NBER WORKING PAPER SERIES

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Working Paper 10159
http://www.nber.org/papers/w10159

NATIONAL BUREAU OF ECONOMIC RESEARCH
1050 Massachusetts Avenue
Cambridge, MA 02138
December 2003

Comments welcome. We would like to thank Isher Ahluwalia, former Director, Indian Council for Research on International Economic Relations for providing us with access to the primary data used in this study. We also thank seminar participants at Yale and the 2003 NEUDC conference for helpful comments. The views expressed herein are those of the authors and not necessarily those of the National Bureau of Economic Research.

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NBER Working Paper No. 10159
December 2003, Revised July 2006
JEL No. O34, D12, D4, L65, F13

ABSTRACT

Under the TRIPS agreement, WTO members are required to enforce product patents for pharmaceuticals. The debate about the merits of this requirement has been extremely contentious. Many low income economies claim that patent protection for pharmaceuticals will result in substantially higher prices for medicines, with adverse consequences for the health and well-being of their citizens. On the other hand, research-based global pharmaceutical companies, argue that prices are unlikely to rise significantly because most patented products have therapeutic substitutes. In this paper we empirically investigate the basis of these claims. Central to the ongoing debate is the structure of demand for pharmaceuticals in poor economies where, because health insurance coverage is so rare, almost all medical expenses are met out-of-pocket. Using a detailed product-level data set from India, we estimate key price and expenditure elasticities and supply-side parameters for the fluoroquinolones sub-segment of the systemic anti-bacterials (i.e., antibiotics) segment of the Indian pharmaceuticals market. We then use these estimates to carry out counterfactual simulations of what prices, profits, and consumer welfare would have been, had the fluoroquinolone molecules we study been under patent in India as they were in the U.S. at the time. Our results suggest that concerns about the potential adverse welfare effects of TRIPS may have some basis. We estimate that *in the presence price regulation* the total annual welfare losses to the Indian economy from the withdrawal of the four domestic product groups in the fluoroquinolone sub-segment would be on the order of U.S. $305 million, or about 50% of the sales of the entire systemic anti-bacterials segment in 2000. Of this amount, foregone profits of domestic producers constitute roughly $50 million. The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare. In contrast, the profit gains to foreign producers *in the presence price regulation* are estimated to be only around $19.6 million per year.

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1. Introduction

Under the Agreement on Trade-Related Intellectual Property Rights (TRIPS)—finalized during the Uruguay round of multilateral trade negotiations in 1995—nations must, as a condition of membership in the World Trade Organization (WTO), recognize and enforce product patents in all fields of technology, *including pharmaceuticals*. At the time the TRIPS agreement went into effect, many low and middle income countries made an exception for pharmaceuticals, even if they recognized product patents in other areas, because low-cost access to life-saving drugs and essential medicines was deemed to be an overriding public policy priority. To meet their obligations under TRIPS however these countries had to introduce or amend their patent legislation to include pharmaceutical product patents, with the transition- and least-developed economies having until 2005 to do so.

The negotiations leading up to TRIPS, and in particular the provisions relating to pharmaceuticals, were highly contentious. Though more than 10 years have passed since TRIPS was finalized, there continues to be considerable controversy and debate regarding its merits. The main point of contention is the claim made by governments of many poor developing economies that unqualified patent protection for pharmaceuticals will result in substantially higher prices for medicines, with adverse consequences for the health and well-being of their citizens. Countering this claim, research-based global pharmaceutical companies, which have potentially lost billions of dollars because of patent infringement by Third World firms that have reverse-engineered their products, argue that the introduction of product patents is unlikely to significantly raise prices because most patented products have many therapeutic substitutes. Moreover, they claim that the absence of patent protection has served as a disincentive to engage in research on diseases that disproportionately afflict the world's poor, implying that patent protection for pharmaceuticals will actually benefit less-developed economies by stimulating innovation and transfer of technology.

Given the scope of TRIPS and the intensity of the accompanying debate, it is remarkable how sparse the evidence is, on which these divergent claims are based.[1] Apart from the findings of a small number of studies that we refer to in more detail below, little is known about the extent to which pharmaceutical prices in less-developed economies might increase with the introduction of product patents, and the magnitude of the associated welfare losses.[2] Past empirical studies on the impact of

[1] There is a sizeable theoretical literature on the welfare impact of patent protection that generally finds that the effects of patents in a multi-country setting are substantially more complicated than their respective effects in a single closed economy where both innovating firms and innovation beneficiaries (i.e., consumers) are of the same nationality (see Nordhaus (1969), Chin and Grossman (1990), Diwan and Rodrik (1991), Deardorff (1992), Helpman (1993), and Grossman and Lai (2003) for related arguments). Empirical work in this area is however still in its infancy.

[2] Even less is known about the other central questions relevant to the TRIPS debate, namely the extent to which pharmaceutical research and product development priorities are likely to shift as a result of TRIPS, and how large the welfare benefits of any therapeutically innovative drugs that result from this shift are likely to be. The only paper that has carefully addressed such questions is Lanjouw and Cockburn (2001).

patents on prices and innovative activity in various sectors, including pharmaceuticals, have focused almost exclusively on *developed* economies. Aside from the fact that none of these studies estimate welfare effects, the conclusions from these studies are not directly pertinent to the TRIPS debate because the structure of demand for pharmaceuticals in less-developed economies differs from that in developed economies in several critical respects[3].

Any assessment of the potential price and welfare effects of TRIPS needs therefore to be based on a better empirically-grounded understanding of the characteristics of demand and the structure of markets for pharmaceuticals in poor developing economies. To what extent are consumers willing to trade off lower prices for older, possibly less effective therapies? How does this vary across different therapeutic segments? Are consumers willing to pay a premium for the pedigree and brand reputation of products marketed by subsidiaries of foreign multinationals? How competitive are pharmaceutical markets? The welfare of consumers depends on the pricing strategies and decisions of pharmaceutical firms. But these in turn derive from the firms' assessment of the structure of market demand. If consumers are unwilling to pay substantially more for newer patented drugs for which there exist older, possibly slightly less effective generic substitutes, the ability of patent-holders to charge a premium will be limited. As mentioned above, there have been a few studies that carefully considered these issues and used explicit models of consumer and firm behavior to simulate the welfare losses implied by patent protection[4]. However, their findings are ultimately limited by the fact that the simulations that are used to evaluate the potential impact of patents are in each instance based on *assumptions* about demand characteristics and market structure, rather than on actual *estimates* of the relevant parameters.

This paper takes a first step towards filling this gap. We provide the first rigorously-derived estimates of the possible impact of pharmaceutical product patents on prices and welfare in a developing economy. Using detailed product-level data on monthly pharmaceutical prices and sales over a two year period from January 1999 to December 2000, we estimate key price and expenditure elasticities and supply-side parameters for the fluoroquinolone (quinolone henceforth[5]) segment of systemic anti-bacterials (i.e., antibiotics) in the Indian pharmaceuticals market. We chose this segment both because it contains several products that were still under patent in the U.S. during our sample period, and because antibiotics are important from a public health policy point of view (compared to let's say Prozac, Viagra, or other life-style drugs that were also under patent protection in the U.S. during this period). We then use our estimates to carry out counterfactual simulations of what prices, profits

[3] For a representative example of estimation of pharmaceuticals demand in developed countries see Ellison, Cockburn, Griliches and Hausman (1997).

[4] See for instance, Challu (1991), Fink (2000), Maskus and Konan (1994), Nogues (1993), Subramanian (1995), and Wattal (2000).

[5] Technically, the term "fluoroquinolones" refers to the latest generation of quinolones. However, older quinolones (e.g., nalidixic acid) have market shares close to zero.

(of both domestic firms and subsidiaries of foreign multinationals) and consumer welfare would have been, had the quinolone molecules we study been under patent in India as they were in the U.S. at the time. The presence of many therapeutic substitutes within the antibiotics segment, make this product category ideal for investigating the claim that the presence of close substitutes will prevent drug prices from rising once patent protection is enforced. Of course, to the extent that our estimates refer to antibiotics, they are not directly applicable to other pharmaceutical product categories that may have different demand structures. For example, a finding of large substitution effects towards non-patented products would not necessarily apply to a market segment with only few, or possibly no therapeutic substitutes. Still, a finding of limited substitution towards other drugs and associated large price increases, would suggest that the effects of patent enforcement in other pharmaceutical segments with fewer therapeutic substitutes might be even larger.

India provides a natural setting for our analysis for a number of reasons. It is a leading example of a low-income country that did not recognize pharmaceutical product patents at the time the TRIPS agreement went into effect. In fact, during the Uruguay round of negotiations, India led the opposition to the TRIPS articles mandating pharmaceutical product patents. In terms of the structure of demand, India is a prototypical example of a low-income country with a large number of poor households who, because health insurance coverage is non-existent, have to meet all medical expenses out-of-pocket. Moreover, the disease profile of the Indian population mirrors that of many other low-income countries and is considerably different from that of most developed economies. Lastly, the domestic Indian pharmaceutical industry, which as of 2002 was the largest producer of generic drugs in the world in terms of volume, is typical of that in many middle-income countries with large numbers of small and medium sized firms with significant imitative capabilities producing and marketing drugs domestically that are under patent elsewhere.

During the period covered by our data, several molecules in the quinolone family were still under patent in the U.S., but products containing these molecules were being produced and distributed in India by both a number of domestic firms and a number of local subsidiaries of foreign multinationals. We aggregate these products into a number of mutually exclusive product groups where, within each product group all products contain the same quinolone molecule (e.g., ciprofloxacin or norfloxacin, etc.), and are produced by firms with the same domestic or foreign status. We then estimate a two-level demand system employing the Almost Ideal Demand System (AIDS) specification of Deaton and Muellbauer (1980) in both levels. The higher level corresponds to the allocation of expenditures to various sub-segments within the systemic anti-bacterials segment of the market. At the lower level we estimate the parameters relevant for the allocation of expenditures within the quinolone sub-segment to the various product groups within this sub-segment (e.g., foreign ciprofloxacin, domestic ciprofloxacin, domestic norfloxacin, etc.).

With these estimates in hand we turn to the counterfactuals. The basic counterfactual scenarios we consider all involve the withdrawal of one or more of the domestic quinolone product groups from the market. The idea here is that had U.S. patents for, say, ciprofloxacin, been recognized in India, all domestic products containing ciprofloxacin would not be present in the market. That would leave only the foreign ciprofloxacin product group in the market. Using our estimates of the own, cross-price, and expenditure elasticities of the various product groups, as well as estimates for the upper and lower bounds of marginal costs of production, we are able to simulate the prices and market shares that would obtain under each of the scenarios. Moreover, using the expenditure function associated with the higher-level AIDS specification we are able to calculate the welfare loss—measured in terms of the compensating variation, i.e., the additional expenditure that the representative Indian consumer would need to incur to maintain her utility level in the face of the domestic product withdrawal(s) and the accompanying price and market share changes—under each of the counterfactual scenarios.

Apart from the fact that our counterfactual simulations are based on estimated rather than assumed parameter values, this paper builds upon the earlier studies in two substantive, and (it turns out) empirically important, ways.

First, by accommodating the possibility that consumers may differentiate between domestic and foreign products even when these products contain the same patentable molecule, we allow for an additional channel through which the introduction of product patents and the consequent withdrawal of domestic products may adversely affect consumers; and that is through the loss of product variety. In contrast, previous studies on developing countries assume that consumers are indifferent between foreign and domestic products that contain the same molecule. What this implies is that any adverse welfare effects are only realized through increased prices. The difference is most evident if we consider a scenario under which domestic products are forced to withdraw from the market because of the introduction of product patents, but strict price regulations maintain prices at pre-patent levels. In our approach consumers would still experience a welfare loss, whereas in the framework adopted in earlier studies, such a scenario would entail no loss of welfare.

Empirically, the component of the consumer welfare loss attributable to the reduction of variety from the withdrawal of domestic products turns out to be significant. We interpret this component as capturing primarily an "ease of access" effect: due to differences in the marketing and distribution networks, domestic products are more readily available to Indian consumers than products produced by foreign subsidiaries. From a policy perspective, this suggests a possible role for compulsory licensing in addition to or in lieu of price regulation, since the latter, by itself, will not alleviate the welfare loss due to loss of variety. Alternatively, one could argue that - to the extent that the loss we attribute to the reduction of product variety is due to the fact that the current product portfolios and distribution networks of foreign producers are limited - it is purely a transitional phenomenon, and should thus not

be included in the welfare calculations. This is a controversial point that we discuss in detail in the results section. If foreign firms respond to patent enforcement by investing in distribution networks or by using licensing agreements with domestic firms to make their products more readily available to Indian consumers, the "ease of access" effect would indeed diminish in importance in the longer run, though of course it could be significant in the first years after patent enforcement. However, whether these investments will materialize, is open to debate. If TRIPS is accompanied by price regulation in order to limit price increases in poor developing countries, the incentives of multinationals to invest in marketing and distribution in these countries may diminish. At any rate, to take into account the possibility that the welfare loss due to the reduction of variety is a temporary phenomenon, we also present a more conservative welfare loss estimate, by subtracting the "product variety" component from our total loss estimate. This gives us a lower bound estimate that is due to price increases alone. Though only about a third of our upper bound estimate, in absolute terms this lower bound estimate is still very large, representing 24% of antibiotic sales in 2000.

A second, and perhaps even more important methodological difference between this paper and earlier studies is that we allow for and flexibly estimate a range of cross-product-group and cross-molecule substitution effects. In contrast, cross-price effects are ignored in earlier studies. To see why cross-price effects are likely to significantly alter estimated welfare effects in this context, imagine a scenario where the introduction of patents leads to monopoly pricing in the market for a particular patentable molecule. If the markets for potential substitutes are imperfectly competitive, then the increase in price in the original patentable market will lead to corresponding upward price adjustments in the related markets as producers of substitute products reoptimize in the face of the increased demand for their products. The magnitude of any upward adjustments will naturally vary with the degree of competition in related markets, and with the strength of the cross-price effects. But as long as the cross-price effects are positive, and related markets are not perfectly competitive, the loss of consumer surplus because of monopoly pricing in one market will be multiplied through the ripple effects of upward price adjustments in related markets.

If this were just a theoretical possibility it would not be of much interest. However, these multiplier effects turn out to be substantial in our counterfactual scenarios. Most strikingly, the estimated loss of consumer welfare from the simultaneous withdrawal of all four domestic product groups—the scenario that most closely resembles what is likely to happen under TRIPS—is more than two times the *sum of the estimated losses* from the four separate scenarios in each of which only one of the domestic product groups is withdrawn. What this very clearly indicates is that past studies that have estimated the aggregate effects of patent protection by adding up the losses, estimated *separately* in each of a number of patentable markets, may have substantially underestimated the magnitude of the consumer welfare losses from the introduction of pharmaceutical product patents.

In absolute terms, we estimate that *in the absence of any price regulation* the prices of foreign patented products would rise between 100% and 400%. In the more realistic case of some form of price regulation that would keep drug prices fixed at their pre-TRIPS level, the total annual welfare losses to the Indian economy from the withdrawal of all four domestic product groups in the quinolone sub-segment would be on the order of Rs. 13.70 billion, or about 50% of the sales of the entire systemic anti-bacterials segment in 2000. At the then prevailing exchange rate this translates into a figure of U.S. $305 million. Of this amount, foregone profits of domestic producers constitute roughly Rs. 2.3 billion or U.S. $50 million. The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare.

The welfare loss we estimate represents only the static costs of patent enforcement arising from pricing distortions and reduction in product variety. Our approach does not address the potential dynamic benefits of innovations that may result from international property rights protection. Nevertheless, we believe that estimating these static costs is important whenever there is a radical change in policy - which TRIPS represents for a good part of the developing world. Even if there is the potential for long-term benefits, knowledge of the short-run costs is important for designing an appropriate policy response that will potentially mitigate the adverse short-run impact. Having said that, it is worth noting that according to our estimates, the total profit gains of patent enforcement to foreign producers *in the absence of any price regulation* would be only about U.S. $53 million per year. *With price regulation* that would keep the prices of drugs supplied by multinational subsidiaries at their pre-TRIPS level, the profit gains become only U.S. $19.6 million per year.

The remainder of this paper is organized as follows. In the next section we lay out the essential features of the Indian pharmaceuticals market, provide more detail about the segments that we focus on in the empirical analysis, and briefly describe the primary data we use. Section 3 describes the analytic framework and the econometric strategy we use to estimate the relevant parameters and construct the counterfactual scenarios. We discuss our results in Section 4. Section 5 concludes.

2. The setting and the data

Between April 1972, when the Indian Patents Act (1970) became effective, and March 2005, when India's parliament passed the 3rd Amendment of the Patents Act, India did not recognize product patents for pharmaceuticals. The Indian Patents Act (1970), which replaced the inherited British colonial law regarding intellectual property rights, specifically excluded pharmaceutical product patents and only admitted process patents for a period of seven years. In contrast the latest amendment recognizes patents on end products that under the new regime will remain in force for twenty years.[6]

[6]Indian companies that are now producing drugs for which patent applications were submitted between the signing of the TRIPS agreement in 1995 and January 1, 2005 will be allowed to continue producing if they pay a royalty to the

The two stated objectives of the 1970 act were: the development of an indigenous pharmaceuticals industry; and the provision of low-cost access to medicines for Indian consumers. Consistent with these objectives, and with the broader leftward tilt in policy, a number of other measures were introduced—drug price controls, restrictions on capacity expansion, limits on multinational equity shares, etc.—that in the years since have, on the one hand, kept pharmaceutical prices low, and on the other encouraged the development of the Indian pharmaceutical industry. Many of these regulations and restrictions have been lifted or eased since the mid-1980s with marked acceleration in the pace of liberalization during the 1990s.

Over the last twenty years the Indian pharmaceutical industry has grown rapidly to the point where it is now the world's largest producer of formulations in terms of volume, and one of the world's largest producers of bulk drugs.[7] The structure of the industry has also evolved. In 1970 the industry was dominated by multinational subsidiaries; by 2001, Indian-owned firms were not just the leading players in the industry, many had also become major exporters.

The data we use in this paper are from the retail pharmaceutical audits of ORG-MARG, India's premier market research and consulting firm. The audit provides detailed product-level information—estimates of monthly retail sales in each of the four geographic zones of India, price, dosage form, launch date, brand name, chemical name, therapeutic categorization, etc.—on all pharmaceutical products sold in India by about 300 of the largest firms, representing roughly 90% of domestic retail sales of pharmaceuticals. The coverage of the audit is extensive, reaching a representative panel of thousands of retail chemists in over 350 cities and towns. The data collected, which provide the only real source of disaggregate information on the Indian pharmaceutical market, are used by both the government of India in formulating pricing policy and other decisions, and the Indian pharmaceutical industry in determining pricing and marketing strategies. We have information at a monthly frequency for the period of January 1999 to December 2000. Tables 1-3 provide a set of descriptive statistics that are essential for understanding the focus of our analysis and interpreting our results.

As noted earlier, the characteristics of demand for pharmaceuticals in India are likely to differ considerably from those in developed economies. With a share of 23%, the anti-infectives segment ranks second in India, whereas in the world market it is fifth and has a share of only 9.0%. Hence, anti-infectives are important in India not only from a health-public-policy point of view, but also as a source of firm revenue.

With this in mind, we focus in this paper on one particular sub-segment of anti-infectives, namely

patent holder.

[7] *Bulk drugs* are the therapeutically relevant active pharmaceutical ingredients that are combined with a variety of inactive ingredients to make the *formulations* that are ultimately consumed by patients. Firms in the pharmaceutical sector can be of one of three types: bulk drugs producers, pure formulators, or integrated firms, which produce both bulk drugs and market formulations.

the quinolone sub-segment. Quinolones fall into the systemic anti-biotics and anti-bacterials segment of the Indian pharmaceuticals market, which generates over three-quarters of the revenues in the anti-infectives segment[8]. The systemic anti-bacterials segment includes all of the original miracle drugs that first sparked the growth of the global research-based pharmaceutical industry in the post-World War II period, as well as later generations of molecules that have been introduced in the last four decades.

Among systemic anti-bacterials, quinolones are the latest generation molecules available in India. We focus our analysis on quinolones for several reasons. First, quinolones are the drug of choice for a large number of bacterial infections, some of which are also treated by alternative drugs (see Table A1 in the Appendix, which outlines the spectrum of activity for each molecule family within the anti-bacterials segment). Hence, if there were one product group for which we would expect to have many substitutes readily available, this would be quinolones. Second, with a share of 20% in the sales of systemic anti-bacterials, quinolones represent one of the largest sub-segments within this therapeutic category. Finally, several molecules within the quinolone sub-segment were still under patent in the U.S. at the time of our investigation. This is shown in Table 2 that details the basic information about the four quinolone molecules that are the focus of our analysis. The first row shows the year of U.S. patent expiry; this ranges from 1998 for norfloxacin, to 2010 for sparfloxacin. Quinolones include in principle four more molecules that are listed at the bottom of Table 1; however, the market shares of these molecules are negligible, so that we exclude these molecules from our analysis.

Table 2 reveals several other interesting facts about competition in the quinolone market in India. First, note the large number of firms operating in this sub-segment. The large number of domestic firms is perhaps not that surprising given that pharmaceutical product patents were not recognized in India.[9] What is more surprising is the number of foreign firms selling patented products (e.g., ciprofloxacin); the fact that multiple foreign firms sell a patented product indicates that such firms often "infringe"[10] patent laws in India, while complying with them in developed world countries. The last two rows of Table 2 further indicate that domestic products often sell at a premium. With the exception of ofloxacin, the average prices of products offered by Indian firms are higher than the prices of products offered by foreign subsidiaries. This preliminary evidence suggests that Indian consumers do not place a premium on the brand name and reputation of big multinational pharmaceutical concerns. Moreover, the higher price of domestic products does not seem to prevent domestic companies from capturing a large market share. This is most evident in the case of ciprofloxacin, where domestic firms have, with

[8] In addition to anti-bacterials, this segment contains also anti-virals.

[9] Accordingly, the common distinction between "branded" and "generic" products is irrelevant here.

[10] We emphasize here that the word "infringe" belongs in quotes: Because patent laws do not currently exist in India, infringement in the legal sense is not possible. It is however striking that the same firms that accuse Indian producers of "piracy" sell in India products that are patented in the U.S., and for which the patent is held by a different multinational corporation.

53%, the largest share in the total sales of quinolones; and this despite the fact that the average price of these products is 10% higher than the price of foreign products containing the same molecule.

Table 3 provides additional summary statistics for our data, broken down by region. The first two rows of the table report the average annual household expenditure on quinolones and antibiotics respectively. Note that in both cases the average expenditure is higher in North and West; these regions include states with higher per-capita incomes, and tend to be more industrialized and urbanized than those in the East and South. Pharmaceutical products are available in multiple presentations, that is combinations of dosage forms (capsule, tablet, syrup, etc.), strength (100 milligrams, 500 milligrams, etc.), and packet sizes (50 capsule bottle, 100 tablet bottle, etc.). The various presentations in which a product is available are often referred to as stock-keeping units or SKUs.[11] The number of SKUs for each product group within quinolones is reported at the top of Table 3. As with the more aggregate numbers on firms and products reported in Table 2, the difference between domestic and foreign products is striking. The number of SKUs offered by Indian firms is consistently larger than the number offered by subsidiaries of foreign multinationals. The number of SKUs varies slightly across regions, but, more importantly, it varies across time, as some SKUs disappear, while new ones get introduced during our sample period.

Many pharmaceutical products in India are subject to price controls.[12] While the specifics of the price regulation are too complex for any economic model to adequately capture, the main concern for the empirical analysis is that price controls may lead to a lack of price variation over time, so that the demand function cannot be identified. Prices at the most disaggregate, SKU, level are relatively stable over time; there are variations due to occasional changes in the estimated cost (due for example to changes in exchange rates that affect the cost of imported materials or bulk drugs), but such variations tend to be infrequent and small in magnitude. The degree of time variation is however substantially larger once one aggregates to the product level. This variability stems not only from the fact that the SKUs over which we aggregate may experience changes in their respective prices at different points in time, but also from the fact that the range of SKUs offered in the market does not remain constant over time. The entry and exit of presentations within the same product group that have different prices effectively affects the price that consumers face for this drug in each period.

The middle portion of Table 3 reports the mean price and standard deviation for each product group by region. Prices vary by region, though there is no clear pattern emerging from the table with regard to the cross-regional variation (in the sense of some regions being systematically more

[11] For instance, a 100 capsule bottle of 100 milligram capsules of a particular branded drug, and a 50 capsule bottle of 100 milligram capsules of the same branded drug would be identified as two separate SKUs.

[12] The details of the procedures for price fixation can be found in the official government website: http://www.nppaindia.nic.in/index1.html, under the link "Drug Price Control Order 1995". A new pharmaceutical policy was introduced in 2002, but our data were collected before that year.

expensive than others). To examine what portion of the total price variation is due to time versus regional variation, we conducted an analysis of variance of prices that we report in Table 4. The table is based on separate regressions for each product group (pooling data across groups with big differences in their average prices is not particularly informative, as most of the price variation is accounted for by product group dummies). The last two columns of the table show the fraction of price variation that is accounted for by region and time dummies respectively. As evident from the table, a significant fraction of the total variance in prices can be attributed to time variation. In the demand estimation we include a full set of *product group-specific* regional dummies, so that the price parameters are identified entirely based on this time variation within each product group. The time variation of product group prices is driven primarily by compositional changes within each group: the revenue shares of the individual SKUs that comprise each product group change over time (see the related discussion in section 3.3), while in each period, there is entry and exit of SKUs into the sample. To check whether this pattern reflects genuine entry and exit, as opposed to sampling variation, we examined the revenue shares of the SKUs that leave the sample relative to the ones that remain during the entire period. The results are reported in Table 5. While the SKUs that exit tend to be smaller (their average share is 1% as opposed to 3.4% for those SKUs that are present during the entire sample period), the shares of the two groups do not seem orders of magnitude apart[13]. In addition, our data cover only the 300 largest firms selling in the Indian market, so that firms with very small shares are not included in our sample.

3. The analytic framework and estimation approach

Patent enforcement in the Indian pharmaceutical market will have the effect of eliminating domestic products whose active pharmaceutical ingredients are protected by (foreign) patents. Thus, assessing the effects of patent enforcement is tantamount to assessing the effects of withdrawing domestic products from the market. This task is the converse of evaluating new product introduction; accordingly, the conceptual framework we use to address the questions of interest is similar to the one developed in the literature for the valuation of new goods.[14]

We start by estimating demand for quinolones. Given that the market is characterized by imperfect competition, the counterfactual analysis requires that we also model the supply side, as removal of one product will affect the prices of other products, especially those that are close competitors. The existence of price regulation in the Indian pharmaceutical market imposes potential constraints on

[13] While we cannot completely rule out the possibility that some of the exit is due to sampling variation, note that the latter should be reflected in low precision of the demand parameter estimates. However, the demand parameters are precisely estimated.

[14] See Trajtenberg (1989), Hausman (1994), and Bresnahan (2004) for representative examples and a discussion of the relevant issues.

firms' maximization problem. Given these constraints and the complexity of the price regulation process, the typical approach of deriving estimates of actual marginal costs and markups by exploiting the first order conditions of profit maximizing firms does not seem particularly promising. Instead, we use our demand estimates to place upper and lower bounds on marginal costs and markups.

With demand elasticities and upper and lower bounds for marginal costs in place, we then conduct counterfactual simulations. We consider several alternative scenarios depending on the number of domestic products that are affected by patent enforcement. For each scenario, we compute the counterfactual prices, and use them to assess the effects of domestic product withdrawal on consumer welfare (as measured by the compensating variation), firm profits, and social welfare. As with the valuation of new products, the big conceptual problem facing this part of the analysis is that we need to extrapolate from the region of the data to the point at which demand for the products that exit the market becomes zero. This conceptual issue is present in any attempt to evaluate a major policy change for which no historical precedent exists, like the enforcement of patent laws in India. One advantage of the present study is that we have a limited set of price data for Pakistan, a country with similar demographics as India, but with a market structure that resembles the one that would emerge in India under patent enforcement (monopoly of multinational subsidiaries). By comparing the prices of products offered by multinationals in Pakistan to those we compute in our counterfactual simulations for the products that *would be* offered by multinationals in India *if* patent laws were enforced, we can get a sense of how plausible our counterfactual estimates are.

3.1. Demand

The demand modelling is based on the multi-stage budgeting approach. Our primary motivation for adopting this approach was a practical one. In the multi-stage budgeting approach the dependent variable is defined as a revenue share, which is appealing here given that the products we include in the analysis contain different molecules (i.e., active pharmaceutical ingredients, or APIs). Even though we do have data on the quantity of the relevant API (e.g., 100 milligrams of ciprofloxacin) contained in each product, converting the revenue shares to physical shares is extremely difficult, if not infeasible, in the case of anti-biotics. Because such drugs are "systemic" by nature, they are used to treat a large number of infections, and the dosage of each drug depends on the particular infection it is supposed to address (for example the dosage will differ depending on whether the anti-biotic is used to combat an ear-infection or tuberculosis). This particular feature of anti-biotics complicates the conversion of revenue to physical shares.

The basic idea of the multi-stage budgeting approach is to use the therapeutic classification of a product—i.e., the therapeutic segment and sub-segment the product belongs to—to organize all products in the systemic anti-bacterials segment into a hierarchical taxonomy, consisting of two lev-

els. At the higher level are the various sub-segments of systemic anti-bacterials. The first stage of budgeting corresponds to the allocation of expenditures across the sub-segments in this upper level of the taxonomy.

In the second stage of the budgeting process, corresponding to the lower level of the taxonomy, a flexible functional form is adopted to model how the expenditures allocated to each sub-segment are distributed across the products within that sub-segment. In particular, to model demand at the second stage we employ the "Almost Ideal Demand System" (AIDS) specification proposed by Deaton and Muellbauer (1980).[15]

While the two-stage demand estimation approach offers functional form flexibility, its application to the Indian systemic antibiotics market poses a couple of problems. The first one is that due to entry and exit, many SKUs and even products in our sample are not present in every period. AIDS does not have a good way of dealing with a varying number of products, as it was developed with broad commodity categories in mind, which are consumed by all consumers every period. To solve this problem, we aggregate within each sub-segment (e.g., quinolones) SKUs into *product groups,* where within each product group, all SKUs contain the same molecule and are produced by firms with the same domestic/foreign status. Specifically, let a SKU k be indexed by its molecule (or API) M, its domestic/foreign status DF indicating whether it is produced by a domestic (Indian) or a subsidiary of a foreign (multinational) firm, a particular presentation s, and the particular firm f that produces it. We aggregate SKUs over presentations and firms to obtain a newly defined product group i, which is only indexed by molecule M and domestic/foreign status DF, and has revenue $R_i = \Sigma_{f,s} R_k$, with $i \in (M, DF), k \in (M, DF, f, s)$, and price $p_i = \Sigma_{f,s} \omega_k p_k$, where ω_k denotes the conditional (on M and DF) revenue share of this particular product, i.e.,:

$$\omega_k = \frac{R_k}{R_i} \tag{3.1}$$

In most cases, the resulting product groups are broad enough to be present every period[16].

The usual concern with this aggregation procedure is that it may lead us to overstate firms' market power, as we ignore competition among firms with the same domestic/foreign status, producing the same molecule. However, in the present application this concern is unlikely to be of great importance, as the effect of patent enforcement is to wipe out all domestic competition at once, while granting

[15] Representative applications of the multi-stage budgeting approach include Ellison, Cockburn, Griliches and Hausman (1997), Hausman (1994), and Hausman and Leonard (2002).

[16] We are only missing 4 observations (i.e., month/region combinations), all for the drug group of Foreign Norfloxacin: Aug. 1999 in the South, May 2000 in the West, Oct. 2000 in the South, and Nov. 2000 in the East. In these cases, we set the revenue shares of Foreign Norfloxacin equal to zero. In general, with 0.1% of quinolone sales (see Table 1, row 2), Foreign Norfloxacin has a very small share of the market. This probably explains why the results pertaining to this drug group are unreliable: it is the only drug group for which we do not obtain a significant price elasticity of demand, while its cross-price elasticities with other foreign drug groups often have the wrong sign.

foreign firms monopoly power; hence, competition among firms for patented molecules becomes irrelevant. The aggregation according to the domestic/foreign status (within a particular molecule) thus corresponds to the scope of our analysis and the particular questions of interest.

The second problem is that for our approach to be useful in welfare analysis, the allocation of total expenditures to group expenditures at the higher stage has to be modelled in a way consistent with utility maximization. In general, the solution of this allocation problem requires knowledge of all individual product prices. From an empirical point of view this is not particularly useful, as it eliminates all computational advantages of the two-stage approach. To address this problem we adopt an *approximate* solution to model the higher level expenditure allocation along the lines suggested by Deaton and Muellbauer (1980b, pp. 131-132). This gives rise to a two-level AIDS specification.

Consider the lower level estimation first, which refers to the allocation of a particular sub-segment's expenditure to the product groups within the sub-segment. In our application the relevant sub-segment is quinolones, which we index with Q. Let the product groups within this sub-segment be indexed by $i = 1, ...N$, p_i be the price of product group i (where, as noted above, i refers to a particular molecule and domestic/foreign status combination), and X_Q the total expenditure on the quinolone segment. The revenue share of each product group is given by:

$$\omega_i = \alpha_i + \Sigma_j \gamma_{ij} \ln p_j + \beta_i \ln(\frac{X_Q}{P_Q}) \tag{3.2}$$

where ω_i, the revenue share of product group i, is defined as:

$$\omega_i \equiv \frac{p_i q_i}{\Sigma_j p_j q_j} = \frac{x_i}{X_Q}, \text{ with } i, j \in Q \tag{3.3}$$

X_Q is the overall expenditure on the quinolone sub-segment, and P_Q is a price index given by:

$$\ln P_Q = a(p) = \alpha_0 + \Sigma_i \alpha_i \ln p_i + \frac{1}{2} \Sigma_i \Sigma_j \widetilde{\gamma}_{ij} \ln p_i \ln p_j \tag{3.4}$$

With a limited number of product groups and a sufficiently large number of time-series observations, the flexibility implied by the AIDS model does not impose too many demands on the data. However, in the present application where the number of observations is limited, the AIDS model is not estimable in this general form. To reduce the number of parameters that need to be estimated, we impose two sets of restrictions.

The first set of restrictions are implied by the theory of utility maximization. Specifically, these restrictions are:

- *Adding-up:* $\Sigma_k \alpha_k = 1$; $\Sigma_k \beta_k = 0$; $\Sigma_k \widetilde{\gamma}_{kj} = 0$, $\forall j$.
- *Homogeneity:* $\Sigma_k \widetilde{\gamma}_{jk} = 0$, $\forall j$.

- *Symmetry:* $\gamma_{ij} = \frac{1}{2}[\widetilde{\gamma}_{ij} + \widetilde{\gamma}_{ji}] = \gamma_{ji}$. This last restriction by itself reduces the number of γ parameters to $\frac{N(N+1)}{2}$.

The second set of restrictions we impose aims at further reducing the number of γ parameters to be estimated by exploiting our knowledge of this particular market. Specifically, for each product group i, we allow one γ_{ij} parameter for all product groups j that have different molecules from product group i and are produced by foreign firms, and one γ_{ij} for product groups j with different molecules produced by domestic firms. We don't impose any restrictions on the γ_{ij} parameter when product group j has the same molecule as product group i. (By construction, product groups i and j contain products produced by firms with different domestic/foreign status.)

To better illustrate the nature of the restrictions we impose on the patterns of substitution across products, some additional notation is needed. Let $d(i,j)$ be an indicator of the degree of similarity (or difference) between product group i and product group j, along the dimensions we are able to observe (molecule M and domestic/foreign status DF). For any two product groups, i and j, $d(i,j)$ can take on one of the following three values:[17]

$$d(i,j) = \begin{cases} (1,0) & \text{if } M_i = M_j, DF_i \neq DF_j \\ (0,1) & \text{if } M_i \neq M_j, DF_i = DF_j \\ (0,0) & \text{if } M_i \neq M_j, DF_i \neq DF_j \end{cases} \tag{3.5}$$

Let

$$D_i^{ab} = \{j : d(i,j) = (a,b)\} \tag{3.6}$$

the equation at the lower level becomes:

$$\begin{aligned} \omega_i \quad = \quad & \alpha_i + \gamma_{ii} \ln p_i + \Sigma_{j \in D_i^{10}}[\gamma_{i,10} \ln p_j] + \Sigma_{j \in D_i^{01}}[\gamma_{i,01} \ln p_j] \\ & + \Sigma_{j \in D_i^{00}}[\gamma_{i,00} \ln p_j] + \beta_i \ln(\frac{X_Q}{P_Q}) \end{aligned} \tag{3.7}$$

Note that:

- the parameter γ_{ii} captures a product group's own price effect (note that there will be as many γ_{ii} parameters as number of product groups).
- the parameter $\gamma_{i,10}$ captures the cross-price effects across product groups containing products with the same molecule but produced by firms of different nationality.

[17] The sequence $(1,1)$ is not possible for two different products; in this case the γ parameter corresponds to the product's own price effect, that is γ_{ii}.

- the parameter $\gamma_{i,01}$ captures the cross-price effects of product groups containing products with different molecules but produced by firms with the same nationality.
- the parameter $\gamma_{i,00}$ captures the cross-price effects of product groups containing products with different molecules produced by firms of different nationality.

Before we take the demand equation to the data, we make two modifications. The first one is to let the product specific effects α_i vary by region r. The resulting product-specific regional effects α_{ir} have two interpretations: first, they control for the "quality" of each drug, with quality differences being allowed to vary across regions; second, they proxy for demographics and other demand shifters, which vary by region, and may affect the demand of each product group differently[18]. Note that by including product-specific regional effects in the demand specification, we estimate the price parameters based on the within product group variation of prices in each region. In an earlier version of the paper we also estimated the demand system without regional dummies and obtained similar results.

The second modification that allows us to go from a deterministic to a stochastic specification of the demand equation is to include an additive error term in (3.2). The latter takes into account the fact that (3.2) is not expected to fit the data exactly. The error term ε_{irt} accounts for measurement error (due to the fact that the product group prices p_{jrt} we employ in the estimation are not exact price indices, but approximations thereof) and (potentially region-specific) demand shocks that may affect the demand for a product in particular period. Examples of such shocks include an advertising campaign for a particular product that temporarily increases the demand for this product; the outbreak of a (potentially region-specific) epidemic, that calls for the use of a particular drug, etc. We discuss the interpretation and properties of this error term in more detail in the next section.

The final form of the equation we estimate at the lower level becomes (with subscript t denoting month, and subscript r denoting region):

$$\begin{aligned} \omega_{irt} &= \alpha_i + \alpha_{ir} + \gamma_{ii} \ln p_{irt} + \Sigma_{j \in D_i^{10}} [\gamma_{i,10} \ln p_{jrt}] + \Sigma_{j \in D_i^{01}} [\gamma_{i,01} \ln p_{jrt}] \\ &\quad + \Sigma_{j \in D_i^{00}} [\gamma_{i,00} \ln p_{jrt}] + \beta_i \ln(\frac{X_{Qrt}}{P_{Qrt}}) + \varepsilon_{irt} \end{aligned} \tag{3.8}$$

The analysis so far has conditioned on the expenditure allocated to the quinolone sub-segment X_Q. The upper level of the estimation considers the problem of allocating total expenditure across the different systemic anti-biotics sub-segments, one of which is quinolones. The upper level demand function is given by:

$$\omega_G = \alpha_G + \Sigma_H \gamma_{GH} \ln P_H + \beta_G \ln(\frac{X}{P}) \tag{3.9}$$

[18] Given the short time span of our sample, typical demand shifters, such as age distribution, income distribution, education, etc., hardly change over our sample period. Such shifters are therefore absorbed by the region-specific product fixed effects α_{ir}

where all variables denoted by capital letters are defined as before, but now refer to *sub-segments* $(G, H, ...)$ rather than individual *products* within a sub-segment, and the total expenditures on systemic anti-biotics X are deflated by the Stone price index $\log P = \Sigma_H \omega_H \log P_H$. When estimating the above system we impose all the restrictions implied by utility maximization, as we do with the estimation of the lower level AIDS. However, we do not impose any additional restrictions on the substitution patterns at this stage, so that the cross-price effects across segments remain relatively unconstrained.

Estimation of the higher level AIDS allows us to obtain the *unconditional* own- and cross-price elasticities that are used in the formulation of the supply problem and welfare analysis. These will be given by the formula:

$$\varepsilon_{ij} = \varepsilon_{ij}|_{X_Q=\overline{X_Q}} + \frac{\partial \ln q_i}{\partial \ln X_Q} \frac{\partial \ln X_Q}{\partial \ln P_Q} \frac{\partial \ln P_Q}{\partial \ln p_j} \tag{3.10}$$

with the conditional cross price elasticities given by:

$$\varepsilon_{ij}|_{X_Q=\overline{X_Q}} = \left[\frac{\gamma_{ij} - \beta_i[\omega_j - \beta_j \ln(\frac{X_Q}{P_Q})]}{\omega_i} \right]$$

As in the lower stage, we include sub-segment specific regional dummies in the specification of the upper stage demand system, so that the final form of the estimating equation at the upper stage becomes:

$$\omega_{Grt} = \alpha_G + \alpha_{Gr} + \Sigma_H \gamma_{GH} \ln P_{Hrt} + \beta_G \ln(\frac{X_{rt}}{P_{rt}}) + \varepsilon_{Grt} \tag{3.11}$$

In sum, the demand system we take to the data is represented by equations (3.8) and (3.11), and the associated parameter restrictions implied by economic theory.

3.2. Modelling the supply side of the market

Counterfactual simulations concerning the effects of domestic product withdrawal require knowledge of the marginal costs of pharmaceutical firms operating in the Indian market. These are unobservable. The usual approach in the New Empirical Industrial Organization literature has been to exploit the firm equilibrium conditions to infer marginal cost. For example, it is often assumed that the marginal cost c_i is constant and that the industry is an oligopoly engaging in Bertrand competition with differentiated products. Assuming that firms myopically maximize profits each period, one can then derive the firms' first order conditions that correspond to the above assumptions about costs, market structure, and firm behavior.

We deviate from this procedure as the presence of price regulation renders the assumption of unconstrained period-by-period maximization untenable. Ideally, one would like to explicitly incorporate the price and other administrative controls into the firm's optimization problem and derive the first order conditions under the assumption of constrained maximization. However, the complexity of the

price regulation makes this approach infeasible. Therefore we adopt an alternative approach that does not rely on modelling the price setting process, but is instead based on deriving upper and lower bound for marginal costs and markups.

In particular, an upper bound for marginal costs and a lower bound for the markups (zero) can be derived under the assumption of perfect competition. While this assumption is clearly unrealistic in the pharmaceuticals market, it is useful in providing an upper bound for costs c_i^U, which will be given by:

$$c_i^U = p_i \tag{3.12}$$

On the other hand, a lower bound for marginal costs c_i^L (and upper bound for markups) can be derived by assuming that there is perfect collusion within each product group i (where i refers here to a molecule/domestic-foreign combination)[19] and ignoring price controls, so that prices are determined by the first order condition of the jointly profit maximizing firms within product group i. Solving this first order condition for the (lower bound of) marginal cost then gives:

$$c_i^L = p_i * (1 + \frac{1}{\varepsilon_{ii(p_i,p_j)}}) \tag{3.13}$$

where $\varepsilon_{ii(p_i,p_j)}$, the own- price elasticity of demand for product i, will depend on the product's own price p_i, and all other products' prices p_j, with $i \neq j$.

Once we have obtained the demand elasticities through estimation of the demand system, we can calculate the upper and lower bounds for marginal costs and corresponding markups according to (3.12) or (3.13). These will then be employed in the counterfactual simulations. While our counterfactuals use both the lower and upper bounds for costs, most of our discussion will be based on using the lower bounds for costs, since this is the more interesting case in the policy analysis: it gives us the largest possible profits for pharmaceutical firms, and hence corresponds to the worst possible scenario facing Indian firms and the best possible scenario facing multinationals under TRIPS.

3.3. Identification assumptions and estimation approach

The discussion of the demand system has so far abstracted from the issue of price endogeneity. The usual premise in the Industrial Organization literature is that correlation of prices with the error term in the demand equation arises by virtue of the first order conditions of profit-maximizing firms.[20] As we discuss in this section, this source of simultaneity bias is unlikely to be of major concern in the

[19] The reason that this assumption will lead to an understatement of marginal costs (and hence overstatement of market power) is that it assumes away competition among firms *within* each drug group.

[20] See Berry, Levinsohn and Pakes (1995) or Nevo (2001) for a related discussion.

present context because of the existence of price regulation. Our primary concern is instead with the simultaneity bias that is implied by the particular way prices are constructed.

To understand the sources of the simultaneity bias note first that the price of product group p_i we employ in the demand estimation should be thought of as a proxy for an exact price index that we do not observe. As such, p_i contains by definition measurement error, and it will be correlated with the error term of the demand equation. Specifically, the demand equation we are interested in estimating can be written in simplified form (suppressing the subscripts r and t, and ignoring parameter restrictions for convenience) as:

$$\omega_i = \alpha_i + \sum_j \gamma_{ij} \ln p_j^T + \beta_i \ln(\frac{X_Q}{P_Q}) + \varsigma_i$$

where p_j^T denotes the *true* (exact) price index for product group i, and ς_i captures unobserved variables that may affect demand in a particular period (e.g., an advertising campaign, an epidemic, etc.). The price index p_j^T depends on the SKU prices p_k. Note that in the presence of SKU entry and exit into the sample, the price index p_j^T will vary over time, *even if* the prices of the individual SKUs remain stable, as the products (SKUs) that comprise each product group change each period.

Ideally, we would like to compute the exact price index p_j^T for each group and employ these indices in the demand estimation. Under the assumption of predetermined SKU prices each period, the exact price indices would be uncorrelated with the error term, and the demand parameters could be estimated by simple OLS. Unfortunately, this strategy is not feasible in the current context.

To derive an exact price index for each product group it is necessary to model consumer's choice among SKUs *conditional* on the choice of the group. To this end, it is necessary to explicitly introduce a third stage in the demand specification and estimate the parameters associated with the choice at that stage. However, any specification based on 3-stage budgeting (that would require directly specifying a demand function associated with the SKU choice at the third stage *and* imposing additive separability at the higher stages) would be infeasible to estimate for three main reasons: First, there is a large number of SKUs within some groups, so that the demand parameters cannot be estimated even if one imposes parameter restrictions; second, the SKU prices exhibit little variation over time; lastly, the choice sets at this lowest stage vary over time, rendering estimation of the price parameters associated with SKUs that are not available in all periods infeasible. Alternatively, one could abandon the multi-stage budgeting altogether, and adopt a discrete choice approach which is inherently better suited to dealing with varying choice sets and limited price variation. A discrete choice approach would be particularly appealing for modeling the SKU choice conditional on product group choice, given that within each group, all SKUs contain the same molecule and are hence comparable. However, as noted earlier, a discrete choice approach at the higher stages of the demand estimation requires converting

revenue to *physical* shares, which is challenging in the case of *systemic* drugs, such as anti-biotics, for which the appropriate dosage is not well defined. Finally, a combination of a multi-stage budgeting approach for the higher stages and a discrete choice approach for the lowest stage would be feasible to estimate, but inconsistent with a model of utility maximization. For these reasons we have no alternative but to adopt an approximation for measuring the price index for each product group.

Let us denote this approximation by p_j^A, and let μ_j denote the proportional "approximation" error associated with measuring the true price index for group j, so that $\ln p_j^A = \ln p_j^T + \ln \mu_j$. The estimating demand equation can then be written as:

$$\omega_i = \alpha_i + \sum_j \gamma_{ij} \ln p_j^A + \beta_i \ln(\frac{X_Q}{P_Q}) - \sum_j \gamma_{ij} \ln \mu_j + \varsigma_i$$

or

$$\omega_i = \alpha_i + \sum_j \gamma_{ij} \ln p_j^A + \beta_i \ln(\frac{X_Q}{P_Q}) + \varepsilon_i$$

where the new error term $\varepsilon_i = -\sum_j \gamma_{ij} \ln \mu_j + \varsigma_i$ is comprised of two components: the first one reflects "measurement" error due to the fact that the product group prices we employ are approximations and not exact price indices; and the second one captures conventional demand shocks. The demand equation as written above corresponds to the equation we take to the data.

The particular proxy we use for the exact price index for each product group j is the revenue-share-weighted average of the prices of multiple SKUs that are available within this group, that is:

$$p_j^A = \Sigma_{k \in j} \omega_k p_k$$

The above notation illustrates the two source of price variation: variation in the SKU prices p_k, and variation in the weights ω_k.

We are concerned with potential correlation of the so-constructed product group prices with both components of the product group demand error term. The correlation between p_j^A and the first component $-\sum_j \gamma_{ij} \ln \mu_j$, is independent of the particular way we construct p_j^A, and inherent in the fact that we measure the exact price index with error. The potential correlation between $p_j^A$and the second component of the product group demand error, the shock ς_i , arises however because of the specific way we construct the proxy p_j^A, and in particular because of the presence of the revenue share weights ω_k in p_j^A: since the SKU revenue share weights ω_k will generally depend on the product group expenditure, they are likely to be correlated with the product group demand shock ς_i.

To address the simultaneity bias we use instrumental variables. To this end, we need variables that are correlated with the proxies p_j^A, but uncorrelated with the error term ε_i. We use the number of SKUs within each product group j as an instrument, as it does justice to the idea that variation in

the product group price index stems in part from variation in the set of SKUs that are available each period. It is clearly correlated with the average group prices p_j^A, and plausibly uncorrelated with the demand shock ς_i. The assumption that the number of SKUs is uncorrelated with the conventional demand error will however be violated if the introduction of a new SKU changes the perceived quality of a drug[21], or if it is accompanied by promotional activities which will be reflected in ς_i. Our hope is that this is not too often the case. Assuming that the SKU number for each group j is also uncorrelated with the weighted sum of the measurement errors of all product groups $\sum_j \gamma_{ij} \ln \mu_j$, it can be used as an instrument for the product group price p_j^A[22]. If one accepts the premise that prices at the SKU level are exogenous, then SKU prices can also be used as instruments. The final list of instruments we use hence includes: the number of SKUs in each group, the prices of the five largest SKUs for each group, and all other exogenous variables in the demand estimation, such as regional/product dummy interactions and the upper-level total expenditure on anti-biotics. Regressions of group prices on the above instruments yield high R-squares, with most regressors highly significant, indicating that our instruments are highly correlated with prices.[23]

Our sample includes four molecules: ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin. Except for sparfloxacin, all other molecules are produced by both foreign and domestic firms.[24] So we have seven products (domestic ciprofloxacin, foreign ciprofloxacin, etc.), with 96 observations (two years of monthly data, four geographical regions for each period) for each product. The parameters in the lower level AIDS demand system as defined in equation (3.8) are: the product fixed effects α_i, the product-regional dummy interactions α_{ir}, the own revenue-share price elasticities γ_{ii}, the cross revenue-share price elasticities $\gamma_{i,10}, \gamma_{i,01}, \gamma_{i,00}$ and the revenue-share expenditure elasticities β_i. In estimating the parameters, we first regress prices on all instrumental variables, and then plug the predicted values for prices in the constrained least-square regression (for a detailed explanation of the constraints see the previous section).

Given that we impose many cross-equation constraints and employ instrumental variables in the estimation, it is difficult to derive standard errors for the parameter estimates analytically. Our error term interpretation in (3.8) implies that the error terms for each product group are likely to be correlated across regions; for example, if a national advertising campaign increases the demand for a relatively expensive presentation in one region, simultaneously increasing the aggregate demand and

[21] Note that we already proxy for the quality of each product group through the product fixed effects α_i. In the actual estimation we actually let these fixed effects be region-specific (α_{ir}), so that we allow quality to vary across regions.

[22] If the measurement error increases in the number of included SKUs, this assumption will be violated. Unfortunately, we have no way of checking the validity of this assumption.

[23] Specifically the R-squares from the first stage regressions of product group prices on instruments range from 0.57 to 0.95, except for domestic ciprofloxacin, for which the R-square is 0.17.

[24] Sparfloxacin is actually offered by one foreign subsidiary in India (see Table 2). However, its revenue share is miniscule. We therefore treat Sparfloxacin as being produced by domestic firms only.

price index for the corresponding product group in that region, it is likely that the same effect will be observed in other regions. In principle, we could exploit the cross-regional correlation in the error terms to estimate the demand system using SUR. However, this would require us to analytically derive the variance-covariance matrix of the parameters, which as noted above, is cumbersome in the current context. Instead, we use the bootstrap method, choosing to remain agnostic about the structure of the variance-covariance matrix. The potential disadvantage of this approach over SUR is a loss in efficiency, but as will become apparent in the results section, the model parameters are fairly precisely estimated. To maintain the market structure, we randomly sample the periods (with replacement) and use the same periods for all products. Regarding the optimal number of bootstrap repetitions, ideally one would follow the three-step method proposed by Andrews et al (2000). However, empirical evidence suggests that one rarely needs more than 200 replications to estimate the standard errors[25]. To be safe, we generate 300 bootstrap samples (with replacement) based on the original data, and estimate the standard errors using the standard errors of the bootstrap sample estimates.

The estimation of the top level AIDS system is similar. The constraints imposed on this top-level demand system are adding up, homogeneity and symmetry. Again bootstrapping is used to obtain the standard errors of the parameter estimates.

3.4. The counterfactual scenarios

In assessing the effects of patent enforcement we start by focusing on the most extreme case, in which compulsory licensing is not an option, and foreign firms are not subject to price controls. We use the results from the analysis of this case as a benchmark. In reality, the outcome of the WTO negotiations is more likely to involve some constraints on the monopoly power of foreign firms selling patented products in developing countries, such as price caps or compulsory licensing. Our framework can easily accommodate these cases, as will become apparent in the next subsection.

We now focus on the effects of potential patent enforcement in the quinolone segment. We consider several scenarios that vary in the number and size of domestic products that will be removed from the market. In particular, we consider the following five scenarios:[26]

[25] See Efron and Tibshirani (1993).

[26] As Table 2 indicates, most of the patents for the drugs in the quinolone segment have expired by now, so that none of the scenarios described in this section is going to materialize in practice. The reason we consider these alternative scenarios in our counterfactual simulations is to get a sense of how the presence and extent of domestic competition affects welfare calculations. Such calculations may become relevant in the future in other therapeutic classes in which patents have not expired yet, and where domestic firms compete with foreign patent holders. While the particular exit scenarios will depend on the exact year of patent expiry of drugs in each therapeutic class and the specific way in which patents will be enforced (e.g., whether or not certain domestic drugs will be grandfathered in), the general conclusion that emerges from our calculations is that the consumer welfare loss is substantially smaller in cases where *some* domestic competition remains present in the market. Hence, the particular way in which patent enforcement is implemented is essential for assessing its welfare impact.

- withdrawal of one large domestic product group only: domestic ciprofloxacin
- withdrawal of one relatively small domestic product group only: domestic ofloxacin
- withdrawal of three domestic product groups: domestic ciprofloxacin, ofloxacin, and norfloxacin
- withdrawal of three domestic product groups: domestic ciprofloxacin, ofloxacin and sparfloxacin
- withdrawal of all four domestic quinolone product groups

As the above list suggests, we proceed from analyzing the effects of single product withdrawal to the analysis of eliminating the entire domestic segment. This approach was motivated by early empirical results that indicated that the existence and extent of competition from domestic firms has a significant bearing on the predicted effects of patent enforcement; that is, our predictions regarding prices and welfare vary substantially depending on how many domestic products are affected by patent enforcement and on whether some domestic competition will remain present after TRIPS. In addition, the size of the affected domestic groups is relevant for the welfare predictions; accordingly, we examine both scenarios in which a large domestic product group, such as domestic ciprofloxacin, is eliminated from the market, and scenarios in which the eliminated domestic group is relatively small (e.g., domestic ofloxacin). In all scenarios we maintain the assumption that the set of products offered by the remaining firms in the market does not change in response to patent enforcement.

3.5. Computation of virtual prices and new equilibrium prices

The first step in the counterfactual analysis is to derive the new equilibrium prices under patent enforcement[27]. In this context there are two sets of prices that are relevant. The first set consists of the virtual prices of those (domestic) products that will not be available once TRIPS is put in effect. To calculate these virtual prices we set the expenditures of the relevant products equal to zero. The second set of prices consists of the prices of those products that remain in the market. In deriving these prices we start by assuming profit maximization *without any form of price regulation*: the firms remaining in the market reoptimize in response to the policy change, and set new prices, taking the prices of all other firms as given.[28] Of course, at the equilibrium all prices change in response to the fact that some domestic products are no longer present. The new equilibrium prices for products that

[27] Of course, until product patents are in fact introduced, these prices will not be observable. Note also that we are assuming here that the range of products that are available will not change with the introduction of patents.

[28] As mentioned above, this first set of calculations abstracts from the existence of remaining price controls or other government regulations that would impose constraints on the firms' profit maximization problem. Accordingly, the resulting numbers should be interpreted as a benchmark of what would happen if markets were completely unregulated. To examine what the welfare effects of TRIPS would be in the more realistic scenario of price regulation, we subsequently consider a scenario in which regulation keeps the prices of the products provided by patent-holders at their pre-TRIPS level. For a more detailed discussion see the results section.

remain in the market are thus computed by utilizing the first order conditions of profit maximizing firms, into which the virtual prices of the eliminated products are substituted. Hence, to compute the new equilibrium prices we solve an equation system of the following form:

- For products i that are withdrawn from the market*:*

$$\begin{aligned} 0 &= \alpha_{ir} + \gamma_{ii} \ln p_{ir}^{V} + \Sigma_{j \in D_i^{10}} [\gamma_{i,10} \ln p_{jr}^{'}] + \Sigma_{j \in D_i^{01}} [\gamma_{i,01} \ln p_{jr}^{'}] \\ &\quad + \Sigma_{j \in D_i^{00}} [\gamma_{i,00} \ln p_{jr}^{'}] + \beta_i \ln(\frac{X_{Qr}^{'}}{P_{Qr}^{'}}) \end{aligned} \tag{3.14}$$

- For products k that remain in the market:

$$p_{kr}^{'} = c_{kr} * (1 + \frac{1}{\varepsilon_{kk(p_{kr}^{'}, p_{jr}^{'}, p_{ir}^{V})}})^{-1} \tag{3.15}$$

In the above equations p_{ir}^{V} denotes the virtual prices of the products that are removed from the market, while $p_{jr}^{'}$ denotes the updated prices of all other products. Note that when solving for the virtual prices we account for the fact that both the price index for quinolones P_{Qr}, and the expenditure allocated to this sub-segment X_{Qr}, need to be updated to reflect the fact that as a result of the price changes there may be substitution away from this sub-segment. To obtain the new quinolone expenditure $X_{Qr}^{'}$ and the new price index $P_{Qr}^{'}$, we use the estimates and formulas for the higher level AIDS system. In equation (3.15), c_k refers to the marginal cost for product k that we have obtained from the previous estimation stage. As mentioned in the previous sub-section, we conducted the simulations using both the upper and lower bounds for marginal cost, c_k^u and c_k^L respectively. The term $\varepsilon_{kk(p_{kr}^{'}, p_{jr}^{'}, p_{ir}^{V})}$ refers to the unconditional own price-elasticity for product k, which is a function of the eliminated products' virtual prices and the remaining products' new equilibrium prices. We conduct the counterfactual simulations and welfare analysis at the regional level because the presence of region-specific product effects in the demand estimation implies region-specific demand elasticities, and hence region-specific marginal costs and markups. The presentation and discussion of our results focus on national averages of the relevant variables that we construct by computing weighted averages across regions, using the population of each region as a weight.

3.6. Welfare assessment

The simulation of the new equilibrium under patent protection can provide important insights into how consumers and firms will respond to the removal of domestic products in the market (for example, towards which products consumers will substitute; which prices will increase the most, etc..). To get a more precise idea of how people's well-being will be ultimately affected by TRIPS, we compute as a

last step in our analysis the welfare effects of the policy change. Social welfare is defined as the sum of domestic firm profits, and consumer welfare. The change in domestic profits can easily be calculated by comparing the domestic firm (variable) profits at the pre-TRIPS prices to the profits these firms will realize at the new simulated prices. Although foreign firm profits do not count in domestic welfare calculations, we also compute the effects of patent enforcement on foreign firm profits, to get an idea of how large the expected benefits of TRIPS for these firms are. This provides in some sense an indirect way of assessing whether the claims that patent enforcement in countries like India will lead to more research on developing-country-specific diseases (such as malaria) have any validity; if, for example, we find that the effect of patent enforcement on the foreign firm profits realized in India is small in magnitude, it is unlikely that foreign firms will engage in more developing-country-specific research in response to TRIPS. It is important to note that in all these calculations we work with the lower bound estimates for marginal costs, since these give rise to the highest possible markups. Hence, our estimate of profit loss for domestic producers most likely overstates this loss.

On the consumer side, we measure changes in consumer welfare by the compensating variation (CV), defined as the additional expenditure that consumers need in order to achieve the same utility level as before patent enforcement at the new prices. Specifically, let P^0 denote the price vector before patent enforcement, $P^{'}$ the simulated price vector post-TRIPS (that we obtained using the methods described in the previous subsection), u^0 the utility attained by consumers before TRIPS, and $E(u, P)$ the higher level expenditure function. Then the compensating variation is given by:

$$CV = E(u^0, P^{'}) - E(u^0, P^0) \tag{3.16}$$

Note that the CV as computed in (3.16) represents the combination of three effects:

- The pure *product variety* effect; that is the effect that arises because one or more products are not available to consumers anymore, *holding the prices of all other remaining products, and the total expenditure on the quinolone sub-segment X_Q constant.*
- The *expenditure switching* effect; that is the effect arising from substitution away from quinolones, and towards other sub-segments of the anti-biotics market, again *holding the prices of all other remaining products constant.*
- The *reduced competition* effect; that is the effect that arises because the firms remaining in the market adjust (increase) their prices in response to the removal of domestic products.

From both an analytical and a policy point of view, it is desirable to assess how large each of the above effects is. Accordingly, we decompose the total effect on consumer welfare (the CV as given by equation (3.16)), using the following procedure:

To get the pure product variety effect, we compute virtual prices for the products that are removed from the market holding the quinolone expenditure X_Q and the prices of all other products fixed. Let us call the resulting price vector P^1. Then the pure product variety effect is represented by $E(u^0, P^1) - E(u^0, P^0)$.

To compute the expenditure switching effect, we compute another set of virtual prices, again holding the prices of all remaining products fixed, but letting quinolone expenditure adjust in response to the new price index for the quinolone segment (given that the prices of the remaining products remain fixed, the change in the price index arises only because of the removal of one or more domestic products). Note that this scenario most closely resembles the case in which patent laws are enforced, but strict price regulation keeps the prices of the products offered in the market at their pre-TRIP level. Let us label the so-computed price vector P^2. The expenditure switching effect is then $E(u^0, P^2) - E(u^0, P^1)$.

Finally, the reduced competition effect arising from higher prices for the remaining products is computed as the residual change in the compensating variation once the product variety and expenditure effects have been accounted for, that is $E(u^0, P') - E(u^0, P^2)$, where the price vector $P'$is computed according to the formulas (3.14) and (3.15) to reflect the adjustment of prices to the new regime.

To compute the standard errors associated with the counterfactual simulations (that is the standard errors for the counterfactual prices and welfare estimates), we again use bootstrapping: We first bootstrap the original sample (sales and prices of all the drugs) 300 times. Next, we estimate the AIDS model for each of these samples, and compute the counterfactual equilibrium prices and welfare losses corresponding to each policy scenario for each of the 300 simulations. In the final step, we compute standard errors[29].

One limitation of our framework is that it does not allow for a heterogeneous response of consumers to the policy change. Accordingly, our framework is not suited to addressing the question of how different groups in the population will be affected by patent law enforcement.[30] Along the same lines, our framework does not accommodate the possibility of price discrimination, which might lead to different results regarding welfare losses and profit gains relative to uniform pricing[31]. Still, we believe that the results of the counterfactual simulations can provide important insights into the likely aggregate response to patent enforcement and the factors that drive this response.

[29] In cases some of the simulations do not converge, we compute the standard errors using only those simulations that converged.

[30] Addressing this question would require at a minimum micro data on consumer purchases as in Goldberg (1995). To our knowledge such data do not exist for the Indian pharmaceutical market.

[31] See Berndt (1994) for an extensive discussion of uniform pricing.

4. Results

4.1. The structure of demand

Tables A2 and A3 in the Appendix display the results from estimation of the lower- and upper-level AIDS system respectively. For ease of interpretation, rather than discussing the coefficient estimates, we focus our discussion on the implied unconditional price and expenditure elasticities reported in Table 6. Given that the region-specific product group effects α_{ir} reported in the last four columns of Tables A2 and A3 imply region-specific demand elasticities, we report separate elasticities for each region in Tables 6(a) and 6(b). As evident from the comparison of these tables, the elasticities are very similar across regions, so that we can focus the remaining discussion on the elasticities of one region only, the Northern region, displayed in Table 6(a).

The diagonal terms of Table 6(a) report the own price elasticities, which are, in all but one case, negative and highly significant. The one exception is the foreign norfloxacin product group—whose share of quinolone sales is 0.07%—for which we estimate a negative but insignificant own price elasticity. For the remaining product groups, demand appears to be highly elastic, with the estimated elasticities being lower than -2 in four out of the six cases. The magnitude of the own-price elasticities matches the features of the Indian pharmaceutical market mentioned earlier, which would suggest that Indian consumers are likely to be quite price-sensitive.[32]The elasticities appear especially large if one takes into account that they refer to product groups (such as domestic ciprofloxacin) and not individual drugs offered by particular firms. Their relative magnitudes are also intuitive: the drug with the largest market share and a relatively high price (domestic ciprofloxacin) appears to be one of the least elastic. In contrast, foreign ciprofloxacin is highly price elastic; this is plausible as ciprofloxacin drugs offered by subsidiaries of multinationals face the stiffest competition in this market segment from approximately 75 Indian firms offering the same molecule.

The estimated expenditure elasticities appear in the last column. These are all positive, indicating that the demand for all product groups is normal. The remaining cells display the estimated cross-price elasticities. As one might perhaps expect for products within a therapeutic sub-segment, these are mostly positive. Out of a total of 49 price elasticities we estimate, there are 6 that do not conform to expectations; these are the cross-price elasticities between different foreign product groups, that are estimated to be negative and significant.[33] Fortunately, these elasticities have negligible impact

[32]In developed economies, elasticities of this magnitude have typically only been found for generic drugs (and even then, only rarely) or among consumers who lack health insurance.

[33]While these elasticities are clearly counterintuitive, they are not inconsistent with the underlying demand system, which imposes no restrictions on the sign of the cross-price elasticities. We do not have a good explanation of why these elasticities are estimated to be negative. A potential explanation is that the shares of the foreign products are very small; given this, we observe very few consumers switching from one (very small) foreign group to another (very small) foreign group, when the price of the first foreign group goes up, and hence the inference is not very reliable in this case.

on the welfare analysis: given that our counterfactuals focus on the effect of withdrawing one or more *domestic* products from the market, the most relevant elasticities are the ones which capture the response of various product group shares to a change in the price of one or more *domestic* groups; these elasticities are the cross-price elasticities between various domestic groups, and the ones between domestic and foreign groups, which are plausible and precisely estimated[34].

Regarding these elasticities, a striking aspect of our estimates is how large, positive and significant the cross-price elasticities between different domestic product groups are—in fact, for norfloxacin and ofloxacin we estimate that domestic product groups containing different molecules are closer substitutes for one another than product groups that contain the same molecule but are produced by foreign firms. In contrast, for ciprofloxacin (the molecule with the largest revenue share) we estimate a large positive cross-price elasticity between the domestic and foreign versions.

The fact that domestic products appear to be close substitutes for other domestic products that contain different molecules truly represents an "empirical" finding in the sense that we do not impose it through any of our assumptions regarding the demand function. The question that naturally arises then, is what might explain this finding. While we cannot formally address this question, anecdotal accounts in various industry studies suggest that the explanation may lie in the differences between domestic and foreign firms in the structure and coverage of retail distribution networks.

Distribution networks for pharmaceuticals in India are typically organized in a hierarchical fashion. Pharmaceutical companies deal mainly with carrying and forwarding (C&F) agents, in many instances regionally based, who each supply a network of stockists (wholesalers). These stockists in turn deal with the retail pharmacists through whom retail sales ultimately occur.[35] The market share enjoyed by a particular pharmaceutical product therefore depends in part on the number of retail pharmacists who stock the product. And it is here that there appears to be a distinction between domestic firms and multinational subsidiaries. In particular, the retail reach of domestic firms, as a group, tends to be much more comprehensive than that of multinational subsidiaries (ICRA (1999)).[36]

[34] The cross-price elasticities between foreign drug groups containing different molecules will also have an effect on the welfare estimates, given that the withdrawal of domestic products will generally lead to changes in the prices of all foreign products, and market shares will be reallocated from some foreign products to other foreign products based on the new prices. However, this reallocation from "foreign to foreign" is truly second order in our case, compared to the reallocation from "domestic to domestic", and "domestic to foreign" products. In scenarios in which we consider patent enforcement accompanied by strict price regulation, the cross-price elasticities between foreign product groups are in fact completely irrelevant, as the prices of foreign products are not allowed to increase in these cases. Still, our welfare loss estimates remain substantial, driven – as before – by the loss of product variety.

[35] There are estimated to be some 300,000 retail pharmacists in India. On average stockists deal with about 75 retailers (ICRA (1999)). There are naturally variations in this structure, and a host of specific exclusive dealing and other arrangements exist in practice. Pharmaceutical firms also maintain networks of medical representatives whose main function is to market the company's products to doctors who do the actual prescribing of drugs. In some instances, firms do sell directly to the doctors who then become the "retailer" as far as patients are concerned, but these are relatively rare.

[36] These differences were also highlighted in conversations that one of the authors had with CEOs and Managing

There appear to be two reasons for this. The first is that many of the larger Indian firms, because they have a much larger portfolio of products over which to spread the associated fixed costs, typically have more extensive networks of medical representatives. The second is simply that there are many more domestic firms (and products) on the market. At the retail level this would imply that local pharmacists might be more likely to stock domestic products containing two different molecules, say ciprofloxacin and norfloxacin, than they would domestic and foreign versions of the same molecule. To the extent that patients (or their doctors) are willing to substitute across molecules in order to save on transport or search costs (e.g., going to another pharmacy to check whether a particular foreign product is in stock), in aggregate data we would expect to find precisely the substitution patterns that we report in Table 6.

Whether or not the particular explanation we provide above is the correct one, the high degree of substitutability between domestic product groups turns out to have important implications for the welfare calculations. We discuss these in more detail below when we present the results of the counterfactual welfare analysis. Another elasticity with important implications for the counterfactuals is the price elasticity for the quinolone sub-segment as a whole, which indicates how likely consumers are to switch to other anti-biotics groups, when faced with a price increase for quinolones. This elasticity is computed on the basis of the results in Table A3, and it is at -1.11 (standard error: 0.24) large in magnitude, but – as expected – smaller in absolute value than the own-price elasticities of the product groups within the quinolone sub-segment.

The results in Tables 6(a) and 6(b) are based on our preferred specification discussed in Section 3. In Tables A4-A6 in the Appendix we experimented with some alternative specifications. Tables A4(a)-A4(c) correspond to a specification that includes in addition to product-group-specific regional fixed effects, product-group-specific (and for the upper level antibiotics-segment-specific) seasonal effects. We distinguish between 3 seasons: the Summer, Monsoon, and Winter, and report the unconditional demand elasticities for the Northern region for each of these seasons. As evident from the tables in the Appendix, our elasticity estimates are robust to the inclusion of seasonal effects. The demand elasticities in Table A5 are based on estimation of the demand system by OLS. Compared to the elasticities obtained by IV, the OLS elasticities are smaller in absolute value implying that welfare calculations based on the OLS estimates would produce larger welfare loss estimates. Nevertheless, some of the patterns regarding the cross-price elasticities discussed earlier are also evident in the OLS results; in particular, the cross-price elasticities between different domestic product groups are all positive, large, and significant, and in most instances larger than the cross-price elasticities between drugs that contain the same molecule but are produced by firms of different domestic/foreign status. The close substitutability of domestic products indicated by both the OLS and IV estimates seems to

Directors of several pharmaceutical firms as part of a separate study.

be one of the most robust findings of the paper.

4.2. Cost and markup estimates

Table 7 displays the marginal costs, markups and profits implied by the price elasticity estimates of Tables 6(a) and 6(b) for each of the seven product groups. Given that our regional effects imply different price elasticities for each region, our marginal cost and markup estimates also differ by region. However, given that based on Tables 6(a) and 6(b) the price elasticities do not seem to substantially differ across regions, we report for ease of exposition only the national averages for marginal costs and markups in Table 7.

Table 7 has two parts. In the left part (first three columns) we report the *lower bound* for marginal cost and the corresponding *upper bound* for markup, and *upper bound* for total annual profit for each product group. These numbers are based on the price elasticities we obtained from estimating the 2-level AIDS demand system. Since we do not have a reliable estimate for the price elasticity of foreign norfloxacin (the point estimate is negative, but less than 1 in absolute value, and insignificant), we cannot compute the lower bound for marginal cost in this case. It is important to note that these estimates do not reflect either the actual marginal cost or the actual markup for these drugs, both because the existence of price regulation implies that the unconstrained first order conditions are unlikely to hold each period, and because our aggregation across firms of the same domestic/foreign status supplying the same molecule makes the interpretation of these estimates problematic. In particular, the fact that we ignore competition among firms within each product group implies that our estimates will tend to overstate market power. However, these numbers will prove useful in the counterfactual simulations as they can give us a sense of how large the maximum profit gains for multinationals and the maximum profit losses for domestic firms are likely to be under patent enforcement. The right part of the table (last three columns) reports the *upper bound* for marginal cost which we obtain by simply taking the marginal cost to be equal to the observed price. We do not report standard errors in this case since the numbers are based on actual data. The markups corresponding to these marginal cost upper bounds are of course zero. We conduct the counterfactual simulations using both the lower and upper bounds for marginal costs.

The (upper bounds for) markups on the left side of the table are generally plausible. The domestic ciprofloxacin product group that dominates the quinolone sub-segment, and for which we documented high prices, a high market share, and a relatively low elasticity of demand, enjoys one of the highest markup upper bounds (60%) and accounts for nearly 70% of all profits derived within the sub-segment. Foreign ciprofloxacin on the other hand, which faces the stiffest competition from domestic firms, and for which we estimated a highly elastic demand, has the lowest markup upper bound (19%).

4.3. Counterfactual estimates of the impact on prices and welfare

With estimates of the key demand and cost parameters in hand, we turn to the counterfactuals. We consider the five separate scenarios listed in the previous section. All of the scenarios involve the withdrawal of one or more of the domestic product groups from the market. Table 8 displays our estimates of the consumer welfare losses that result under the different scenarios. The losses are expressed in billion Rs. per year. All numbers presented in Table 8 and subsequent tables are based on using the lower bounds for marginal cost and upper bounds for markup in the simulations. As discussed earlier, these numbers are the more interesting to work with, since they give us an upper bound for the changes in the profits of domestic and foreign firms that would result from patent enforcement. In the Appendix we also present results based on using the upper bounds for marginal costs in the simulations, in which case the pre-TRIPS profits of domestic and foreign firms are zero. In all cases, marginal costs are assumed to be constant in output. While naturally the profit implications differ depending on whether one uses the upper or lower bounds for marginal costs (firm profits are zero if one assumes the upper bound of marginal cost, in which case price equals marginal cost), the estimated consumer welfare losses are similar in the two cases. We discuss these results at the end of this section in more detail.

The first column presents our estimates of the consumer welfare losses attributable to the pure loss of product variety effect, where we fix the prices of all remaining products as well as the overall expenditure on quinolones while withdrawing one or more of the domestic product groups. Note that had we not, in our initial specification of the demand system, allowed for the possibility that consumers might differentiate between domestic and foreign products even when they contain the same molecule, this particular component of the loss of consumer welfare would not have arisen.

The estimates reported in the second column incorporate the expenditure switching effect on top of the loss of product variety. Here, based upon the price elasticity estimates from the higher-level AIDS system, we adjust (downwards) the expenditures allocated to the quinolone sub-segment as the composite price of quinolones effectively increases as a consequence of the higher virtual prices of the domestic product groups that are withdrawn from the market. Because the estimates in this column are generated assuming that the prices of the products that remain in the market are not adjusted upwards, they provide a sense of what consumer losses would be if the introduction of product patents was coupled with strict price-regulation aimed at maintaining prices at pre-patent levels. Alternatively, they can be thought of as the relevant welfare numbers if intense competition among firms within the remaining product groups kept the prices of the products that were still offered in the market close to the firms' marginal costs.

The last column displays the estimated consumer welfare losses when both cross-segment expenditure-switching and within-segment upward price adjustments are taken into account.

If we compare the results across the first, second and third columns, all the counterfactual scenarios produce qualitatively similar patterns, patterns that are consistent with what we would expect. Starting from the initial loss of welfare attributable to the loss of product variety, the option of switching expenditures out of the quinolone sub-segment to other sub-segments mitigates some of the initial welfare loss. But if we then incorporate the upward price adjustments that result in response to the reduced competition, the welfare losses are magnified.

Of particular interest from a policy perspective are the relative magnitudes of these three effects, which are similar under all the counterfactual scenarios though the absolute levels vary considerably. First, despite the fact that the demand for quinolones is quite sensitive to the composite price of quinolones—the upper level price elasticity is -1.11—the cross-sub-segment expenditure switching effects are, in all the cases, small (in absolute value terms) *relative* to the other two effects. For instance, under the scenario where all the domestic quinolone product groups are withdrawn from the market, the overall consumer welfare loss of Rs. 17.81 billion per year can be decomposed into an initial loss of Rs. 11.76 billion (66%) attributable to the loss of product variety, a slight *reduction* in this initial loss of Rs. 0.41 billion (-2%), from Rs. 11.76 billion to Rs. 11.35 billion, because of expenditure switching, and a subsequent additional loss of Rs. 6.46 billion (36%), from Rs. 11.35 billion to Rs. 17.81 billion, because of the reduced competition and consequent price increases.

The basic claim made by proponents of TRIPS is that any adverse impacts on consumer welfare from the introduction of a product patent in a particular market will be mitigated by the availability of close therapeutic substitutes. The relatively minor role that *cross-sub-segment* expenditure switching appears to play suggests that for this claim to be valid, there need to be unpatented (i.e., patent-expired) substitutes available within fairly narrowly defined therapeutic categories. Since the extent to which this is true will vary across therapeutic segments, the impact of TRIPS is likely to be correspondingly variegated, a point emphasized by Maskus (2000, p.163).

Price regulation and compulsory licensing are two of the most widely mentioned post-TRIPS policy options available to governments of developing economies. There is an ongoing debate about how much leeway governments should have to introduce these options and about the relative efficacy of the two options in limiting price increases. The magnitude and importance of the welfare losses we estimate from the loss of product variety suggest that there may be an independent role for compulsory licensing in addition to or in lieu of price regulation for the sole purpose of mitigating the loss of product variety.

Turning next to a comparison of the consumer welfare losses under the different scenarios the most striking result is that the estimated loss of consumer welfare (Rs. 17.81 billion) from the simultaneous withdrawal of all four domestic product groups—the scenario that most closely resembles what is likely to happen under TRIPS—is more than two times the *sum of the estimated losses* from the four

separate scenarios in each of which only one of the domestic product groups is withdrawn.[37] What this very clearly indicates is that past studies that have estimated the aggregate effects of patent protection by adding up the losses, estimated *separately,* in each of a number of patentable markets may have substantially underestimated the magnitude of the consumer welfare losses from the introduction of pharmaceutical product patents.

The result that the *simultaneous* withdrawal of all domestic products magnifies the scale of the welfare losses is driven by our estimates of high, positive cross-price elasticities between domestic products. As noted earlier, these elasticities imply that such products are close substitutes to one another. Hence, when all four domestic products disappear from the market, the resulting consumer loss is substantial. In contrast, the welfare losses associated with the withdrawal of a single domestic product or a subset of domestic products are more modest; with domestic product groups within the quinolone sub-segment being relatively good substitutes, if only one of them is withdrawn, consumers switch to the others, and this limits any welfare losses.

We should note that if, as we speculated above, the high degree of substitutability between domestic products stems in part from the differential reach of the distribution networks of domestic and foreign firms, these estimates may overstate the welfare loss from the simultaneous withdrawal of all domestic products. That is because, with India becoming TRIPS compliant, foreign subsidiaries may well choose to expand their product portfolios in India and simultaneously expand their distribution networks in India, most likely through joint marketing ventures with Indian firms. Media accounts and interviews with industry sources indicate that such initiatives are increasing in number. In this case, the welfare loss from the reduction in variety would be a purely transitional phenomenon. Over time, foreign products would be more readily available in local pharmacies throughout India and this would compensate for the reduction in the number of domestic products. Alternatively, if Indian consumers insist in buying products produced by Indian firms, foreign multinationals could use licensing to recover the welfare loss associated with the loss of variety. Note however, that even under this scenario, the component of consumer welfare loss due to upward price adjustment remains. And a crude calculation based on the estimates in the last row of Table 8 suggests that this is likely to be significant. In particular, if we subtract from our estimate of the overall consumer welfare loss (Rs. 17.81 billion), the component attributable to the reduction in variety taking into account expenditure switching (Rs. 11.35 billion), we are still left with an estimated welfare loss of Rs. 6.46 billion. Given the size of the welfare loss due to upward price adjustment policymakers may be tempted to continue

[37] For ease of exposition, Table 8 reports only a subset of the scenarios we have investigated. The consumer welfare loss associated with the withdrawal of domestic norfloxacin only (not reported in Table 8) is approximately Rs. 0.1 billion; the welfare loss associated with the withdrawal of sparfloxacin only is close to zero. Hence, the sum of the estimated welfare losses from the scenarios in which only one domestic product is withdrawn is (7.32+0.23+0.1 +0) = Rs. 7.6 billion per year.

the use of price controls and other domestic regulations. However, such policies would put a limit not only on prices, but also on the incentives of foreign producers to expand their operations in the Indian market, so that the welfare loss due to the reduction of product variety could become a permanent phenomenon.

Table 9 documents our estimates of the price increases that would result under the various counterfactual scenarios. The table reports the price increases for the product groups, foreign or domestic, that would remain in the market under each of our scenarios. The groups that are withdrawn from the market are indicated by the shaded areas. For the foreign products that would remain in the market, we estimate price increases between 100% and 400%. While these numbers are based on simulations, and thus not observed, we can obtain a rough idea about their plausibility by comparing them to the prices of the same products observed in countries "similar" to India in terms of demographics, but which have less competitive domestic markets. Pakistan is a natural candidate. For the drug ciprofloxacin, for example, we predict that the price of the (patented) foreign products in India would be approximately 5 times higher than it is now (see last row of Table 9, first column; the relevant scenario here is one where *all* domestic products are withdrawn from the market, since this is the situation that most closely resembles Pakistan). Lanjouw (1998), p. 39, Table 2, reports that the price of ciprofloxacin in Pakistan is about 7 times the price of the same drug in India. The two numbers are of similar order of magnitude, though our estimate is on the low side. These comparisons give us confidence that the empirical framework we use as a basis for conducting counterfactual simulations in India captures the main features of this market.

Table 10 presents our estimates of the *net* impact of the withdrawal of one or more domestic product groups on the collective profits of domestic Indian firms in the quinolone sub-segment. Under the scenario where all the domestic product groups are withdrawn from the market, the net impact equals the gross impact and is simply the loss of the profits initially enjoyed by domestic firms: Rs. 2.34 billion per year. In the other cases, the foregone profits of those domestic firms whose products are withdrawn from the market are partly or wholly offset by the increased profits of those domestic firms that remain in the market and benefit from the reduced competition. From Table 10 it can be seen that this latter result arises when domestic ofloxacin is withdrawn from the market, in which case consumers switch to other domestic drugs within quinolones, increasing the profits of the domestic firms selling those drugs.[38]

Critics of the Indian government's stance on TRIPS frequently assert that it is motivated less by concerns about consumer welfare than it is by a desire to protect the domestic pharmaceutical industry. Whether or not that is the case, the estimates presented in Table 10 indicate that the

[38] To be consistent with Table 8, which reported consumer welfare losses as positive numbers, Table 10 reports foregone profits as positive numbers. Thus, if the collective profits of domestic Indian firms actually increase, negative numbers are reported.

loss of domestic producer surplus is unlikely to be the biggest consequence of TRIPS-induced patent protection. First, as just mentioned, there are scenarios under which the collective profits of domestic firms would actually go up, though there always is a segment that would be adversely affected.[39] Second, even when the collective profits do go down, a comparison with Table 8 indicates that the loss of consumer welfare is much greater in every instance. And under the scenario where the collective loss of profits is the greatest and there are no winners among the domestic Indian firms, the loss incurred by producers—Rs. 2.3 billion on an annualized basis—pales in comparison to the decrease in consumer welfare reported in Table 8 under the same scenario—Rs. 17.81 billion annually, especially if one takes into account that the profit loss of Rs. 2.3 billion, was derived by using an upper bound for the domestic firms' Pre-TRIPS markups, and hence clearly overstates the profit loss that the domestic sector would actually incur.[40]

Table A6 in the Appendix reports results from counterfactual simulations in which we used the upper bound for marginal costs. The pre-TRIPS domestic firm profits are of course zero in this case, since the upper bound was derived by setting marginal cost equal to price. Interestingly, the results in Table A6 that report the loss in consumer welfare, indicate that the consumer loss would be slightly higher than before. This is due to the fact that due to the higher marginal cost estimates, the price increases are now higher compared to the case where the lower bound of marginal cost was used. The new consumer welfare loss estimate is however roughly of the same order of magnitude as before, so we focus the rest of our discussion on the results we obtained by using the lower bound of marginal cost.

Adding up the estimates of consumer welfare losses from Table 8 and producer losses from Table 10 we get estimates of the total welfare losses to the Indian economy. These are reported in Table 11. At the upper bound we estimate that *in the absence of any price regulation or compulsory licensing* the total annual welfare losses to the Indian economy from the withdrawal of just four domestic product groups in the quinolone sub-segment would be on the order of Rs. 20.16 billion, which translates at the then prevailing exchange rate into a figure of U.S. $450 million.

Given that in practice the simultaneous enforcement of intellectual property rights and elimination of price controls is unlikely, a more realistic estimate of the welfare loss can be obtained by assuming that price regulation will prevent upward price adjustments as a result of product withdrawals. This gives us a mid-range estimate of Rs. 13.7 billion or about U.S. $305 million per year for the scenario

[39] This may in part explain why the Indian pharmaceutical industry has been divided in its reaction to TRIPS. The Organization of Pharmaceutical Producers of India, which includes among its members most of the leading Indian firms as well the subsidiaries of foreign MNCs, is openly supportive of strengthening India's intellectual property rights regime (http://www.indiaoppi.com/). Other industry associations such as the Indian Drug Manufacturers Association with memberships drawn from smaller firms tend to be more critical of TRIPS.

[40] There are other factors as well that might serve to mitigate the losses experienced by Indian firms, among them the possibility of joint ventures with, or contract manufacturing for multinationals. Such collaborations are increasing in frequency in the Indian pharmaceutical industry.

involving withdrawal of all four domestic quinolone product groups. Of this amount, foregone profits of domestic producers constitute roughly Rs. 2.3 billion, or U.S. $50 million (ca. 16% of the total welfare loss). The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare.

Lastly, if we assume that the welfare losses due to the reduction in variety are a purely transitional phenomenon or that they could be neutralized through expanded use of licensing, and subtract these from our upper bound estimates, we obtain a lower bound estimate of Rs. 6.5 billion (=20.16-13.7) or $144 million annually. Though only about 30% of our upper bound estimate, in absolute terms this lower bound estimate is still very large, representing about 24% of antibiotic sales in 2000.

Finally, Table 12 presents our estimates of the profit gains realized by foreign producers as a result of patent introduction. These estimates indicate that the total profit gains to foreign producers would be only about Rs. 2.4 billion or approximately U.S. $53 million per year. More importantly, the U.S. $53 million per year estimate corresponds to the rather unrealistic case where there is no price regulation, so that multinationals are free to adjust their prices upward in response to the reduced competition. In the presence of price regulation that would keep prices fixed at their pre-patent-enforcement level (column 2 in Table 12), the profit gain for foreign multinationals becomes Rs. 0.88 billion, or U.S. $19.6 million per year, only. To put the above numbers in perspective, sales of Cipro alone, the main patented ciprofloxacin product of Bayer, were roughly U.S. $1.6 billion in 2000 (Hensley (2001)). Assuming a 40% markup (the markup usually quoted for the pharmaceutical industry), this translates to annual profits of roughly U.S. $640 million per year, for Bayer's Cipro alone.

5. Conclusion

The results of our analysis suggest that concerns about the potentially adverse welfare effects of TRIPS in developing countries may have some basis. Specifically, we estimate that in the quinolone sub-segment of the systemic anti-bacterials segment alone, patent enforcement would result in a large welfare loss for the Indian economy. The estimated loss ranges from $144 million to an upper bound of $450 million annually, depending on the way policies are implemented, the extent of price regulation, and the degree to which foreign multinationals respond to patent protection by expanding their distribution networks or using licensing more extensively. Of this amount, only a small fraction accounts for the forgone profits of domestic (Indian) pharmaceutical firms. Hence, we do not find much support for the claim that TRIPS would have detrimental effects on the Indian pharmaceutical industry. In fact, under some scenarios we find that the profits of domestic firms may even *increase*; this happens because, when certain domestic products become unavailable as a result of patent enforcement, consumers substitute towards other domestic products containing different molecules, rather than foreign products containing the same molecule. This differential effect of TRIPS on domestic firms' profits

may partly explain the divided position of the Indian pharmaceutical industry regarding TRIPS.

With respect to the subsidiaries of foreign multinationals, we estimate the profit gains of these firms to be approximately U.S. $53 million per year when patents are enforced. This is in the absence of compulsory licensing or price regulation. With price regulation that would keep the prices of drugs supplied by multinational subsidiaries at their pre-TRIPS level, the profit gains drop to only U.S. $19.6 million per year. While we certainly do not attempt to draw any conclusions about the relationship between intellectual property rights protection and research and innovation, we note that this number represents a very small fraction of the annual sales of big pharmaceutical firms in this sub-segment.

By far, the biggest effects of TRIPS concern the Indian consumers, for whom we estimate substantial welfare losses. The losses increase in the number of domestic products that are affected by TRIPS. The worst case scenario involves simultaneous withdrawal of all domestic product groups in the quinolone sub-segment. In contrast, when only one domestic product, or a subset of domestic products are withdrawn, the consumer losses are modest. This pattern is driven by the empirical finding that domestic products are viewed by Indian consumers as close substitutes; accordingly, the existence of some degree of domestic competition has a big impact on consumer well-being.

Finally, our decomposition of the total consumer loss into a "product variety" effect, an "expenditure switching" effect, and a "price adjustment" effect, has interesting policy implications. We find that a substantial fraction of the total welfare loss is attributable to the loss of variety, which we interpret as primarily capturing an "ease of access" effect: because the retail coverage of domestic firms in India is substantially more extensive than the one of foreign multinationals, drugs produced by domestic firms are more readily available to Indian consumers than drugs sold by foreign producers. This suggests a potentially independent role of compulsory licensing in addition to, or in lieu of price regulation, for the sole purpose of mitigating the loss of product variety effect. Even if one considers this effect to be only a transitional phenomenon that will diminish in importance as foreign firms respond to TRIPS enforcement by expanding their product portfolios and distribution networks, or by using licensing more extensively, the welfare loss due to upward price adjustment remains substantial. The "price adjustment" component of welfare loss could potentially be mitigated by appropriate price controls or other regulations. However in this case, the incentives of multinationals to expand their operations in the Indian market would become questionable, and the welfare loss attributable to the loss of product variety could become a permanent effect.

In general, our simulations indicate that from a consumer welfare point of view the issue of product *availability* is as important as the issue of *affordability*. In this sense our analysis suggests that policy makers should evaluate TRIPS related policies not only in terms of their effects on drug prices, but also in terms of their impact on product availability. This observation is more relevant the more likely it is that there will be tension between policies designed towards addressing these two sets of

effects. Intellectual property rights enforcement without price regulation is likely to bolster foreign firms' incentives to market their products in developing countries and use licensing more extensively than in the past, but it brings with it the potential of substantial price increases of patented products. Accompanying price regulation can prevent patent holders from exploiting their market power but not without diminishing the incentives of such firms to expand their operations in the developing world. A combination of policies that would completely neutralize TRIPS' adverse effects on consumer welfare is hence unlikely.

Lastly, we find that expenditure switching across sub-segments has a limited role in containing consumer welfare loss. The claim of TRIPS proponents that any adverse effects arising from the introduction of a patent in a particular market would be mitigated by the availability of close therapeutic substitutes is thus only valid if there are patent-expired substitutes available within fairly narrowly defined therapeutic categories.

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Table 1
The Quinolones Sub-segment

Molecule	Shares (%) of Quinolones Sales		Sales (Rs. Mill): 2000	
	Domestic Firms	Foreign Subsidiaries	Domestic Firms	Foreign Subsidiaries
Ciprofloxacin	53.0	2.7	3,030	156
Norfloxacin	11.2	0.1	640	3
Ofloxacin	11.6	3.1	665	177
Sparfloxacin	10.8	0.1	620	4
Lomefloxacin	1.5	.	86	.
Pefloxacin	1.3	0.1	72	5
Levofloxacin	0.0	.	0	.
Nalidixic acid	1.3	.	73	.

Table 2
Basic Information about the Four Quinolones Molecules: 2000

	Ciprofloxacin	Norfloxacin	Ofloxacin	Sparfloxacin
U.S. or European Patent Holder	Bayer	Merck	Ortho-McNeil	Rhone-Poulenc
Year of U.S. Patent Expiry	2003	1998	2003	2010
Year of US-FDA Approval	1987	1986	1990	1996
Year First Introduced in India	1989	1988	1990	1996
No. of Domestic Indian Firms	75	40	17	25
No. of Foreign Subsidiaries	8	2	2	1
Sales Weighted Average Per-unit API* Price of Products Produced by:				
Domestic Indian Firms	11.24	9.05	90.08	78.84
Foreign Subsidiaries	10.35	5.28	108.47	.

*API: Active pharmaceutical ingredient.

Table 3
Summary Statistics for the Quinolones Sub-segment: 1999 - 2000

	North	East	West	South
Annual Quinolones Expenditure Per Household (Rs.)	31.25 (3.66)	19.75 (3.67)	27.64 (4.07)	23.59 (2.86)
Annual Anti-Biotics Expenditure Per Household (Rs.)	119.88 (12.24)	84.24 (12.24)	110.52 (9.60)	96.24 (9.96)
No. of SKUs:				
Foreign Ciprofloxacin	12.38 (1.50)	11.29 (1.90)	13.08 (1.02)	12.46 (1.06)
Foreign Norfloxacin	1.83 (0.70)	1.71 (0.75)	2.00 (0.88)	1.58 (0.83)
Foreign Ofloxacin	3.04 (0.86)	2.96 (0.86)	2.96 (0.91)	3.00 (0.88)
Domestic Ciprofloxacin	106.21 (5.99)	97.63 (4.34)	103.42 (7.22)	105.50 (4.51)
Domestic Norfloxacin	38.96 (2.71)	34.96 (2.68)	36.17 (2.51)	39.42 (3.79)
Domestic Ofloxacin	18.46 (6.80)	16.00 (6.34)	17.25 (5.86)	17.25 (6.35)
Domestic Sparfloxacin	29.83 (5.57)	28.29 (6.38)	31.21 (6.88)	29.29 (6.57)
Price Per-unit API* (Rs.):				
Foreign Ciprofloxacin	9.58 (1.28)	10.90 (0.66)	10.85 (0.71)	10.07 (0.58)
Foreign Norfloxacin	5.63 (0.77)	5.09 (1.33)	6.05 (1.39)	4.35 (1.47)
Foreign Ofloxacin	109.46 (6.20)	109.43 (6.64)	108.86 (7.00)	106.12 (11.40)
Domestic Ciprofloxacin	11.43 (0.16)	10.67 (0.15)	11.31 (0.17)	11.52 (0.13)
Domestic Norfloxacin	9.51 (0.24)	9.07 (0.35)	8.88 (0.37)	8.73 (0.20)
Domestic Ofloxacin	91.63 (16.15)	89.64 (15.65)	85.65 (14.22)	93.41 (14.07)
Domestic Sparfloxacin	79.72 (9.76)	78.49 (10.14)	76.88 (11.85)	80.28 (10.37)
Annual Sales (Rs. Mill)				
Foreign Ciprofloxacin	41.79 (15.34)	24.31 (8.16)	45.20 (12.73)	29.47 (6.48)
Foreign Norfloxacin	1.28 (1.01)	1.00 (0.82)	0.58 (0.44)	0.73 (0.57)
Foreign Ofloxacin	54.46 (13.99)	31.84 (9.33)	35.22 (9.06)	31.11 (7.03)
Domestic Ciprofloxacin	962.29 (106.26)	585.91 (130.26)	678.74 (122.26)	703.81 (87.40)
Domestic Norfloxacin	222.55 (38.84)	119.71 (19.45)	149.18 (26.91)	158.29 (16.26)
Domestic Ofloxacin	125.02 (44.34)	96.21 (30.11)	149.36 (52.82)	112.05 (42.59)
Domestic Sparfloxacin	156.17 (31.41)	121.75 (25.76)	161.30 (46.74)	98.11 (34.20)

*API: Active pharmaceutical ingredient.
Note: Standard deviations in parentheses.

Table 4
Analysis of Product Price Variance

Product Group	Partial SS Time	Partial SS Region	Total SS	Percentage Explained by Time	Percentage Explained by Region
Foreign Ciprofloxacin	0.296	0.306	1.047	28.3%	29.2%
Foreign Norfloxacin	1.036	1.002	4.179	24.8%	24.0%
Foreign Ofloxacin	0.429	0.021	0.571	75.2%	3.6%
Domestic Ciprofloxacin	0.005	0.088	0.104	5.0%	84.1%
Domestic Norfloxacin	0.059	0.098	0.198	29.6%	49.4%
Domestic Ofloxacin	2.858	0.104	3.056	93.5%	3.4%
Domestic Sparfloxacin	1.754	0.032	1.860	94.3%	1.7%

Table 5
Revenue Shares of the Exiting SKUs

	Revenue Share of Exiting SKUs	Revenue Shares of All SKUs
Full Sample	1.0%	3.4%
Northern Region	0.8%	3.3%
Eastern Region	1.2%	3.6%
Western Region	1.0%	3.4%
Southern Region	1.2%	3.3%

Table 6 (a)
Demand Patterns within the Quinolones Sub-Segment:
Unconditional Price and Expenditure Elasticities in the Northern Region

Product Group	Elasticity with Respect to:							
	Prices of Foreign Product Groups			Prices of Domestic Product Groups				Overall Quinolones Expenditure
	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo	
Foreign Ciprofloxacin	-5.57*	-0.13†	-0.15*	4.01*	0.11†	0.11†	0.16*	1.37*
	(1.79)	(0.07)	(0.07)	(1.84)	(0.06)	(0.06)	(0.06)	(0.29)
Foreign Norfloxacin	-4.27†	-0.45	-4.27†	3.50†	-6.02	4.51*	4.65*	2.20*
	(2.42)	(1.12)	(2.42)	(2.10)	(6.23)	(1.84)	(1.83)	(1.05)
Foreign Ofloxacin	-0.11*	-0.10†	-1.38*	-0.09	0.09†	0.23	0.11*	1.16*
	(0.05)	(0.05)	(0.31)	(0.27)	(0.05)	(0.28)	(0.04)	(0.17)
Domestic Ciprofloxacin	0.18*	0.01*	-0.01	-1.68*	0.08*	0.08*	0.10*	1.17*
	(0.08)	(0.00)	(0.01)	(0.23)	(0.02)	(0.02)	(0.02)	(0.03)
Domestic Norfloxacin	0.04*	-0.03	0.04*	0.58*	-2.23*	0.42*	0.40*	0.73*
	(0.01)	(0.03)	(0.01)	(0.17)	(0.11)	(0.04)	(0.03)	(0.09)
Domestic Ofloxacin	0.05*	0.05*	0.11	0.77*	0.74*	-3.42*	0.74*	0.89*
	(0.02)	(0.02)	(0.13)	(0.28)	(0.08)	(0.25)	(0.08)	(0.21)
Domestic Sparfloxacin	0.07*	0.04*	0.07*	1.15*	0.63*	0.63*	-2.88*	0.28*
	(0.02)	(0.01)	(0.02)	(0.15)	(0.06)	(0.06)	(0.17)	(0.12)

Notes: Standard errors in parentheses. Elasticities evaluated at average revenue shares. Asterisk (*) denotes significance at the 5% significance level, and stagger (†) denotes significance at the 10% level.

Table 6 (b)
Demand Patterns within the Quinolones Sub-Segment:
Unconditional Price and Expenditure Elasticities in Other Regions

Demand Patterns in the Eastern Region								
	Elasticity with Respect to:							
Product	Foreign Groups' Prices			Domestic Groups' Prices				Quinolones
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo	Expenditure
Foreign Ciprofloxacin	-5.94*	-0.14†	-0.16*	4.31*	0.13*	0.11	0.17*	1.40*
	(1.95)	(0.08)	(0.08)	(2.01)	(0.06)	(0.07)	(0.07)	(0.31)
Foreign Norfloxacin	-3.29†	-0.58	-3.29†	2.64†	-4.60	3.46*	3.59*	1.92*
	(1.80)	(0.83)	(1.79)	(1.53)	(4.51)	(1.38)	(1.39)	(0.82)
Foreign Ofloxacin	-0.12*	-0.10†	-1.40*	-0.10	0.10*	0.24	0.13*	1.17*
	(0.06)	(0.06)	(0.34)	(0.31)	(0.05)	(0.30)	(0.05)	(0.19)
Domestic Ciprofloxacin	0.18*	0.01*	-0.01	-1.72*	0.09*	0.08*	0.11*	1.17*
	(0.08)	(0.00)	(0.02)	(0.27)	(0.02)	(0.03)	(0.02)	(0.03)
Domestic Norfloxacin	0.04*	-0.04	0.04*	0.68*	-2.42*	0.49*	0.46*	0.70*
	(0.02)	(0.04)	(0.02)	(0.20)	(0.13)	(0.05)	(0.04)	(0.10)
Domestic Ofloxacin	0.04†	0.04*	0.09	0.61*	0.60*	-2.95*	0.60*	0.92*
	(0.02)	(0.01)	(0.10)	(0.28)	(0.07)	(0.22)	(0.07)	(0.17)
Domestic Sparfloxacin	0.05*	0.03*	0.05*	0.92*	0.48*	0.51*	-2.51*	0.43*
	(0.02)	(0.01)	(0.01)	(0.17)	(0.05)	(0.06)	(0.16)	(0.10)

Demand Patterns in the Western Region								
	Elasticity with Respect to:							
Product	Foreign Groups' Prices			Domestic Groups' Prices				Quinolones
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo	Expenditure
Foreign Ciprofloxacin	-4.27*	-0.09†	-0.11*	2.86*	0.08*	0.06	0.11*	1.26*
	(1.29)	(0.05)	(0.05)	(1.33)	(0.04)	(0.05)	(0.04)	(0.21)
Foreign Norfloxacin	-7.14†	-0.08	-7.10†	5.94†	-9.95	7.42*	7.70*	2.99†
	(3.69)	(1.83)	(3.68)	(3.28)	(10.15)	(2.97)	(2.96)	(1.78)
Foreign Ofloxacin	-0.13*	-0.12†	-1.45*	-0.09	0.12*	0.26	0.13*	1.19*
	(0.07)	(0.06)	(0.37)	(0.29)	(0.05)	(0.33)	(0.05)	(0.21)
Domestic Ciprofloxacin	0.19*	0.01*	0.00	-1.74*	0.09*	0.08*	0.11*	1.18*
	(0.08)	(0.00)	(0.01)	(0.24)	(0.02)	(0.03)	(0.02)	(0.04)
Domestic Norfloxacin	0.04*	-0.04	0.04*	0.67*	-2.43*	0.50*	0.47*	0.69*
	(0.02)	(0.04)	(0.01)	(0.18)	(0.14)	(0.05)	(0.04)	(0.10)
Domestic Ofloxacin	0.03	0.03*	0.07	0.48*	0.48*	-2.57*	0.48*	0.93*
	(0.02)	(0.01)	(0.08)	(0.22)	(0.05)	(0.15)	(0.04)	(0.14)
Domestic Sparfloxacin	0.06*	0.03*	0.05*	0.83*	0.46*	0.49*	-2.41*	0.46*
	(0.02)	(0.01)	(0.01)	(0.14)	(0.04)	(0.05)	(0.12)	(0.09)

Demand Patterns in the Southern Region								
	Elasticity with Respect to:							
Product	Foreign Groups' Prices			Domestic Groups' Prices				Quinolones
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo	Expenditure
Foreign Ciprofloxacin	-5.60*	-0.13†	-0.15*	4.02*	0.11*	0.10	0.17*	1.37*
	(1.82)	(0.07)	(0.07)	(1.87)	(0.06)	(0.06)	(0.07)	(0.29)
Foreign Norfloxacin	-5.33†	-0.31	-5.31†	4.31†	-7.48	5.59*	5.84*	2.49†
	(3.01)	(1.34)	(3.00)	(2.45)	(7.34)	(2.19)	(2.19)	(1.28)
Foreign Ofloxacin	-0.14*	-0.12†	-1.48*	-0.11	0.12*	0.29	0.16*	1.20*
	(0.07)	(0.07)	(0.39)	(0.33)	(0.06)	(0.35)	(0.06)	(0.22)
Domestic Ciprofloxacin	0.17*	0.01*	0.00	-1.69*	0.08*	0.07*	0.11*	1.16*
	(0.08)	(0.00)	(0.01)	(0.25)	(0.02)	(0.03)	(0.02)	(0.03)
Domestic Norfloxacin	0.04*	-0.03	0.03*	0.59*	-2.25*	0.43*	0.40*	0.73*
	(0.01)	(0.03)	(0.01)	(0.19)	(0.12)	(0.04)	(0.04)	(0.09)
Domestic Ofloxacin	0.04†	0.04*	0.09	0.62*	0.60*	-2.96*	0.60*	0.91*
	(0.02)	(0.01)	(0.10)	(0.26)	(0.06)	(0.19)	(0.07)	(0.17)
Domestic Sparfloxacin	0.08*	0.05*	0.08*	1.38*	0.73*	0.75*	-3.23*	0.16
	(0.02)	(0.01)	(0.02)	(0.18)	(0.07)	(0.08)	(0.21)	(0.14)

Notes: Standard errors in parentheses. Elasticities evaluated at average revenue shares. Asterisk (*) denotes significance at 5% level, and stagger (†) denotes significance at the 10% level.

Table 7
Upper and Lower Bounds for Marginal Cost, Markup, and Annual Profit by Product Groups within the Quinolone Sub-segment

Product Group	Lower Bound for MC (Rs.)	Upper Bound for Markup (Rs.)	Upper Bound for Profit (Rs. Mill)	Upper Bound for MC (Rs.)	Lower Bound for Markup (Rs.)	Lower Bound for Profit (Rs.)
Foreign Ciprofloxacin	8.3* (1.23)	19% (0.12)	26.9 (16.55)	10.3	0%	0.0
Foreign Norfloxacin	NA	NA	NA	5.3	0%	0.0
Foreign Ofloxacin	32.3 (23.16)	70%* (0.21)	106.1* (31.85)	108.5	0%	0.0
Domestic Ciprofloxacin	4.7* (1.14)	59%* (0.10)	1,701.9* (298.58)	11.2	0%	0.0
Domestic Norfloxacin	5.2* (0.20)	43%* (0.02)	280.7* (15.32)	9.0	0%	0.0
Domestic Ofloxacin	58.7* (2.18)	34%* (0.02)	161.2* (12.80)	90.1	0%	0.0
Domestic Sparfloxacin	49.5* (1.57)	37%* (0.02)	198.5* (11.00)	78.8	0%	0.0

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% level. Estimated lower bound for Foreign Norfloxacin's marginal cost is negative, since the estimated price elasticity is less than 1 in absolute value.

Table 8
Counterfactual Estimates of Consumer Welfare Losses from Product Withdrawal Due to the Introduction of Pharmaceutical Patents (Rs. Bill Per Year)

Counterfactual Scenarios: Withdrawal of One or More Domestic Product Groups	Pure Loss of Variety	Loss of Variety and:	
		Cross-segment Expenditure Switching	Within-segment Price-Adjustment and Cross-segment Expenditure Switching
Only Ciprofloxacin	4.98* (0.87)	4.92* (0.89)	7.32* (1.46)
Only Ofloxacin	0.08 (0.08)	0.08 (0.08)	0.23* (0.10)
Ciprofloxacin, Ofloxacin, and Norfloxacin	7.52* (1.77)	7.40* (1.80)	12.53* (4.15)
Ciprofloxacin, Ofloxacin, and Sparfloxacin	6.14* (1.42)	6.03* (1.45)	10.58* (3.31)
All Four Domestic Quinolones Products	11.76† (6.43)	11.35† (6.34)	17.81 (12.70)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% significance level, and stagger (†) denotes significance at the 10% level.

Table 9
Counterfactual Estimates of Drug Price Changes
After Product Withdrawal due to Introduction of Pharmaceutical Patents

Counterfactual Scenarios: Withdrawal of One or More Domestic Product Groups	Changes in Prices with Cross-segment Expenditure Switching and Within-segment Price Adjustment (% of Original Prices)						
	Foreign Product Groups			Domestic Product Groups			
	Cipro	**Norflo**	**Oflo**	**Cipro**	**Norflo**	**Oflo**	**Spar**
Only Ciprofloxacin	189.4%* (0.18)	314.7% NA	98.2%* (0.21)	.	148.6%* (0.09)	141.4%* (0.08)	164.1%* (0.08)
Only Ofloxacin	100.4%* (0.01)	150.0% NA	102.9%* (0.08)	102.4%* (0.01)	108.3%* (0.01)	.	110.7%* (0.01)
Ciprofloxacin, Ofloxacin, and Norfloxacin	247.6%* (0.42)	627.8% NA	154.4%* (0.39)	.	.	.	296.3%* (0.70)
Ciprofloxacin, Ofloxacin, and Sparfloxacin	255.2%* (0.40)	627.8% NA	158.3%* (0.37)	.	250.1%* (0.64)	.	.
All Four Domestic Quinolones Products	396.4% (3.34)	627.8% NA	318.4%† (1.73)	.	.	.	.

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% level, and stagger (†) denotes significance at the 10% level. We fix Foreign Norflo's price at the numbers shown, because an estimate for the MC lower bound is not available for this drug. We tried many different values for Foreign Norflo's counterfactual prices and the results are remarkably robust.

Table 10
Counterfactual Estimates of Foregone Profits of Domestic Producers from Product Withdrawal due to the Introduction of Pharmaceutical Patents (Rs. Bill Per Year)

Counterfactual Scenarios: Withdrawal of One or More Domestic Product Groups	Pure Loss of Variety	Loss of Variety and:	
		Cross-segment Expenditure Switching	Within-segment Price-Adjustment and Cross-segment Expenditure Switching
Only Ciprofloxacin	0.95* (0.16)	1.09* (0.08)	0.40 (0.31)
Only Ofloxacin	-0.04* (0.01)	-0.03† (0.02)	-0.14* (0.04)
Ciprofloxacin, Ofloxacin, and Norfloxacin	1.24* (0.17)	1.40* (0.11)	0.42 (0.60)
Ciprofloxacin, Ofloxacin, and Sparfloxacin	1.11* (0.17)	1.26* (0.11)	0.48 (0.50)
All Four Domestic Quinolones Products	2.34* (0.19)	2.34* (0.19)	2.34* (0.19)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% level, and stagger (†) denotes significance at the 10% level.

Table 11
Counterfactual Estimates of Total Welfare Losses from Product Withdrawal due to the Introduction of Pharmaceutical Patents (Rs. Bill Per Year)

Counterfactual Scenarios: Withdrawal of One or More Domestic Product Groups	Pure Loss of Variety	Loss of Variety and:	
		Cross-segment Expenditure Switching	Within-segment Price-Adjustment and Cross-segment Expenditure Switching
Only Ciprofloxacin	5.94* (0.94)	6.01* (0.87)	7.72* (1.20)
Only Ofloxacin	0.04 (0.08)	0.05 (0.09)	0.09 (0.10)
Ciprofloxacin, Ofloxacin, and Norfloxacin	8.76* (1.84)	8.80* (1.77)	12.95* (3.61)
Ciprofloxacin, Ofloxacin, and Sparfloxacin	7.25* (1.46)	7.28* (1.42)	11.07* (2.88)
All Four Domestic Quinolones Products	14.10* (6.57)	13.70* (6.48)	20.16 (12.85)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% level.

Table 12
Counterfactual Estimates of Profit Gains of Foreign Producers from Product Withdrawal due to the Introduction of Pharmaceutical Patents (Rs. Bill Per Year)

Counterfactual Scenarios: Withdrawal of One or More Domestic Product Groups	Pure Loss of Variety	Loss of Variety and:	
		Cross-segment Expenditure Switching	Within-segment Price-Adjustment and Cross-segment Expenditure Switching
Only Ciprofloxacin	0.17* (0.03)	0.14* (0.06)	0.35* (0.17)
Only Ofloxacin	0.02 (0.01)	0.02 (0.01)	0.01 (0.02)
Ciprofloxacin, Ofloxacin, and Norfloxacin	0.36* (0.05)	0.28* (0.11)	0.71† (0.40)
Ciprofloxacin, Ofloxacin, and Sparfloxacin	0.37* (0.05)	0.30* (0.10)	0.79* (0.38)
All Four Domestic Quinolones Products	1.17* (0.31)	0.88* (0.41)	2.43† (1.44)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% significance level, and stagger (†) denotes significance at the 10% level.

APPENDIX

Additional Tables and Robustness Checks

Table A1
Spectrum of Activity of Various Families of Anti-bacterial Drugs

Organism	Tetra-cyclines	Chloram-penicols	Ampicillin, Amoxycillin	Cephalo-Sporins	Trimethoprim Combinations	Macro-lides	Other Penicillins	Amino-glycosides	Fluoro-quinolones
Gram-positive Cocci									
Staphylococcus Aureus									
Non-penicillinase Producing				X		x	x	x	x
Penicillinase Producing				X		x	x	x	x
Streptococcus Bovis									
Serious Infections			X				x	x	
Uncomplicated Urinary Tract Infection			X					x	x
Streptococcus Pneumoniae		x		X		x	x	x	x
Gram-negative Cocci									
Neisseria Meningitidis		x		X			x		
Neisseria Gonorrhaoeae									
Non-beta-lactamase Producing			X	X	x		x		x
Beta-lactamase Producing			X	X	x				x
Gram-negative Bacilli									
Acinetobacter Spp.			X	X	x				x
Brucella Spp.	x				x			x	x
Campylobacter Jejuni	x					x		x	x
Enterobacter Spp.				X			x	x	x
Escherichia Coli									
Uncomplicated Urinary Tract Infection	x		X	X	x				x
Systemic Infection			X	X				x	x
Francisella Tularensis	x	x						x	x
Haemophilus Influenzae									
Meningitis		x	X	X	x				x
Other Infections			X	X	x				x
Klebisiella Pneumonia	x	x		X	x			x	x
Legionella Spp.	x				x	x			x
Proteus Mirabillis			X	X	x			x	
Other Proteus Spp.			X	X	x			x	x
Providencia Spp.			X	X	x			x	x
Pseudomonas Aeruginosa				X			x	x	x
Salmonella Spp.			X	X	x				x
Serratia Marcescens			X	X			x	x	x
Shigella Spp.			X		x				x
Yersinia Pestis	x	x						x	x
Anaerobic Bacteria									
Anaerobic Streptococci	x	x		X		x	x		
Bacteroides Spp.									
Oropharyngeal Strains	x	x	X	X		X	x		
Gastrointestinal Strains		x	X	X		X	x		
Clostridium spp.	x	x				X			

Notes: An “x” in a cell indicates that at least one member of the family of drugs indicated in the column heading is listed as the anti-microbial drug of choice or as an alternative agent for the treatment of the bacterial infection indicated in the row heading.
Source: Table 15-1, pp.225-226, Principles and practice of infectious diseases, edited by Gerald L. Mandell, John E. Bennett, Raphael Dolin, 5th edition, 2000.

Table A2
Coefficient Estimates from the Lower-Level AIDS System

Product Group	Constant	Own Price Coeffi-cients	Cross-Price Coefficients			Coefficient on Quinolones Expenditure	Eastern Region Dummy	Western Region Dummy	Southern Region Dummy
			Same Molecule, Different Status	Different Molecule, Foreign Group	Different Molecule, Domestic Group				
Foreign Ciprofloxacin	0.013	-0.120*	0.115*	-0.003†	0.004*	0.010	0.027*	0.031*	0.007*
	(0.02)	(0.05)	(0.05)	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	(0.00)
Foreign Norfloxacin	-0.006	0.000	-0.005	-0.003†	0.004*	0.001	0.001*	0.000	0.000
	(0.01)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)
Foreign Ofloxacin	0.047*	-0.013	0.008	-0.003†	0.004*	0.005	0.001	-0.003	-0.007*
	(0.02)	(0.01)	(0.01)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.00)
Domestic Ciprofloxacin	0.603*	-0.298*	0.115*	0.004*	0.058*	0.102*	-0.001	-0.044*	0.033*
	(0.04)	(0.05)	(0.05)	(0.00)	(0.00)	(0.02)	(0.01)	(0.01)	(0.01)
Domestic Norfloxacin	-0.206*	-0.177*	-0.005	0.004*	0.058*	-0.038*	-0.041*	-0.034*	-0.031*
	(0.03)	(0.02)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	(0.01)
Domestic Ofloxacin	0.339*	-0.191*	0.008	0.004*	0.058*	-0.008	0.018	0.034*	0.026*
	(0.04)	(0.01)	(0.01)	(0.00)	(0.00)	(0.02)	(0.01)	(0.01)	(0.01)
Domestic Sparfloxacin	0.209*	-0.186*		0.004*	0.058*	-0.072*	-0.006	0.016*	-0.028*
	(0.03)	(0.02)		(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.00)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% level, and stagger (†) denotes significance at the 10% level.

Table A3
Coefficient Estimates from the Upper-Level AIDS System

Product Group	Cons-tant	Cross-Price Coefficients								Antibiotics Expenditure	Eastern Region Dummy	Western Region Dummy	Southern Region Dummy
		Tetra-cycline	Chloram-phenicol	Ampi-cillin	Cephalo-sporin	Trime-thoprim	Macro-lides	Other penicillin	Quino-lones				
Tetracyline	-0.11	-0.05	-0.03	-0.14†	0.13*	0.07†	0.08†	-0.02	-0.05	-0.03*	-0.03*	0.00	0.00
	(0.09)	(0.06)	(0.02)	(0.08)	(0.06)	(0.04)	(0.04)	(0.03)	(0.05)	(0.01)	(0.01)	(0.04)	(0.04)
Chloramphenicol	-0.02	-0.03	0.04*	-0.15*	0.09*	0.00	-0.09*	0.00	0.14*	0.02*	0.02*	0.01	0.01
	(0.05)	(0.02)	(0.01)	(0.04)	(0.03)	(0.02)	(0.02)	(0.02)	(0.04)	(0.00)	(0.01)	(0.01)	(0.01)
Ampicillin	0.27	-0.14†	-0.15*	0.00	0.10	0.02	0.04	0.09	0.03	-0.01	0.07*	0.13*	0.18*
	(0.17)	(0.08)	(0.04)	(0.14)	(0.10)	(0.06)	(0.08)	(0.07)	(0.07)	(0.01)	(0.03)	(0.05)	(0.05)
Cephalosporin	-0.22	0.13*	0.09*	0.10	0.26†	-0.15†	-0.08	-0.16†	-0.19*	-0.03*	-0.09*	-0.03	-0.06
	(0.22)	(0.06)	(0.03)	(0.10)	(0.15)	(0.08)	(0.10)	(0.09)	(0.08)	(0.01)	(0.02)	(0.05)	(0.05)
Trimethoprim	0.36*	0.07†	0.00	0.02	-0.15†	-0.04	-0.16*	0.03	0.22*	0.01*	0.01	-0.06*	-0.05†
	(0.13)	(0.04)	(0.02)	(0.06)	(0.08)	(0.13)	(0.06)	(0.07)	(0.05)	(0.01)	(0.01)	(0.03)	(0.03)
Macrolides	0.14	0.08†	-0.09*	0.04	-0.08	-0.16*	0.19†	0.08	-0.05	0.00	-0.02	-0.04	-0.03
	(0.21)	(0.04)	(0.02)	(0.08)	(0.10)	(0.06)	(0.11)	(0.08)	(0.05)	(0.01)	(0.02)	(0.03)	(0.03)
Other penicillin	0.17	-0.02	0.00	0.09	-0.16†	0.03	0.08	0.06	-0.08†	-0.01	0.02†	0.00	0.00
	(0.18)	(0.03)	(0.02)	(0.07)	(0.09)	(0.07)	(0.08)	(0.07)	(0.05)	(0.00)	(0.01)	(0.02)	(0.03)
Quinolones	0.41*	-0.05	0.14*	0.03	-0.19*	0.22*	-0.05	-0.08†	-0.02	0.04*	0.03	-0.01	-0.03
	(0.11)	(0.05)	(0.04)	(0.07)	(0.08)	(0.05)	(0.05)	(0.05)	(0.06)	(0.02)	(0.02)	(0.03)	(0.03)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at the 5% confidence level, and stagger (†) denotes significance at the 10% confidence level.

Table A4
Other Specifications for the Northern Region

A4(a): Demand Patterns with Seasonal Dummies: Summer							
	Elasticity with Respect to:						
Product	Foreign Groups' Prices			Domestic Groups' Prices			
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo
Foreign Ciprofloxacin	-6.06*	-0.14†	-0.15*	4.54*	0.12	0.13†	0.16*
	(1.91)	(0.07)	(0.08)	(2.15)	(0.07)	(0.07)	(0.07)
Foreign Norfloxacin	-6.10	0.12	-6.09	5.27	-7.47	6.10	6.19
	(4.55)	(2.26)	(4.55)	(6.01)	(11.68)	(4.62)	(4.58)
Foreign Ofloxacin	-0.11†	-0.11†	-1.58*	0.08	0.11*	0.47	0.11*
	(0.06)	(0.06)	(0.32)	(0.32)	(0.05)	(0.29)	(0.06)
Domestic Ciprofloxacin	0.18*	0.01†	0.00	-1.72*	0.07*	0.07*	0.10*
	(0.08)	(0.00)	(0.01)	(0.29)	(0.03)	(0.02)	(0.03)
Domestic Norfloxacin	0.03*	-0.03	0.03*	0.58*	-2.04*	0.36*	0.33*
	(0.01)	(0.03)	(0.01)	(0.19)	(0.11)	(0.04)	(0.04)
Domestic Ofloxacin	0.06†	0.05*	0.23†	0.89*	0.79*	-3.67*	0.77*
	(0.03)	(0.02)	(0.14)	(0.40)	(0.11)	(0.36)	(0.12)
Domestic Sparfloxacin	0.07*	0.04*	0.06*	1.25*	0.60*	0.58*	-2.81*
	(0.03)	(0.02)	(0.02)	(0.20)	(0.06)	(0.07)	(0.17)

A4(b): Demand Patterns with Seasonal Dummies: Monsoon							
	Elasticity with Respect to:						
Product	Foreign Groups' Prices			Domestic Groups' Prices			
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo
Foreign Ciprofloxacin	-5.80*	-0.13†	-0.15*	4.32*	0.11†	0.11	0.15*
	(1.89)	(0.07)	(0.07)	(2.07)	(0.07)	(0.07)	(0.07)
Foreign Norfloxacin	-3.52	-0.35	-3.52	3.03	-4.31	3.51*	3.57*
	(2.19)	(1.04)	(2.19)	(2.17)	(4.92)	(1.71)	(1.72)
Foreign Ofloxacin	-0.10†	-0.09†	-1.51*	0.06	0.09*	0.41†	0.10*
	(0.05)	(0.05)	(0.26)	(0.29)	(0.04)	(0.25)	(0.04)
Domestic Ciprofloxacin	0.19*	0.01*	0.00	-1.72*	0.07*	0.07*	0.10*
	(0.08)	(0.00)	(0.01)	(0.29)	(0.02)	(0.03)	(0.02)
Domestic Norfloxacin	0.04*	-0.03	0.03*	0.61*	-2.10*	0.38*	0.35*
	(0.01)	(0.03)	(0.01)	(0.19)	(0.11)	(0.04)	(0.04)
Domestic Ofloxacin	0.05†	0.04*	0.19†	0.72*	0.65*	-3.20*	0.64*
	(0.02)	(0.02)	(0.11)	(0.32)	(0.08)	(0.27)	(0.09)
Domestic Sparfloxacin	0.07*	0.04*	0.07*	1.25*	0.60*	0.61*	-2.82*
	(0.02)	(0.02)	(0.02)	(0.21)	(0.07)	(0.07)	(0.19)

A4(c): Demand Patterns with Seasonal Dummies: Winter							
	Elasticity with Respect to:						
Product	Foreign Groups' Prices			Domestic Groups' Prices			
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo
Foreign Ciprofloxacin	-5.66*	-0.13†	-0.14†	4.19*	0.12†	0.11	0.14*
	(1.80)	(0.07)	(0.07)	(2.02)	(0.07)	(0.08)	(0.07)
Foreign Norfloxacin	-4.37†	-0.20	-4.36†	3.78	-5.33	4.34*	4.41*
	(2.54)	(1.42)	(2.53)	(2.66)	(6.10)	(2.13)	(2.13)
Foreign Ofloxacin	-0.10†	-0.10†	-1.55*	0.07	0.10*	0.44†	0.10*
	(0.06)	(0.05)	(0.28)	(0.30)	(0.05)	(0.26)	(0.05)
Domestic Ciprofloxacin	0.19*	0.01*	0.00	-1.73*	0.07*	0.07*	0.10*
	(0.08)	(0.00)	(0.01)	(0.29)	(0.02)	(0.03)	(0.02)
Domestic Norfloxacin	0.04*	-0.03	0.04*	0.68*	-2.22*	0.43*	0.39*
	(0.02)	(0.03)	(0.02)	(0.20)	(0.13)	(0.05)	(0.04)
Domestic Ofloxacin	0.04†	0.04*	0.18	0.68*	0.61*	-3.08*	0.61*
	(0.03)	(0.02)	(0.12)	(0.33)	(0.10)	(0.35)	(0.10)
Domestic Sparfloxacin	0.06*	0.03*	0.06*	1.06*	0.51*	0.53*	-2.56*
	(0.02)	(0.01)	(0.02)	(0.20)	(0.06)	(0.07)	(0.18)

Notes: Standard errors in parentheses. Elasticities evaluated at average revenue shares. Asterisk (*) denotes significance at the 5% confidence level, and stagger (†) denotes significance at the 10% confidence level.

Table A5

Demand Patterns with OLS Coefficients							
	Elasticity with Respect to:						
Product	Foreign Groups' Prices			Domestic Groups' Prices			
Group	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo
Foreign Ciprofloxacin	-2.76*	-0.05	-0.06	1.39	0.00	-0.01	0.05
	(0.82)	(0.05)	(0.05)	(0.92)	(0.07)	(0.07)	(0.07)
Foreign Norfloxacin	-1.66	1.24	-1.64	0.59	-2.25	1.02	1.10
	(1.75)	(1.61)	(1.75)	(2.04)	(6.73)	(2.04)	(2.07)
Foreign Ofloxacin	-0.04	-0.04	-0.99*	-0.07	0.02	-0.02	0.03
	(0.05)	(0.04)	(0.26)	(0.24)	(0.05)	(0.23)	(0.05)
Domestic Ciprofloxacin	0.06	0.00	-0.01	-1.56*	0.07*	0.07*	0.10*
	(0.04)	(0.00)	(0.01)	(0.25)	(0.03)	(0.03)	(0.02)
Domestic Norfloxacin	0.01	-0.01	0.01	0.46*	-2.18*	0.40*	0.39*
	(0.02)	(0.04)	(0.01)	(0.20)	(0.11)	(0.04)	(0.04)
Domestic Ofloxacin	0.02	0.01	0.00	0.81*	0.73*	-3.16*	0.71*
	(0.03)	(0.02)	(0.10)	(0.22)	(0.07)	(0.24)	(0.07)
Domestic Sparfloxacin	0.06*	0.01	0.04†	1.25*	0.63*	0.64*	-2.76*
	(0.02)	(0.02)	(0.02)	(0.15)	(0.06)	(0.06)	(0.17)

Table A6
Counterfactual Estimates of Consumer Welfare Losses from Product Withdrawal Due to the Introduction of Pharmaceutical Patents, Assuming MC = P (Rs. Bill Per Year)

Counterfactual Scenarios: Withdrawal of One or More Domestic Product Groups	Pure Loss of Variety	Loss of Variety and:	
		Cross-segment Expenditure Switching	Within-segment Price-Adjustment and Cross-segment Expenditure Switching
Only Ciprofloxacin	4.98*	4.92*	9.47*
	(0.92)	(0.94)	(2.32)
Only Ofloxacin	0.08	0.08	4.08*
	(0.09)	(0.09)	(0.83)
Ciprofloxacin, Ofloxacin, and Norfloxacin	7.52*	7.40*	14.67*
	(1.83)	(1.88)	(5.52)
Ciprofloxacin, Ofloxacin, and Sparfloxacin	6.14*	6.03*	12.83*
	(1.41)	(1.46)	(4.57)
All Four Domestic Quinolones Products	11.76†	11.35†	19.46
	(6.28)	(6.28)	(15.20)

Notes: Standard errors in parentheses. Asterisk (*) denotes significance at 5% confidence level, and stagger (†) denotes significance at 10% confidence level.