c_m is the constant component of the marginal cost and ω_{jm} is a firm-specific deviation from this constant cost. Equations (7) and (8) allow us to generate the following supply-side equation:[13]

$$\ln(p_{jm} - \Delta(p, x, \xi)^{-1}s_{jm}(p, x, \xi)) = c_m + \omega_{jm}. \quad (9)$$

[12] The instruments used in the reported regressions are constructed using the characteristics *FirmExp*, *MktPres*, and *FormNo*. These instruments are valid only if a firm's competitors do not change these characteristics in anticipation of the firm's product-specific shock. Since *FirmExp* and *MktPres* are most likely to meet this condition, a robustness test of the instruments uses only these two characteristics to construct instruments and finds similar results.

[13] To potentially improve the precision of the estimates of marginal costs in equation (9), I tried an alternative specification that adds a vector of controls including variables that are expected to be systematically correlated with the pricing decisions of firms, such as the firm's and its rivals' characteristics. The results are found to be consistent across both specifications.

TABLE 4.—FIRM CHARACTERISTICS, BY FIRM TYPE

		Mean	s.d.	Minimum	Maximum
(a) Big domestic firms (8 firms, 135 molecules, 30 markets)	Average number of molecules	66.0	17.7	38.0	85.0
	Average number of markets	25.1	3.6	19.0	29.0
	Average market experience	9.6	4.6	1.5	17.3
(b) Foreign firms (20 firms, 89 molecules, 31 markets)	Average number of molecules	7.3	4.9	1.0	18.0
	Average number of markets	5.7	4.0	1.0	15.0
	Average market experience	7.5	2.33	0.0	18.5
(c) Small domestic firms (187 firms, 148 molecules, 31 markets)	Average number of molecules	10.6	10.7	1.0	59.0
	Average number of markets	6.8	4.9	1.0	25.0
	Average market experience	4.8	2.1	0.4	12.0

B. *Drugs under Price Control*

Of the 155 drugs in the sample, 14 are price controlled. The pricing rule used by the regulatory authority allows a small, prespecified margin over the cost of materials, the cost of converting the bulk drug into the formulation, and the cost of packaging the drug. I estimate the marginal costs of these products with the following equation,

$$p_{jm} = c_m + b_m c_m,$$

where c_m is once again the constant-cost component and b_m is the allowed margin on each product, which varies between 10% and 15%.

VII. Entry

The final part of the model is the estimation of the fixed costs for each molecule. Because of the computational difficulties associated with modeling individual firm-level differences in fixed costs, entry models often rely heavily on homogeneity assumptions. However, the standard symmetry assumptions seem less plausible in the present context because of the very large number and variety of firms in the industry. To address this concern, I switch to a model of entry that uses two simplifying assumptions.

The first assumption allows some heterogeneity in fixed costs across different kinds of firms, while still imposing a degree of symmetry to ease the estimation of fixed costs. Firms are divided into the three categories defined in an earlier section—big domestic, foreign, and small domestic firms—and fixed costs are backed out separately for each of these categories in each market.[14] This categorization seems fairly natural because foreign and domestic firms are likely to have very different fixed costs owing to differences in their marketing and distribution networks in India. Among the set of domestic firms, the scale of operation as well as the marketing and distribution networks of big domestic firms are potentially very different from those for all other domestic firms, which are likely to be reflected in their fixed costs. The second assumption is that firms behave as single-product firms within a given market. This helps to abstract away from the large variety of product portfolios across different firms in any given market, including firms that may belong to the same firm type category. Given the low cross-price elasticities estimated between molecules that compete in the same market, this assumption does not seem to be too restrictive. The simplified symmetric single-product firm model of entry is developed below.

A. *Equilibrium Entry Conditions*

I model a firm's entry decision into an individual molecule by assuming that fixed costs are identically distributed for each category of firm in a given molecule.[15] As in Bresnahan and Reiss (1991) and Berry and Waldfogel (1999), fixed costs are estimated under the assumption that N firms are observed to produce a particular molecule if N firms expected to make positive profits but $N + 1$ firms did not. Let a firm's type be represented by f, where $f = B$ (big domestic), F(foreign), and S (small domestic). Then N_{Bm}, N_{Fm}, N_{Sm} represents the observed number of firms of each type in molecule m if the following condition holds for $f = B,\ F,\ S$:

$$E\pi_{Fm}(N_{fm}, N_{-fm}) - K_{fm} > 0 \ \&\ E\pi_{Fm}((N_{fm} + 1), N_{-fm}) - K_{fm} < 0.$$

B. *Symmetric Market Shares and Prices*

The assumption of symmetry within each firm type can now be used to express market shares and prices as functions of the number of firms in a molecule. I restrict mean utility for each firm type within each molecule to be identical but allow heterogeneity across firm types and across molecules by specifying the mean utility for a product containing molecule m produced by firm type f to be

$$\delta_{fm} = \sum X_{fm}\widehat{\beta_{fm}}. \tag{10}$$

X_{fm} is the average value for each firm type's characteristics for that molecule, and $\hat{\beta}$ is the vector of estimated coefficients for these characteristics from the nested logit

[14] In other words, firms of the same type make entry decisions into a molecule with symmetric expectations. Ex-post differences in their outcomes should be attributed to unobservable components of demand and costs.

[15] The entry decision could be modeled as a complex portfolio decision where firms choose the optimal combination of molecules in any given market. However, with even as few as three distinct molecules, this requires the imposition of a large number of inequality constraints and becomes a computationally infeasible task.

demand regressions. The characteristics included in the mean utility are those that were used during the estimation of demand: *MolAge*, *Price*, *FirmExp*, *MktPres*, *FormNo*, *Branded*, *BigDom*, and *Foreign*.

Restricting the mean utilities to be equal within each category of firms allows us to express the market share for each of type of firm in each molecule in terms of the number of firms in each molecule. The conditional market shares of a firm of firm type f are given by

$$s_{f/m} = \frac{e^{\delta_{fm}/(1-\sigma)}}{N_{Bm}e^{\delta_{Bm}/(1-\sigma)} + N_{Fm}e^{\delta_{Fm}/(1-\sigma)} + N_{Sm}e^{\delta_{Sm}/(1-\sigma)}}. \tag{11}$$

Denoting $N_{Bm}e^{\delta_{Bm}/(1-\sigma)} + N_{Fm}e^{\delta_{Fm}/(1-\sigma)} + N_{Sm}e^{\delta_{mS}/(1-\sigma)}$ as $D_{m,}$ the overall share of each molecule m is given by

$$s_m = \frac{D_m^{1-\sigma}}{\left[1 + \sum_k D_k^{1-\sigma}\right]}. \tag{12}$$

In order to be able to relate profits to the number of firms in each market, prices need to be mapped to the number of firms in a molecule. If firms are modeled to be multiproduct oligopolists, one would have to account for the different portfolio of products seen among firms in the actual data. Since this violates the assumption of symmetry within each firm type, I abstract away from these complications and provide an alternative approach.

C. Single-Product Firm Model

If firms behaved as single-product oligopolists, then a firm f's profit function for an individual molecule m can be described as

$$\Pi_{fm} = M(p_{fm} - c_m)s_{fm}.$$

The first-order condition for this firm gives rise to

$$p_{fm} = c_m - s_{fm}/(\partial s_{fm}/\partial p_{fm}).$$

Using equation (5) and the assumption of within-firm type symmetry, this can be rewritten as

$$p_{fm} = c_m + \frac{(1-\sigma)}{\alpha[1 - \sigma s_{f/m} - (1-\sigma)s_{fm}]}. \tag{13}$$

From equations (11), (12), and (13), $s_{f/m}$ and s_m can both be expressed in terms of N_{Fm}, N_{Bm} and N_{Sm} and p_{fm}. The simulation routine then iterates over prices and market shares to solve for the optimal single-product prices for each firm type in every molecule.

D. Distribution of Fixed Costs

The equilibrium entry conditions for each molecule are used to estimate a common entry cost for each market. Fixed costs are allowed to vary across molecules in every market by introducing the age of the molecule as an explanatory variable in the estimation of fixed costs. The fixed cost for a molecule m produced by firm type f in market p is specified

$$\ln K_{fm} = \beta_f MolAge_m + \gamma_{fp} + \lambda_f \varepsilon_f,$$

where ε is assumed to have the standard normal distribution and β_m, γ_{fp}, and λ_f are parameters to be estimated.

Omitting the subscript m, the equilibrium conditions imply that for each firm type f in a molecule, the value of the entry cost K_f must lie between the values of $E\pi_f(N_f, N_{-f})$ and $E\pi_f(N_f+1, N_{-f})$. In terms of the model of symmetric market shares, this implies that K_f must be such that

$$\begin{aligned}(p_f(N_f, N_{-f}) - c)s_f(N, N_{-f}) &> K_f \\ &> (p_f(N_f + 1, N_{-f}) - c)s_f(N_f + 1, N_{-f}).\end{aligned} \tag{14}$$

Equation (14) is an ordered probit where the upper and lower bounds for the interval are specified to be the variable profits with N and $N + 1$ firms, respectively. Denoting $(p_f(N_f, N_{-f}) - c)s_f(N,)$ as $V_f(N_f)$ and $(p_f(N_f + 1, N_{-f}) - c)s_f(N_f + 1, N_{-f})$ as $V_f(N_f + 1)$, the above condition can be estimated by defining and maximizing the following likelihood function:

$$\begin{aligned}L = \Phi&\left[\frac{(\ln V_f(N_f) - \gamma_f - \beta_f MolAge)}{\lambda_f}\right] \\ &- \Phi\left[\frac{(\ln V_f(N_f+1) - \gamma_f - \beta_f MolAge)}{\lambda_f}\right].\end{aligned} \tag{15}$$

VIII. Results

A. Demand Estimation

Table 5 presents the OLS and IV estimates of the demand parameters, based on equation (3). Demand is estimated separately by therapeutic category.[16] The response of market shares to prices and other characteristics differs considerably across therapeutic categories. For each case, instrumenting the price and the within-group shares modifies the estimates of the two endogenous variables. The set of six instrumental variables used in the demand estimation is found to be jointly significant in every case.

The coefficient on the variable *Price* is α and can be interpreted as being the response of the mean utility to price. This coefficient varies considerably across the different therapeutic categories. In four out of the five therapeutic categories, the price coefficient becomes more negative after accounting for its endogeneity. In the case of musculoskeletal drugs and systemic anti-infectives, the coefficient increases to double the size of the OLS coefficient, and in the case of drugs of

[16] The regression results for the full sample and detailed descriptive statistics are available as supplementary material from the journal's Web site, http://www.mitpressjournals.org/doi/suppl/10.1162/REST_a_00056.

TABLE 5.—DEMAND ESTIMATION, BY THERAPEUTIC GROUP

	Group A		Group C		Group J		Group M		Group N	
	OLS	IV	OLS	IV	OLS	IV	OLS	IV	OLS	IV
Price	−0.14	−0.1	−0.06	−0.07	−0.02	−0.04	−0.21	−0.42	−0.04	−0.13
	(0.005)	(0.027)	(0.006)	(0.016)	(0.001)	(0.002)	(0.016)	(0.061)	(0.003)	(0.019)
LnCondShare	0.92	0.21	0.85	0.24	0.88	0.41	0.93	0.34	0.83	0.68
	(0.012)	(0.102)	(0.018)	(0.067)	(0.010)	(0.041)	(0.014)	(0.101)	(0.017)	(0.059)
MolAge	−0.006	−0.07	4.2E-03	−0.04	0.02	−0.02	−0.03	−0.05	0.01	7.4E-03
	(0.004)	(0.010)	(0.008)	(0.013)	(0.003)	(0.005)	(0.005)	(0.013)	(0.004)	(0.006)
FirmExp	0.01	0.13	0.01	0.1	−0.02	5.4E-04	−0.01	0.04	−9.5E-04	0.01
	(0.005)	(0.018)	(0.009)	(0.016)	(0.004)	(0.006)	(0.006)	(0.015)	(0.005)	(0.008)
BigDom	0.12	0.53	0.15	1.41	−0.13	0.25	0.19	0.52	0.31	0.63
	−0.075	(0.141)	(0.119)	(0.223)	(0.062)	(0.092)	(0.098)	(0.183)	(0.093)	(0.135)
Foreign	0.16	0.91	−0.19	1.56	−0.19	0.29	0.25	0.85	0.53	2.34
	(0.162)	(0.242)	(0.184)	(0.333)	(0.105)	(0.152)	(0.165)	(0.314)	(0.210)	(0.395)
MktPres	−0.42	0.53	−2.19	−1.77	−0.2	1.24	−1.05	0.42	−0.79	0.05
	(0.122)	(0.313)	(0.308)	(0.478)	(0.123)	(0.199)	(0.150)	(0.346)	(0.174)	(0.262)
FormNo	0.56	1.11	−0.13	0.42	0.46	0.88	−0.13	0.43	0.88	1.32
	(0.181)	(0.327)	(0.210)	(0.328)	(0.028)	(0.047)	(0.159)	(0.310)	(0.131)	(0.181)
Branded	−0.34	0.62	−0.9	−0.93	0.29	0.63	0.49	1.3	0.74	1.08
	(0.117)	(0.237)	(0.494)	(0.762)	(0.067)	(0.097)	(0.146)	(0.278)	(0.226)	(0.289)
Observations	1,387	1,387	810	810	2,463	2,463	914	914	1,351	1,351
F, first stage										
Price		93.12		79.03		221.26		74.59		13.6
CondShare		31.89		27.68		58.19		14.12		37.04

Dependent variable is $LnShareDiff = Ln(sj) - Ln(so)$. $Ln(sj)$ is the number of daily doses of a molecule sold by a firm as a proportion of the total market size. Ln(so) is the log of the outside good share. Standard errors in parentheses.

the nervous system, the coefficient becomes more than three times the magnitude in OLS specification. Although it is difficult to interpret the exact implications of the differences in α across the different therapeutic categories, a higher value of α would lead to a higher elasticity of demand, holding other factors constant.

Another important parameter of interest is σ, the coefficient on the variable *LnCondShare*, which is a measure of the correlation of the products in the same molecule group. Random utility maximization implies that the estimate of σ should lie between 0 and 1, with equation (3) taking the form of the multinomial logit model when σ is equal to 0. Table 5 shows that the estimates of σ differ significantly from 0. The estimates of σ for the different therapeutic groups vary in range between 0.21 (alimentary and metabolism system) and 0.68 (nervous system).

The variable *MolAge* picks up a negative coefficient in most cases, suggesting that newer molecules typically command higher market shares. For the remaining product characteristics, the signs of the coefficients seem to be as expected in most therapeutic categories. The variable *FirmExp* picks up a positive coefficient for three of the five therapeutic categories, indicating that a firm's experience in the market has a positive impact on its market share. *Foreign* and *BigDom* pick up positive and significant coefficients in all cases. Moreover, the coefficient on *Foreign* is found to be larger than the coefficient on *BigDom* in every therapeutic category, revealing a demand-side advantage for foreign products. The variables *FormNo* and *Branded* pick up positive and significant coefficients in most cases, which suggests that firms can increase their market shares by differentiating themselves in terms of brand and presentation.

In table 6, I report the average own-price elasticities of demand and the cross-price elasticities of demand for products in each indication group using the group-wise estimates of α and σ from the demand estimation. The estimated cross-price elasticities between molecules are very low, which is consistent with many previous studies on drugs. Drugs for life-threatening diseases such as hypertension appear to have low own-price elasticities. The own-price elasticity estimates for cephalosporins in India appear to be a little higher than those found in the Ellison et al. (1997) study for the same group of drugs in the United States. Similarly, the own-price elasticity estimates for selected antidepressants in the Cleanthous (2003) study on the United States antidepressants market are found to be smaller than those in India. The Cleanthous estimates of elasticities are close to 0 for most molecules. For example, Cleanthous estimates an own-price elasticity of −0.065 for the drug sertraline in the United States where Pfizer has a monopoly, whereas estimates from this study suggest an average own-price elasticity of −1.26 for India, where 22 firms produce the molecule. Similarly, the own-price elasticity for the older tricyclic antidepressant amitriptyline is estimated to be −0.456 for the U.S. market, while in this study, the same drug is estimated to have an own-price elasticity of −1.15. This difference is not surprising as treatments for nervous system disorders are often highly discretionary, and this is especially more likely to be the case in India than in the United States. because of the much lower purchasing power of the consumers. Another reason that own-price elasticities might be expected to be higher in India is that health insurance coverage in India is extremely limited, believed to cover less than 3% of the population at the time of this study, which implies that almost all of the burden of medical expenses in India is borne by the patient.

TABLE 6.—OWN AND CROSS ELASTICITIES, BY THERAPEUTIC GROUP

Therapeutic Group	Indication Group	Observations	Own Price		Cross, Intramolecule		Cross, Intermolecule	
			Mean	s.d.	Mean	s.d.	Mean	s.d.
A	Antidiabetic	356	−0.610	0.390	0.010	0.020	0.003	0.006
	Antiemetic	216	−1.430	0.990	0.030	0.020	0.006	0.002
	Antiulcerant	658	−0.300	0.210	0.004	0.008	0.001	0.000
	Gastroprokinetic	157	−1.000	0.650	0.010	0.010	0.002	0.001
C	Antihypertensive	810	−0.660	0.580	0.020	0.040	0.001	0.002
J	Antibacterial	2451	−1.130	1.180	0.020	0.050	0.001	0.004
	Antiviral	12	−1.120	0.360	0.100	0.060	0.025	0.012
M	Antirheumatic	914	−1.490	1.080	0.020	0.050	0.002	0.001
N	Antianxiety	289	−1.100	1.940	0.040	0.150	0.002	0.000
	Antidepressant	405	−1.370	1.030	0.090	0.140	0.002	0.000
	Antiepileptic	245	−2.480	2.760	0.200	0.340	0.014	0.002
	Antiinsomnia	84	−0.620	0.370	0.040	0.040	0.005	0.002
	Anti-Parkinson's	67	−2.060	4.310	0.480	1.520	0.005	0.004
	Antipsychotic	261	−1.730	1.810	0.100	0.130	0.003	0.001

TABLE 7.—MARGINAL COSTS AND MARKUPS, BY THERAPEUTIC GROUP

Therapeutic Group	Price		Cost		Markup	
	Mean	s.d.	Mean	s.d.	Mean	s.d.
A	5.1	5.2	1.4	0.9	3.6	4.6
C	7.4	6.6	1.8	0.7	5.6	6.0
J	21.3	33.2	3.5	2.8	17.6	21.8
M	2.6	1.9	1.5	0.5	1.1	1.7
N	8.0	11.0	1.8	0.7	6.3	10.6

All figure in rupees per daily dose. Rs. 45 = $1.

B. Marginal and Fixed Cost Estimation

Equation (9) estimates a constant marginal cost for each of the 141 molecules not under price control. I am able to estimate precise estimates of the marginal costs for 154 of the 155 molecules. For the only remaining molecule, the coefficient on the molecule dummy does not significantly differ from 0.[17] I do not report the individual cost parameters, but table 7 presents the means and standard deviations of average daily dose prices, average marginal costs and markups by therapeutic category.

Table 7 shows that the markups vary across the different therapeutic categories. Systemic anti-infectives appear to have a significantly higher average markup—at over Rs 17.6 per daily dose—than the estimated markups for the other four categories of drugs, which range between Rs 1 and Rs 6.23 per daily dose. However, a closer inspection of the data reveals that the high markups in anti-infectives is driven largely by two groups of drugs, macrolides and the newer variants of cephalosporins, which command higher prices than most other drugs in this category.

Table 8 presents the predicted fixed costs and profits, derived by estimating equation (15).[18] Molecule age does not have a significant effect on fixed costs for either category of domestic firm, but it is positive for foreign firms. This is likely to be driven by the fact that for many of the newer lifestyle drugs, foreign firms are reported to undertake heavy advertising and marketing. In almost every case, foreign firms appear to have the largest fixed costs, followed by the large domestic firms and, finally, the smaller domestic firms. This inference follows from the fact that foreign firms appear to have the highest variable profits in many categories of drugs, but there are significantly fewer foreign firms in most molecules than the other two categories of firm types. Since a large component of the fixed costs in the Indian pharmaceutical industry should be attributed to marketing and distribution costs (as opposed to R&D costs, which would have placed foreign firms at an advantage), the difference between foreign firms and large domestic firms suggests that foreign firms could be at a comparative disadvantage in terms of their marketing and distribution networks in India. Moreover, the big domestic firms and foreign firms also operate at a much bigger scale than smaller firms, earning higher profits but incurring higher fixed costs.

In a comparison of fixed costs across the different therapeutic groups, the fixed costs seem to be the highest for drugs of the nervous system, followed by the drugs belonging to

TABLE 8.—FIXED COSTS AND TOTAL PROFITS, BY THERAPEUTIC GROUP

Therapeutic Group	Firm Type	Observations	Fixed Cost[a]		Total Profit[b]	
			Mean	s.d.	Mean	s.d.
A	Big domestic	64	13.2	12.5	9.3	42.5
	Foreign	45	16.5	21.5	5.1	34.3
	Small domestic	68	2.2	1.9	0.6	2.6
C	Big domestic	65	6.6	5.4	3.1	8.1
	Foreign	46	11.2	6.8	3.8	9.5
	Small domestic	69	0.6	0.5	0.4	1.3
J	Big domestic	80	11.1	11.6	31.9	150.5
	Foreign	69	10.0	8.3	14.3	60.6
	Small domestic	69	3.1	3.0	1.3	5.6
M	Big domestic	29	2.1	0.4	1.6	3.9
	Foreign	17	2.1	1.0	0.6	1.2
	Small domestic	29	0.5	0.2	0.3	0.9
N	Big domestic	131	6.3	3.9	4.6	12.6
	Foreign	62	47.8	84.6	40.4	95.6
	Small domestic	140	1.2	1.4	0.7	2.7

[a] Measured in Rs. million. Rs. 45 = $1.
[b] Total profit = variable profit − fixed cost.

[17] The average price of a daily dose of this molecule is also very close to 0.

[18] The coefficient estimates from the ordered probit regression that were used to calculate these costs and profits are available as supplementary material from the journal.

the cardiovascular system and the alimentary and metabolism system. This result is consistent with industry reports suggesting that marketing and distribution play a major role in these therapeutic groups, particularly in drugs of the nervous system, which have high costs but high margins. Profits are also significantly higher in this group of drugs, when compared to the other four groups.

IX. Policy: Price Deregulation and Patent Enforcement

The costs and benefits of introducing stronger patent protection in the Indian pharmaceutical industry have been discussed widely. The most cited reason for protection of IPR in pharmaceutical markets is that they create increased incentives for innovation. Several studies show that market size—in purchasing power terms—is a crucial determinant for innovation.[19] The low purchasing power of consumers in India has prompted many opponents of the TRIPs agreement to contend that the longer-term welfare gain to the Indian economy from more innovation may be fairly small.

In this section, I use estimates from the previous sections to study the effect of patent enforcement and price deregulation in the industry. Foreign firms are present in 89 molecules. Of these, I focus on 43 molecules where the prices and predicted firm shares generated by the model for the prepatent phase match closely with the data. The insights from these policy simulations contribute to the policy discourse on the consequences of stronger IPR regimes in developing countries, in terms of both their effects on consumer welfare and their ability to generate incentives for global innovation.

A. *Consumer Surplus*

Let L_p denote the set of products in market p and M be the total market size, including consumers who consume the outside good. Then the yearly consumer surplus in the nested logit model outlined above is given by (Small & Rosen 1981)

$$CS_p = \frac{1}{\alpha} M \ln \left[1 + \sum_{m \in L_p} \sum_{f=B,F,S} N_{fm} e^{\delta_{fm}/(1-\sigma)} \right],$$

where δ_{fm} is the mean utility provided by each firm type f in molecule m (where $f = BigDom, Foreign, SmallDom$) and N_{fm} is the number of firms of each type.

The log of the denominator of the upper logit model—$\log[1 + \sum_k D_k^{1-\sigma}]$—is the expected utility of the average consumer from the market p in the nested logit model.[20] This includes the expected utility of the outside good, as well as the expected utilities from each of the lower nests or molecules. The expected utilities of each molecule, in turn, are increasing functions of the mean utilities of each molecule-level product and the within-group correlation, σ. As one would expect, consumer surplus is increasing in the mean utilities of the inside goods, as well as the total number of firms that provide these mean utilities. Consumer surplus is also increasing in the total market size of the product. Finally, the consumer surplus is decreasing in the price-sensitivity parameter α, which converts the consumer surplus from utility to monetary terms.

B. *Price*

The simulation of prices in the model merits further elaboration. Equation (13) shows that the markup can be expressed as the product of two terms: the first term is a constant equal to $(1-\sigma)/\alpha$, where σ is the within-group correlation parameter, and α is the price sensitivity parameter. The second term, $\frac{1}{[1-\sigma s_{f/m}-(1-\sigma)s_{fm}]}$, is an expression that involves σ, the conditional firm share, $s_{f/m}$, and total firm share, s_{fm}. The initial shock to prices following patent enforcement or price deregulation is provided by the change in the conditional and total firm shares. However, because firm shares are a function of prices, the initial change in prices feeds back into the conditional and total firm shares. The final prices, conditional and firm shares, are revealed by the simulation routine when this feedback between the prices and firm shares is complete. However, because the first-order shock to the eventual prices comes from the initial change in the conditional and firm shares, the relationship of the three variables is discussed in greater detail below.

The first term, $(1-\sigma)/\alpha$, is decreasing in both the within-group correlation parameter, σ, and the price sensitivity parameter, α. The economic logic for this is straightforward: a higher α means that the consumer is more sensitive to price and therefore, holding all else constant, this should correspond to a lower markup. A higher value of σ implies a greater degree of within-group correlation between products within a nest relative to products outside the nest. The greater the within-molecule correlation of products within a nest, the more difficult it is for an individual firm within the nest to differentiate itself from other firms in the nest. Therefore, a higher within-group correlation between products sold within a molecule category indicates lower markup possibilities for any individual firm producing the molecule.

While the ratio $(1-\sigma)/\alpha$ plays an important role in determining the markup across markets, it plays a smaller role in the current policy simulations because both σ nor α are constant within a given market. Instead, the more relevant expression in this context is the second term, $\frac{1}{[1-\sigma s_{f/m}-(1-\sigma)s_{fm}]}$. From this term, it is clear that when σ is equal to 1, products within a nest are perfectly correlated relative to products across different nests and the firm's markup is entirely determined by its conditional share, $s_{f/m}$. At the other extreme, when σ is 0, there is no within-group correlation between products within a nest, and products are completely independent. Here, a firm's markup depends on its total share, s_{fm}. In the policy simulations that follow, a higher value of

[19] For example, Acemoglu and Linn (2004) find a large effect of potential market size on the entry of nongeneric drugs and new molecular entities. See Kremer (2002) for a discussion about the low levels of R&D expenditure allocated to products needed by developing countries, such as a vaccine for malaria.

[20] See Train (2003) for a discussion on this.

σ implies that the change in the firm's markup will be determined largely by the change in its conditional share $s_{f/m}$, while a lower value of σ indicates that changes in firm's total share s_{fm} will make a larger difference to the change in the markup.

The firm's total share s_{fm} is the product of the conditional share, $s_{f/m}$, and the group share, s_m. Let P represent the postpatent outcome, FE the free entry outcome, and Δs the change in the market share between the free entry and the postpatent situation. It is easy to show that in the move from free entry to patent enforcement, the change in the total firm share, Δs_{fm}, will be given by

$$\Delta s_{fm} = [s_m(FE) \times \Delta s_{f/m}] - [s_{f/m}(P) \times \Delta s_m]. \quad (16)$$

In equation (16), $s_{f/m}(P)$, the postpatent conditional share of the only remaining firm, is 1. Therefore, the change in the firm's total share s_{fm} will depend on the level of the initial group share, s_m; the change in this group share, Δs_m; and the change in the conditional share, $\Delta s_{f/m}$. Conditional on a given value of σ, the change in conditional share of the foreign patent holder is large if either the original mean utility of the foreign firm was small compared to that of other firms.[21] or if a large number of firms operated in the molecule in the free entry scenario, which drove down the prepatent conditional share of each firm. The initial level of and change in the group share following patent enforcement, $s_m(FE)$ and Δs_m, will depend on the relative strength of the molecule-level characteristics such as its age and its marginal cost, as well as the characteristics of the foreign firm, which accounts for some part of the molecule's attractiveness in the postpatent phase.

C. Descriptive Statistics

Table 9 offers some preliminary descriptive statistics of the 43 molecules for which simulation results are presented. The table shows that in the prepatent phase, there is considerable variation in the total number of competing firms with a given molecule. At one extreme are heavily populated antibacterial drugs such as the quinolone ciprofloxacin and the cephalosporin cefadroxil, which are produced by 88 and 62 firms, respectively. At the other extreme are drugs with little competition even in the prepatent regime—for example, two different types of antihypertensive drugs, the ace inhibitor perindropril and the diuretic furosemide, are populated by only one foreign firm and one small domestic firm, even before patent enforcement.

As discussed in the preceding section, the extent to which the price effects will matter also depends greatly on σ, the within-molecule correlation. While in theory, σ could vary between 0 and 1, its empirical estimates vary between 0.11 and 0.66.

[21] This is usually not the case for foreign firms in most molecules because of the large, positive coefficients on the *Foreign* dummy in most markets.

Finally, as discussed in the previous section, the change in prices following patent enforcement can be understood more easily by considering the effects on the conditional and total firm shares, $s_{f/m}$ and s_{fm}. The conditional share depends not only on the number of firms competing in the market but on specific firm-level characteristics that are deemed to be significant in the demand regressions. For example, foreign firms in the molecules hydroxyzine and perindopril have conditional shares of almost 1 even before the imposition of patent reforms. But the only foreign firm producing the molecule cefadroxil competes with 61 domestic firms in the prepatent phase, and its conditional share is a very small 0.003.

The total firm shares are, by construction, smaller than the conditional shares. However, for many of the molecules, the total firm share is particularly small, and this is partially explained by the size of the group shares of the molecules. For example, in the case of the antiepileptic drug phenytoin and the antidepressant fluvoxamine, the foreign firm commands similar prepatent conditional shares of 0.48. But because the group share of phenytoin is relatively high (approximately 0.25), this translates into a large total firm share of 0.12. In comparison, the group share of fluvoxamine is tiny (only 0.002), and the corresponding total firm share for the foreign firm is only 0.001.

D. Simulation Results

In this section, I discuss the results of the policy simulations, which measure the effect on welfare of deregulating prices in regulated markets and granting patent protection to a single foreign patent holder. Table 10 considers the welfare effects of patent enforcement for drugs that are not affected by price regulation. Table 11 considers the effect of price deregulation on the three molecules that were under price control, as well as its effect on other molecules that belong to the same markets as the price-controlled drugs. Table 12 considers the effect of patent enforcement on each of these molecules. I first provide a summary of the overall results of the simulation presented in these tables. This is followed by a more detailed discussion on the price and market share simulation results for a few selected markets.

Overview of simulation results. In the prepatent phase, the price per daily dose of the 43 molecules varies between Rs 0.4 and Rs 105, while in the postpatent phase, the price varies from Rs 3.7 to Rs 131.7. The average percentage increase in price following both price deregulation and patent imposition is approximately 42%. However, because 3 of the 43 molecules are under price control, it is useful to study the effects of the twin policy measures of price deregulation and patent enforcement separately.[22] Of these 3 molecules, ciprofloxacin has the largest number of firms with 8 big

[22] Other drugs belonging to the same market as these three price-controlled drugs do not respond in any significant way to their price deregulation. This is consistent with the general finding of negligible spillover effects across molecules.

TABLE 9.—DESCRIPTIVE STATISTICS, MOLECULES SELECTED FOR SIMULATION

Market	Total Molecules	Sigma	Molecule	Number of Firms Prepatent: Big Domestic	Number of Firms Prepatent: Foreign	Number of Firms Prepatent: Small Domestic	Foreign Firm Shares: Conditional Prepatent	Foreign Firm Shares: Total Prepatent	Foreign Firm Shares: Total Postpatent
ACE inhibitors	5	0.24	Enalapril	5	1	13	0.19	3.60E-004	4.40E-004
			Lisinopril	4	1	13	0.34	2.13E-004	2.32E-004
			Perindopril	0	1	1	0.98	1.01E-003	1.01E-003
Alpha blockers	4	0.66	Prazosin	1	1	1	0.56	1.51E-002	1.40E-002
			Terazosin	2	2	3	0.37	4.68E-003	5.20E-003
ARBs	5	0.24	Valsartan	2	1	1	0.38	9.00E-005	9.70E-005
Antianxiety	6	0.55	Hydroxyzine	0	1	3	0.99	9.02E-002	9.01E-002
			Lorazepam	2	1	9	0.84	7.24E-002	6.77E-002
Antiemetic	7	0.11	Ondansetron	4	1	5	0.14	1.56E-004	1.76E-004
Antiepilepsy	11	0.52	Clonazepam	4	1	10	0.49	1.06E-002	1.09E-002
			Phenytoin	2	2	4	0.48	1.21E-001	1.30E-001
			Topiramate	3	1	1	0.40	1.31E-003	1.42E-003
Beta blockers	5	0.24	Atenolol	4	1	32	0.04	3.56E-004	6.13E-004
			Bisoprolol	0	1	2	0.93	1.10E-003	1.10E-003
			Metoprolol	1	2	4	0.26	5.13E-004	5.85E-004
Calcium channel blockers	7	0.24	Amlodipine	7	4	39	0.03	2.24E-004	4.03E-004
			Diltiazem	6	1	12	0.13	5.00E-005	6.60E-005
			Felodipine	1	1	0	0.63	1.26E-003	1.27E-003
			Nifedipine	4	2	6	0.12	7.10E-004	9.46E-004
Cephalosporins	7	0.54	Cefaclor	1	1	5	0.32	1.57E-002	1.92E-002
			Cefadroxil	5	1	56	0.003	2.14E-004	2.56E-003
			Cefixime	6	2	35	0.05	7.81E-004	2.40E-003
			Cefpodoxime	2	2	14	0.04	8.42E-004	2.81E-003
			Cefuroxime	3	2	24	0.25	1.97E-003	2.68E-003
			Cephalexin	7	3	36	0.03	1.77E-003	8.03E-003
Diuretics	4	0.24	Furosemide	0	1	1	0.99	1.50E-001	6.33E-002
			Indapamide	1	1	5	0.55	1.55E-003	1.74E-003
Macrolides	4	0.28	Azithromycin	3	1	16	0.07	3.90E-005	6.50E-005
			Clarithromycin	2	3	13	0.06	1.84E-004	2.91E-004
			Roxithromycin	7	2	47	0.08	1.84E-004	2.91E-004
Novel Antipsychotic	6	0.26	Risperidone	4	1	11	0.05	8.41E-004	1.45E-003
Perticillin V	4	0.18	Ampicillin	4	2	18	0.01	3.20E-005	6.30E-005
Quinolones	10	0.28	Ciprofloxacin	8	4	76	0.04	3.44E-004	5.66E-004
			Levofloxacin	2	1	17	0.16	3.94E-004	5.20E-004
			Sparfloxacin	7	1	42	0.08	2.31E-004	3.67E-004
SRIs	7	0.55	Fluvoxamine	2	2	0	0.47	1.13E-003	1.15E-003
			Sertraline	6	1	15	0.65	2.29E-002	2.16E-002
Sulfonyureas	4	0.11	Gliclazide	3	2	30	0.12	9.08E-004	1.05E-003
Tetracyclines	4	0.28	Minocycline	1	1	0	0.79	4.58E-004	4.54E-004
Tricyclic	9		Clomipramine	1	1	6	0.88	3.56E-003	3.36E-003
			Dothiepin	1	1	6	0.91	3.35E-002	3.19E-002
Typical antipsychotic	5	0.26	Haloperidol	2	1	9	0.24	1.65E-003	1.94E-003
			Thioridazine	2	1	7	0.20	5.67E-004	6.92E-004

domestic firms, 4 foreign firms, and 76 small domestic firms, followed by cefadroxil, with 5 big domestic firms, 1 foreign, and 56 small domestic firms. Furosemide is at the other extreme, with only two firms—1 foreign and 1 small domestic. Therefore, one should expect the removal of the price control to play a relatively larger role in the latter molecule, where the price control is especially binding, while patent enforcement is likely to be more important in the two heavily populated antibacterial drugs that are under price control.

The effect of price deregulation alone is to raise the price per daily dose of furosemide from Rs 0.4 to Rs 3.2 per daily dose, a 650% increase. In percentage terms, the effect of price deregulation for the two antibacterial drugs, ciprofloxacin and cefadroxil, is much more modest. For ciprofloxacin, the price increases from Rs 11.5 to Rs 16.23, a 42% increase, while for cefadroxil, the price increases from Rs 20.5 to Rs 35.4, a 72% increase. For furosemide, the additional enforcement of patents has limited impact, since only one other firm competed with the foreign firm in the prepatent phase; the effect is only a Rs 0.7 increase (an additional percentage increase of 17%). However, for the molecules ciprofloxacin and cefadroxil, the move from price deregulation to patent enforcement has considerable impact: an additional 34% and 73% increase in the respective prices of ciprofloxacin and cefadroxil following patent enforcement.

Another way to look at the relative roles of the two policy measures is the following: the price of ciprofloxacin undergoes a 90% increase in price following both price deregulation and patent enforcement, and the two policy measures play roughly similar roles in this price increase. For the molecule cefadroxil, the total increase in price following both policy measures is 204% with 64% of this change caused by

TABLE 10.—EFFECT OF PATENT ENFORCEMENT ON WELFARE INDICATORS: MARKETS WITHOUT PRICE CONTROLLED DRUGS

	Average Molecule Price (*in Rs per daily dose*)			Consumer Surplus (*in Rs Million*)			Profit of Patent Holder (*in Rs Million*)			Number of Consumers (*in 1,000*)		
Molecule	Prepatent	Postpatent	% Diff	Prepatent	Postpatent	% Diff	Prepatent	Postpatent	% Diff	Prepatent	Postpatent	% Diff
Enalapril	13.7	15.4	12	47.2	34.9	−26	−2.3	−1.0	56	16.7	12.4	−26
Lisinopril	24.3	25.9	7	47.2	44.0	−7	−2.8	−2.3	16	16.7	15.6	−7
Perindopril	17.7	18.7	5	47.2	47.0	0	4.1	4.2	1	16.7	16.7	0
Prazosin	14.0	18.0	28	162.0	127.0	−22	11.9	27.8	133	60.2	47.6	−21
Terazosin	15.1	19.5	29	162.0	142.4	−12	−2.2	6.0	380	60.2	53.2	−12
Valsartan	23.8	25.3	6	17.7	16.8	−5	−0.8	−0.7	16	6.3	6.0	−5
Hydroxyzine	14.9	16.2	9	2,352.7	2,352.6	0	527.2	527.3	0	1,385.1	1,385.0	0
Lorazepam	4.7	6.6	40	2,352.7	2,197.9	−7	107.8	170.9	59	1,385.1	1,306.6	−6
Ondansetron	29.2	30.2	3	234.8	229.3	−2	−2.9	−2.7	7	230.0	224.8	−2
Clonazepam	16.0	22.7	42	7,759.0	7,650.0	−1	40.9	80.5	97	1,023.2	1,013.8	−1
Phenytoin	10.8	19.3	79	7,759.0	6,305.2	−19	732.6	1,370.1	87	1,023.2	888.3	−13
Topiramate	36.9	43.3	17	7,759.0	7,741.0	0	−12.9	−6.8	47	1,023.2	1,021.6	0
Atenolol	5.5	6.3	14	257.9	138.8	−46	−11.6	−6.7	43	203.1	109.7	−46
Bisoprolol	6.0	6.5	7	257.9	256.7	0	3.2	3.5	8	203.1	202.2	0
Metoprolol	10.5	11.1	6	257.9	238.1	−8	−11.8	−9.3	21	203.1	187.6	−8
Amlodipine	6.3	7.1	13	348.0	230.0	−34	−6.8	−2.5	64	274.0	181.7	−34
Diltiazem	15.7	16.5	5	348.0	341.9	−2	−13.0	−12.5	4	274.0	269.2	−2
Felodipine	6.3	6.8	7	348.0	334.4	−4	10.3	12.9	26	274.0	263.3	−4
Nifedipine	6.2	6.9	13	348.0	258.4	−26	−5.2	2.2	142	274.0	203.9	−26
Azithromycin	45.5	50.7	11	251.8	141.7	−44	2.6	8.3	214	320	19	−94
Clarithromycin	70.1	75.3	7	251.8	207.9	−17	−1.4	−0.7	52	320	28	−91
Roxithromycin	35.6	41.0	15	251.8	176.5	−30	0.3	3.5	929	320	24	−92
Risperidone	14.3	17.0	19	323.7	227.4	−30	0.0	5.1	56,433	78	55	−29
Ampicillin	26.8	29.7	11	197.1	158.2	−20	−1.0	−0.6	38	299	241	−20
Fluvoxamine	20.9	22.8	9	846.3	841.0	−1	−7.0	−5.0	28	525	522	−1
Sertraline	9.2	11.1	21	846.3	788.6	−7	58.5	82.2	40	525	493	−6
Gliclazide	15.9	17.0	7	1,574.3	1,295.1	−18	−8.4	1.4	117	424	350	−17
Minocycline	42.2	45.3	7	420.4	321.6	−24	14.0	15.1	9	57	43	−25
Clomipramine	17.6	19.2	9	671.8	669.0	0	−9.0	−7.9	12	425	423	0
Dothiepin	8.9	10.6	19	671.8	650.4	−3	101.7	109.8	8	425	412	−3
Haloperidol	14.2	16.7	18	42.1	34.5	−18	−0.4	0.6	248	10	8	−18
Thioridazine	24.7	27.3	10	42.1	38.7	−8	−0.6	−0.2	69	10	9	−8

TABLE 11.—EFFECT OF PRICE DEREGULATION ON WELFARE INDICATORS: MARKETS WITH PRICE-CONTROLLED DRUGS

	Average Molecule Price (*in Rs per daily dose*)			Consumer Surplus (*in Rs Million*)			Profit of Patent Holder (*in Rs Million*)			Number of Consumers (*in 1,000*)		
Molecule	Regulated	Deregulated	% Diff	Regulated	Deregulated	% Diff	Regulated	Deregulated	% Diff	Regulated	Deregulated	% Diff
Ciprofloxacin[a]	11.5	16.3	42	2,441.9	2,231.8	−9	−0.8	1.9	330	3,081.0	2,819.0	−9
Levofloxacin	26.9	26.9	0	2,441.9	2,231.8	−9	15.3	15.4	0	3,081.0	2,819.0	−9
Sparfloxacin	27.7	27.7	0	2,441.9	2,231.8	−9	1.6	1.6	2	3,081.0	2,819.0	−9
Cefaclor	94.7	94.7	0	16,356.8	15,097.2	−8	450.1	461.5	3	7,200.2	6,720.9	−7
Cefadroxil[a]	20.5	35.4	73	16,356.8	15,097.2	−8	−20.1	−17.8	11	7,200.2	6,720.9	−7
Cefixime	105.0	105.0	0	16,356.8	15,097.2	−8	2.7	3.2	17	7,200.2	6,720.9	−7
Cefpodoxime	75.7	75.7	0	16,356.8	15,097.2	−8	7.5	8.0	7	7,200.2	6,720.9	−7
Cefuroxime	100.0	100.0	0	16,356.8	15,097.2	−8	36.6	37.9	4	7,200.2	6,720.9	−7
Cephalexin	46.9	46.9	0	16,356.8	15,097.2	−8	12.3	13.4	9	7,200.2	6,720.9	−7
Furosemide[a]	0.4	3.2	650	1,091.6	458.7	−58	69.3	404.4	484	798.2	351.8	−56
Indapamide	6.5	6.5	0	1,091.6	458.7	−58	−5.0	−4.1	18	798.2	351.8	−56

[a]The molecule is under price control in the data.

patent enforcement and 36% by price deregulation. Finally, at the other extreme is the molecule furosemide, for which the two policy measures together cause a 776% increase in price. Of this total increase, 84% of the change is caused by price deregulation, while only 16% is caused by patent enforcement.

For the remaining 40 molecules that were not under price control, the average percentage change following patent enforcement is 18% and ranges from an almost 80% increase in price of the antiepileptic drug phenytoin to a 3.5% increase in the price of the antiemetic drug ondansetron.

The second measure of welfare is consumer surplus, which depends on the size of the market, the sensitivity of the consumer to price, and the expected utility from each molecule in the market. The 43 drugs for which simulation is undertaken span 19 out of the 31 markets in the sample. Tables 10 through 12 show that the average consumer surplus in the 19 markets is Rs 1.8 billion and ranges from Rs 16.4 billion for the antibacterial segment of cephalosporins to Rs 18 million for the antihypertensive segment of ARBs. For the price-controlled drug ciprofloxacin, the effect of price deregulation is to decrease consumer surplus by Rs 210 million, a

TABLE 12.—EFFECT OF PATENT ENFORCEMENT ON WELFARE INDICATORS: MARKETS WITH PRICE CONTROLLED DRUGS

	Average Molecule Price (*in Rs per daily dose*)			Consumer Surplus (*in Rs Million*)			Profit of Patent Holder (*in Rs Million*)			Number of Consumers (*in 1,000*)		
Molecule	Prepatent	Postpatent	% Diff	Prepatent	Postpatent	% Diff	Prepatent	Postpatent	% Diff	Prepatent	Postpatent	% Diff
Ciprofloxacin[a]	16.3	21.8	34	2,231.8	1,656.0	−26	1.9	33.7	1665	2,819.0	2,097.9	−26
Levofloxacin	26.9	32.1	19	2,231.8	2,041.3	−9	15.4	36.4	136	2,819.0	2,581.0	−8
Sparfloxacin	27.7	33.2	20	2,231.8	1,978.6	−11	1.6	20.1	1143	2,819.0	2,502.6	−11
Cefaclor	94.7	116.4	23	15,097.2	13,434.2	−11	461.5	1,025.3	122	6,720.9	6,070.3	−10
Cefadroxil[a]	35.4	62.4	76	15,097.2	11,210.1	−26	−17.8	115.4	750	6,720.9	5,168.2	−23
Cefixime	105.0	131.7	25	15,097.2	14,372.4	−5	3.2	111.0	3412	6,720.9	6,439.7	−4
Cefpodoxime	75.7	101.9	35	15,097.2	14,174.9	−6	8.0	136.4	1601	6,720.9	6,362.5	−5
Cefuroxime	100.0	125.8	26	15,097.2	14,809.8	−2	37.9	123.5	226	6,720.9	6,609.9	−2
Cephalexin	46.9	73.8	57	15,097.2	11,706.0	−22	13.4	399.3	2884	6,720.9	5,372.4	−20
Furosemide[a]	3.2	3.7	17	458.7	453.7	−1	404.4	405.8	0	351.8	348.1	−1
Indapamide	6.5	7.1	9	458.7	449.9	−2	−4.1	−2.5	38	351.8	345.3	−2

[a]The molecule is under price control in the data.

drop of 9%. The effect of patent imposition is to cause a further Rs 575 million (26%) decline in the consumer surplus. For cefadroxil, the effect of the price deregulation is to reduce consumer surplus by Rs 1.3 billion, an 8% decrease. The addition of patent protection in this molecule decreases consumer surplus by an additional Rs 3.8 billion, a 26% decrease. Finally, for the molecule furosemide, the effect of price deregulation on the molecule is to decrease consumer surplus by Rs 632 million, a decrease of 58%. Patent enforcement for furosemide reduces consumer surplus by only an additional Rs 5 million (a 1% decrease).

Overall, the percentage decrease in consumer surplus for ciprofloxacin is 32%, of which 27% is owed to price deregulation and 73% to patent enforcement. The breakdown is similar for cefadroxil, for which patent enforcement alone explains roughly three-quarters of the overall 31% decrease in consumer surplus. However, the opposite story applies to furosemide: almost all of the 60% decrease in consumer surplus can be attributed to price deregulation.

For the remaining 40 molecules, the average decrease in consumer surplus is Rs 261.5 million. This ranges from Rs 70,000 for the small molecule hydroxyzine, where the foreign firm faces minimal competition even in the prepatent period, to Rs 3.4 billion for the molecule cephalexin, in which 46 firms competed in the prepatent phase and there is a 57% price increase following patent enforcement.

The increase in the profit of the foreign patent holder is an important element of the argument, since it provides an indirect measure of the additional incentives provided to the patent holder from patent protection. In the overall sample of the 43 drugs, the average increase in the profit of the patent holder is about Rs 63 million following both price deregulation and patent enforcement. This can once again be analyzed separately, depending on whether the price of the drug was regulated during the sample period. For ciprofloxacin, price deregulation increases the firm's profit by Rs 2.74 million, a 330% increase. The additional enforcement of patent enforcement increases profits by an additional Rs 33 million. For cefadroxil, price deregulation increases the foreign firm's profits by about Rs 2.3 million. Patent enforcement further increases the patent holder's profit by Rs 133 million. On the other hand, for the molecule furosemide, price deregulation increases the foreign firm's profits by Rs 335 million but the addition of patent enforcement increases this figure by only another Rs 1.36 million. For drugs that were not subject to price regulation, the average increase in profits following patent enforcement is approximately Rs 55 million.

Finally, I also consider the change in the number of patients following patent enforcement.[23] As with previous measures of welfare, there is significant variation in the number of patients who are active in each market: the two large antibacterial segments serve between 3 million and 6 million patients, while the segment of typical antipsychotic drugs serves only about 10,000 patients. Across the 43 molecules, there is an average decrease of 196,000 patients following both price deregulation and patent enforcement. For the three molecules that are under price control, one can also separately consider the short-term losses for consumers from price deregulation and patent enforcement. Price deregulation reduces the market size by 262,000 patients for ciprofloxacin and 479,000 patients for cefadroxil. Although small in percentage terms, these are very large losses in an absolute sense. The reductions in market size following patent enforcement in the two antibacterial drugs ciprofloxacin and cefadroxil are staggeringly large: in addition to the approximately 0.3 million patients lost to price deregulation, the quinolones segment loses an additional 0.7 million patients from patent enforcement of ciprofloxacin. The cephalosporins segment loses an additional 1.5 million patients owing to patent enforcement of cefadroxil, bringing the total loss from price deregulation and patent enforcement of cefadroxil to 2 million patients. For the price-controlled diuretic furosemide, where the effect of price deregulation has been seen to be much greater than that of patent enforcement throughout this analysis, the number of patients is approximately halved following price deregulation, from 0.8 million to 0.4 million. Patent enforcement leads to a further loss of an additional 6,500 patients for this molecule. In the remaining 40

[23] The average length of drug therapy is held constant in calculating the number of patients. Therefore, a predicted decrease in sales is represented here as a reduction in the number of of patients, although it is also possible that each patient may continue to consume a reduced quantity of the product.

molecules with no price controls, the average loss in the number of patients due to patent enforcement is approximately 153,000, with the largest loss of 1.3 million patients from the cephalosporin cephalexin and the smallest loss of 30 patients from the antianxiety drug hydroxyzine, where the foreign firm has a near monopoly even before patent enforcement. Overall, the twin policy measures together reduce the total number of patients in the nineteen markets from approximately 16.4 million patients to 8 million patients, amounting to a decrease of over 50%.

Case studies of markets. Here, I provide more detailed discussion of six drugs across three different markets to explain how the estimated parameters of the cost and utility functions, along with the firm and molecule-level characteristics, affect the price increases in the policy simulations.

1. *Antiemetic: Ondansetron*: Ondansetron has four big domestic firms, one foreign firm, and five small domestic firms. Following patent enforcement, the conditional share of the foreign firm increases from 0.14 to 1 in the postpatent phase, a relatively large increase in conditional share. However, the σ parameter for this segment is estimated to be low (0.11), which indicates a relatively low degree of correlation among different products within the same molecule. From the discussion above, this implies that the change in price following patent enforcement will be determined largely by changes in firm's total, as opposed to its conditional, share. In this case, the group share of the molecule, s_m, is only 0.001. This means that both the level and the change in its group share following patent enforcement are small in absolute terms. The resulting prediction of the model is that patent enforcement leads to only a small 3% increase in the price of the drug.
2. *Antiepilepsy: Clonazepam, phenytoin, and topiramate*: The within-group correlation is 0.52, which indicates that the change in price will place roughly equal weight on changes in both the conditional and firm share. Table 9 shows that although there are more firms operating in the molecule clonazepam than in topiramate before patent enforcement, the prepatent conditional shares of the foreign firm are almost equal for the two molecules. Therefore, one should expect the price change attributable to change in conditional share to be roughly equal. However, molecule-level characteristics, such as the age of the molecule and the superior characteristics of the foreign firm in clonazepam, predict a significantly higher group share for clonazepam than for topiramate, in both the pre- and the postpatent phase. Therefore, the foreign firm's total share s_{jm} is significantly higher for clonazepam in both the pre- and the postpatent phase. In the end, this translates into a 42% increase in the price of clonazapam following patent enforcement and only a 17% increase in the price of topiramate.

   In terms of market share, phenytoin is the largest player in the market with a group share of 0.2. This group share is ten times higher than the group share of clonazepam in both the pre- and the postpatent phase and almost 100 times greater than the group share of Topiramate. There are two big, two foreign, and four small domestic firms that compete in this molecule in the prepatent setting. The conditional share of the foreign firm in this molecule is 0.48, which is close to the conditional shares of clonazapam and topiramate. However, because of the large group share of phenytoin, the total firm share of the foreign firm is significantly higher for this molecule in both the pre- and the postpatent phase. The resulting increase in the price of the molecule following patent enforcement is 79%.
3. *Serotonin reuptake inhibitors: Fluvoxamine and sertraline*: Sertraline has six big domestic, one foreign and fifteen small domestic firms, while fluvoxamine has two big domestic firms and two foreign firms. The within-group correlation is 0.55, which once again means that almost equal weight will be placed on changes in conditional and total firm share. The prepatent conditional share of the foreign firm is 0.47 for fluvoxamine and 0.7 for sertraline, implying that the change in conditional share after patent enforcement will be smaller for sertraline than for fluvoxamine. However, the total firm share for the two molecules is significantly different owing to a large difference in their molecule group shares, s_m: the group share for fluvoxamine is only 0.002, while it is 0.03 for sertraline. This is largely due to the fact that the marginal cost of fluvoxamine is estimated to be almost three times higher than that of sertraline, resulting in a higher initial price for fluvoxamine and, consequently, a lower mean utility. Because of this large difference in the group share s_m and in the resultant firm share s_{jm}, the final price increase for sertraline is considerably higher, despite the smaller change in its conditional share.

This discussion suggests that several things are important in predicting the price increases that will follow patent enforcement. First, if the initial conditional share of the foreign firm is high because of few firms in the market or because the foreign firm already occupies a dominant position in the molecule, the price increase following patent enforcement will be lower. Second, if the molecule itself has strong characteristics, such as low marginal costs of production or a higher impact on utility because of its novelty or reputation, then the firm will be able to increase its price without losing too much market share, and the resulting price increase will be higher.

Changes in the consumer surplus will correspondingly vary across the different molecules and will depend on the mean utility of the different molecules, as well as on the total size of the market, M, and the price-sensitivity parameter, α.

Of the latter two factors, the variation in M is significantly higher than the variation in α and is often the key to explaining the large differences in consumer surplus across markets.

The findings in this section add further evidence in the direction of the results of Chaudhuri et al. (2006), who estimate large welfare losses for consumers but small gains for patent holders following patent enforcement for four drugs in the quinolones subsegment. However, their estimate of consumer welfare loss from patent enforcement on ciprofloxacin is Rs 7.1 billion, while this study estimates only a Rs 785 million reduction in consumer surplus. There appear to be a few reasons for this difference. First, the inclusion of the outside good and its dominant share in most markets is interpreted in the model to mean that the expected utility from the inside goods is very low relative to the expected utility of the outside good. Therefore, the absolute level of the consumer surplus is of a different order of magnitude in this study compared to that of Chaudhuri et al. (2006). Second, the large outside share of the outside good also predicts extremely low cross-price elasticities between different molecules in my model, which means that the spillover effects from one molecule to the other are almost negligible. The economic intuition for this is that when faced with a price increase in one molecule, a consumer is more likely to substitute the outside good than any of the other inside goods.[24]

Finally, the estimates of the increase in the foreign patent holder's profit have important implications for policy. The average increase in firm profit is approximately Rs 63 million ($1.4 million), which is small in light of the fact that it takes between $300 million and $800 million to develop a new drug. Moreover, given that India is one of the most profitable markets in the developing world, it is a reasonable upper bound for the expected increase in the profits of patent holders from patent enforcement in a developing country. Another caveat here is that while the average increase in the foreign firm's profit is low, there is wide variation in this figure across markets. For example, for the antiepileptic drug phenytoin, the foreign patent holder is able to increase its price by 79% in the prepatent phase and is estimated to increase its profit by almost $14 million. While on its own, this is not a big enough figure to turn the direction of R&D away from the current portfolio of pharmaceutical products and toward more developing country–specific products, it is large enough to make a significant *partial* contribution to increasing the level of global R&D in existing categories of drugs.

X. Conclusion

In this paper, I develop a model of demand, supply, and entry for a large cross-section of drugs in the Indian pharmaceutical industry. The estimation of this model recovers parameters that measure utility from consumption as well as the marginal and fixed costs of production of each drug. Demand estimation reveals that firm and market characteristics are important factors in understanding demand patterns. Fixed costs are estimated to be higher for foreign firms than for domestic firms in most categories of drugs.

Estimates from the model are used to derive counterfactual predictions of the effects of the controversial 1994 TRIPs agreement, which mandated that India begin to enforce strict patent protection on drugs that were under patent in the West. For the 43 drugs for which I simulate patent enforcement and price deregulation, the average price increase is estimated to be approximately 42%. The total loss in consumer welfare from patent enforcement and price deregulation in these 43 drugs is estimated to be $378.5 million, an average loss of $9 million per drug. In addition, estimates suggest a total loss of almost 8.5 million patients from the implementation of the two policy measures, which amounts to a decrease of over 50%. In contrast, the average annual gain to the foreign patent holder from the policy exercise is estimated to be $1.4 million per drug. Although this figure varies across different drugs, it is typically quite small when compared to the costs of new drug development, which range between $300 million and $800 million.

The results presented in this paper contribute to the debate surrounding the TRIPs agreement and the adoption of more stringent standards of IPR protection by developing countries. In the larger global context, the market size in India is fairly small. Even in the absence of any price regulation, this small market size translates into modest gains from patent protection for most patent holders. The implication of these findings can be interpreted to mean that a dominant immediate effect of the TRIPs agreement would be a reduction in consumer welfare unless the new regime is accompanied by other changes in the health care system that would shift some of the burden of medical expenses away from consumers. However, a complete cost-benefit analysis of the consequences of TRIPs in India cannot be conducted without information on its potential longer-term effects, such as the possibility of greater local innovation in India.

[24] In counterfactual simulations where the outside good is assumed to be 0, I find that the implied loss in consumer surplus is Rs 6.2 billion, a figure that is close to Chaudhuri et al.'s (2006) prediction of Rs 7.1 billion.

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