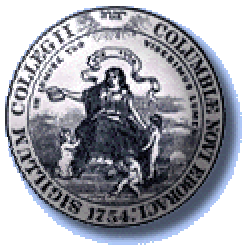

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The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of the Indian Pharmaceutical Market

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The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of the Indian Pharmaceutical Market*

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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 and continues to be extremely contentious. Many poor developing 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, which claim to have lost billions of dollars because of patent infringement, 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 expense are met out-of-pocket. Using a product-level data set from India, which is unique in terms of its detail and coverage, 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 (of both domestic firms and multinational subsidiaries) 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 absence of any price regulation or compulsory licensing*, 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. $713 million, or about 118% of the sales of the entire systemic anti-bacterials segment in 2000. Of this amount, foregone profits of domestic producers constitute roughly $50 million (or 7%). The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare. In contrast, the profit gains to foreign producers are estimated to be only around $57 million per year.

JEL Codes: O34, D12, D4, L65, F13

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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, which culminated in the formation of the World Trade Organization (WTO) in 1995—nations must, as a condition of membership in the 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.[1] To meet their obligations under TRIPS these countries must however 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 over 8 years have passed since TRIPS was finalized, there continues to be considerable controversy and debate regarding its merits.[2] 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.[3]

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. Apart from the findings of a small number of studies that we describe 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

[1] Even among OECD countries, pharmaceutical product patents are a relatively recent phenomenon. For instance, pharmaceutical products were excluded from patent protection in Germany until 1968, Switzerland until 1977, Italy until 1978, Spain, Portugal and Norway until 1992, and Finland until 1995. Moreover, in countries with a longer history of pharmaceutical product patents, such as Canada, France and the U.K., compulsory licensing provisions are quite liberal (Scherer and Watal (2001)).

[2] For instance, at the fourth WTO Ministerial Conference in Doha, Qatar in November 2001, the details of TRIPS were again the subject of much discussion (see Stevenson (2001)). Underlying the continued debate is the fact that there remain critical unresolved questions about how various provisions of TRIPS ought to be interpreted—the language in many of the articles is deliberately vague—and the flexibility that WTO member nations ought to have in applying various policy options, for instance, compulsory licensing or price controls, that are permitted under TRIPS (see Barton (2001), Scherer and Watal (2001)).

[3] Arguments have also been made that the problems of low-cost access have less to do with the high prices associated with patents, and more with the weaknesses of public health infrastructure and delivery systems (see for instance, Bale (2001)).

losses.[4]

There have been several empirical studies on the impact of patents on prices and innovative activity in various sectors including pharmaceuticals, in the context of *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 four critical respects.

The first is simply the fact that households are much poorer in less-developed economies and hence, per-capita health expenditures are several orders of magnitude lower than in developed economies. The second crucial difference is that health insurance coverage is much rarer in less-developed economies. As a result, the bulk of a household's medical expenditures are met out-of-pocket. Third, the burden of disease in low-income countries stems from somewhat different causes than in developed economies, and in particular, there are certain diseases that are almost exclusively suffered by Third World populations. And fourth, as Lanjouw and Cockburn (2000) point out, because the conditions under which drugs are stored, transported or administered are considerably different in less-developed economies, the relative value that consumers place on characteristics such as storability, transportability or ease of administration are likely to be different as well. Table 2, which is derived from statistics reported in the *World Health Report* for 2002 (WHO (2002)), provides examples of these differences.

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, a number of studies have carefully considered these issues, and have used explicit models of consumer and firm behavior to simulate the welfare losses implied by patent protection.[5] But these studies, while they provide some useful indicative figures, 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-

[4] 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 (2000).

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

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 market structure parameters for the fluoroquinolone (quinolone henceforth[6]) segment of systemic anti-bacterials in the Indian pharmaceuticals market. We chose this segment because it contains several products that were still under patent in the U.S. during our sample period. We then use these estimates to carry out counterfactual simulations of what prices, profits (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.

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.[7] In fact, during the Uruguay round of negotiations, India led the opposition to the TRIPS articles mandating pharmaceutical product patents. And at the fourth WTO Ministerial Conference in Doha, India was the leading co-sponsor of the Doha Declaration on TRIPS and Public Health, which called for clarifying and reconfirming that the TRIPS agreement should be interpreted and implemented in a manner that ensures the rights of WTO members to protect public health and promote access to medicines.

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

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

[7]Only in 2002 did India finally amend its patent legislation in accordance with TRIPS. The Patents (Amendment) Act of 2002, the provisions of which went into effect in May 2003, recognizes pharmaceutical product patents for a period of 20 years.

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 have to be removed from 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 the estimates 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.[8] 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 loss of consumer welfare attributable to the loss of variety from the withdrawal of domestic products turns out to be significant. 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 the loss we attribute to the reduction of product variety is a purely transitional phenomenon, due to the fact that the current product portfolios and distribution networks of foreign producers are limited. We discuss these views in detail in the results section.

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

[8] This is the exact analog of the gains from additional variety emphasized in the studies of the valuation of new product introductions, for instance Hausman (1994), and Hausman and Leonard (2002).

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 three 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 or compulsory licensing* 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. 32 billion, or about 118% 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. $ 713 million. Of this amount, foregone profits of domestic producers constitute roughly Rs. 2.3 billion or U.S. $50 million (ca. 7%). The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare.[9]

Worth noting as well is that our estimates indicate that the total profit gains to foreign producers would be only about Rs. 2.6 billion or approximately U.S. $57 million per year. To put this number in perspective, sales of Cipro, the main patented ciprofloxacin product of Bayer, were roughly U.S. $1.6 billion in 2000 (Hensley (2001)). We estimate that the prices of foreign products would rise between 200% and 750%.

The remainder of this paper is organized as follows. In the next section we briefly review, from a conceptual perspective, the various hypothesized costs and benefits of product patents. We also briefly summarize the existing evidence on the impact of pharmaceutical patents. The following section lays out the essential features of the Indian pharmaceuticals market, provides more detail about the segments that we focus on in the empirical analysis, and briefly describes the primary data we use.

Section 4 is the core methodological section of the paper. There we describe in detail the analytic framework and the econometric strategy we use to estimate the relevant parameters and construct the counterfactual scenarios. We discuss our results in the fifth section. Section 6 concludes.

[9]Not surprisingly in light of the discussion above, our estimates of the consumer welfare losses are much higher than those reported in earlier studies for the entire pharmaceuticals market.

2. Conceptual preliminaries and the existing evidence

The basic economic theory regarding the impact of patent protection on product prices and consumer welfare is simple. Patents, by providing monopoly power—i.e., exclusive rights to produce and sell the patented good—to the patent-holder, enable the latter to raise the price of the patented good above the level that would have prevailed in a competitive market. That is the immediate (static) effect of patents. On the other hand, a longer-term, more dynamic perspective suggests that the promise of these monopoly profits is precisely what is needed to spur research and innovation that will lead to the introduction of newer and better products, which will over time displace the older patented products and raise consumer welfare.[10]

Within a multi-country setting the trade-offs are no longer so simple. From the perspective of any individual economy, the welfare consequences of patent protection depend on whether the patent-holders are foreign or domestic firms, and on the extent to which patent protection serves to stimulate appropriate research and innovation; this, in turn, will depend on what other nations are doing, and on the importance of the economy in question in influencing the priority areas of research.[11] The pricing decisions of patent-holders may also be altered. Specifically, foreign patent holders may have a variety of reasons—concerns about a public backlash in their home markets or the possibility of parallel imports, etc.—to engage in global reference pricing, i.e., set prices not to maximize profits in the particular national market but to maximize profits worldwide. For many poor economies this may mean prices that are higher than domestic monopoly prices, magnifying the static pricing distortions that arise from patents.

Matters become even more complicated when one considers markets characterized by differentiated products, such as pharmaceuticals. Even within narrowly specified therapeutic segments, consumers often have a choice of several alternative drugs, of varying vintages and levels of therapeutic effectiveness, produced by companies with varying reputations for quality. Even if producers enjoy *de facto* monopoly power in the sales of their own products, the presence of other 'similar' though not identical products in the market can inhibit the ability of individual producers to manifest this monopoly power through higher prices. An empirical assessment of the likely impact of patent protection in such markets therefore requires a much more detailed understanding of the structure of demand.

A large number of empirical studies have attempted to estimate the impact of product patents on prices and/or consumer welfare. Some studies have exploited data from

[10] Of course, patents are not the only way of providing incentives for research and innovation. Direct subsidies for research, prizes and tournaments, and patent buyouts are all alternative mechanisms for doing so, many of which have been used historically. In fact, because of the static pricing distortions they bring about, the costs of any attempts at reverse engineering they may induce, and the fact that they do not provide sufficient incentives for research that may have substantial spillovers, patents may be a particularly inefficient way of encouraging discovery. For a discussion of the varying economic perspectives on patents, see M. Kremer (1998), Mazzoleni, R. and R. R. Nelson, (1998a, 1998b), and B. Wright (1983). The fact that, even with full patent protection, market-oriented R&D is unlikely to result in new treatments for certain tropical diseases that are exclusively the burden of poor populations (with limited ability to pay), has led to calls for increased public funding for such efforts (see for instance, Sachs (2002) and Ganslandt et al. (2001)).

[11] See Chin and Grossman (1990), Deardoff (1992), Helpman (1993), Grossman and Lai (2003) and especially Diwan and Rodrik (1991) for detailed analyses along these lines.

particular historical episodes, or cleverly formulated comparisons to identify the effects of patents and competition on prices. For instance, Caves et al. (1991) compare the wholesale prices of branded drugs to those of generic substitutes, and find that the relative price of generic substitutes decreased with the number of generic substitutes available for a particular branded drug. Lu and Comanor (1998) report that newly patented drugs that provided significant therapeutic gains over existing substitutes were launched at considerably higher relative prices than those that offered more modest therapeutic gain.[12] While these studies are able to isolate the likely impact of patent enforcement on prices, they are limited by the fact that they do not (and cannot) provide any sense of the magnitude of the welfare loss that consumers are likely to suffer, since they are not grounded in any explicit model of consumer behavior.

3. The setting and the data

Between April 1972, when the Indian Patents Act (1970) became effective, and May 2003, when the provisions of the Patents (Amendment) Act of 2002 went into effect, 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.

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 (see Figures 1 and 2) 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.[13] 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. Table 1 documents this shift.

Table 2, which we alluded to earlier, conveys the basic point that the characteristics of demand for pharmaceuticals in India is likely to differ considerably from those in developed economies. Table 3 reinforces this point. The table shows the shares of overall retail sales of the major therapeutic segments into which pharmaceutical products are typically classified,

[12] See also Frank, R.G. and D.S. Salkever (1997), Rozek, R.P. and R. Berkowitz (1998), and Wattal (1996) for other examples.

[13] *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.

for the world market (in 2001) and the Indian market (in 2000). Note that 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%. Once again, this highlights the fact that the diseases that are most relevant in developing countries do not necessarily coincide with those that are viewed as most pressing in the developed world.

With this in mind, we focus in this paper on one particular sub-segment of anti-infectives, namely 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[14]. 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. Table 4 lists the major families of molecules in the systemic anti-bacterials segment and outlines the spectrum of activity for each family. Table 5 provides details about the systemic anti-bacterials segment of the Indian market.

Among systemic anti-bacterials, quinolones are the latest generation molecules available in India. We focus our analysis on quinolones for several reasons. First, as the last column of Table 4 indicates, quinolones are the drug of choice for a large number of bacterial infections, some of which are also treated by alternative drugs. 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 (see Table 5), 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 7 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 6; however, the market shares of these molecules are negligible, so that we exclude these molecules from our analysis.

Table 7 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.[15] 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" patent laws in India, while complying with them in developed world countries. The last two rows of Table 7 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

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

[15] Accordingly, the common distinction between "branded" and "generic" products is irrelevant here. The large number of domestic firms is due to the fact that many Indian firms sell only in particular regions of the country.

to prevent domestic companies from capturing a large market share. This is most evident in the case of ciprofloxacin, where domestic firms have, with 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.

Our data 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 data on monthly sales for the period of January 1999 to December 2000.

4. The analytic framework and estimation approach

4.1. Overview

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.

In order to assess the effects of product withdrawal we need to derive for each product withdrawn its *virtual price*, that is the notional price that would set this product's demand equal to zero. Estimation of this virtual price requires estimation of the demand function. Hence, the first step in the analysis is demand estimation. The demand parameters allow us to estimate the price elasticities of demand and substitution patterns across products in the antibiotics market, which are needed in the computation of virtual prices and subsequent welfare analysis. Given the significance of the demand estimates in our analysis, it is important to adopt a relatively general and flexible demand specification. We discuss the available alternatives and our specification choices in detail in the next subsection.

While with perfect competition estimation of the demand function for a particular product is sufficient for assessing the effects of this product's elimination from the market, imperfect competition requires modelling of the entire market, as removal of one product will affect the prices of other products, especially those that are close competitors. To evaluate the effects of a product's withdrawal on other products' prices, it is necessary to model the supply side, that is firms' costs and strategic behavior. While strategic interaction seems a-priori important in the Indian pharmaceutical market, the market is also characterized by price controls which impose potential constraints on firms' maximization problem. We

discuss these issues in the following subsection. We exploit the firms' first order conditions associated with the solution of the profit maximization problem and/or the existence of price controls to estimate marginal costs and markups, and use those estimates in subsequent counterfactual simulations.

With demand and cost parameters in place, we are then ready to 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 first compute the virtual prices of the products that are removed from the market. To do this, we set the demand of these products equal to zero, while allowing firms that remain in the market to reoptimize and set new prices in response to the exit of domestic products. Hence, we derive the virtual prices of the products that are being withdrawn and the predicted prices of the products remaining in the market in the same step. These counterfactual prices are then used to assess the effects of domestic product withdrawal on consumer welfare, firm profits, and social welfare. While the computation of the profit changes is straightforward, the calculation of the consumer welfare changes is more involved. To the extent that the demand system is consistent with utility maximization, we can use the demand function to derive the associated expenditure function, that is the minimum amount of income required for the average (representative) consumer to achieve a particular utility level at given prices. We then measure the welfare change associated with the elimination of domestic products by the compensating variation, that is the additional expenditure that consumers need in order to achieve the same utility level as before patent enforcement at the new prices. Details of these computations and exact formulas are provided in sub-section describing how we construct the counterfactuals.

4.2. Empirical specification of demand

Demand estimation on pharmaceuticals has traditionally faced two challenges. The first one is that because many drugs in developed countries can be bought only with prescription, and a substantial number of consumers are covered by insurance, agency (i.e., the relationship between doctors and patients) and moral hazard issues (i.e., doctors may prescribe more expensive products than they would in the absence of insurance) can have important implications for the estimated demand patterns and their interpretation.[16] Fortunately, these issues do not arise in the Indian pharmaceutical market. As discussed earlier, in India basically all private health expenses are met out-of-pocket because health insurance coverage is so rare.

The second challenge is that the pharmaceutical market is a classic differentiated product market. Even within narrowly specified therapeutic segments, consumers often have a choice among products containing different active pharmaceutical ingredients, of varying vintages and levels of therapeutic effectiveness, produced by companies with varying reputations for quality[17]. Moreover, such products are available in multiple presentations, that

[16] Cleanthous(2003) for example reports a very low price elasticity of demand for the U.S. market of antidepressants. Breaking down the results by insurance status, he finds that the low price elasticity of demand is primarily driven by the price insensitivity of consumers who are insured. For such consumers, one cannot reject the hypothesis that the price elasticity of demand is zero; in contrast, consumers without insurance have significantly higher price elasticity of demand.

[17] Note that the familiar (from developed countries) distinction between branded and generic drugs is not

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.[18] Even if we define *products* by aggregating across the multiple *presentations,* in which drugs containing the same *active pharmaceutical ingredient* are marketed by a particular manufacturer (in which case a product represents a unique combination of a *manufacturer* and an active pharmaceutical ingredient (API)), the number of products in the segment of interest is large. For instance, in 1991, there were, under our definition, 589 distinct products available in the systemic anti-biotics and anti-bacterials sub-segment of the Indian market. By 2000, that number had risen to 1242.

The multiplicity of differentiated products poses problems for the standard techniques of demand estimation. Over the last ten years, however, new strategies and techniques have been proposed for the estimation of demand parameters in differentiated products markets. Among them, the two approaches that have been used most frequently in empirical work are the discrete-choice framework (e.g., Trajtenberg (1989), Goldberg (1995), Berry et al. (1995), Nevo (2001), etc.) and the multi-stage budgeting approach (Ellison et al (1997), Hausman (1994), Hausman and Leonard (2002), etc.).

In the case of pharmaceuticals, the discrete-choice approach presents some difficulties, both conceptual and practical. At a conceptual level, the basic assumption of unit demand by individual consumers that underlies the discrete choice framework seems untenable. Moreover, it is well known that computationally tractable versions of discrete choice models tend to overstate the welfare effects of product entry or exit, since the implied demand functions never intersect the vertical axis, that is, product demand can never become zero (in other words, the implied virtual prices are infinity). This feature arises because the presence of an idiosyncratic error term in the underlying utility function implies a taste for variety; accordingly, each additional product generates an increment in utility, and the product space can never become too crowded[19]. In practice, the consequences of this aspect of discrete choice models for welfare analysis can be mitigated through the adoption of relatively general functional forms (e.g., random coefficient models) and/or the use of micro data. Unfortunately, we do not have micro data in the present application. Furthermore, the type of counterfactuals we are interested in makes us particularly cautious not to adopt an approach that would—by its nature—tend to overstate the welfare effects of product entry and exit. In particular, while welfare analysis has typically been applied to evaluate the introduction of a *single* product, in the present case we are interested in evaluating the effects of simultaneously withdrawing multiple domestic products from the market—potentially the whole domestic segment. Even if a flexible random coefficient model only slightly overstated the welfare effects of a single product's withdrawal, the cumulative effect of such overstatement when multiple products are withdrawn from the market could be

meaningful in a market with no patent protection.

[18] 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.

[19] For a discussion see, for example, Berry and Pakes (2001). The other extreme, a model without the idiosyncratic error term (the pure hedonic model discussed in Berry and Pakes (2001)), would also be unappealing in the current context, as the therepeutic effectiveness of a drug is not completely captured by its observed characteristics but varies by consumer.

significant.

In practical terms, the discrete choice approach requires data on physical sales shares (as opposed to revenue shares). If the analysis were limited to sales of pharmaceutical products containing a single molecule (i.e., active pharmaceutical ingredient), this would not pose a problem as we have data on the quantity of the relevant API (e.g., 100 milligrams of ibuprofen) contained in each of the products in our database. But if the analysis were to be extended to include products containing other molecules that represent close therapeutic substitutes, it is not clear that physical sales shares are terribly meaningful. For instance, 100 milligrams of ciprofloxacin are not directly comparable with 100 milligrams of norfloxacin.

For all these reasons, we base our estimation strategy on a multi-stage budgeting approach. The basic idea of this 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 levels. At the higher level are the various sub-segments of systemic anti-bacterials, listed in Table 5. The first stage of budgeting then 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).

The two-stage demand estimation approach we propose presents many advantages. Functional form flexibility is one of them. While the a-priori segmentation of the product space at the higher level imposes some restrictions on the demand patterns, the substitution patterns implied by the AIDS specification at the lower level are very general, as they permit (in principle) an unconstrained pattern of conditional cross-price elasticities across products within a sub-segment. Given that competition among differentiated products tends to be highest within sub-segments, this lack of restrictions at the lower stage is a considerable advantage of AIDS over alternative approaches. An additional advantage is that the AIDS model, though developed with micro data in mind, aggregates perfectly over consumers without requiring linear Engel curves. This is important here, since we work with aggregate data. Finally, the implied demand curves intersect the price axis, so that the virtual price is not infinity.

However, the application of the two-level demand estimation to the Indian systemic antibiotics market also 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, within each sub-segment (e.g., quinolones), we aggregate 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.,:

$$\omega_k = \frac{R_k}{R_i} \tag{4.1}$$

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

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 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. Ideally, we would like to use a single price and quantity index for each product group when modelling the allocation of total expenditure to groups. The necessary and sufficient conditions for this practice to be consistent with utility maximization were derived by Gorman and turn out to be so restrictive that they are empirically implausible (e.g., additive separability and a group indirect utility function of the Gorman Generalized Polar Form). More flexible functional forms (such as a double-log specification for modelling the higher level expenditure allocation) violate the conditions for *exact* two-stage budgeting. Given these difficulties 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 that we describe in detail below.

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), u_Q be the utility consumers derive from quinolones, and X_Q the total expenditure on the quinolone segment. The AIDS model is based on the following specification of the expenditure function for quinolones e_Q:

$$\ln e_Q(u_Q, p) = a(p) + u_Q b(p) \tag{4.2}$$

where:

$$a(p) = \alpha_0 + \Sigma_i \alpha_i \ln p_i + \frac{1}{2} \Sigma_i \Sigma_j \widetilde{\gamma}_{ij} \ln p_i \ln p_j \tag{4.3}$$

and:

$$b(p) = \beta_0 \Pi_i p_i^{\beta_i} \tag{4.4}$$

This specification of the expenditure function yields an expression for the revenue share of each product group, which provides the basis for estimation:

$$\omega_i = \alpha_i + \Sigma_j \gamma_{ij} \ln p_j + \beta_i \ln(\frac{X_Q}{P_Q}) \tag{4.5}$$

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

$$\omega_i \equiv \frac{p_i q_i}{\Sigma_j p_j q_j} = \frac{x_i}{X_Q}, \text{ with } i, j \in Q \tag{4.6}$$

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

$$\ln P_Q = a(p) = \alpha_0 + \Sigma_i \alpha_i \ln p_i + \frac{1}{2} \Sigma_i \Sigma_j \widetilde{\gamma}_{ij} \ln p_i \ln p_j \tag{4.7}$$

The AIDS model was originally developed with micro data in mind, so that X_Q and ω_i in the equations above refer to a *household's* expenditure and expenditure shares respectively. However, Muellbauer (1975, 1976) and Deaton and Muellbauer (1980) show that exact aggregation over households is possible so that equation (4.5) above can be applied in nearly identical form to aggregate data, with ω_i denoting the aggregate conditional expenditure share of product group i, and X_Q denoting the *average* expenditure of a representative household.[20] Thus interpreted, equation (4.5) can be estimated with aggregate product-level data on revenue shares, prices, and average household expenditure. Note that if equation (4.5) did not involve the exact price index P_Q, it would be linear in the parameters to be estimated. To avoid non-linearities, P_Q can be approximated by the Stone price index P_{QS} ($\log P_{Q,S} = \Sigma_k \omega_k \log p_k$) along the lines discussed by Deaton and Muellbauer (1980a).

The AIDS model in this, its most general form, is extremely flexible, imposing few implicit restrictions on patterns of substitution across product groups. For instance, the constant-expenditure cross price elasticity of any product group i with respect to the price of any other product group j, with $i \neq j$, is given by:

$$\varepsilon_{ij}|_{X_Q = \overline{X_Q}} = \left. \frac{\partial \ln q_i}{\partial \ln p_j} \right|_{X_Q = \overline{X_Q}} = \left. \frac{\partial \ln \omega_i}{\partial \ln p_j} \right|_{X_Q = \overline{X}_Q} \tag{4.8}$$

[20] Specifically, the *aggregate* version of equation (4.5) becomes:

$$\overline{\omega}_i = \alpha_i + \Sigma_j \widetilde{\gamma}_{ij} \ln p_j + \beta_i \ln(\frac{\overline{X}_Q}{k P_Q})$$

where $\overline{\omega}_i$ denotes the share of aggregate expenditure on product i in the aggregate budget of all households, and $\overline{X}_Q$ is the average level of quinolone expenditure. The index k reflects the demographic structure and distribution of budgets across households. Ideally, one would try to model k using data on the distribution of household budgets and characteristics. In the absence of such information this approach is infeasible. However, given that our data span only a short time period (two years), it is reasonable to assume that the distribution of household budgets and characteristics is invariant, in which case k is a constant. In this case one can redefine $\alpha_i^* = \alpha_i - \beta_i \log k$, and apply this modified version of equation (4.5) to aggregate data.

$$= \left[\frac{\widetilde{\gamma}_{ij} + \beta_i[\omega_j - \beta_j \ln(\frac{X_Q}{P_Q})]}{\omega_i}\right]$$

The flexibility of the AIDS model thus derives from the fact that it includes N^2 parameters that directly influence the patterns of substitution. They are the elements of the matrix:

$$\Gamma = \begin{bmatrix} \widetilde{\gamma}_{11} & ...\widetilde{\gamma}_{1i}... & \widetilde{\gamma}_{1N} \\ \widetilde{\gamma}_{i1} & ...\widetilde{\gamma}_{ii}... & \widetilde{\gamma}_{iN} \\ \widetilde{\gamma}_{N,1} & ...\widetilde{\gamma}_{Ni}... & \widetilde{\gamma}_{NN} \end{bmatrix} \tag{4.9}$$

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 directly on the elements of the matrix Γ.

The first set of restrictions are implied by the theory of utility maximization. We impose these restrictions despite the fact that they have been routinely rejected in applications of the AIDS model to broader product categories, for two reasons. First, as noted above, we need to restrict the number of parameters, and imposing the restrictions implied by economic theory provides a natural way to do so. Second, given that we are interested in conducting welfare analysis, it is important that our framework satisfies the restrictions implied by 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 nationality.)

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:[21]

$$d(i,j) = \begin{cases} (1,0) & \text{if } M_i = M_j, DF_i \neq DF_j \\ (0,1) & \text{if } M_i \neq M_j, DF_i = DF_j \\ (0,0) & \text{if } M_i \neq M_j, DF_i \neq DF_j \end{cases} \tag{4.10}$$

Let

$$D_i^{ab} = \{j : d(i,j) = (a,b)\} \tag{4.11}$$

the final form of the equation we estimate at the lower level becomes (with subscript t denoting month):

$$\begin{aligned} \omega_{it} &= \alpha_i + \gamma_{ii} \ln p_{it} + \Sigma_{j \in D_i^{10}} [\gamma_{i,10} \ln p_{jt}] + \Sigma_{j \in D_i^{01}} [\gamma_{i,01} \ln p_{jt}] \\ &\quad + \Sigma_{j \in D_i^{00}} [\gamma_{i,00} \ln p_{jt}] + \beta_i \ln(\frac{X_{Qt}}{P_{Qt}}) \end{aligned} \tag{4.12}$$

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.
- 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.

The analysis so far has conditioned on the expenditure allocated to the quinolone subsegment 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.[22] This problem is more involved than the lower level budgeting problem considered above. To see why, let u be the direct utility consumers derive from consuming commodity vector q. Assuming weak separability, the utility function can be written as

$$u = v(q) = f[v_1(q_1), ...v_Q(q_Q), ...v_G(q_G)] = f(u_1, ...u_Q, ...u_G) \tag{4.13}$$

where $v_1, v_2, ...v_G$ are well-behaved subutility functions of the non-overlapping product vectors $q_1, q_2, ...q_G$. The subscripts here refer to "groups" or "sub-segments" within the systemic anti-biotics market. A utility function of this form gives rise to second-stage demand functions of all products within segment G of the form $q_i = g_i(x_G, p_G)$, where x_G is the expenditure on group G, and p_G is the vector of within-group prices. The demand functions

[21] 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}.

[22] This formulation of the problem conditions on the total expenditure allocated to the market of systemic antibiotics.While the allocation of total income to systemic antibiotics could potentially be modelled by introducing a third stage in the demand estimation, we abstract from this problem in this paper.

represented by (4.5) or (4.12) above fall into this category. Utility function (4.13) is to be maximized subject to the budget constraint

$$\Sigma_G e_G(u_G, p_G) = X \tag{4.14}$$

where $e_G(u_G, p_G)$ is the group expenditure function which minimizes the expenditure of reaching group utility level u_G given the within-group price vector p_G, that is $e_G(u_G, p_G) = \min_{q_G}[\Sigma_{k \in G} p_k q_k; v_G(q_G) = u_G]$. It is easy to see that in general this maximization problem requires knowledge of all individual prices within each group, unless one imposes the restrictive conditions discussed at the beginning of this section. The approximate solution proposed by Deaton and Muellbauer (1980b) relies on first rewriting the expenditure function of each group G as follows:

$$e_G(u_G, p_G) = e_G(u_G, p_G^0) * \frac{e_G(u_G, p_G)}{e_G(u_G, p_G^0)} \tag{4.15}$$

where p_G^0 is a base period price vector. The second term on the right hand side is the true cost-of-living price index for group G. This can be written as $P_G(p_G, p_G^0, u_G)$ to emphasize the dependence of the exact price index on the utility level u_G. The first term of the right hand side can be interpreted as the money cost of reaching utility level u_G with the base period price vector p_G^0. Accordingly, this term can be interpreted as a quantity index denoted by Q_G. The utility maximization problem can now be reformulated as maximizing the indirect utility function corresponding to (4.13) subject to the budget constraint

$$\Sigma_G P_G(p_G, p_G^0, u_G) Q_G = X \tag{4.16}$$

This is the standard form, with matching price and quantity indices, P_G and Q_G respectively. Still, the difficulty remains that the exact price index P_G is a function of the utility level u_G, so that in principle we are where we started. However, Deaton and Muellbauer observe that if the empirical variation of P_G with u_G is not too great, then the exact price index can be *approximated* by commonly used price indices. This approximation allows one to solve the maximization problem to obtain first stage demand functions of the form:

$$Q_G = g_G(P_1, ...P_G, X) \tag{4.17}$$

where P_G is a commonly used price index, and Q_G is a quantity index. This specification gives rise to an *approximate* two-stage budgeting system that is easy to implement empirically.

In particular, we employ Deaton and Muellbauer's approximation to justify a higher level AIDS system that has the following form:

$$\text{Expenditure function: } \ln E(u, P) = A(P) + uB(P) \tag{4.18}$$

$$\text{Demand function: } \omega_G = \alpha_G + \Sigma_H \gamma_{GH} \ln P_H + \beta_G \ln(\frac{X}{P}) \tag{4.19}$$

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:

$$\varepsilon_{ij} = \varepsilon_{ij}|_{X_Q=\overline{X_Q}} + \frac{\partial \ln q_i}{\partial \ln X_Q} \frac{\partial \ln X_Q}{\partial \ln P_Q} \frac{\partial \ln P_Q}{\partial \ln p_j} \tag{4.20}$$

In sum, the demand system we take to the data is represented by equations (4.12) and (4.19) and the associated parameter restrictions implied by economic theory.

4.3. 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. In the absence of cost data, we follow the usual approach in the New Empirical Industrial Organization literature of exploiting the firm equilibrium conditions to infer marginal costs. We assume constant marginal costs c_i, and model the industry as an oligopoly engaging in Bertrand competition with differentiated products. The usual procedure is then to assume that firms myopically maximize profits each period, and derive the firms' first order conditions under the above assumptions about market structure and firm behavior.

We deviate from this procedure for two reasons. First, simple inspection of our price data suggests that the assumption of period-by-period maximization is implausible; prices are remarkably stable at a disaggregate level (SKU or presentation level), indicating that firms do not adjust them every period (see also the related discussion in the next subsection under identification). It seems more likely that firms set prices only periodically, in response to entry or exit, or other major changes in market conditions, and then keep them fixed until the next big shock. The second reason for not relying on period-by-period maximization to obtain the marginal costs is that many products are subject to price controls and other regulations. Price controls are imposed at the molecule (API) level. For products subject to price controls, prices are roughly equal to the production cost (based on the cost of the API) plus a predetermined markup. Given this, we employ the following approach.

Let the superscripts c and u denote products that are constrained (by price controls), and products that are unconstrained respectively. For constrained products we model their *average* (over our sample period) prices as:

$$\overline{p_i^c} = \overline{c_i^c} + m_i^c \tag{4.21}$$

where $\overline{p_i^c}$ denotes the average price of the product, $\overline{c_i^c}$ is the average (over the sample period) marginal cost, and m_i^c is the allowed markup, which usually varies between 10% and 15%. Equation (4.21) provides a straightforward way for obtaining the marginal costs of constrained products.

For unconstrained products, we assume that the first order conditions of profit maximization hold *in an average sense*, that is:

$$\overline{p_i^u} = \overline{c_i^u} * (1 + \frac{1}{\varepsilon_{ii(\overline{p_i^u},\overline{p_j})}})^{-1} \tag{4.22}$$

with $\overline{p_i^u}$ and $\overline{c_i^u}$ denoting the average (over the sample period) price and cost of the unconstrained product respectively, and $\varepsilon_{ii(\overline{p_i^u},\overline{p_j})}$ the own- price elasticity of demand for product i, evaluated at the sample mean of the product's own price $\overline{p_i^u}$, and the sample means of all other products' prices $\overline{p_j}$, with $i \neq j$.[23]

Once we have obtained the demand elasticities through estimation of the demand system, we can calculate marginal costs according to (4.21) or (4.22) depending on whether the product falls into the constrained category or not. The final issue to resolve is which products are "constrained", and which are not. For products with molecules that are not subject to price controls, obviously (4.22) applies. However, for products with molecules under price controls, we need a criterion for deciding whether these controls were binding over our sample period or not. Unfortunately, price controls exhibit virtually no time variation over our sample period, so that formal identification of their effects is impossible. However, in many cases the price data themselves are revealing. Specifically, if there is a product that has the same molecule as another product, but consistently exhibits lower price, it seems safe to infer that the price controls on the lower-price product are not binding (this is for example the case with foreign norfloxacin, whose price is consistently lower than the price of domestic norfloxacin) . In ambiguous cases, we experiment with both approaches of employing (4.21) and (4.22) to infer marginal costs.

4.4. Identification assumptions and estimation approach

The discussion of the demand system has so far treated prices as exogenous. In fact, economic endogeneity of prices is unlikely to be an issue, as the discussion of the previous subsection suggests. The usual premise in the recent 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. However, the existence of price controls and other institutional regulations in the Indian pharmaceutical market, and the relative stability that disaggregate prices (at the SKU level) exhibit empirically over time, make the premise that the first order conditions hold each period implausible. Instead, the assumption that prices (at the SKU level) are predetermined in each period seems more appropriate in the present context.

However, a more serious concern is the econometric endogeneity of prices that arises because of measurement error induced by our aggregation procedure. Remember that in order to obtain the prices of each product category that appear on the right hand side of the revenue share equation, we aggregate at the extremely disaggregate SKU (presentation) level, using the current revenue shares of the corresponding SKU's as weights. It is clear

[23] Note that given that product category i here refers to a molecule/domestic-foreign combination, this procedure will tend to understate marginal costs, and overstate markups, as we ignore the competition within each product category. However, this approach should not affect the welfare analysis in a substantial manner, since we condition on the obtained marginal costs when we conduct counterfactual analysis. This is of course not an issue when we use equation (4.21) to obtain marginal costs, as the competition within the product category is in this case irrelevant for price setting.

that this procedure can induce correlation between prices and the error term of the demand equation. Suppose, for example, that due to a special promotion the demand for a drug's relatively more expensive presentation increases in some period, while all prices, and the demand of all other presentations for this product remain fixed. Our aggregation approach would imply both a higher demand and a higher price for that product in this period (since the weight of the expensive presentation would increase). Hence, in this case we would erroneously infer that demand is positively related to prices, though in reality this result is simply an artifact of our aggregation procedure.

To address this simultaneity bias we employ instrumental variables. As usual, valid instruments are variables that are correlated with product prices, but are orthogonal to the error terms of the demand equations at the product-group level. Prices at the SKU level are obvious candidates, as they are clearly correlated with product prices (product prices are indeed revenue-weighted averages of SKU prices), but do not affect the demand of the product directly.[24] In addition, to account for the fact that firms may reset prices periodically in response to changing market conditions, such as the number of competitors, we include in our instruments variables that proxy for the intensity of competition. After some experimentation, our final list of instruments includes the prices of the five largest SKU's for each group, and the Herfindahl index for each group. 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. We have also experimented with using the number of presentations in each group in various combinations with SKU prices as instruments. The demand parameters are fairly stable across these experiments.

Our sample includes four molecules: ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin. Except for sparfloxacin, all other molecules are produced by both foreign and domestic firms. 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 (4.12) are: the constants α_i, 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 vari-

[24] The implicit assumption here is that entry and exit of SKU's into the sample affect product demand *only* through their effect on the (revenue-share weighted) product price, but have no direct effect on demand at the product level. For example, if in a particular month domestic ciprofloxacin is available only in small bottles, which are more expensive than the big bottles, this affects demand only because consumers effectively face a higher price for domestic ciprofloxacin (in other words, they would be indifferent between small and big bottles, if it were not for the higher price of the former). While this seems a reasonable assumption in the context of some presentations (e.g., bottles), it is more questionable for others, for example syrups versus pills, where consumers may have a true preference for one presentation. To examine the robustness of our results in this case, we also considered an alternative identification strategy, in which instead of instrumenting, we constructed product prices using fixed weights (i.e., the *average* over our sample period revenue share of each SKU), and then applied OLS. The results based on this estimation approach were very similar to the ones we obtain with instrumental variables, but significantly different from the ones we obtain when running OLS with prices constructed using current shares. This confirms our view that simultaneity bias is driven here by the use of current SKU revenue shares in the construction of product prices.

ables in the estimation, it is difficult to derive standard errors for the parameter estimates directly. Instead, we use the bootstrap method. 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] Accordingly, we generate 200 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.

4.5. 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 licencing. 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 of domestic products that will be removed from the market. In particular, we consider the following scenarios:

- withdrawal of the domestic ciprofloxacin product group only
- withdrawal of the domestic norfloxacin product group only
- withdrawal of the domestic ofloxacin product group only
- withdrawal of the domestic sparfloxacin product group only
- withdrawal of the domestic ciprofloxacin, norfloxacin and ofloxacin product groups
- withdrawal of the domestic ciprofloxacin, norfloxacin and sparfloxacin product groups
- withdrawal of the domestic ciprofloxacin, ofloxacin and sparfloxacin product groups
- withdrawal of the domestic norfloxacin, ofloxacin and sparfloxacin product groups
- 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

[25] See Efron and Tibshirani (1993).

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. In addition, our early results indicated that the treatment of domestic ciprofloxacin, a product group with a significant share (53%) of the quinolone market, has a significant impact on the results. Accordingly, we consider various scenarios depending on whether or not the domestic ciprofloxacin product group is affected by patent enforcement.

4.6. 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[26]. 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 revenue shares (or alternatively the quantities) 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 assume (consistent with the assumption of Bertrand competition) that firms reoptimize in response to the policy change, and set new prices, taking the prices of all other firms as given. Of course, at the equilibrium all prices change in response to the fact that some domestic products are no longer present[27]. The new equilibrium prices for products that 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:

$$\begin{aligned} 0 &= \alpha_i + \gamma_{ii} \ln p_{it}^V + \Sigma_{j \in D_i^{10}} [\gamma_{i,10} \ln p_{jt}^{'}] + \Sigma_{j \in D_i^{01}} [\gamma_{i,01} \ln p_{jt}^{'}] \\ &\quad + \Sigma_{j \in D_i^{00}} [\gamma_{i,00} \ln p_{jt}^{'}] + \beta_i \ln(\frac{X_{Qt}^{'}}{P_{Qt}^{'}}) \end{aligned} \tag{4.23}$$

- For products k that remain in the market:

$$p_{kt}^{'} = \overline{c_k} * (1 + \frac{1}{\varepsilon_{kk(p_{kt}^{'}, p_{jt}^{'}, p_{it}^V)}})^{-1} \tag{4.24}$$

[26] 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.

[27] As mentioned above, this approach abstracts from the existence of remaining price controls or other government regulations that would impose constraints on the firms' profit maximization problem. However, incorporating such controls in our analysis is straightforward. If remaining firms face price controls, their prices are dictated by their marginal costs plus a predetermined markup, rather than the first order conditions.

In the above equations p_{it}^{V} denotes the virtual price of the product that is removed from the market, while $p_{jt}^{'}$ denotes the updated prices of all other products. In the case of multiple product withdrawal, the $p_{jt}^{'}$ gets replaced by p_{jt}^{V}, that is the virtual prices of the products that are being eliminated. Note that when solving for the virtual prices we account for the fact that both the price index for quinolones P_{Qt}, and the expenditure allocated to this sub-segment X_{Qt}, 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 $X_{Qt}^{'}$ and the new price index $P_{Qt}^{'}$, we use the estimates and formulas for the higher level AIDS system. In equation (4.24), $\overline{c_k}$ refers to the average (over the sample period) marginal cost for product k that we have obtained from the previous estimation stage. The term $\varepsilon_{kk(p_{kt}^{'},p_{jt}^{'},p_{it}^{V})}$ 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.

4.7. 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, which products consumers will substitute towards; 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.

The effects on consumer welfare are slightly more involved to compute. 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 given by equation (4.18). Then the compensating variation is given by:

$$CV = E(u^0, P^{'}) - E(u^0, P^0) \tag{4.25}$$

where $E(u^0, P')$ and $E(u^0, P^0)$ are computed according to (4.18).[28] Note that the CV as computed in (4.25) represents the combination of three effects:

[28] Note that in this calculation the utility u refers to the utility consumers derive from the consumption of

- 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 (4.25)), 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). Let us call 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 (4.23) and (4.24) to reflect the adjustment of prices to the new regime.

5. Results

5.1. The structure of demand

Table 8 displays the results from estimation of the lower-level AIDS system characterizing demand patterns within the quinolone sub-segment. For ease of interpretation, rather than report the coefficient estimates directly, we report the implied conditional (i.e., constant-expenditure) price and expenditure elasticities evaluated at the average expenditure shares for each of the product groups.

The first column of Table 8 reports the own price elasticities we estimate, 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 positive

systemic anti-biotics. This is the utility that we keep constant at u^0. We thus ignore potential substitution away from antibiotics altogether as a result of patent enforcement. However, we believe that such substitution effects are likely to be small in practice.

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.[29]

The estimated expenditure elasticities appear in the last column. These are all positive, indicating that the demand for all the product groups is normal. Domestic ciprofloxacin and norfloxacin, and foreign ofloxacin appear to be "luxuries", with expenditure elasticities greater than 1. This suggests that these product groups capture a disproportionate share of incremental sales when consumers choose to spend more in the quinolone sub-segment. In the case of domestic ciprofloxacin and norfloxacin this might be explained by the large number of products (90 and 48 respectively) and firms (75 and 40 respectively) that are represented in these two product groups.

The middle columns display the estimated cross-price elasticities. As one might perhaps expect for products within a therapeutic sub-segment, these are positive in all but two cases. What is striking however, 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 firms of different domestic/foreign status. 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.[30] 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

[29] 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.

[30] 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.

more comprehensive than that of multinational subsidiaries (ICRA (1999)).[31]

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 8.

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.

Table 9 displays the results from estimation of the higher-level AIDS system characterizing demand patterns across the systemic anti-bacterials segment. Again, we report the results in the form of implied price and expenditure elasticities. All of the own price elasticities are significant and negative. As we would expect, the price elasticity for the quinolone sub-segment as a whole is, at -1.166, smaller (in absolute value) than the own-price elasticities of the product groups within the sub-segment.

Estimation of the higher level AIDS system allows us to obtain the *unconditional* own- and cross-price elasticities for the quinolone product groups. These are needed both for the formulation of the supply problem and to capture the strength of the expenditure switching effect when we simulate the effects of the introduction of patent protection in the quinolone sub-segment. These unconditional elasticities are displayed in Table 10. They differ only slightly from the conditional elasticities discussed earlier. Own price elasticities are large and negative, while all pairs of domestic product groups continue to have large positive cross-price elasticities.

5.2. Cost and markup estimates

Table 11 displays the marginal costs, markups and profits implied by the price elasticity estimates of Table 10 for each of the seven product groups. Since we do not have a reliable estimate of the price elasticity for foreign norfloxacin (the point estimate is positive and insignificant), we set its marginal cost to be the same as its price. The estimates in Table 11 are calculated assuming that firms set prices to maximize their profits, and price controls are not binding. During the period covered by our data, two of the four molecules in our sample, ciprofloxacin and norfloxacin, were nominally under price control. If we were to assume that the price controls were binding, and that the regulated markup was about 15%, then the profit figures for domestic ciprofloxacin and domestic norfloxacin would be Rs. 428.4 million and Rs. 94.8 million per year respectively, instead of Rs. 1752.28 and Rs.

[31] These differences were also highlighted in conversations that one of the authors had with CEOs and Managing Directors of several pharmaceutical firms as part of a separate study.

268.92 million. Because the average prices of foreign ciprofloxacin and foreign norfloxacin are much lower than those of their domestic counterparts, it is reasonable to assume that price controls were not binding for them.[32] We emphasize however, that the estimates in Table 11 should be thought of as an upper bound on profits.

The foreign ofloxacin product group is estimated to have the highest markup. But it is the domestic ciprofloxacin product group that dominates the quinolone sub-segment, enjoying a markup of over 60% and accounting for nearly 70% of all profits derived within the sub-segment.

5.3. 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 nine 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 12 displays our estimates of the consumer welfare losses that result under the different scenarios. The top panel of Table 12 displays the results in terms of Rs. per household per year, while the bottom panel presents the estimates in aggregate terms in Rs. billion per year.

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 (Table 10), 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.

In the third column, we consider the somewhat artificial case where the prices of the remaining products are adjusted upwards as one or more of the domestic product groups are withdrawn, but expenditures on quinolones are held fixed. And 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.

[32] The price controls are imposed at the molecule level. Domestic and foreign products sharing the same molecule should thus have the same prices if price controls were binding.

If we compare the results across the first, second and fourth 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—a price elasticity of -1.166 (see Table 9)—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. 154.87 per household per year can be decomposed into an initial loss of Rs. 110.82 (71%) attributable to the loss of product variety, a slight *reduction* in this initial loss of Rs. 6.97 (-5%), from Rs. 110.82 to Rs. 103.85, because of expenditure switching, and a subsequent additional loss of Rs. 51.02 (33%), from Rs. 103.85 to Rs. 154.87, 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).

The relative magnitudes of the two other effects varies with the initial market share of the domestic product groups being withdrawn – if the initial market share is large as is the case with domestic ciprofloxacin, the fraction of the overall welfare loss that is attributable to loss of variety is also large – but in all except one case the loss of variety remains the more important of the two components of the overall consumer welfare loss. Under almost all the counterfactual scenarios we consider, the welfare loss due to loss of variety constitutes more than 50% of the overall welfare loss and in some instances it is as high as 70%.

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. 29.7 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 three 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.

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.[33] 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. 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 12 suggests that this is likely to be significant. In particular, if we subtract from our estimate (Rs. 29.7 billion) of the overall consumer welfare loss, the component attributable to the reduction in variety (Rs. 21.3 billion), we are still left with an estimated welfare loss of Rs. 8.4 billion. Given the size of the welfare loss due to upward price adjustment policymakers may be tempted to continue 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 13 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 product groups that are withdrawn from the market are indicated by the shaded areas. For these product groups, we have computed "virtual prices", that is the prices that would be required for the demand of these drugs to be zero, and employed these estimates in the counterfactual simulations. Of course, virtual prices are never observed in any market. We should note however, that most of the virtual price numbers we obtain seem

[33] Media accounts and interviews with industry sources indicate that such initiatives are increasing in number.

a-priori plausible. For scenarios that involve a *single* product withdrawal and drugs with small market shares, such as norfloxacin, ofloxacin and sparfloxacin, the virtual prices are roughly 2 to 3 times higher than the prices we observe for these drugs in our sample period. In contrast, it takes an 8-fold price increase to drive demand for domestic ciprofloxacin, the product with the largest market share within quinolones, down to zero. The virtual prices are however substantially higher in scenarios that involve simultaneous withdrawal of multiple domestic products, especially if domestic ciprofloxacin is one of them. This is driven by the large market share of domestic ciprofloxacin, in combination with the large, positive cross-price elasticities between domestic products.

For the foreign products that would remain in the market, we estimate price increases between 200% and 750%. This is on the high side of the estimates reported in other studies. While these numbers are again 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, which have had stricter patent laws in the past. Pakistan is a natural candidate. The similarity between our predictions in Table 13 and the numbers reported in Lanjouw (1998), p. 39, Table 2, for drugs sold in Pakistan, is striking. For the drug ciprofloxacin, for example, we predict that the price of the (patented) foreign products in India would be approximately 8 times higher than it is now (see last row of Table 13, 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). This matches exactly the number reported by Lanjouw (1998) for patented ciprofloxacin in Pakistan. 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 14 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. These numbers are based on our initial estimates of the marginal costs of production and, depending on the scenario being considered, our estimates of the price increases that would result from product withdrawal.

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. Our estimate of this loss, Rs. 2,379 million per year, is reported in Table 11, and the bottom row of Table 14 reproduces this estimate. 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 14 it can be seen that this result arises in nearly half the cases (cells).[34]

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 14 indicate that the loss of domestic producer surplus is unlikely to be the biggest consequence of TRIPS-induced patent protection. First, as just mentioned, there are many scenarios un-

[34] To be consistent with Table 12, which reported consumer welfare losses as positive numbers, Table 14 reports foregone profits as positive numbers. Thus the cases where the collective profits of domestic Indian firms actually increase are those for which negative numbers are reported.

der which the collective profits of domestic firms would actually go up, though there always is a segment that would be adversely affected.[35] Second, even when the collective profits do go down (just over half the cases (cells)), a comparison with Table 12 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 12 under the same scenario—Rs. 29.7 billion annually.[36]

Adding up the estimates of consumer welfare losses from Table 12 and producer losses from Table 14 we get estimates of the total welfare losses to the Indian economy. These are reported in Table 15. 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. 32 billion, or about 118% 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. $713 million. Of this amount, foregone profits of domestic producers constitute roughly Rs. 2.3 billion, or U.S. $50 million (ca. 7% of the total welfare loss). The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare.

A mid-range estimate—obtained assuming there are no upward price adjustments as a result of product withdrawals—would be Rs. 22.2 billion or about U.S. $495 million per year for the scenario involving withdrawal of all four domestic quinolone product groups. And lastly, if we assume that the welfare losses due to the reduction in variety that would result from patent protection are a purely transitional phenomenon and subtract these from our upper bound estimates, we obtain a lower bound estimate of Rs. 7.6 billion (=32.1-23.6) or $169 million annually. Though only about a fourth of our upper bound estimate, in absolute terms this lower bound estimate is still very large, representing 28% of antibiotic sales in 2000.

Finally, Table 16 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. 2.6 billion or approximately U.S. $57 million per year. To put this number in perspective, sales of Cipro, the main patented ciprofloxacin product of Bayer, were roughly U.S. $1.6 billion in 2000 (Hensley (2001)). While we do not want to put too much emphasis on these results, they do suggest that the promise of patent-induced profits in less developed economies is unlikely to shift the R&D priorities of global pharmaceutical companies. The development of new treatments for the diseases that disproportionately afflict the populations of poor (mostly tropical) economies and increased access to essential medicines are, therefore, likely to depend critically on publicly funded

[35] 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.

[36] 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.

efforts such as those proposed by Sachs (2002) and Ganslandt et al (2001).

6. 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 total annual welfare loss of U.S. $713 million for the Indian economy. Of this amount, only 7% account 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 profits of these firms to rise by approximately U.S. $57 per year when patents are enforced. 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. Thus, it seems unlikely that patent-induced profits in developing countries would shift the research priorities of global pharmaceutical companies.

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. 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, 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. 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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Figure 1
Production, exports, imports and domestic sales of pharmaceutical formulations
(Rs. billions)

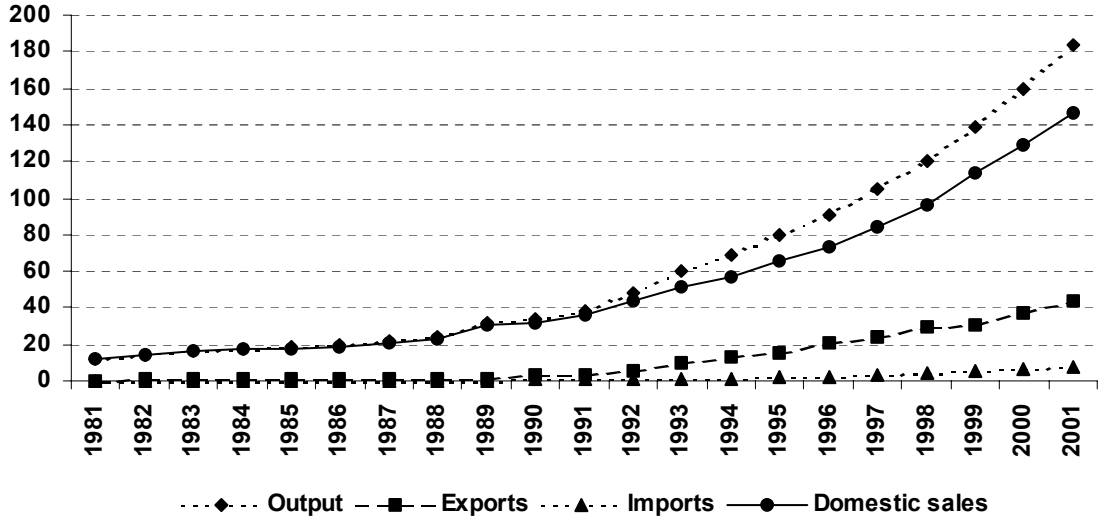

Figure 2
Production, exports, imports and domestic sales of bulk drugs
(Rs. billions)

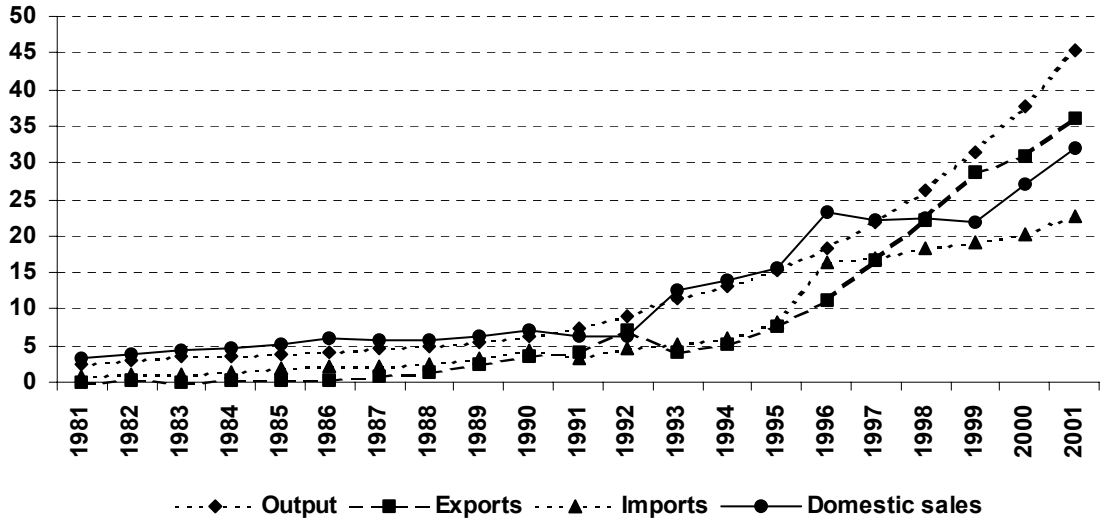

Table 1

Top twenty firms by domestic retail pharmaceutical sales in India

Rank	Year					
	1971		1981		2001	
	Company	**Origin**	**Company**	**Origin**	**Company**	**Origin**
1	Sarabhai	Dom	Glaxo	For	Glaxo SKB	For
2	Glaxo	For	Hoechst	For	Ranbaxy	Dom
3	Pfizer	For	Pfizer	For	Cipla	Dom
4	Alembic	Dom	Alembic	Dom	Nicholas Piramal	Dom
5	Hoechst	For	Geoffrey Manner	For	Aventis	For
6	Lederle	For	Burroughs Wellcome	For	Sun	Dom
7	Ciba	For	Ranbaxy	Dom	Dr. Reddy's	Dom
8	May & Baker	For	Boots	For	Zydus Cadila	Dom
9	Parke Davis	For	German Remedies	For	Knoll	For
10	Abbott	For	Richardson Hindustan	For	Pfizer	For
11	Sharp & Dome	For	Parke Davis	For	Wockhardt	Dom
12	Sudrid Geigy	For	Warner-Hindustan	For	Alkem	Dom
13	Unichem	Dom	Roche	For	Lupin	Dom
14	East India	Dom	Merck, Sharp & Dome	For	Novartis	For
15	Sandoz	For	Cynamid	For	Aristo	Dom
16	Deys	Dom	Unichem	Dom	Pharma Marketing	Dom
17	Boots	For	Cadilla	Dom	Torrent	Dom
18	T.C.F.	Dom	Standard	Dom	Alembic	Dom
19	Warner Hindustan	For	E. Merck	For	Cadila Pharmaceutical	Dom
20	John Wyeth	For	East India	Dom	USV	Dom

	Year			
	1970	**1981**	**1991**	**2000**
Foreign subsidiaries' share of domestic retail sales (%)	75-90	60-75	49-55	28-35

Notes: If companies are ranked in terms of overall sales (including exports), nine out of the top ten firms in 2001 were of domestic origin.

Notes: Precise estimates of the share of foreign subsidiaries in domestic retail sales are hard to come by because of the scarcity of comprehensive industry-wide data. The figures in this table represent rough estimates put together by compiling data from multiple sources.

Sources: For 1971, Redwood (1994) and ICRA (2000) both of which rely on data from ORG-MARG; for 1981, Narayana (1984); for 1991 and 2000, authors' estimates from ORG-MARG retail pharmaceutical audits, 1991-2000.

Table 2
Comparing the health sector in low-income and developed economies

	India	Pakistan	Canada	U.S.A.
Information on health expenditures				
Total health expenditures as % of GDP	4.9	4.1	9.1	13.0
Per-capita total health expenditures (US $)	23	18	2058	4499
Public health expenditures as % of total	17.8	22.9	72.0	44.3
Private health expenditures as % of total	82.2	77.1	28.0	55.7
Out-of-pocket expenditures as % of total	82.2	77.1	15.5	15.3

Top ten leading causes of burden of disease in 1998: all ages

India		U.S.A. and Canada	
Cause	**DALYs (000)**	**Cause**	**DALYs (000)**
Acute lower respiratory infection	24,806	Ischaemic heart disease	2,955
Perinatal conditions	23,316	Unipolar major depression	2,511
Diarrhoeal diseases	22,005	Alcohol dependence	1,736
Ischaemic heart disease	11,697	Road traffic injuries	1,670
Falls	10,897	Cerebrovascular disease	1,651
Unipolar major depression	9,679	Osteoarthritis	1,029
Tuberculosis	7,578	Diabetes mellitus	1,017
Congenital abnormalities	7,454	Trachea/bronchus/lung cancers	996
Road traffic injuries	7,204	Dementias	940
Measles	6,474	Self-inflicted injuries	858

Sources: World Health Report, WHO(2002).
DALY stands for "Disability-Adjusted-Life-Year".

Table 3
Comparing the Indian pharmaceuticals market to the world market:
Shares of major therapeutic segments in retail sales

Therapeutic segment	**Share of retail sales (%)**			
	World: 2001		**India: 2000**	
	Rank	**Share(%)**	**Rank**	**Share(%)**
Cardiovascular system	1	19.6	4	8.0
Central nervous system (CNS)	2	16.9	6	6.7
Alimentary tract and metabolism	3	15.3	1	23.6
Respiratory system	4	9.5	3	10.4
Anti-infectives	5	9.0	2	23.0
Musculo-skeletal	6	6.1	5	7.3
Genito-urinary	7	5.7	9	3.1
Cytostatics and immunosuppressants	8	4.0	13	0.1
Dermatologicals	9	3.3	7	5.6
Blood and blood-forming agents	10	3.1	8	3.9
Sensory organs	11	2.1	10	1.6
Diagnostic agents	12	1.8	12	0.1
Systemic hormonal products	13	1.6	11	1.5
Others including parasitology	.	2.3	.	5.4

Source: World sales shares from IMS World Drug Purchases—Retail Pharmacies, IMS Drug Monitor, 2001. Indian domestic sales shares based on authors' calculations from ORG-MARG retail pharmaceutical audit.

Table 4
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 5
All India sales share of and expenditures on various sub-segments within the systemic anti-bacterials therapeutic segment
2000

Therapeutic sub-segment	Share (%) of sales of systemic anti-bacterials: 2000	Sales (Rs. millions): 2000
Tetracycline, doxycycline and combinations	5.0	1,367
Chloramphenicols and combinations	1.7	460
Ampicillin, amoxycillin, cloxicillin	24.1	6,631
Cephalosporins	27.9	7,671
Trimethoprim and combinations	3.3	903
Macrolides	10.6	2,913
Penicillins	2.5	685
Other anti-biotics including aminoglycosides	4.2	1,158
Quinolones and fluoroquinolones	20.8	5,722
Total	100	27,509

Table 6
The fluoroquinolones sub-segment

Molecule	Share (%) of sales of quinolones		Sales (Rs. millions): 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 7
Basic information about the four fluoroquinolone molecules

	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
No. of products of domestic firms	90	48	21	30
No. of products of foreign subsidiaries	10	2	2	1
Sales weighted average price per-unit API of products produced by:				
Domestic Indian firms	11.23	9.04	88.73	78.11
Foreign subsidiaries	10.29	4.99	108.15	.

Table 8
Estimates of demand patterns within the quinolone sub-segment from lower-level AIDS system: Implied conditional price and expenditure elasticities

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	-4.812*	0.016	0.040	4.140*	0.149	0.067	0.023	0.378
	(1.526)	(0.063)	(0.061)	(1.800)	(0.094)	(0.062)	(0.057)	(0.381)
Foreign norfloxacin	0.610	1.631	0.621	1.966	-9.150	1.785	1.769	0.767
	(2.521)	(1.755)	(2.502)	(2.465)	(5.892)	(2.216)	(2.196)	(0.792)
Foreign ofloxacin	0.016	0.015	-1.343*	-0.046	0.025	0.177	0.047	1.109*
	(0.058)	(0.058)	(0.348)	(0.111)	(0.059)	(0.333)	(0.052)	(0.113)
Domestic ciprofloxacin	0.174*	0.002	-0.004	-1.617*	0.074*	0.096*	0.108*	1.167*
	(0.075)	(0.003)	(0.003)	(0.100)	(0.012)	(0.012)	(0.014)	(0.027)
Domestic norfloxacin	0.011	-0.051	0.006	0.366*	-2.359*	0.454*	0.462*	1.113*
	(0.013)	(0.032)	(0.013)	(0.069)	(0.163)	(0.054)	(0.055)	(0.063)
Domestic ofloxacin	0.010	0.013	0.068	0.869*	0.667*	-2.920*	0.604*	0.688*
	(0.017)	(0.016)	(0.105)	(0.107)	(0.072)	(0.219)	(0.065)	(0.086)
Domestic sparfloxacin	0.006	0.012	0.036*	1.055*	0.650*	0.568*	-2.701*	0.373*
	(0.018)	(0.014)	(0.015)	(0.111)	(0.069)	(0.060)	(0.186)	(0.080)

Notes: Standard errors in parentheses. Elasticities calculated at average revenue shares. Asterisk denotes significance at 5% confidence level.

Table 9
Estimates of demand patterns within the systemic anti-bacterials segment from the higher-level AIDS system: Implied price and expenditure elasticities

	Prices								Systemic anti-bacterials expenditure
	Tetra-cycline	Chloram-penicol	Ampicillin	Cephalo-sporin	Trimetho-prim	Macrolides	Other penicillin	Quinolones	
Tetracyline and related	-1.155* (0.064)	-0.209* (0.067)	1.043* (0.156)	-0.279* (0.119)	-0.761* (0.099)	0.210* (0.092)	0.127* (0.059)	-0.017 (0.207)	1.042* (0.074)
Chloramphenicols	-0.685* (0.200)	-1.940* (0.292)	-2.769* (0.596)	2.275* (0.444)	0.886* (0.368)	-1.094* (0.409)	0.144 (0.214)	1.636* (0.775)	1.546* (0.243)
Ampicillin and amoxycillin	0.240* (0.035)	-0.172* (0.042)	-1.187* (0.126)	-0.310* (0.056)	0.389* (0.098)	0.251* (0.063)	0.248* (0.068)	-0.180* (0.076)	0.721* (0.028)
Cephalosporins	-0.088* (0.035)	0.213* (0.042)	-0.547* (0.077)	-0.748* (0.074)	-0.245* (0.045)	0.135* (0.052)	-0.063† (0.043)	0.154* (0.077)	1.190* (0.041)
Trimethoprim combinations	-1.009* (0.129)	0.396* (0.156)	2.466* (0.635)	-1.076* (0.210)	-1.130† (0.630)	-1.232* (0.309)	-0.410* (0.207)	1.226* (0.377)	0.769* (0.106)
Macrolides	0.104* (0.042)	-0.155* (0.063)	0.493* (0.137)	0.271* (0.082)	-0.442* (0.105)	-0.959* (0.121)	-0.131* (0.065)	-0.147 (0.148)	0.966* (0.045)
Other penicillins	0.696* (0.278)	0.257 (0.335)	5.974* (1.623)	-0.797 (0.713)	-1.442* (0.768)	-1.203* (0.671)	-2.873* (0.613)	-0.391 (1.244)	-0.222 (0.281)
Quinolones	-0.014 (0.045)	0.127* (0.059)	-0.335* (0.083)	0.121* (0.059)	0.191* (0.064)	-0.103 (0.070)	-0.036 (0.057)	-1.166* (0.102)	1.215* (0.035)

Notes: Standard errors in parentheses. Elasticities calculated at average revenue shares. Asterisk denotes significance at 5% confidence level.

Table 10
Implied unconditional price and expenditure elasticities within the quinolones sub-segment

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	-4.813*	0.016	0.042	4.192*	0.159	0.069	0.020	0.378
	(1.527)	(0.063)	(0.061)	(1.831)	(0.100)	(0.062)	(0.057)	(0.381)
Foreign norfloxacin	0.610	1.631	0.622	1.986	-9.146	1.786	1.768	0.767
	(2.521)	(1.755)	(2.500)	(2.499)	(5.897)	(2.216)	(2.195)	(0.792)
Foreign ofloxacin	0.016	0.015	-1.343*	-0.055	0.023	0.177	0.047	1.109*
	(0.058)	(0.058)	(0.349)	(0.119)	(0.060)	(0.333)	(0.052)	(0.113)
Domestic ciprofloxacin	0.174*	0.002	-0.005	-1.631*	0.071*	0.096*	0.109*	1.167*
	(0.075)	(0.003)	(0.003)	(0.103)	(0.012)	(0.012)	(0.014)	(0.027)
Domestic norfloxacin	0.011	-0.051	0.005	0.356*	-2.361*	0.453*	0.462*	1.113*
	(0.013)	(0.032)	(0.013)	(0.072)	(0.163)	(0.054)	(0.055)	(0.063)
Domestic ofloxacin	0.010	0.013	0.070	0.895*	0.673*	-2.919*	0.603*	0.688*
	(0.017)	(0.016)	(0.105)	(0.113)	(0.072)	(0.219)	(0.064)	(0.086)
Domestic sparfloxacin	0.005	0.012	0.038*	1.107*	0.661*	0.570*	-2.703*	0.373*
	(0.019)	(0.014)	(0.015)	(0.118)	(0.070)	(0.061)	(0.187)	(0.080)

Notes: Standard errors in parentheses. Elasticities calculated at average revenue shares. Asterisk denotes significance at 5% confidence level.

Table 11
Estimated markups and profits by product group within the quinolone sub-segment

Product group	Average group price (Rs.)	Estimated marginal cost	Estimated markup	Estimated annual profit (Rs. millions)	Group share (%) of total estimated profits from quinolone sales
Foreign ciprofloxacin	10.29	8.16	20.78%	28.22	1.12%
Foreign norfloxacin	4.99	4.99	0.00%	0.00	0.00%
Foreign ofloxacin	108.15	27.64	74.45%	109.64	4.36%
			Foreign Total	137.86	5.48%
Domestic ciprofloxacin	11.23	4.34	61.30%	1752.28	69.62%
Domestic norfloxacin	9.04	5.21	42.35%	268.92	10.68%
Domestic ofloxacin	88.73	58.33	34.26%	161.53	6.42%
Domestic sparfloxacin	78.11	49.21	36.99%	196.35	7.80%
			Domestic Total	2379.08	94.52%
Average observed all-India annual sales of quinolones: Rs. 5.722 billion			**Average estimated all-India annual profits from sales of quinolones: Rs. 2.379 billion**		

Table 12
Counterfactual estimates of consumer welfare losses from product withdrawals due to the introduction of pharmaceutical patents

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	Within-segment price-adjustment and cross-segment expenditure switching
Compensating variation measured in Rs. per household per year				
Only ciprofloxacin	30.300*	29.925*	43.471*	42.695*
	(3.750)	(3.665)	(4.224)	(4.100)
Only norfloxacin	3.898*	3.898*	5.337*	4.979*
	(0.458)	(0.457)	(0.447)	(0.444)
Only ofloxacin	1.648*	1.648*	2.995*	2.679*
	(0.338)	(0.337)	(0.360)	(0.371)
Only sparfloxacin	0.441	0.449	1.924*	1.632*
	(0.307)	(0.304)	(0.326)	(0.328)
Ciprofloxacin, norfloxacin and ofloxacin	50.539*	49.512*	80.972*	78.619*
	(7.775)	(7.474)	(9.865)	(9.124)
Ciprofloxacin, norfloxacin and sparfloxacin	45.158*	44.191*	75.044*	72.811*
	(7.834)	(7.551)	(9.904)	(9.314)
Ciprofloxacin, ofloxacin and sparfloxacin	35.227*	34.529*	61.496*	59.662*
	(6.055)	(5.884)	(7.676)	(7.338)
Norfloxacin, ofloxacin and sparfloxacin	1.787†	1.788†	7.441*	6.858*
	(1.056)	(1.044)	(1.330)	(1.330)
Ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin	110.821*	103.851*	158.803*	154.870*
	(41.745)	(42.651)	(32.974)	(33.183)
Total compensating variation measured in Rs. billion (per year)				
Only ciprofloxacin	5.814*	5.742*	8.341*	8.192*
	(0.720)	(0.703)	(0.810)	(0.787)
Only norfloxacin	0.748*	0.748*	1.024*	0.955*
	(0.088)	(0.088)	(0.086)	(0.085)
Only ofloxacin	0.316*	0.316*	0.575*	0.514*
	(0.065)	(0.065)	(0.069)	(0.071)
Only sparfloxacin	0.085	0.086	0.369*	0.313*
	(0.059)	(0.058)	(0.062)	(0.063)
Ciprofloxacin, norfloxacin and ofloxacin	9.698*	9.500*	15.537*	15.086*
	(1.492)	(1.434)	(1.893)	(1.751)
Ciprofloxacin, norfloxacin and sparfloxacin	8.665*	8.479*	14.400*	13.971*
	(1.503)	(1.449)	(1.900)	(1.787)
Ciprofloxacin, ofloxacin and sparfloxacin	6.759*	6.625*	11.800*	11.448*
	(1.162)	(1.129)	(1.473)	(1.408)
Norfloxacin, ofloxacin and sparfloxacin	0.343†	0.343†	1.428*	1.316*
	(0.203)	(0.200)	(0.255)	(0.255)
Ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin	21.265*	19.927*	30.471*	29.717*
	(8.010)	(8.184)	(6.327)	(6.367)

Notes: Bootstrapped standard errors in parentheses; * denotes significant at 5% confidence level; † denotes significant at 10% confidence level.

Table 13
Counterfactual estimates of drug price increases
after product withdrawals 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 price)						
	Foreign product groups			Domestic product groups			
	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Sparflo
Only ciprofloxacin	119.61%* (0.158)	200.00% NA	3.15% (0.136)	.	31.77%* (0.050)	51.74%* (0.073)	65.13%* (0.086)
Only norfloxacin	3.19%* (0.014)	200.00% NA	4.07% (0.028)	3.53%* (0.005)	.	14.05%* (0.024)	14.97%* (0.022)
Only ofloxacin	2.13% (0.014)	200.00% NA	7.70% (0.081)	2.99%* (0.004)	7.24%* (0.011)	.	9.97%* (0.014)
Only sparfloxacin	2.18% (0.014)	200.00% NA	4.18%† (0.025)	3.73%* (0.004)	8.51%* (0.012)	10.72%* (0.019)	.
Ciprofloxacin, norfloxacin and ofloxacin	199.36%* (0.230)	500.00% NA	38.49% (0.393)	.	.	.	226.47%* (0.358)
Ciprofloxacin, norfloxacin and sparfloxacin	222.74%* (0.254)	500.00% NA	25.88% (0.341)	.	.	212.50%* (0.352)	.
Ciprofloxacin, ofloxacin and sparfloxacin	224.80%* (0.244)	500.00% NA	49.94% (0.393)	.	144.24%* (0.208)	.	.
Norfloxacin, ofloxacin and sparfloxacin	14.60%* (0.047)	500.00% NA	33.58%† (0.185)	23.56%* (0.018)	.	.	.
Ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin	754.22%* (2.485)	500.00% NA	210.23% (1.809)	.	.	.	.

Notes: Shaded areas refer to product groups that are withdrawn from the market.

Table 14
Counterfactual estimates of foregone profits of domestic producers from product withdrawals due to the introduction of pharmaceutical patents
(millions of rupees 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	Within-segment price-adjustment and cross-segment expenditure switching
Only ciprofloxacin	1039.700*	1192.324*	221.946*	580.504*
	(98.595)	(72.265)	(171.736)	(112.878)
Only norfloxacin	-7.161	13.980	-178.325*	-131.634*
	(21.203)	(23.442)	(20.944)	(21.082)
Only ofloxacin	-51.218*	-53.680*	-162.264*	-140.422*
	(12.138)	(14.218)	(14.784)	(15.609)
Only sparfloxacin	-48.991*	-64.062*	-173.191*	-162.761*
	(14.665)	(16.862)	(13.247)	(13.880)
Ciprofloxacin, norfloxacin and ofloxacin	1235.615*	1457.821*	-160.188	694.400*
	(125.857)	(68.902)	(304.882)	(117.348)
Ciprofloxacin, norfloxacin and sparfloxacin	1343.305*	1522.861*	-38.435	704.810*
	(132.197)	(79.370)	(333.752)	(129.365)
Ciprofloxacin, ofloxacin and sparfloxacin	1165.991*	1329.050*	138.590	692.196*
	(151.633)	(106.079)	(308.518)	(168.213)
Norfloxacin, ofloxacin and sparfloxacin	-339.157*	-340.213*	-637.678*	-552.083*
	(42.546)	(45.242)	(53.249)	(48.899)
Ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin	2379.083*	2379.083*	2379.083*	2379.083*
	(169.680)	(169.680)	(169.680)	(169.680)

Table 15
Counterfactual estimates of total welfare losses from product withdrawals due to the introduction of pharmaceutical patents:
(billions of rupees 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	Within-segment price-adjustment and cross-segment expenditure switching
Only ciprofloxacin	6.854*	6.934*	8.563*	8.773*
	(0.653)	(0.666)	(0.691)	(0.727)
Only norfloxacin	0.741*	0.762*	0.846*	0.824*
	(0.098)	(0.103)	(0.091)	(0.095)
Only ofloxacin	0.265*	0.263*	0.412*	0.374*
	(0.072)	(0.075)	(0.074)	(0.080)
Only sparfloxacin	0.036	0.022	0.196*	0.150*
	(0.069)	(0.071)	(0.068)	(0.072)
Ciprofloxacin, norfloxacin and ofloxacin	10.933*	10.958*	15.377*	15.780*
	(1.393)	(1.400)	(1.643)	(1.768)
Ciprofloxacin, norfloxacin and sparfloxacin	10.008*	10.002*	14.361*	14.676*
	(1.399)	(1.403)	(1.624)	(1.753)
Ciprofloxacin, ofloxacin and sparfloxacin	7.925*	7.954*	11.939*	12.140*
	(1.049)	(1.065)	(1.243)	(1.324)
Norfloxacin, ofloxacin and sparfloxacin	0.004	0.003	0.790*	0.764*
	(0.211)	(0.220)	(0.248)	(0.264)
Ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin	23.644*	22.306*	32.850*	32.096*
	(8.010)	(8.184)	(6.327)	(6.367)

Table 16
Counterfactual estimates of profit gains of foreign producers from product withdrawals due to the introduction of pharmaceutical patents
(millions of rupees 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	Within-segment price-adjustment and cross-segment expenditure switching
Only ciprofloxacin	191.837*	150.466*	580.502*	448.265*
	(60.004)	(56.159)	(141.936)	(122.364)
Only norfloxacin	4.852	3.704	17.647*	13.831*
	(6.296)	(6.269)	(6.762)	(6.586)
Only ofloxacin	10.891	11.025	33.233†	30.765†
	(13.971)	(14.003)	(17.452)	(17.368)
Only sparfloxacin	3.173	3.964	26.748*	25.030*
	(4.759)	(4.742)	(8.246)	(8.173)
Ciprofloxacin, norfloxacin and ofloxacin	334.959*	233.738*	1096.669*	644.942*
	(88.213)	(78.809)	(233.072)	(196.646)
Ciprofloxacin, norfloxacin and sparfloxacin	330.056*	243.271*	1186.147*	756.352*
	(96.694)	(89.463)	(260.333)	(223.347)
Ciprofloxacin, ofloxacin and sparfloxacin	372.315*	301.896*	1287.924*	929.492*
	(91.409)	(85.644)	(250.924)	(220.054)
Norfloxacin, ofloxacin and sparfloxacin	58.295	58.362	111.261*	102.020*
	(42.728)	(42.714)	(46.714)	(45.233)
Ciprofloxacin, norfloxacin, ofloxacin and sparfloxacin	1182.492*	428.543	4338.432*	2609.371*
	(277.008)	(421.396)	(291.126)	(342.118)