Intellectual Property Rights Protection in Developing Countries: The Case of Pharmaceuticals*

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Abstract

Patent enforcement in developing countries generates considerable controversy, especially when patents involve potentially life-saving drugs. This paper argues that common concerns regarding the effects of patents on prices and on research incentives of pharmaceutical multinationals are misplaced. Rather, the most significant effects are likely to concern *access* to patented drugs in poor countries. Because prices in developing countries are much lower than in the developed world, multinationals may choose to enter such markets with a delay, or not at all, implying a complete loss of access to patented drugs in developing countries. Even when multinationals enter countries like India, their marketing and distribution networks are not currently built out, leading to limited access within the country. Such considerations may provide a justification for policies targeting access in the short and medium run, such as compulsory licensing.

Keywords: Intellectual Property Rights, Patents, TRIPS, Pharmaceuticals, Developing Countries, India

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

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1. Introduction

The trade-off between promoting competition and protecting intellectual property has emerged as a principal issue not only in domestic but also in international policy in recent years[1]. In the international domain, companies in developed economies have been complaining for years that patent infringement and duplication of their products by firms in third-world countries significantly cut into their profits. In response to these complaints, the World Trade Organization (WTO) approved the so-called TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) agreement in the Uruguay Round of Trade Negotiations in 1995. Under TRIPS, all countries must, as a condition for membership in the World Trade Organization, recognize and enforce patents in all fields of technology, including pharmaceuticals. While many low and middle income countries initially made an exception for pharmaceuticals, they agreed to introduce or amend their patent legislation to include pharmaceutical product patents by 2005.

Not surprisingly, the enforcement of this rule in developing countries generates considerable controversy. Much of this controversy is centered on pharmaceuticals, due to both the extensive research investment and the public policy importance of this sector. On one side of the debate, TRIPS critics point out that patent enforcement leads to higher prices. This effect seems particularly undesirable in the market for pharmaceuticals, where many believe that it is "unethical" for firms to make profits from selling life-saving medicines. A quote by Indira Gandhi crisply summarizes this view: "The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death" [Indira Gandhi (1982)]. On the other hand, TRIPS supporters emphasize that TRIPS compliant patent laws attract foreign R&D investment in developing countries and promote technology transfer. Furthermore, patents may provide incentives for research on developing-country specific diseases (e.g., malaria).

These arguments reflect the classic trade-off between the static efficiency loss (higher prices) and potential dynamic gains (research, new products) associated with IPR protection. The thesis of this paper is that neither effect is likely to materialize in the aftermath of TRIPS. Price

[1] The challenges facing domestic competition policy are succinctly summarized in John Vickers' April 2009 Presidential Address to the Royal Economic Society Meeting along with a fascinating account of recent court cases in the U.S. and Europe [see Vickers (2009)].

increases are unlikely, both because of existing price controls and regulation in most countries and because developing country consumers are simply too poor to afford higher priced medicines. Dynamic gains are equally unlikely as developing country markets are too small at present to change the research priorities of pharmaceutical concerns. In contrast, the potentially largest effects of IPR enforcement in developing countries are to be expected in the distribution and availability of new products, both temporally and geographically. I present evidence that new products are often launched by domestic firms in developing countries, while multinational patent-holders enter these markets with a delay. Even after their launch, the distribution and marketing networks of multinationals are limited, so that their products may not be reaching remote rural areas. These considerations may provide a justification for policy measures such as compulsory licensing on top of price controls, unless IPR enforcement leads to investments by multinationals in distribution infrastructure or joint ventures and licensing arrangements with domestic firms.

Given the small size of developing country markets, one may further wonder why multinational corporations have invested so much money and effort in the cause of IPR enforcement in developing countries. I argue that "global reference pricing", that is the policy of some countries to regulate their drug prices by reference to the prices of the same drugs in other countries, is a much more important consideration for multinationals in the pharmaceutical sector than the profit losses they may have experienced due to patent infringement by firms in the third world. Concerns about growing exports of generics from developing countries in the long run, may have provided an additional motivation for their lobbying in favor of stricter enforcement of IPR in the third world.

The remainder of the paper is organized as follows. In Section 2, I discuss theoretical arguments pertaining to IPR. The main message of this section is that theory does not provide unambiguous recommendations regarding the strength of IPR protection in low-income countries. In Section 3, I discuss the challenges facing empirical researchers in addressing IPR-related questions in the context of developing countries. Section 4 describes results from a case study of antibiotics in India and discusses the main lessons that can be learnt from it. Section 5 presents some cross-country evidence that strongly suggests that the patterns revealed in the case study are likely to generalize to other settings. Section 6 discusses the policy implications of

these findings and section 7 provides a very preliminary account of developments in India since the enactment of patent legislation in 2005.

2. Theoretical Foundations of Intellectual Property Rights Protection

The basic economic theory regarding the impact of IPR protection, patents in particular, on product prices and consumer welfare in a closed economy is straightforward. 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. This 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 the 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[2]. As Nordhaus showed in 1969, the optimal patent policy is one that equates the marginal static efficiency loss to the marginal dynamic benefit. Of course, implementing this prescription is substantially more involved in practice than in theory.

In a multi-country setting, the trade-offs become more complicated, even at the theoretical level. The issue is that there is a fundamental externality involved: the benefits of innovation are spread beyond national boundaries, while governments are typically concerned with national and not global welfare. If countries were symmetric, this would not present a major problem for patent analysis. But in reality, countries differ both in the size of their respective domestic markets and in their skill endowments and technical know-how. As a result, they also differ in their capacity for innovation and their importance in influencing research priorities. Several papers in the literature have incorporated these considerations in theoretical models to show that the welfare consequences of patent protection depend on the particular conditions facing each country [e.g., Chin and Grossman (1990), Diwan and Rodrik (1991), Deardoff (1992), Helpman (1993), Grossman and Lai (2004)]. Against this background, it comes as no surprise that the reaction of many trade economists to TRIPS has been guarded, despite these economists' unequivocal support for free trade.

[2] 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 seen use historically.

Perhaps most pertinent to TRIPS is the analysis by Grossman and Lai (2004), who explicitly address the question of whether harmonization of patent regimes across countries is a condition for global efficiency. An "efficient global regime of IPRs" is defined in their framework as a regime that provides the optimal incentives for innovation to investors across the world. Interestingly, they find that the set of policies for achieving this global efficiency is not unique. However, different policy combinations have different welfare implications for developing and developed countries; the stronger IPR protection is in developing countries, the better off are developed countries and the worse off developing countries. While the particular results are dependent on model and functional form assumptions, the main message of the paper is that patent policy harmonization is neither a necessary nor a sufficient condition for global efficiency. These results speak directly to the concern that lax IPR protection in developing countries diminishes incentives to engage in research and innovation.

In a multi-country setting, 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, the use of reference prices, the possibility of parallel imports, etc. - to engage in global pricing, where prices are set not to maximize profits in the particular national market but rather 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 assessment of the likely impact of patent protection in such markets therefore requires a deep understanding of the demand structure.

3. Challenges on the Empirical Side: What Makes Developing Countries Different

Given that the main message from theoretical studies is that the effects of patent enforcement in developing countries are likely to be case-dependent, it is natural to turn to empirical studies to inform our understanding of IPR protection in the developing world. Unfortunately, while studies on developed countries abound, work that is specific to developing countries, especially concerning the pharmaceuticals sector, is scarce[3].

A few studies have used explicit models of consumer and firm behavior to simulate the welfare losses implied by patent protection in developing countries [e.g., Challu (1991), Fink (2000), Maskus and Konan (1994), Nogues (1993), Subramanian (1995), Watal (2000)]. However, the findings of these studies 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. A common assumption in this literature is that domestic and foreign products with the same chemical composition (i.e., the same active ingredient) are perfect substitutes. A direct implication of this assumption is that any welfare losses associated with patent enforcement stem from price increases of foreign products alone. While the premise that products containing the same chemical ingredients are perfect substitutes may seem intuitively plausible, I provide evidence from India that strongly contradicts this premise. Further, work based on developed countries suggests that consumers often view pharmaceutical products containing the same ingredients as imperfect substitutes; specifically, several studies have shown that consumers do not consider "branded" and "generic" drugs to be perfect substitutes, though the reasons for this behavior are less clear. Relaxing the assumption of perfect substitutability has profound implications for the welfare calculations associated with patent enforcement and the resulting policy prescriptions, as I show later in the paper. A further limitation of many studies is that they ignore substitution towards other drugs and therapeutic segments.

Any assessment of the potential price and welfare effects of IPR protection needs therefore to be based on a better empirically-grounded understanding of the characteristics of demand and the structure of markets for pharmaceuticals in developing economies. To what extent are consumers willing to trade off lower prices for older, possibly less effective therapies?

[3] A notable exception is the work by Lanjouw (1998, 2005) and Cockburn and Lanjouw (2001).

How does this sensitivity 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.

Given that substantial work has been devoted to analyzing related issues in the context of developed countries[4], it would be tempting to apply the findings of that literature to developing countries. Yet, the findings of these studies do not turn out to be directly pertinent to the IPR debate because the structure of demand for pharmaceuticals in less-developed economies differs from that in developed economies in five 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. The top five rows of Table 1, which is derived from statistics reported in the World Health Report for 2002 (WHO (2002)), clearly illustrate these differences. From an empirical point of view, the "silver-lining" of this lack of insurance is that one does not need to worry about the impact of moral hazard when estimating demand for drugs in developing countries since consumers bear the cost of the products they purchase. 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. The bottom panel of Table 1displays the top ten causes of burden of disease, measured in DALYs (Disability Adjusted Life Years). While in the U.S. and Canada, heart disease, depression, alcohol dependence and traffic injuries feature prominently at the top of the table, these conditions are less important in India, where the primary causes of disease burden involve respiratory infections, perinatal conditions and diarrhoeal diseases. Interestingly, these differences in the causes of disease burden translate into differences in the sources of retail sales.

[4] The work of Berndt (1994) and Ellison et al (1997) is particularly relevant here.

Table 1

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 2 displays the shares of the major therapeutic segments in the retail sales of pharmaceutical companies in India and the World as a whole. The table reinforces the widely held view that the research priorities of pharmaceutical companies are determined by the diseases that afflict the first world: the Cardiovascular and Central Nervous Systems that are #1 and #2 in terms of retail sales in the world, are only #4 and #5 respectively in India. Anti-infectives, ranked #2 in terms of retail sales in India, appear only at #5 for the World as a whole. It is important to note here that the world sales of pharmaceutical products are dominated by the sales in the first world, with the developing countries having miniscule shares; hence, "world" can be interpreted in the table as a synonym for "first world".

Table 2
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.

A fourth important difference between developed and developing countries, pointed out by Lanjouw and Cockburn (2001), is that 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 is likely to be different as well. Finally, developing and developed countries also differ in their respective requirements for prescriptions; many drugs that require prescription in the first world are available over the counter in developing countries. Consumers who are financially constrained may thus by able to buy less than a full dosage. Further, it is reported that there is also a resale market for pharmaceutical products, where individual pills are offered for sale. This behavior may lead to peculiar demand patterns. For example, a general presumption in Economics is that the long-run elasticities of demand are larger than the short-run elasticities, as economic agents have time to adjust. However, this may not be the case in pharmaceuticals. For

example, consider the response to a price increase of a particular drug in a low-income country without insurance and without prescriptions. In the short run, demand may decrease in response to the price increase; this demand decrease is likely to take the form of taking less than the full dosage of a particular drug, rather than people not taking it at all. But consuming less than the full dosage implies that people are likely to get sick again, in which case they will purchase the (incomplete) dosage again, driving the long-run price elasticity of demand down. More importantly, there are significant externalities in health care; remaining sick for a longer period implies that one has a higher likelihood of making everyone around her/him sick too, further increasing the demand for drugs. Hence, while the absence of insurance would suggest that the price sensitivity of demand in developing countries is substantially higher than in developed countries, the lack of prescription requirements and the associated externalities work in the opposite direction. These considerations call for a distinct treatment of pharmaceutical markets in developing countries.

4. Lessons from a Case Study of Antibiotics in India

4.1 The Question and Approach

Such a treatment is provided in a recent study by Chaudhuri, Goldberg and Jia (2006) that analyzed the effects of patent enforcement for a sub-segment of antibiotics in India. In this section, I discuss the general lessons that one can draw from this analysis and their implications for policy design; for technical details I refer the reader to the corresponding publication. Though the study focused on a particular country and pharmaceutical segment, I argue that the main insights are applicable to many other low- and middle-income developing countries.

Before I lay out the argument, it is important to draw a clear distinction between the *actual*, short-run effects that we expect to observe in India with TRIPS enforcement and the general concerns about patent enforcement in developing countries. The actual effects of TRIPS are likely to be small for several reasons. First, TRIPS affects only patents issued after 1995; given that the majority of the products currently marketed in India involve molecules with either expired patents or patents that were issued pre-1995, only a very small number of products will be directly affected by TRIPS-enforcing legislation. A good fraction of such recently patented products are life-quality drugs, which are arguably less important in developing countries from a public health policy perspective. Along the same lines, some of the newer drugs may be

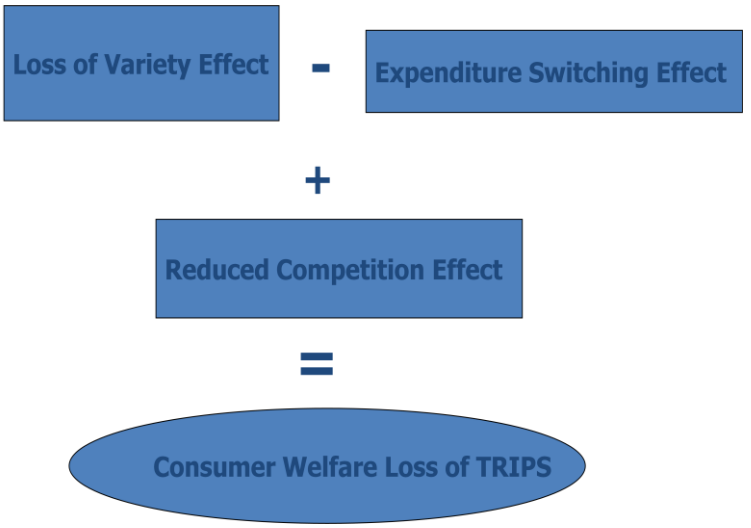
marginal improvements to existing ones rather than important new medicines. The short-run effects of patent enforcement are further attenuated by a provision that allows Indian companies that are now producing drugs for which patent applications were submitted between the signing of the TRIPS agreement in 1995 and January 1, 2005 to continue producing if they pay a royalty to the patent holder. Finally, TRIPS has several loopholes (e.g., for epidemics) that aim at guaranteeing access to life-saving medicines in cases where new patented drugs may not be readily available in developing countries. For all these reasons, it is unlikely that patent enforcement will have any dramatic effects in the short run.

However, the main concern with patent enforcement in developing countries regards not the specific effects of TRIPS, but rather the new equilibrium that would emerge if IPR systems were harmonized across the world. Specifically, the concern is that important, potentially life-saving medicines that are invented in the future may not reach consumers in poorer countries in a timely fashion, or that they may be sold at prices that are simply unaffordable for the majority of the population in developing countries. To address this concern, one needs to imagine a new steady state, in which domestic substitutes for patented products offered by multinationals do not exist. Evaluating this new steady state from a welfare point of view is a difficult task, because these new products simply do not exist – hence, one cannot use past, historical experience to assess how their availability and prices would be impacted by patents in the developing world. This is the reason that Chaudhuri, Goldberg and Jia adopt a structural approach in order to characterize this new steady state. Specifically, we estimate a model of supply and demand for a specific sub-segment of the pharmaceuticals market and then use the estimated model parameters to conduct simulations and provide a counterfactual analysis of what prices, sales, consumer welfare and firm profits would have been, if patents had been in effect. It is important to note that this exercise does not inform us about the actual effects of TRIPS. Rather it derives the effects associated with a thought experiment, in which India is at a steady state with full IPR protection. In other words, the question this approach tries to answer is, "suppose that the modern-day analog of antibiotics were invented in 2010, how soon and at what prices would the new drugs reach India?"

To this end, Chaudhuri, Goldberg and Jia consider the following thought experiment. Before 2005, India did not recognize pharmaceutical product patents; hence many products that were produced and sold by Indian firms were under patent in the U.S. Now suppose that patents

had been in effect. Then, many of the products manufactured by Indian firms would be absent from the market. The consumer welfare implications of this notional "withdrawal" can be explored by applying the same techniques developed in the context of the welfare analysis of new products; product withdrawal is the logical converse to product introduction. Importantly, our analysis did not impose the assumption that products manufactured by patent-holders in the first world are perfect substitutes to the products offered by Indian firms. Accordingly, the consumer welfare change associated with patent enforcement has three components, illustrated in Diagram 1:

Diagram 1: Components of Consumer Welfare Loss



The first component is the "loss of variety effect" arising from the fact that consumers may experience a loss if certain products are no longer available. Note that in studies that assume perfect substitutability between "branded" and "generic" products, this component is equal to zero by assumption. The second component denoted the "expenditure switching effect" that captures the fact that consumers may switch to alternative products when their preferred drugs are no longer available. This component will mitigate the consumer loss; its magnitude will depend on the degree of substitutability between products with alternative chemical compositions. The third component is the "reduced competition effect" arising from the fact that in the absence of domestic competition, prices of products offered by patent-holders may rise.

This is the effect that has been traditionally the focus of earlier work and public debate. As with the other components, the magnitude of the price increases will depend on the substitutability of different products. The description of these components demonstrates the key role that the price elasticities of demand play in the analysis.

To estimate these elasticities, as well as other key parameters of the model, Chaudhuri, Goldberg and Jia used detailed product level data provided by ORG-MARG in India to estimate a structural model of a particular sub-segment within antibiotics: the quinolone sub-segment. The approach yielded estimates of the key demand and supply parameters: the own- and cross-price elasticities of various products, expenditure elasticities, and upper and lower bounds for marginal costs. These were then used in the counterfactual analysis described above. As I emphasized above, the limitation of the counterfactual analysis is that it does not tell us what will actually happen once patents are enforced, but only what *would have* happened if patents had been enforced in the period covered by the data. However, given that TRIPS represents an unprecedented policy change, there is no alternative approach that would inform the questions at hand.

Before I describe the main insights obtained from this study, I briefly discuss why the focus on India and Quinolones is informative in the current context.

4.2 The Indian Pharmaceuticals Industry

India is a leading example of a low-income developing country that had not recognized patents prior to 1995 and did in fact lead the opposition of developing countries to TRIPS. It provides the ideal setting for studying the effects of patent enforcement for two main reasons. First, on the consumer side, the disease profile of the Indian population mirrors that of many low-income countries. Second, on the producer side, the domestic Indian pharmaceutical industry was as of 2002 the largest producer of "generic" drugs in the world (followed by Brazil). The market structure of the industry involves many small and medium-sized domestic firms selling drugs that are patented elsewhere.

This prominent position of Indian firms in the global pharmaceutical industry is the result of a unique and successful industrial policy in the 1970's and 1980's. Between April 1972, when the Indian Patents Act (1970) became effective, and March 2005, when India's parliament passed the 3rd Amendment of the Patents Act, India did not recognize product patents for

pharmaceuticals. The Indian Patents Act (1970), which replaced the inherited British colonial law regarding intellectual property rights, specifically excluded pharmaceutical product patents and only admitted process patents for a period of seven years. In addition, a number of other measures, such as drug price controls, restrictions on capacity expansion, limits on multinational equity shares, etc., encouraged the development of the Indian pharmaceutical industry, while keeping prices low for domestic consumers. 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.

As a result of these policies, the Indian pharmaceutical industry grew 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[5]. While in the early 1970's the industry was dominated by multinational subsidiaries, by 2001, Indian-owned firms had become major players. Table 3 documents this shift: in 1970, the collective share of foreign subsidiaries in domestic retail sales was 75-90%; by 2000, it had declined to 28-35%.

[5] 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.

Figure 1

Production, exports, imports and domestic sales of pharmaceutical formulations in India (Rs. Billions)

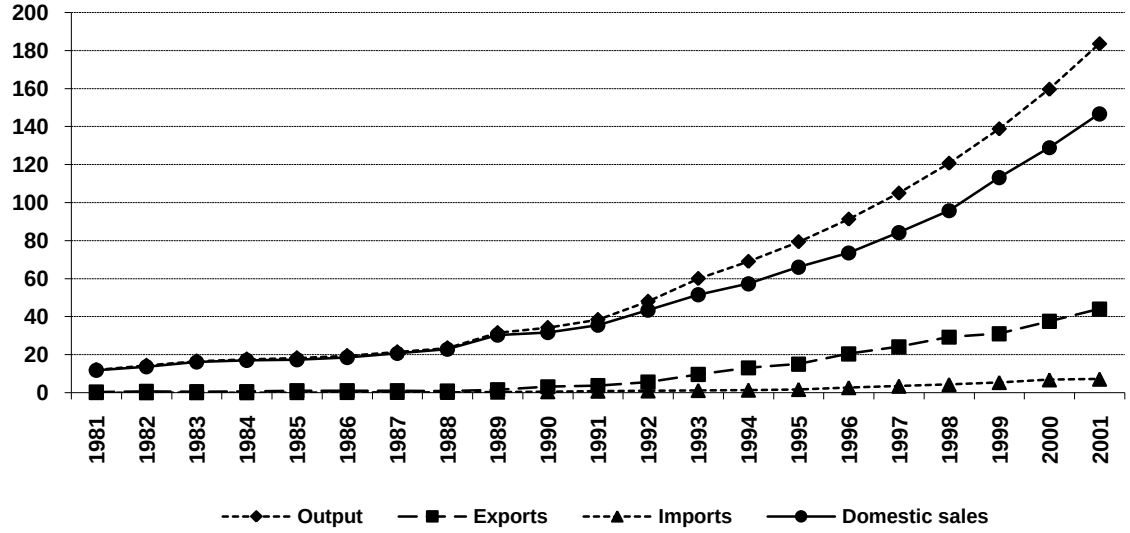


Figure 2

Production, exports, imports and domestic sales of bulk drugs in India (Rs. billions)

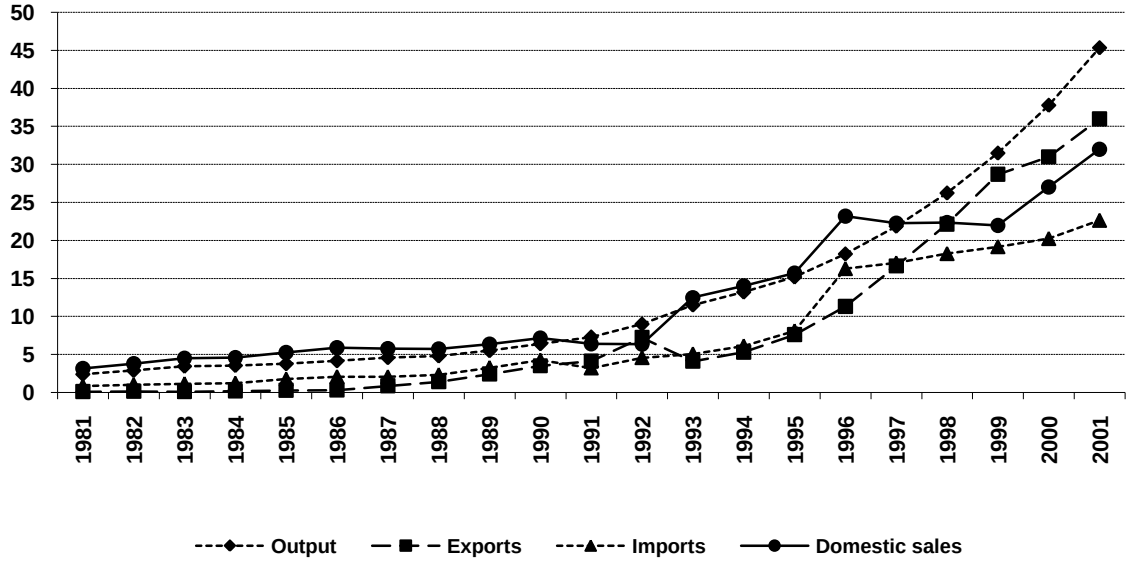


Table 3

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

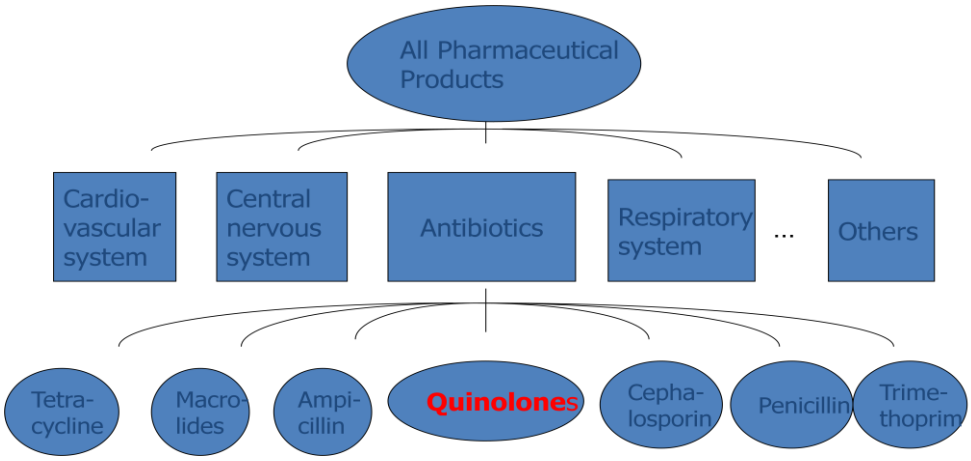
Notes: If companies are ranked in terms of overall sales (including exports), nine out of the top ten firms in 2001 were of domestic origin.
Notes: Precise estimates of the share of foreign subsidiaries in domestic retail sales are hard to come by because of the scarcity of comprehensive industry-wide 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.

4.3 The Antibiotics Segment

The case-study focused on the systemic anti-bacterials (antibiotics) segment of the market, and within that on the quinolones sub-segment. The segment of antibiotics includes all the original miracle drugs (for treatment of bacterial infections) that sparked the development of the research-based pharmaceutical industry post World War II, as well as later generations of molecules. The segment is important as it accounted for about 20% of retail pharmaceutical sales in India in 2000 and ranked #2 in the country in terms of its contribution to firm revenues. The antibiotics segment is itself divided into several sub-segments, each representing a family of

related molecules. The following diagram represents the classification system of pharmaceutical products followed by the WHO and all major market research and consulting firms in the sector:

Diagram 2: Classification of Pharmaceutical Products



The focus on antibiotics and quinolones in particular was motivated by several considerations. Antibiotics are obviously important in a country where infections are a major cause of disease. Many of the new products developed by pharmaceutical companies these days are life quality enhancing drugs, such as anti-depressants, Viagra, etc. While these newer products will presumably be affected more by patents than antibiotics, they are arguably less important from a public health policy perspective. Moreover, as noted above, antibiotics are also important in terms of their revenue share in India.

Within antibiotics, quinolones one of the largest sub-segments with 20.8% revenue share. Quinolones belong to the latest generation of antibiotics and are the drug of choice for most infections. This implies there should be many substitutes available. Finally, several quinolone products were still under patent protection in the U.S. during the period covered by our data.

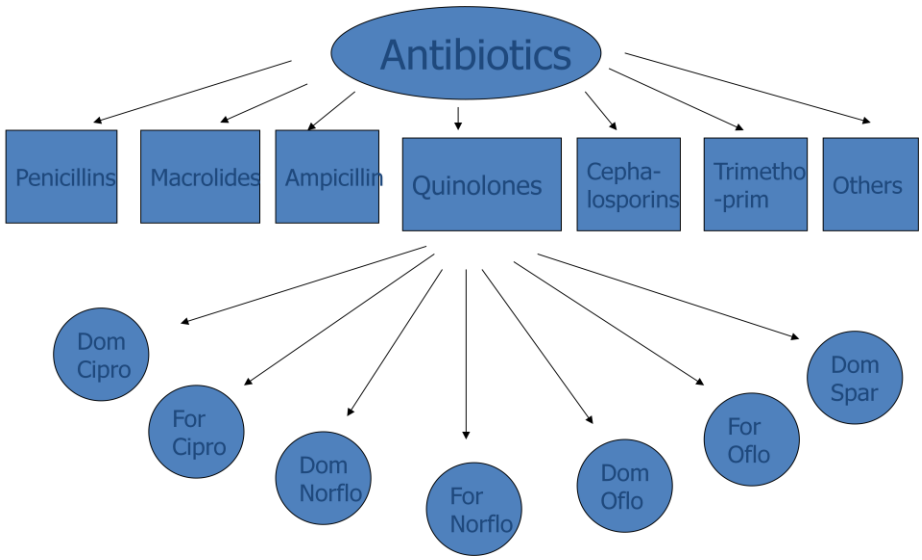
4.4 Some (Strongly Suggestive) Patterns in the Data

As noted earlier, the case study relied on a structural model to estimate the key demand and supply parameters and carry out simulations. Because structural models are by their nature subject to the criticism that the results may be the artifact of the structure, I start by discussing

some patterns in the raw data that should prepare the reader for the findings of the structural estimation. Importantly, I argue that these patterns are not unique to quinolones and India, but apply to other developing country markets as well.

There are four main molecules within quinolones: Ciprofloxacin, Norfloxacin, Ofloxacin and Sparfloxacin. As with all pharmaceutical products, quinolones are offered by many firms, some domestic, some foreign, and are available in multiple presentations, that is combinations of dosage forms (capsule, tablet, syrup, etc.), strength (100 milligrams, 500 milligrams, etc.), and packet sizes (50 capsule bottle, 100 tablet bottle, etc.). The various presentations in which a product is available are often referred to as stock-keeping units or SKUs. We aggregate across SKUs and across firms, so as to maintain differentiation of products along two dimensions: chemical composition (i.e., molecule) and nationality (domestic/foreign). This yields the following classification scheme for the products used in the analysis:

Diagram 3: Classification of Quinolones



Tables 4 and 5 present several interesting facts regarding these four molecules. Note first that the share of domestic firms in each case is substantially larger than the share of foreign subsidiaries (Table 4). The case of ciprofloxacin is the most striking; domestic firms command a share of 53% of total quinolone sales compared to only 2.7% for foreign subsidiaries. One might speculate that the higher shares of domestic firms are due to lower prices. However, the last two rows of Table 5 show that this is not the case. Domestic products are not cheaper; their prices

are on average substantially higher than the ones for products sold by multinationals. Foreign Ciprofloxacin for example, sells at a 10% discount relative to domestic Ciprofloxacin. This preliminary evidence suggests that Indian consumers do not place a premium on the brand name and reputation of big multinational pharmaceutical concerns; on the contrary, it is the domestic products that sell at a premium. The same pattern was evident for other products outside the antibiotics segment.

Table 4
The quinolones 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

Table 5
Basic information about the four quinolone 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 5 reveals several other interesting facts about competition in the quinolone market in India. The first row shows the year of U.S. patent expiry; this ranges from 1998 for Norfloxacin, to 2010 for Sparfloxacin. The second row shows the year of FDA approval in the U.S. and the third row displays the year of each drug's launch in India. What the table does not report, but is one of the most intriguing aspects of the pharmaceuticals sector, is the identity of the firm that launched each new drug in India. In many cases, the new drugs are not launched by the multinational patent-holder, but by a domestic firm. The launch of Ciprofloxacin in India is a case in point: Ciprofloxacin was introduced to the Indian market by a domestic firm, Ranbaxy, in 1989, and not by Bayer, the international patent-holder. Bayer entered the Indian market only years later and never caught up with the larger market share of the established seller of the product, Ranbaxy. Similar entry patterns are present for other molecules and segments of the market. Overall, it appears that new products are introduced in India by domestic firms, while foreign firms enter with a delay. This may explain the premium for domestic products discussed earlier. By the time foreign firms enter, domestic products are well established, commanding higher prices and market shares.

While this behavior of multinationals may appear peculiar at first, it can be easily rationalized in a world characterized by "global reference pricing", in which prices in India may be used as a reference point when prices in Canada or Europe are set. From the perspective of multinational corporations, it may seem sensible to delay their entry in developing country markets, where prices are naturally capped by the limited purchasing power of domestic consumers, until they have negotiated prices with higher income countries. The foregone profits in the Indian market are too small compared to the additional profits in the first world to incentivize globally operating firms to enter developing country markets earlier. Later in the paper I explore the policy implications of this pattern.

Finally, note the large number of firms operating in the quinolone sub-segment. The large number of domestic firms is perhaps not that surprising given that pharmaceutical product patents were not recognized in India. 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 "infringed"[6] patent laws in India, while complying with them in developed world countries.

In sum, the descriptive evidence suggests that – perhaps contrary to expectations – domestic products sell at a premium in India. The late entry of multinationals in this market provides a plausible explanation for their apparent unfavorable position in the market.

4.5 Results and Interpretation

I now turn to the main results and insights obtained from the estimation of the structural model. As noted earlier, key to the welfare calculations is the demand estimation that delivers the price and expenditure elasticities of demand. It is therefore critical to adopt a specification that allows for as much flexibility as possible and which does not dictate – by assumption – the substitution patterns across products. To this end, we estimated a two-level demand system employing the Almost Ideal Demand System (AIDS) specification of Deaton and Muellbauer (1980) in both levels (see Diagram 3). The higher level corresponds to the allocation of expenditures to various sub-segments within the antibiotics segment of the market. At the lower level we estimated the parameters relevant for the allocation of expenditures within the quinolone sub-segment to the various product groups within this sub-segment (e.g., foreign ciprofloxacin, domestic ciprofloxacin, domestic norfloxacin, etc.).

For our purposes, the AIDS specification offers several advantages. First and foremost, it does not impose any structure on the substitution patterns across products, given that the price parameters are estimated freely. This was our highest priority. Second, the two-level system displayed in Diagram 3 naturally corresponds to the therapeutic classification suggested by the WHO. Third, AIDS lends itself to estimation with both consumer level and aggregate data; given that purchases of pharmaceutical products were available to us only at an aggregate level, it was important to adopt a system that could be consistently estimated with such data. Finally, AIDS implies finite virtual prices; hence, unlike the standard discrete choice models that have become popular in demand estimation in recent years, it does not imply by construction large welfare changes when new products are added or old products are discontinued. This was an

[6] The word “infringe” is in quotes, because as I emphasized earlier, there were no patent laws at that time in India. Hence, foreign subsidiaries selling products that were patented elsewhere were not in formal violation of any laws.

important consideration in our setting given that we were ultimately interested in calculations of consumer welfare losses.

The most striking feature of the demand side results was the finding of very large cross price elasticities between domestic products with different molecules.[7] In fact, some domestic products with different chemical compositions were found to be closer substitutes to one another than domestic/foreign products containing the same molecule. I emphasize once more that this was a genuine empirical result: there was nothing in the structure of the demand system that implied this finding. Given that this finding, which has significant implications for the welfare calculations, is rather counterintuitive, one may wonder what is driving it. Our preferred explanation is that the close substitutability of domestic products reflects differences between domestic and foreign firms in the respective marketing and distribution networks. In particular, the retail coverage of domestic firms (as a group) is much more comprehensive than that of multinational subsidiaries for two main reasons. First, because many of the larger Indian firms have larger portfolios of products over which to spread the associated fixed costs, they typically have more extensive networks of medical representatives. Second, there are simply many more domestic firms (and products) on the market. At the retail level this implies that local pharmacists are more likely to stock domestic products containing two different molecules, say ciprofloxacin and norfloxacin, than 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 document.

To summarize the evidence so far, the raw data and demand estimates suggest that: (a) Consumers seem to prefer domestic to foreign products (as indicated by the higher prices and higher market shares of the former); (b) Domestic products are close substitutes to one another. As I discussed earlier, likely reasons for these patterns include the delay in the launch of new products by multinational patent-holders in India (possibly due to reference pricing), and the lack of well developed distribution and marketing networks by multinationals. Even without any additional analysis, these findings by themselves have an important policy implication: the loss

[7] The detailed results can be found in the AER publication, Chaudhuri, Goldberg and Jia (2006), Tables 6(a) and 6(b).

of variety as a result of patent protection is likely to be substantial. Assuming no changes in the behavior of multinationals post-TRIPS, new drugs would be available to Indian consumers with a delay and after their launch, their distribution might be lacking, especially in rural areas. These projections are of course only valid to the extent that TRIPS would not alter the incentives and behavior of foreign firms operating in the Indian market. I discuss this issue in detail in Section 6.

Consistent with these demand side results, the consumer welfare loss was found to be substantial: elimination of the domestic competition from the market would result in a consumer welfare loss that is approximately 65% of the sales of the entire antibiotics market in India in 2000. A substantial fraction of the loss is due to the loss of product variety. To remind the reader, this is the loss that would arise even if we kept the prices of the remaining products fixed. Hence, it corresponds to the case where strict price regulation would keep the prices at their pre-TRIPS level. The main implication of these calculations is that price regulation alone would not be sufficient to mitigate the loss suffered by Indian consumers. The large loss due to lost product variety is a direct consequence of the large cross price elasticities between domestic products. Consistent with this interpretation, we also find that the loss is largest, when *all* domestic products disappear from the market; in fact, the total effect in this case is larger than the sum of its components, that is the sum of the losses associated with withdrawing single domestic products from the market, one at a time. The consumer loss becomes smaller when some domestic competition remains. In fact, if the *only* product withdrawn from the market were Sparfloxacin, the welfare loss would be close to zero. This is because in this case consumers would switch to other domestic products in the same group. This example illustrates once again the difference between the *actual* short-run effects of patent enforcement, and the thought experiment considered here. Since Sparfloxacin is the only molecule still under patent (see Table 5), it would be the only one affected by TRIPS-enforcing legislation. Hence, the calculations above imply that the *actual* welfare loss of TRIPS would be miniscule. However, as I argued above, the relevant counterfactual that one needs to consider when assessing the impact of patent enforcement in the developing world going forward, is one in which consumers would not have the option to switch to other similar domestic products. In other words, at a steady state with patent enforcement, domestic versions of Ciprofloxacin, Norfloxacin and Ofloxacin would simply not exist for the first 20 years after these molecules were patented. In this case, the

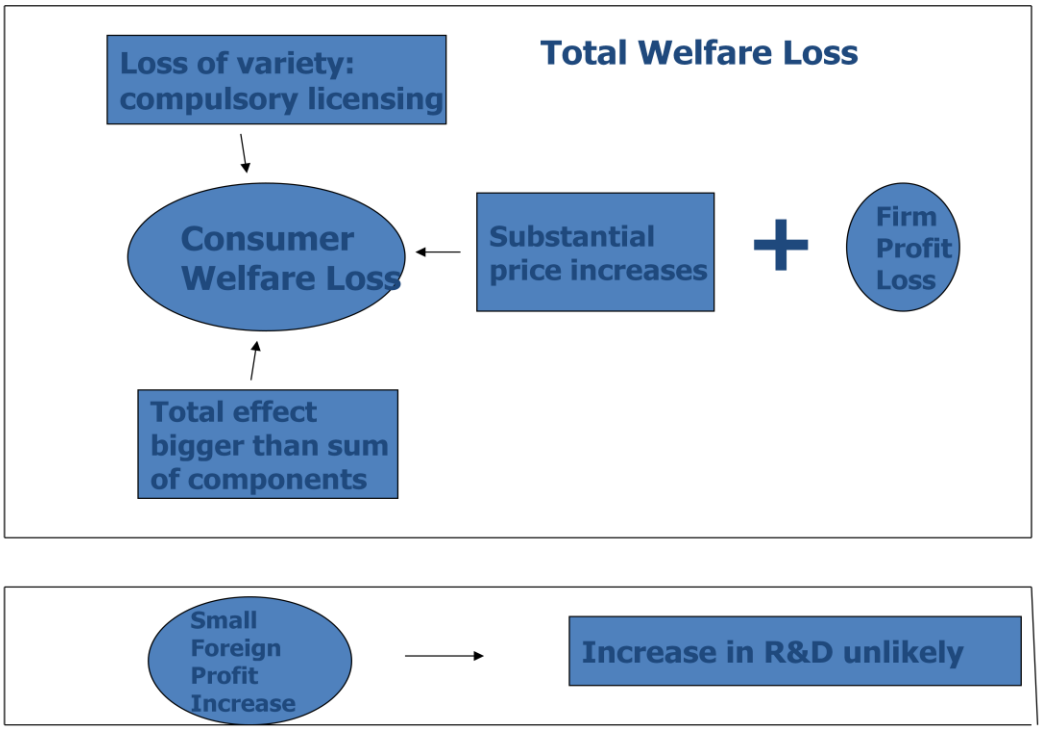
relevant counterfactual for the welfare calculations is one in which there is no domestic competition within this subclass of products. As I discussed earlier, such a scenario implies substantial welfare losses due to the loss of variety.

The counterfactual simulations also predict price increases between 100% and 400%. As with the work on new products, these calculations suffer from the problem that we extrapolate from the range covered by the data to a region that may lie far from the actual observations. While there is no way of conceptually resolving this issue, one advantage of our setting was that we can compare our price projections to the prices of the same products observed in countries "similar" to India, which have had stricter patent laws in the past. A comparison between our predicted prices and those observed in Pakistan, as reported by Lanjouw (1998), p. 39, Table 2, is encouraging. For the drug ciprofloxacin, for example, we predict that the price of the (patented) foreign products in India would be approximately 5 times higher than it was in 2001, if all domestic products were withdrawn from the market. According to Lanjouw, ciprofloxacin sells in Pakistan for approximately 7 times the price in India. The two numbers are of similar magnitude, giving us confidence that the empirical framework we use as a basis for conducting counterfactual simulations in India does not produce implausible predictions.

Finally, the analysis also predicts losses for the domestic Indian firms, but these losses pale in comparison to those that will be experienced by consumers. Interestingly, the gains to foreign patent owners under TRIPS are only moderate: $53 million per year in a scenario with no price regulation; $19.6 million per year under a more realistic scenario with price regulation. While these numbers refer to India only, I remind the reader that India presents one of the largest, and fasted growing developing country markets and that within this market, antibiotics represent the second largest segment in terms of revenues. Hence, while under a system of global patent enforcement multinationals would be likely to also make profits in other developing countries, these profits would pale in comparison to those in the Indian market. To put the profit calculations in perspective, the costs of developing a new drug are estimated around $800 million on average. These numbers cast doubt on the claim that patent enforcement will incentivize multinational pharmaceutical companies to focus their research efforts on developing-country-specific diseases. Moreover, they raise the question of why firms in the first world applied so much pressure on the WTO to sign TRIPS in the first place. As I argue below,

global reference pricing may provide the answer. Diagram 4 below summarizes the conclusions from the welfare analysis.

Diagram 4: Summary of Welfare Calculations



5. Do the Lessons Generalize? Cross-Country Evidence

Given that the results above refer to a specific country and segment of the market, a natural question is whether they generalize to other settings. To my knowledge, there exists no direct evidence to date on consumer preference for pharmaceutical products in other developing countries. Hence, it is difficult to say whether the substitution patterns documented earlier would apply to other countries. However, the main point of this paper is that the substitution patterns estimated for quinolones are a direct consequence of the entry behavior of multinationals in India and the current state of their marketing and distribution networks there. To the extent that this behavior is present in other developing country markets, the demand patterns and welfare implications I discussed for quinolones in India will be relevant to other developing countries. Therefore I now turn to evidence related to firm and product entry patterns in various countries.

A large number of studies in the pharmaceuticals literature have used data on drug launches to investigate the timing, pricing and determinants of new drug introduction across countries[8]. Perhaps the most complete investigations are provided by the two recent studies by Lanjouw (2005) and Danzon and Epstein (2008), whose findings are particularly relevant here.

Both studies aim at understanding the determinants of the launch timing of pharmaceutical products. Of particular interest is the question of what role price regulation and IPR protection play in the decisions of firms to market new products in various countries. Lanjouw exploits data from 68 countries of all income levels and drug launches between 1982 and 2002. Danzon and Epstein have data from 15 countries and drug launches in 12 different therapeutic classes between 1992 and 2003. Despite their differences in the country and year coverage, the two studies report similar results. There is strong evidence that price regulation has a big impact on launch timing. In particular, if price regulation reduces prices, it contributes to launch delay. Global reference pricing seems particularly important here. As Danzon and Epstein report, many countries in the European Union use the mean or minimum price in a group of reference countries to cap the prices of new drugs, while Canada uses the median price in seven countries. Even if low-income countries, such as India, are not directly included in the reference group, comparisons of prices across countries and fear of public backlash are likely to induce manufacturers to delay launch in low-price countries to avoid undermining higher prices in other countries. Hence, reference policies adopted in high-price countries impose welfare costs on low-price countries.

Danzon and Epstein exploit the order of entry into national pharmaceuticals markets in conjunction with information on the intensity of price regulation in order to pin down the role of global reference pricing in launch delays. In particular, they split the countries in their sample into three groups: low-price EU countries (France, Italy, Spain, Portugal, Greece), high-price EU countries (Germany, the Netherlands, Sweden and the UK) and high-priced non-EU countries (the US, Japan and Canada) and construct count variables that measure the number of countries in each group where a specific drug has already launched. They employ these count variables (together with a large set of other controls) as explanatory variables in the estimation of a launch hazard model and find that the number of countries in which launch has already

[8] A representative, by no means exhaustive, list includes Danzon and Epstein (2008), Kyle (2007), Danzon, Wang and Wang (2005), and Lanjouw (2005).

occurred has a strong, positive and statistically significant effect on launching a new drug, with the exception of prior launch in the three lowest price EU countries: Spain, Portugal and Greece. They interpret these results as strong evidence that launch in low-priced EU countries is adversely affected by the risk of spillover to higher-price EU countries through global reference pricing. Even more convincing are results that rely on interactions of the above count variables with dummies indicating whether a firm is entering a low- or high-price EU market. The results suggest that the effect of a prior launch in a high-price EU country on launch in a low-price EU country is substantially larger than the effect of a prior launch in another low-price EU country; moreover, the effect on launch in a low-price EU country is greater from a prior launch in a high-price EU country than from a launch in a high-price non-EU country, which is consistent with a referencing-based explanation, as reference pricing within the EU involves only other EU countries. While this analysis does not exploit directly any information on price negotiations between pharmaceutical companies and governments, the cross-country patterns are so robust that it is hard to come up with an alternative explanation for their existence.

I should note that the patterns documented by Danzon and Epstein are substantially stronger for "superior" than "inferior" products. The distinction between "superior" and "inferior" drugs is based on the mechanism of action, conversations of the authors with several physicians and review of articles in PubMed, but it corresponds closely to the distinction between "new" and "old". For "inferior" (older) molecules, the effects of prior launch in low- versus high-price countries I discussed earlier, appear to be small in magnitude and statistically insignificant. This difference indicates that the importance of cross-national spillovers is likely to vary by the age of the drug, with older compounds less likely to be adversely affected by global reference pricing. Along the same lines, global reference pricing will be less relevant in cases where the disease is specific to low-income, developing countries (this might for example be the case with malaria medication). To the extent that IPR enforcement incentivizes pharmaceutical concerns to focus on developing country diseases, there is then no cause for alarm -- though, as I argue in the next section, the size of developing country markets is so small at present, that it is unlikely that this hope will materialize. At any rate, cross-country reference pricing is likely to have significant effects on the launch timing of new products that are aggressively marketed in the first world. Many of these products currently fall into the category of life quality drugs, which are arguably less important from a public health policy perspective. The real concern lies

with potentially life-saving medicines that may be invented in the future and that may be equally important for low- and high- income countries. Given that these medicines do not exist yet, it is impossible to predict when and at what prices they will be launched. But if past experience with antibiotics in India or more generally "superior drugs" across the world is any indication, important medicines invented in the future could be launched with substantial delays in low-income countries if they are also sold in richer countries.

The evidence presented in Lanjouw also suggests an important role for global reference pricing. Lanjouw reports that less than one-half of the new products that are marketed globally are sold in any given country, and those that are sold are often available to consumers in one country only six or seven years after they become available in another. Almost invariably, firms launch new drugs in rich countries first, with launch lags increasing as one goes down the country per-capita-income rankings. In contrast to Danzon and Epstein, Lanjouw does not exploit the order of entry to capture the effects of international pricing externalities on launch delays, but provides anecdotal evidence and case study evidence that strongly support the hypothesis of international pricing spillovers. Perhaps the most striking example concerns one of the products that I discussed earlier in the context of the quinolones case study in India: ciprofloxacin. Based on an interview with a Bayer executive in India in 1997, Lanjouw reports that Bayer chose not to introduce its new patented antibiotic in India in the late 1980s, as the firm was negotiating prices with more important, developed country markets at the time. Only eight years later, and after several local producers (most importantly Ranbaxy) had entered the market, did Bayer finally market ciprofloxacin in India. Along the same lines, the Wall Street Journal reported in 2003 that GlaxoSmithKline and Pfizer had cut back supplies of their products to Canada to prevent re-importation of these products into the United States, where these firms enjoy higher prices. This case study evidence taken together with the cross-country evidence of Danzon and Epstein establish a pattern strongly suggestive of cross-country pricing spillovers.

Interestingly, the effects of IPR protection on launch timing are reported to be ambiguous. This is not surprising given that the authors do not explicitly consider the identity of the firm that launched the new product in each market. As demonstrated earlier for the case of India, new products are often launched there by domestic firms; Indian consumers did not experience a delay in access to new products in the past precisely because of the absence of patent protection that allowed domestic firms to introduce these products in the domestic market.

The low level of IPR protection was thus not associated with a launch delay in this case. However, it is possible that under TRIPS, consumers in India will experience the same delay documented for other low-income countries, as domestic "generics" will no longer be available.

In sum, the findings of cross-country studies and case study evidence seem consistent with the entry patterns discussed earlier for the quinolone sub-segment in the Indian market and suggest that the data and demand patterns we documented for that market are likely to generalize to other settings involving medicines that are relevant to both the developed and developing world.

6. Policy Implications

The substantial loss in consumer welfare arising from the loss of product variety has a direct policy implication: Price regulation is not sufficient to mitigate the potentially adverse effects of patent enforcement; additional measures, such as compulsory licensing, are called for in order to guarantee access to new medicines, at least in the short and medium run. Earlier in the paper I argued that the value of product variety derives from the coverage of distribution networks and associated ease of access. In that sense, the justification for policies that will ease the transition to a TRIPS-compliant regime is different here than the one traditionally offered. The usual concerns expressed by policy makers and consumer advocates emphasize the higher prices that patent enforcement may induce. However, higher prices are unlikely to materialize given the existence of price regulation and the low purchasing power of Indian consumers. At the same time, price regulation also implies that the potential profit gains of multinationals as a result of TRIPS will be limited. Hence, the big shift in incentives and research priorities of global pharmaceutical concerns predicted by TRIPS advocates seems equally unlikely.

Of course, to the extent that the value of product variety is related to the limited marketing and distribution networks of multinational subsidiaries, one may argue that the loss of variety is only transitory. With India recognizing patents, multinational subsidiaries might invest in expanding their marketing and distribution networks; moreover, they might form joint ventures with domestic firms or enter in licensing agreements with them. Such agreements could enable them to take advantage of the current distribution infrastructure of Indian firms without any major investments. While this is certainly a possibility, there are several reasons that might leave one skeptical as to whether these changes will materialize.

The main source for concern is that as long as the market remains small, any incentives for global companies to change their current behavior will be limited. Price controls, which are deemed as necessary for guaranteeing low-cost access to medicines for Indian consumers, can only further reduce incentives. A concrete example can give a sense of how small the Indian market is compared to first world markets.

In 2000, the world sales of Ciprofloxacin, the patented drug of Bayer, were $1.6 billion. Assuming a 40% markup, which is standard in the industry, these revenues translate into a $640 million profit for Bayer from Ciprofloxacin alone, for that year. In contrast, the sales in the *entire antibiotics* segment in India in 2000 were $630 million. This comparison shows that the revenues in the developed and developing world are several orders of magnitude apart. The difference becomes even more striking if one considers that India is not among the lowest income countries in the world and that antibiotics represents one of the most significant segments of the pharmaceutical sector in terms of revenue. Even if patent enforcement led to an expansion of multinationals' activity in India, and hence higher market shares and prices for multinational subsidiaries, the Indian market would still be small compared to the markets in North America and Europe. At a minimum, this implies that the delays in the launch of new products discussed earlier might become an issue in India, leading to lower access to new medicines over time. In the worst possible scenario, patent enforcement might also lead to lower access to new drugs in remote, rural areas that are currently served by Indian firms. This last effect is however likely to disappear in the long run if foreign subsidiaries manage to successfully outsource the marketing and distribution of their products to domestic Indian firms. Of course, as countries like India grow, their market size may increase to the point where it is comparable to that of developed countries, creating additional incentives for foreign firms to enter the market. Whether this happens is an important question that future research should try to address.

7. What Has Happened since 2005?

In March 2005, India's parliament passed the 3rd Amendment of the Patents Act, which recognizes product patents. The four subsequent years are too short a period to provide a comprehensive assessment of how the market has been affected by the enforcement of IPRs. However, there are some preliminary papers and reports that speak to the issues and concerns raised in this paper.

A recent paper by Arora, Branstetter and Chatterjee (2008) seems to provide grounds for optimism. The authors report a "striking increase in the R&D intensity of Indian pharmaceutical firms" following the enactment of the 2005 legislation. In particular, they find an increase in absolute R&D expenditures; R&D intensity; measures of research output; and stock market valuation of Indian firms' R&D investment. This is the good news. On the negative side, they find no evidence that any of the above developments were driven by "independent innovations". Indian firms have to yet produce a new product. Moreover, there is no evidence of R&D collaboration between Indian and Western firms (with few exceptions that are related to the biggest Indian firms). These findings naturally raise the question "where did the R&D expenditures go?"

After a careful examination of the data, the same authors report that the research expenditures were channeled towards process and not product innovations. As a result of these innovations the sales of Indian generic products abroad soared and the export activity of the Indian pharmaceutical sector exploded. Hence, it appears that the big benefit of TRIPS was to open up to Indian firms the foreign market for TRIPS-legal imitations – the generics market! This of course does not imply that the innovative activity of domestic firms in the last few years did not produce any welfare gains for domestic consumers; in addition to the export revenues generated by the increase in generics sales abroad, process innovations have likely improved take-up through changes in dosing, storage capacity and simplicity. Moreover, as I emphasized earlier, the period that has passed since the enactment of patent enforcing legislation is too brief to allow any definitive conclusions regarding new product development.

At the same time, as early as 2006, Oxford Analytica painted a worrisome picture of the Indian pharmaceuticals market. A briefing issued by that firm in October 2006 warned of price controls that undermine the growth strategy of the pharmaceutical industry. In the same briefing it was reported that in 2005 the number of new drug products introduced to the domestic market fell by 50%, while their contribution to total sales was just 1%. Because of TRIPS, there were no new generic drugs on the market and the industry was confined to re-processing of international drugs patented before 1995. Finally, Oxford Analytica also reported that foreign firms have been slow to introduce new products, showing little interest in the small scale opportunities of the Indian market. These are precisely the concerns raised in the previous section.

Needless to say, these reports are very preliminary; they have neither been refereed nor withstood the test of time. Hence, they should be taken with caution. However, they do point to the relevance of the issues raised in this paper. In the future, as more data become available, it will be important to rigorously examine the impact of patent enforcement in India, focusing not only on prices and R&D, but also on questions related to access and availability of new medicines. In particular, the two questions that research should address are: (1) How soon do new products become available in developing countries? And (2), how widely are they distributed and in particular, do they reach poor rural areas? But perhaps the hardest question, from a welfare perspective, is how one should think about access in countries with no prescription policies, where uninformed patients may buy drugs over the counter based on faulty or incomplete information. Do we really want wide access to new, innovative drugs in such environments?

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