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## **Drug Pricing Under Generic Competition: A Review of the Economics Literature**

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### **1. Introduction**

As a consequence of the TRIPS Agreement at the WTO, many developing countries have implemented or strengthened product patents in pharmaceuticals in recent years, though the Doha Declaration of 2001 clarified that the least developed WTO members may delay such implementation or enforcement of drug patents until 2016. TRIPS requires the provision of patents across virtually all fields of technology, including pharmaceuticals, for a minimum of 20 years. It also sets out restrictive conditions under which compulsory licenses may be issued. The agreement is silent on geographical exhaustion of rights (thereby leaving it up to each country whether to permit parallel trade) and whether governments may allow a research exception from the patent-use exclusive rights. Finally, while requiring protection of confidential test data, does not prescribe terms or a minimum period of protection. In short, TRIPS retains a number of provisions under which governments in developing countries may reasonably use regulatory authority to limit the scope of drug patents.

Not content with this degree of protection, the European Union and, especially, the United States, in negotiating bilateral trade agreements with developing nations, have increasingly demanded intellectual property protection in pharmaceuticals that goes beyond TRIPS into the so-called "TRIPS-Plus" standards. These latter standards involve, among other things, virtually abandoning recourse to compulsory licensing, restricting parallel importation, the recognition of extension or continuation patents, and lengthy periods of confidentiality for clinical-trials test data.<sup>2</sup>

These provisions are designed to slow down considerably the entry of generic competitors in patented pharmaceutical markets, once patents have been registered in the recipient country. Clearly there will be a significant transition as countries with thriving generic industries, such as India and Thailand, register and enforce patents on new drugs (or, sooner, enforce exclusive marketing rights under priority claims before domestic patents are issued). Those generic companies, many of which will close down, consolidate or be taken over, will have to wait longer before imitating new drugs. Thus, as they are phased in the rules will raise a significant challenge for health and competition authorities in developing nations.

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<sup>2</sup> The TRIPS-Plus agenda is described in the context of a recent bilateral trade agreement in Keith E. Maskus, "Intellectual Property Rights in the U.S.-Colombia Free Trade Agreement," in Jeffrey J. Schott, editor, *The Free Trade Agreement between Colombia and the United States* (Washington DC: Institute for International Economics), 2006, forthcoming.

This policy trend raises a number of important concerns but the focus of this paper is on a deceptively simple question: What have studies in the professional economics literature discovered about the impact of generic competition on prices of patented drugs? This seemingly straightforward question cannot easily be answered in universal sense, for the experiences of different countries vary considerably, while much depends on underlying market parameters, demand, competition structure, and institutional details. For example, most of the econometrically noteworthy studies have focused on the United States, where prescribing practices and insurance markets are quite different from those in a representative developing nation. Nonetheless, important lessons can be drawn from the literature, which is the intent here.

I organize the review in sections. First, I analyze what may be called "first generation" partial-equilibrium models that attempt to predict the effects of introducing monopoly-inducing patents overnight in developing countries. Such studies are somewhat informative in terms of important market parameters but cannot be taken seriously. Next, I turn to "current generation" models that ask the same question with a more serious reliance on demand theory and econometrics. These studies illuminate a far richer set of factors to be considered. Third, I ask what might be learned from econometric studies of generic entry in the United States, after the Hatch-Waxman Act of 1984, and how relevant these studies are for poor countries strengthening their patent regimes. Finally, I overview two papers that provide some initial evidence on the prospects for innovation (of sorts) in developing countries after patent reforms.

In preparing this review I chose to highlight major approaches and results from a small number of important studies, which is more informative than attempting simply to list outcomes from a large set of papers. The articles selected here certainly cover the range of relevant forms of inquiry.

## **2. First Generation Partial Equilibrium Models**

As TRIPS was under late negotiation, a few studies appeared to attempt an initial assessment of the potential static costs of implementing drug patents in a few large developing countries. Two are worth reviewing briefly here for they make a number of useful observations. One general observation is that these studies (and those to come in the next two sections) really are about the price impacts of *removing competition* (that is, ending the threat of generics or copiers) rather than the impacts of *adding competition* (that is, entry of generics upon patent expiration). Another is that results of simple simulations should not be taken literally to represent reality. They are not statistical predictions but rather *counterfactuals*, in which a researcher computes what a market situation would have been had a different policy (eg, patents versus no patents) been in place, holding everything else constant. That is the meaning of "overnight" patent protection. But in reality there would be timed phase-ins, imperfect patent protection, price controls, growth, and numerous other factors that cannot be simulated in a basic partial-equilibrium exercise.

### **Subramanian**

A first study was by Arvind Subramanian.<sup>3</sup> He set out the simplest possible static framework for computing the price impacts of drug patents. Specifically, he considered two theoretical possibilities: an initial market structure that was perfectly competitive and one that was a Cournot-Nash duopoly (with one domestic firm and one foreign firm). In both cases he imagined the impact of patent imposition to be the overnight conversion of either market to a full monopoly, which was foreign owned. In essence, these cases "captured" the potential limits of price increases, for moving from perfect competition to monopoly should generate the largest price rise (and loss in consumer benefits), while moving from a duopoly to monopoly would generate a small price rise due to the initial imperfectly competitive market.

This model raises several questions that must be addressed through assumptions about behavior and/or market parameters in order to work through even this simple context. Consider these in terms of both sides of the market.

#### *Demand Issues*

First, are the domestic and foreign goods perfect substitutes in demand or imperfect substitutes? Subramanian assumed the former, so that the foreign good has no advantage in terms of perceived quality or brand-name loyalty. Of course, brand-name loyalty could attach to the domestic good as well. In the model neither the foreign firm nor the domestic firm(s) engages in any marketing, advertising, or selling through intermediaries (such as insurance companies, hospitals and doctors) that would affect demand elasticities or substitution possibilities. Clearly this is an extreme assumption and one that needs to be considered carefully in applied work.

Second, are there other drugs that could offer substitution possibilities, such as those using an off-patent molecule in the same therapeutic group? As we will see later, this is one of the most critical issues determining price and welfare impacts of patents. Subramanian ignored this possibility, permitting him just to consider a single market demand. Thus, given the absence of substitution, the only demand elasticity needed is that for the overall demand curve of the product.

Raising the third question: what is a product? In the pharmaceutical industry this is a deep question, associated with aggregation bias, as will be discussed below. However, because Subramanian only had available rough data on aggregate sales of pharmaceuticals in Argentina and India, he assumed the entire market could be treated as a single product with one demand elasticity, an approach virtually guaranteed to overestimate welfare losses from patents by substantial margins.

Finally, what is the appropriate price elasticity? Even in a perfect-substitutes model with a single product it is important to understand the determinants of demand responsiveness, for the higher is the elasticity the lower is the price hike (but the greater the reduction in sales for a given percentage price increase) and the lower the welfare loss. A related question is whether the

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<sup>3</sup> A. Subramanian, "Putting Some Numbers on the Pharmaceutical Debate," *International Journal of Technology Management* (1994): 1-17. Other first-generation studies worth mentioning were J. Nogues, "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries," *The Developing Economies* (1993), 31: 24-53; and P. Challu, "The Consequences of Pharmaceutical Product Patenting," *World Competition* (1991) 15: 65-126.

researcher wishes to assume a linear demand curve (in which elasticity rises as price rises) constant-elasticity demand curve (one that is hyperbolic and for which elasticity remains the same as price rises), or something else. If demand is linear then elasticity is variable then computing price and quantity changes in more than a marginal sense is misleading.

Rather than attempt to find estimates of demand elasticity, the most critical parameter of all (which would not be very meaningful in any case given the aggregation issue), Subramanian simply adopted standard assumptions of -0.75 (inelastic, or price insensitive), -1.0 (unit elastic), and -2.0 (elastic, or price responsive) and applied them to a linear demand curve, hoping that these would capture the potential price and welfare impacts.

#### *Supply-side Representation*

Equally important is the set of assumptions about how firms are organized and react to changes in the competitive environment. There are at least two basic questions to be addressed in such models.

First, what is the market structure, before and after patent protection? As noted above, Subramanian made two extreme assumptions: moving from domestic perfect competition to foreign monopoly and from domestic vs. foreign duopoly to foreign monopoly.

Second, what are the cost structures of these firms? In general, pharmaceutical companies, whether research-based international firms or local imitative firms, face both fixed costs of entry and marginal costs of production, though such costs are likely to be quite different between firm types. It is rarely possible to find information on fixed costs for a particular market and no studies I have found take that question seriously. While this is a significant omission (when thinking about generic entry after patent expiry) because of the strong heterogeneity of firms and markets, to date it really cannot be helped. Studies focus instead on marginal cost of production (and distribution) for all firms involved.

Having information about marginal costs is important for at least three reasons. (1) Marginal cost is often a parameter used to calibrate or compute price, given the demand elasticity and some concept of markup power. For example, equilibrium under monopoly occurs where marginal revenue equals marginal cost. (2) Marginal cost is a central parameter in determining profits of foreign and domestic firms for welfare purposes. (3) Marginal cost relative to price determines the likelihood of entry and exit. Thus, studies of this kind cannot ignore cost questions on the supply side.

There are two distinctive conceptions of how to deal with marginal costs at this simple level of analysis. First, within a given market, are firms' marginal costs constant or rising? Given the difficulty of finding information at all, it is common to assume constant marginal costs and make some assumption to identify them. Subramanian assumed constant marginal cost at given levels of technology for the monopolist and, since he was interested only in computing relative *changes* in prices and profits, did not need a parametric value for it. However, it could be that a monopolist (post-patent) would move backward down its (rising) marginal cost curve, affecting

the rents calculation.<sup>4</sup> This would be the case if the local market was large enough to affect its cost structure.

Actually, Subramanian took a different, pseudo-dynamic view, of marginal cost. He simulated two possibilities regarding market size for each of the market-structure assumptions. First, suppose the economy is sufficiently small that the foreign firm would not find it worthwhile to invest in R&D as a result of patent protection, leaving it with a constant marginal cost pre- and post-patent. Second, suppose the economy is sufficiently large that the patent-owning firm would invest in better process technology and/or distribution systems, reducing its marginal cost of supplying the market by 50 percent. This assumption clearly reduced the computed welfare losses for the expanded foreign supply capability would moderate any price increases from the small country case.

### *Results*

With this description, Table 1 shows Subramanian's computed partial-equilibrium percentage price increases in India (base year 1990) and annual welfare losses in billions of US dollars from "overnight" patenting. Keep in mind that these calculations are based on a single pair of figures: the size of the patented and unpatented drug markets in India in sales values. Looking at the table, in the "small country" case price would rise by 67% under inelastic demand but just 25% under elastic demand, assuming perfect competition. The welfare declines would be \$2.58 billion and \$0.97 billion, respectively, which are large figures in the context of the Indian market. These losses are entirely on the consumer side because eliminating domestic perfectly competitive firms would not sacrifice any home profits. In contrast, price increases when the initial market is a duopoly are smaller, though there are larger welfare losses due to the loss in profits of the eliminated domestic firm. Finally, in the "large country" case where the foreign firm reduces its costs arbitrarily by 50%, the price increases are smaller (and there is a price decline in the duopoly case). Welfare would still decline (except where there was no price increase in the competitive case) due to higher consumer price and lost home profits in the duopoly.

Subramanian is careful to point out that these figures should be treated cautiously for a number of reasons. An important omission is any treatment of time. Clearly large changes in patent regimes do not happen overnight; nor are market structures changed so radically overnight. Rather, these kinds of impacts would be phased in over a period of years, largely because it would take some time for new patent applications to be granted and marketing approved under exclusive rights. Thus, the welfare costs listed may not begin to accrue for 10 or 15 years by his approach. But considering future paths of costs immediately raises the question of what would happen to growth, incomes, and a multitude of other factors. His back of the envelope calculation, discounting the sum of future (post-ten year period) losses to the present, was around \$8.8 billion.<sup>5</sup>

These calculations cannot be given any credence. His point is important, however: researchers should be clear on the time path of policy reforms and the elasticity of response of foreign firms

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<sup>4</sup> A simple model explaining such calculations is in K.E. Maskus and M. Penubarti, "Patents and International Trade: An Empirical Study," in K.E. Maskus, P. Hooper, E.E. Leamer, and J.D. Richardson, editors, *Quiet Pioneering: The International Economic Legacy of Robert M. Stern*, (Ann Arbor: University of Michigan Press), 1997, 95-118.

<sup>5</sup> He did not seem to consider the shorter-term impacts of exclusive marketing rights.

to their new patenting opportunities. Finally, note that he assumes all foreign profits are repatriated (and therefore lost to domestic welfare when they might be partially recovered through taxes) and that there are no price controls.

### **Maskus - Eby Konan**

Having laid out the critical issues facing such studies, I can briefly cover a second early study, by myself and a former student.<sup>6</sup> Their contribution was to add a richer market structure, one more consistent with prevailing literature. In particular, they added the possibility that a foreign potential patentee is actually a dominant firm facing a local fringe of copying firms (which would be eliminated by patent protection) and one of legitimate competitors selling a closely substitutable drug (and these would remain in the market). However, rather than adding a parameter for the cross-elasticity of substitution between the monopolized good and the legitimate competitor drugs, they misleadingly assumed these goods were perfect substitutes.

Otherwise their calculations were similar to Subramanian's (including constant marginal cost) and used the same basic data points. Their results may be summarized as follows. In the baseline case of perfect competition shifting to monopoly, they found welfare losses corresponding to Subramanian's. However, the addition of a copying fringe and a legitimate fringe forced the foreign firm to optimize along a residual demand curve with higher demand elasticity than the market demand curve. The result was a substantially muted price increase, ranging from six to eleven percent and a considerably smaller loss in consumer surplus. In fact, there was some offsetting gain in profits for the legitimate fringe companies that remain in the market. Consequently, across the various cases the consumer welfare losses ranged from \$1.2 billion to \$223 million. All of these results were sensitive to linear demand and the assumed demand elasticities.

In truth the Maskus - Eby Konan paper was not much of an improvement over Subramanian. It did, however, bring into the calculations the notion that firms would continue to face domestic competition, even after achieving patent protection. While the way this was done was inexpert, it anticipated the next generation of models, which take product substitution seriously.

Before summarizing, a further point is that both Subramanian and Maskus - Eby Konan computed gains in foreign profits. Subramanian thought they would be large enough in the Indian market to induce some additional international R&D for local needs. However, the latter authors found far smaller profits and noted that, spread across the number of international pharmaceutical companies, the expected gain per firm would be relatively small. Their conclusion for induced innovation was pessimistic, a finding that continues in the literature today.

### **Summary**

Studies of this "first generation" kind clearly should not be taken seriously for policy purposes, nor were they designed to be more than illustrative. They do have the particular advantage of being simple to implement and understand, while requiring very little data other than a market-sales figure (preferably averaged over a series of years) and guesses about elasticities and costs.

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<sup>6</sup> Keith E. Maskus and Denise Eby Konan, "Trade-Related Intellectual Property Rights: Issues and Exploratory Results," in Alan V. Deardorff and Robert M. Stern, editors, *Analytical and Negotiating Issues in the Global Trading System* (Ann Arbor: University of Michigan Press), 1994, 401-446.

With sufficient sensitivity analysis one can at least determine the direction of change in static gains and losses from a policy change.

However, the disadvantages are severe, starting from the obvious point that partial-equilibrium studies of a single product say little about the overall pharmaceutical market. Particularly missing in this context is any notion of the importance of product-level substitutability. Further, the results are driven by elasticity values, so more effort needs to be made to find confident estimates of relevant parameters. Next, the models are not well suited to thinking about the impacts of large changes in policy, as a shift in regime clearly is. In part this is because a single elasticity assumed on an unchanged demand curve cannot capture more than marginal changes in market conditions. Nor can such models easily consider other important factors: insurance markets, the costs of providing drugs through medical clinics, and the like. Finally, of course, such models are inherently static despite their claims that "small" or "large" profit gains would have some effect on R&D.

### **3. Second Generation Partial Equilibrium Models**

While remaining firmly within the simulation of a partial-equilibrium framework, two articles from around the year 2000 considerably improved upon the prior work by carefully modeling the possibility of drug-level and therapeutic-level substitution. Because space is limited, I will review closely only one of these, by Carsten Fink. However I begin with some comments on the interesting paper by Jayashree Watal, because it makes additional important points.<sup>7</sup>

As soon as one recognizes that drugs are complex products that do not exist in a vacuum, it becomes important to undertake the analysis at a detailed level, for doing so raises several issues that improve the credibility of the work. Again, it is worth discussing these in analytical terms by listing the questions before reviewing the work.

#### **Watal**

Jayashree Watal explicitly noted that it is difficult to compare prices of drug baskets across countries because of differences in market structure, patent coverage, dosages, formulations and other elements, a fact that is widely discussed in the pharmacoeconomics literature. Thus, she analyzed Indian pre-patent data at the molecule level, where in each of 22 molecules there were a different number of domestic firms and foreign-related enterprises. This permitted a richer treatment of market structure, including calibration of markups over marginal costs. Some of these molecules were on patent in the EU and some were not, permitting a nuanced "overnight patent" scenario across cases.

Watal added two important analytical points to this simulation literature. First, by considering explicitly the number of firms, and the concentration of sales, in India pre-patent she demonstrated that the usual assumption of perfect competition was incorrect. She calibrated elasticities of demand by using prices and initial market structure, allowing them to vary across molecules. On the supply side she permitted no entry and assumed constant marginal costs.

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<sup>7</sup> Carsten Fink, "Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry," *Journal of Industry, Competition and Trade* (2001) 1: 101-121. See also Jayashree Watal, "Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement," *The World Economy* (2000) 23: 733-752.

Next, she introduced substitution between patented drugs and other drugs that would not infringe the patent because they exist in a closely related therapeutic area. This was done in an ad hoc way that probably overstated the amount of true substitution that would emerge between molecules as a result of patents imposed on some. More importantly, it still permitted her to consider only single elasticity parameters along either a linear demand curve or constant elasticity demand curve.

Because of these two changes (oligopoly pre-patent market structure and substitution between patented and non-patented goods), her calculated price increases were small under linear demand but quite large (an average of 242%) under constant-elasticity demand. These latter price changes are not unreasonable given the differences between unpatented prices in India and patented prices in Pakistan and Malaysia. However, welfare losses were far lower than those found by Subramanian, especially using linear demand. In particular, her consumer losses ranged between \$11 million and \$67 million, with total welfare losses for India ranging from \$50 million to \$141 million. Foreign profit transfers would be correspondingly small, especially per pharmaceutical firm, causing her to doubt there would be any induced R&D from abroad or transferred to India.

Watal went on to consider the scope for beneficial government intervention through price controls and compulsory licensing. Applying the particulars of the 1995 Price Control Law in India to those molecules among the 22 studied that had large simulated price increases, she found that straightforward controls could reduce the weighted average price by 41% compared to the post-patent level. However, she was worried about high administrative costs and corruption that might result. This led her to recommend reliance on selective compulsory licensing that could generate 10% market shares for domestic licensees, with a substantial price-reducing impact of perhaps 30 to 60% from the patent equilibrium. Note that, to the extent that "TRIPS-Plus" means that governments cannot engage in compulsory licensing, this is one loose calculation of the potential impacts.

## **Fink**

Carsten Fink went considerably beyond this level to consider seriously the role of product substitution in drugs. Before considering his work it is useful to explain the nature of such effects by considering the demand side of a drugs market. This will be a general description; specifics can be extraordinarily complex depending on regulations, customs, and related factors. The discussion will help understand both aggregation and substitution issues.

At the top level, molecules, or chemical entities, that treat the same disease are classified into therapeutic groups.<sup>8</sup> Two molecules may not work with exactly the same effect but they are therapeutic substitutes. Typically, a doctor would choose which chemical entity to prescribe because she would have more information about side effects, problems when there are multiple therapies in use for a single patient, and the like. This is an important issue for often doctors are not price-sensitive, nor are they concerned with patients' budgets. Thus, there may be rather limited substitution at this level, unless patients must pay out of pocket.

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<sup>8</sup> Molecules may be discovered later to work as treatments for other indications, which is why they may be eligible for patent extensions.

A primary point here is that these *molecules* are the active ingredients that may be patented as treatments. Some chemical entities may be on patent and some may have seen their patents expire. Thus, substitution at this level is an important feature of demand, particularly as prices change. When a patent is granted for one molecule within the group, doctors and patients may switch to other similar treatments.

Within any molecule there may be multiple brands, associated with firms producing an identical chemical. If the molecule is patented, only the patent owner can produce it or license it, suggesting that there will be just one brand or a limited number of competing brands.<sup>9</sup> However, if the patent has expired, or the molecule was not eligible for patent coverage (as in India prior to 2005), many generic firms may produce the chemical formulation and sell it under their names. Competition here depends on first-mover advantages and brand-name loyalty but generic competition rather quickly can drive market price to close to marginal production and distribution cost.

Thus, there are two levels at which substitution is important: choosing a particular brand, which depends largely on price and loyalty, and choosing an active drug (molecule), which depends on the doctor's diagnosis and perhaps a pharmacist's choice. The research analyst should take this complexity into account for otherwise she is likely to considerably overstate the potential price hikes from thinking of a patented market as truly monopolized.

Thus, Fink modeled this problem as a two-stage decision-making process for a patient with a fixed budget and a well specified utility function.<sup>10</sup> At the top level, a budget is allocated to each therapeutic group, then expenditure within the group is determined by a sub-utility function. For that he assumed a constant elasticity of substitution (CES) nest among molecules, which imposes the same elasticity across all pairs of entities. Then, given expenditure on each molecule (which varies by market shares), purchases of individual brands also depend on a CES specification with the same elasticity across pairs of brands. This structure explicitly permits brands to be imperfect substitutes for each other (largely for marketing reasons) and molecules to be imperfect substitutes as well (largely for therapeutic reasons, though price would matter). This is a strong set of assumptions but it does permit identification of shifts in consumption as a function of individual market shares, prices, and elasticities. In effect, Fink used this utility specification to solve for a demand curve for brand *j* in group *i* with the following general form:

$$D_{ij} = F[\text{market shares; elasticities; income; price indexes for therapeutic group, particular molecule, and brands}]$$

This is a far more realistic and flexible specification than that in the earlier models. At the same time it demands much more information on brand-level market shares, number of firms, prices, and substitution elasticities at the brand level and molecule level, and demand elasticity at the therapeutic group level.

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<sup>9</sup> An exception is supply coming from parallel imports, which I discuss later.

<sup>10</sup> There is a third-stage, at which a consumer may choose to reduce consumption of other goods (eg, housing and food) in order to afford drugs at all but that was not taken into account in the data.

On the supply side, Fink assumed constant marginal costs for both potential patent holders (transnational corporations, or TNCs) and domestic generic companies in India. He did introduce fixed entry costs in order to calibrate the model to an endogenous number of Indian firms pre-patent.

The analysis involved choosing a set of elasticities at each level for molecules in two therapeutic groups in 1993, using actual market data in India. One group was quinolones (anti-biotics) with four molecules on patent in the EU and one off patent. The second group was synthetic hypotensives, with two on patent and nine off patent. Of course, none was patented in India. He chose these because the molecules were not subject to price controls and there was substantial entry of domestic firms. In the absence of independent data on elasticities, Fink assumed different values for two of three key parameters and calculated the third to data on markups, assuming constant marginal costs. The substitution elasticity was highest at the brand level (3.5 or 5.5) and lower at the molecule level.

The policy exercise was to remove the brands in the on-patent molecules and compute the implied effects on prices, welfare, and profits. This required an estimate of marginal costs for TNCs, which was unavailable, so he assumed they were the same as the average for domestic companies, thereby ignoring trade and distribution costs. The simulations of the multiple-stage CES specification required a numerical procedure for convergence. Representative results for quinolones are given in Table 2. It is immediately seen that the extent of simulated price increases depends critically on elasticity assumptions. Where there is low substitution among molecules, price increases are around 200% to 300%, but a higher degree of substitution at this level moderates the price rises to around 21% to 46%. Thus, it is critical for the analyst to model substitution at the molecule level. Note also that the welfare losses (measured here as compensating variation in income for consumers to remain equally well off after the patent as before) are simulated to be considerably smaller than what Subramanian found (1.8 billion Rupees is smaller than \$2.6 billion in fairly comparable cases, though the latter was looking at the entire market).

Overall, Fink's contributions were to expand the sophistication of demand modeling in this area. Failure to do that risks misleading overestimation of potential price increases and welfare losses. One additional feature of this work, which is not well brought out, is that there is an additional loss in terms of product variety reductions with the introduction of patents. This effect cannot be calculated but is one subject of the following paper.

#### **4. Current Econometric Analysis**

Despite the advances made in these more recent simulations, the analysis suffered from a number of remaining shortcomings. First and foremost, the elasticity values were assumed rather than estimated, a fact that calibration to a single guesstimate about operating markups does not change. It would be more informative to permit the data to reveal elasticity values subject to a structural model of utility maximization with multiple levels of substitution. Similarly, the analysis had to assume constant marginal costs in order to compute impacts on profit within a limited model of supply response. Third, simply assuming or calibrating parameter values fails to assign standard errors to the results, lending a false sense of certainty about them. Again, a structural model of the pharmaceutical market could be developed to estimate econometrically the relevant demand and supply parameters and assess the dispersion in these estimates.

A current working paper by Chaudhuri, Goldberg and Jia achieved progress in such structural modeling.<sup>11</sup> Econometric estimation may be done with high-frequency price and sales data, which the authors did for the therapeutic group quinolones in India using monthly data from January 1999 through December 2000. Having estimated the relevant parameters they computed the results of a similar counterfactual to Fink's. Specifically, some molecules were on patent in the United States and some were not, permitting them to remove the domestic supply of drugs in the patented segments and work through impacts on prices, sales, profits, and product variety. All of this is consistent with underlying utility theory, supporting computation of an appropriate welfare change measure. Further, they decompose the welfare results in a way that is informative about what would happen if the Indian government retained sharp price controls on patented quinolones.

Thus, this paper offers the first (and only) rigorously derived estimates of the potential impacts of product patents on prices and welfare in a developing nation, taking full account of therapeutic and brand-name substitution. This was done by estimating the parameters of market-share equations for each molecule in the quinolone group simultaneously using the Almost Ideal Demand System (AIDS) of Deaton and Muellbauer.<sup>12</sup> This demand system implements two-stage budgeting in a theoretical framework similar to Fink's. It is a "flexible functional form" that can generate consistent elasticity estimates across stages and products, rather than imposing them externally. However, it is computationally demanding, requiring the authors to limit the scale of the estimation problem through certain aggregation choices and identifying restrictions. In that sense it is not fully flexible, albeit an advance over choosing parameters.

Some comments on the aggregation problems are in order. The authors worked with highly detailed data from an extensive survey, covering prices and sales of products varying by brand, dosage, concentrations, and packages. Trying to identify demand parameters at that level is impossible, so they aggregated products to standard dosages for oral indications. This imposed measurement error in the data series, which they accounted for through their estimated error structure.<sup>13</sup> Next, because the time-series period was fairly short they were forced to aggregate brands into all foreign-sourced goods (imported and/or distributed by licensees of multinational enterprises) and domestic goods. The notion is that the former will become an aggregate monopoly, and the latter will disappear, with patent protection. However, it led to less detail at the lower-level elasticity estimation that would be preferred. A final observation is that to identify the demand functions requires some demand shifters. They proceeded by estimating separate intercepts in the share equations for four separate regions in India, arguing that demand levels may differ because of varying income levels.

With this structure, the task is to regress the revenue share of each quinolone on a series of price and expenditure terms. The parameters identified are a product group's own-price effect, the cross-price effects across product groups containing products using the same molecule but produced by domestic versus foreign firms, the cross-price effects for groups using different

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<sup>11</sup> S. Chaudhuri, P.K. Goldberg and P. Jia, "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India," *American Economic Review* (2006), forthcoming.

<sup>12</sup> A. Deaton and J. Muellbauer, "An Almost Ideal Demand System," *American Economic Review* (1980) 70: 312-326.

<sup>13</sup> Still, it is better than accepting the aggregation underlying market-level data.

molecules but made by firms with the same nationality, and cross-price effects of groups containing products of different molecules made by different nationalities. That is, a “product group” could contain foreign or domestic firms within quinolones, or different domestic and foreign molecules that substitute with quinolones. These parameters were estimated, along with expenditure elasticities for the quinolone molecule level. The upper-stage demand problem estimates substitution elasticities at the aggregated therapeutic level. From these various parameters one can compute demand elasticities.

In the absence of supply side data, they took a conservative approach to computing marginal costs of pharmaceutical firms. Thus, an upper bound for marginal costs would be perfect competition (zero markups), setting marginal cost equal to price by product group (eg, domestic molecule, foreign molecule). A lower bound would involve monopolistic collusion under joint profit maximization (assuming no price controls) and the maximum markup of price over marginal cost. This bound can be computed from the demand-side elasticity estimation and prices. The authors performed the policy counterfactuals with both bounds, noting that the lower marginal cost would correspond to maximum profit transfers abroad from patents.

A final econometric problem had to be faced, the endogeneity of prices in the demand system. They are endogenous to competition on the supply side, meaning that they cannot really be taken as exogenous in the demand system with revenue shares as dependent variables. To control for simultaneity bias, the authors used instrumental variables, taking as instruments the number of detailed package, dosage and formulation differences within each product group (these being a determinant of price variability without necessarily being correlated with error terms in the market shares). Other instruments included other exogenous variables in the system, regional dummies and regional-product dummy interactions.

They estimated this AIDS system for four quinolone molecules, three of which were produced by both foreign and domestic firms, leaving seven product groups. Standard errors had to be bootstrapped. Coefficient estimates are listed in the paper and not of particular interest here, other than to say that the instruments performed well, the system-level own-price and cross-price effects were theoretically sensible, and most were precisely estimated.

The main interest lies in the counterfactual exercises using the estimated parameters. They considered five scenarios in which they removed some or all of the domestic portions of quinolone production because of “overnight” patent protection. The welfare change was the standard compensating variation or the amount of income that Indian consumers would need to return to the original level of utility, given new prices:

$$CV = E(u^0, P') - E(u^0, P^0).$$

A particular novelty here was the decomposition of CV into three types of welfare impacts:

- a. A pure *product variety effect*, arising because some domestic products are no longer available, holding other prices and quinolones expenditure constant.
- b. An *expenditure switching effect*, in which consumers substitute away from quinolones to other sub-segments of anti-biotics, holding other prices constant.
- c. A *reduced competition effect*, arising from the market power given foreign firms when domestic competitors are removed.

Table 3 lists their estimated price impacts across the four product groups as a result of various withdrawal scenarios. Removing Cipro alone would drive up its own price by 189%, the price of Norflo by 315%, and the price of Oflo by 98%. It also would drive up the price of domestic Norflo by 149%, of domestic Oflo by 141%, and of domestic Sparflo by 164%. The price impacts of removing only Oflo would be somewhat smaller on average. Note that the price impact of removing all four quinolones on patent in the United States would be dramatic, with the foreign-product prices going up by between 318% and 628%. These are total impacts, allowing for both cross-segment expenditure switching and within-segment market power pricing.

A major advantage of structural estimation of the full relationships among competitors is that it is meaningful to simulate the effects of changes in exogenous variables, here the change in patent policy. In Table 4 I reproduce their estimates for consumer welfare losses, with the decomposition of the CV changes. Nearly all calculations were significantly different from zero. These results highlight the novelty of this paper. First, the total consumer welfare losses were larger than those in Fink and rise to a remarkably high level of nearly 18 billion rupees per year with all four domestic products forced out of the market.<sup>14</sup> Next, in most cases the largest portion of these losses was due to a loss in variety for consumers associated with the elimination of domestic versions of the goods. Because in this calculation prices were held constant, we might interpret the results loosely as indicating what would happen with patents and a strict price control regime that would not permit prices to rise. There would still be a noticeable loss in consumer welfare.

Also important were price increases within segments due to monopoly power. Finally, there was a small offsetting gain from expenditure switching to relatively cheaper quinolones.

In my view, this econometric analysis is the most credible of the available studies of the Indian market, where an attempt is made to consider the “overnight” patent counterfactual. It is a demanding exercise in terms of data availability and computational ability, but it points out important features of the demand side that need to be accounted for carefully. Unfortunately, it contributes little to our understanding of what might happen in dynamic terms from implementing stronger product patents. The authors did speculate a bit here. By their calculations the gains in foreign profits would be small relative to consumer losses and could not be anticipated to increase R&D incentives sufficiently to make a difference in domestic or foreign innovation.

## **5. The Impact of Parallel Imports**

One element of the "TRIPS-Plus" agenda is to encourage developing nations to establish a policy of national exhaustion in patents, closing their borders to parallel importation. Since parallel imports (PI) represent a potentially significant form of competition for on-patent drugs it is worth reviewing evidence on this question.

As a preliminary matter, medicines procured through PI are not generic drugs, which enter only upon patent expiration. Rather, they are the actual products, placed on the market by the patent holder in another country, either directly or through a licensee producer or wholesaler. Importing them is legal in a country where rights to control distribution are exhausted upon first sale anywhere (i.e., a policy of "international exhaustion"). This exhaustion doctrine could apply to

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<sup>14</sup> Total Indian welfare losses were somewhat higher because of profits foregone by domestic firms.

patents, copyrights, and trademarks differently or equally, depending on perceived economic interests in a country. Thus, PI drugs could compete either with on-patent medicines or off-patent brand-name medicines. They could even compete with branded generic goods if the price markup is high enough to make it profitable.

In a clinical sense, therefore, PI drugs are literally identical products to those protected by IPR. In market terms, however, they tend to sell at a discount relative to original-manufacturer products for a variety of reasons: coming from a different country the packaging and languages can differ, concentrations and dosages might vary, and hospitals and pharmacists in the importing nation may worry that PI firms cannot guarantee a stable source of supply. Drugs are traded through parallel channels by either specialized PI companies or wholesalers. PI undertaken at the retail level by individual consumers is rare and generally not sufficient to matter for prices or market volumes.

There is only one econometric study of the impact of parallel imports on original manufacturer drug prices in the importing country.<sup>15</sup> They analyzed a comprehensive set of prices and quantities for both original-manufacturer drugs (some on patent and all under brand names) and PI sales in Sweden over the period 1995-1999. This was a natural experiment to study because Sweden did not permit PI before joining the EU in 1995. Two of their central tables are reproduced below as Tables 5 and 6. Table 5 makes an important point about PI. Entry of PI firms and products rose rapidly after mid-1996, the time lag reflecting the approximately 18-month time lag for PI firms in achieving marketing approval from the Swedish Health Ministry. Remarkably, by 1998 fully 16 percent of sales of the top 50 molecules in Sweden were accounted for by PI, with this percentage ranging up to 72 percent for the highest-volume drugs. The implication is that, where legal and facing an efficient medical and regulatory infrastructure, PI competition can be an elastic source of competing drugs. However, PI firms generally target only the high-volume, "blockbuster" sorts of products. No one should expect much competition through this channel for smaller-volume drugs.

Table 6 provides the econometric results from the analysis. The authors regressed bi-weekly changes in the relative wholesale prices of original manufacturer drugs on the entry of PI firms, a dummy for the year 1995 and later, a time trend, and product fixed effects. Because of the clear endogeneity that would exist between entry decisions for PI firms and manufacturer prices, they performed a first-stage instrumental variables (IV) estimation to predict entry by product. As may be seen in Table 6, the econometric results suggest that the effect of entry by PI firms (DENTRYHAT) is to reduce original manufacturer's prices by between 12 and 19 percent.<sup>16</sup> This is a substantial impact and suggests an important cost savings for hospitals and pharmacists in Sweden.

The authors pointed out, however, that whether these cost savings are passed on to consumers depends on policies regarding price controls, allowable markups, and procurement decisions under that national health-insurance scheme. It would appear from other evidence that the Swedish government permitted hospitals and pharmacists to sustain a relatively constant retail

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<sup>15</sup> Mattias Ganslandt and Keith E. Maskus, " The Price Impact of Parallel Imports in Pharmaceuticals: Evidence from the European Union," *Journal of Health Economics* (2004), 23: 1035-1057.

<sup>16</sup> There was additional evidence that this price reduction would grow, though at a declining rate, with the number of PI firms that enter up to 4 entrants.

price, permitting them to enjoy larger markups on sales of both original manufacturer goods and PI products. Thus, the cost savings were to budgets (generally from the public purse) rather than to consumers.

The implications for this review are that PI drugs are a potent form of price competition at the wholesale level and health authorities may wish to consider carefully the wisdom of preventing such competition. However, whether consumers ultimately would benefit from PI depends on complementary regulatory policies. Further, the clinical and regulatory infrastructure in Sweden is presumably different from that in most developing countries.

## **6. Studies of Generic Entry and Drug Prices**

Because there are significant costs in organizing parallel imports, surely a more significant form of potential competition is from generic firms, which may enter the market either because a patent has expired or a compulsory license has shifted non-exclusive production rights to a domestic company. There are a few studies of how generic firms decide to enter markets upon expiration of a patent and what the effects are on brand-name prices and generic prices within a period of time. Virtually all of these studies were performed on U.S. data, where the institutional framework is different from that in most developing countries.

Rather than review the technical aspects of these papers in detail I will briefly mention their approaches and primary findings. The hope is that some lessons may be drawn about policy for encouraging generic entry, despite the unique aspects of American regulation and markets.

An initial article was by Grabowski and Vernon.<sup>17</sup> For this review the most important aspect of that paper was their observation that prior to the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") in the United States, generic firms often had to duplicate the pioneer's clinical trials to gain marketing approval. This cost significantly deterred entry even after patent expiration. The Act permitted generic firms simply to demonstrate bioequivalence using the patentee's test data, resulting in significant increases in generic entry post-patent. Further, the Bolar exception from a court decision was written into the law and permitted an early working exception to patent rights to encourage generic companies to be in a position to enter promptly after patent expiration. Both elements of this Act were important encouragements to generic competition in the United States.

The main econometric result found by Grabowski and Vernon, in a sample of 18 major products, was that generic firms enter rapidly into large-volume drug markets upon patent expiration and quickly command large segments of the markets. The impact was to reduce rapidly the prices earned by generic companies, with prices falling by more the greater the number of entrants, and to bring down average prices of drugs faced by hospitals and pharmacists. Specifically, generic prices fell by 22 percent of their initial level by the end of one year and by 35 percent after two years, with the average number of generic suppliers being 25 after two years. This entry quickly drove generic prices toward marginal cost.

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<sup>17</sup> Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act," *Journal of Law and Economics* (1992) 35: 331-350.

Surprisingly, however, after generic entry the prices of pioneer (brand name) drugs went up or did not decline over the same period. That is, post-patent the original manufacturers concentrated on selling small volumes to brand-loyal customers at even higher markups. The authors attributed this to "market segmentation" between original drugs and generic versions. This celebrated finding remains conventional wisdom in U.S. markets: generic entry rapidly diminishes prices of generics and takes large aggregate market shares from the pioneer drug. But the price of the latter would remain constant or increase due to brand loyalty, physician prescription practices, and advertising.<sup>18</sup>

Although the Grabowski-Vernon approach was naïve, relying on reduced-form regressions with no consideration of endogeneity, its basic result was confirmed in a broader study by Frank and Salkever.<sup>19</sup> Those authors estimated a first-stage entry regression to account for endogeneity between generic competition and original price and volumes and included product-level fixed effects in the second-stage brand-name price regression. They found that the amount of generic entry (sales) depended positively and significantly on the volume of patented sales prior to patent expiration. Again, generic companies, like PI companies, are interested primarily in competing in large-volume markets. They also estimated that generic entry actually increased average prices of pioneer drugs marginally but substantially reduced average generic prices. For example, increasing the number of generic competitors from three to six would reduce generic prices by between 17 percent and 22 percent.

A recent paper that improved the econometric analysis considerably is by Reiffen and Ward.<sup>20</sup> The authors constructed and estimated a system of structural equations in a model of dynamic competition in the generic drugs industry in the United States. The paper did not consider the prices of original patented drugs and therefore has nothing to say about the "market segmentation" issue. The analysis found that generic drug prices fall with increasing numbers of competitors but remain above marginal cost until there are eight or more generic products. Further, the number of entrants and their entry path over time is determined primarily by expected market size, meaning again that generic companies are interested mainly in competing for short-term rents in large-volume markets.

A final paper worth mentioning studied the Swedish generics market from 1972-1996.<sup>21</sup> That paper found in a basic regression setup that the quarterly change in market shares of brand-name drugs was significantly and negatively affected by the difference between originator prices and average generic prices. The authors concluded that physicians become more sensitive to the importance of switching to generics as this price gap grows. This finding is not surprising and the econometric specification was again rather naïve. Perhaps more interesting was the extended analysis, in which the authors found (for three of 12 drugs) that when the pricing authority relied

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<sup>18</sup> See Richard E. Caves, Michael D. Whinston, and Mark A. Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics 1991* for an earlier finding of this kind.

<sup>19</sup> Richard G. Frank and David S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics and Management Strategy* (1997), 6: 75-90.

<sup>20</sup> David Reiffen and Michael R. Ward, "Generic Drug Industry Dynamics," *The Review of Economics and Statistics* (2005), 87: 37-49.

<sup>21</sup> Thomas Aronsson, Mats A. Bergman, and Niklas Rudholm, "The Impact of Generic Drug Competition on Brand Name Market Shares -- Evidence from Micro Data," *Review of Industrial Organization* (2001), 19: 425-435.

on a reference pricing system (in 1993-96), involving setting maximum prices dependent on average prices in product categories, the market shares of original manufacturers was cut even more by generic entry. Given the reduced-form nature of the model and the small number of cases where this effect emerged, I believe it would be a mistake to assign any policy relevance to this finding, however.

The basic messages from this review are evident. First, generic competition has a substantial impact on average drug prices in the market, but the price-level competition is largely among the generic producers. The original brand name drugs see their prices rise (or not fall by much) as they sell into much smaller market segments with inelastic demands. Second, generic companies compete only in large-volume drugs where there are substantial economic rents to earn for a period of time. Generic competition is unlikely to provide downward price pressure in smaller-volume drugs developed for specific treatments. Third, reference pricing systems may be complementary to generic entry in bringing down average prices though this finding is tentative at best.

I end this sub-section by pointing out that the U.S. (and Swedish) markets are quite different from those found in most developing countries. For example, there are no studies of which I am aware that focus on generic competition established by compulsory licensing and whether that entry has reduced market prices. More significantly, insurance markets, price regulations (or their absence), and government health provision policies are important factors underlying price impacts.

## **7. Patents in Developing Countries and Induced Innovation**

One of two final questions to address briefly is emerging evidence on whether stronger patents may encourage more R&D in developing countries aimed at the diseases of poor countries. The question seems significant for this literature review for a final form of potential competition is innovation from firms in emerging markets as patents are strengthened.

The early evidence is not encouraging but neither is it definitive. There is just one paper to review that considered this issue carefully.<sup>22</sup> The authors used survey data from India, interviews with industry officials and government officials, and measures of R&D activity to consider whether global research funds were being allocated to products specific to developing-country markets in the 1980s and 1990s. They found limited evidence of an increase of funding for such needs in the U.S. National Institutes of Health in the late 1980s but a leveling off in the 1990s. Further, surveys found little indication that Indian generic companies would seek to turn themselves into developers of drugs for developing-country markets. This is hardly surprising, since those firms presumably attempt to maximize profits. However, the analysis was performed long before TRIPS patent provisions were put into place and a new project seems in order.

The other question is whether stronger patent protection might be expected to result in more rapid launch of internationally patented drugs in developing countries. There is one important review of this possibility, which analyzed whether patent rights and price controls affect marketing of

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<sup>22</sup> Jean O. Lanjouw and Iain Cockburn, "New Pills for Poor People? Empirical Evidence after GATT," *World Development* (2001).

new drugs.<sup>23</sup> This is a critical question that we know little about in developing countries. This study included a sample of both developed and developing nations and looked at drug launches over the period 1982-2002. In a well developed statistical framework, Lanjouw found mixed evidence about the basic question. However, overall it seemed that price controls tended to discourage rapid product entry, while the impacts of patent rights were unclear. The existence of a local capacity to innovate (or imitate) tended to speed up entry of new drugs by a marginal amount.

Thus, the suggestion from this analysis is that, to the extent developing countries are interested in having new international drugs placed quickly on their markets, price controls may be of questionable value. A more nuanced view would be that health authorities may wish to distinguish between new drugs with critical applications to domestic patient needs and other drugs when it comes to price regulation.

## **8. Lessons about Modeling and Parameter Needs**

Following are some conclusions from the literature about modeling needs. I do not consider these to be exhaustive. Rather, they are central points that are supported by prior empirical work but need to be supplemented by facts and wisdom about broader policy and institutional factors.

To the extent possible, analysts should use market data to estimate the relevant demand and supply parameters, rather than use guesstimates about elasticities in partial-equilibrium models. The main reasons are that such estimates provide a better picture of real tradeoffs in drug markets and support policy analysis better than the simple simulation approach.

The last point implies that analysts should invest resources in data and modeling that can credibly support econometric estimation.

Pharmaceutical products do not exist in a competitive vacuum. There are multiple levels of substitution that may provide effective price competition to patented drugs. It is important for the analyst to take a comprehensive view of market participation, rather than analyze single drugs in isolation.

A related point is that the definition of what is a product and, therefore, the level of aggregation at which the analysis will be undertaken, is crucial for understanding the scale of potential pricing problems and for elasticity estimation and/or selection.

One significant impact of patent protection could be a reduction in product variety available from generics, which is an important element for analysts to take into account.

Analysis needs to pay attention not only to price setting by drug firms but also to the institutional setting within which competition happens. Insurance markets, prescribing practices, price and return regulations, and marketing approval mechanisms all matter for the timing and impacts of monopoly pricing and generic competition.

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<sup>23</sup> Jean O. Lanjouw, "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry," University of California Berkeley, working paper (2005).

**Table 1. "First Generation" Estimates of Price Changes (%) and Welfare Losses (\$ billion) in India from Patent Introduction, 1990: Subramanian**

Market Size	Small		Small		Large		Large	
Elasticity	-0.75		-2.0		-0.75		-2.0	
	Price	Welfare	Price	Welfare	Price	Welfare	Price	Welfare
<i>PC to Mon.</i>	+67	-2.58	+25	-0.97	+42	-1.83	0	0
<i>Duop to Mon.</i>	+33	-4.95	+17	-1.87	+25	-4.61	-7	-0.95

**Table 2. Selected Simulation Results for Price Changes (%) and Consumer Welfare Losses (in millions of Rupees) in Quinolones, 1993: Fink**

	= -1.5				= -2.5			
	$\sigma = 1.1$		$\sigma = 2.0$		$\sigma = 1.1$		$\sigma = 2.0$	
$\phi = 3.5$	Price	Welfare	Price	Welfare	Price	Welfare	Price	Welfare
Ciprofloxacin	+234		+46		+119		+31	
Norfloxacin	+252		+43		+141		+30	
Pefloxacin	+353		+36		+268		+27	
Ofloxacin	+319		+21		+309		+21	
Total		-1810		-1286		-827		-744

Note:  $\epsilon$  is the elasticity of demand for the quinolones group;  $\sigma$  is the substitution elasticity among quinolones;  $\phi$  is the substitution elasticity among brands. Welfare is measured as the compensating variation in income.

**Table 3. Counterfactual Estimates of Drug Price Changes (%) after Patents Introduced, 1999-2000 Base (Chaudhuri, Goldberg, Jia)**

Scenario	All Price Adjustments and Expenditure Switching						
	Foreign Product Groups			Domestic Product Groups			
	Cipro	Norflo	Oflo	Cipro	Norflo	Oflo	Spar
<i>Withdraw:</i>							
C only	189	315	98	WD	149	141	164
O only	100	150	103	102	108	WD	111
C,O,N	248	628	154	WD	WD	WD	296
C,O,S	255	628	158	WD	250	WD	WD
C,O,N,S	396	628	318	WD	WD	WD	WD

Note: C is Ciprofloxacin, O is Ofloxacin, N is Norfloxacin, S is Sparfloxacin. WD refers to products withdrawn from the domestic supplier market.

**Table 4. Counterfactual Estimates of Consumer Welfare Losses (billions of rupees per year) after Patents Introduced, 1999-2000 Base (Chaudhuri, Goldberg, Jia)**

Scenario	Variety Loss	Expenditure Switch	Price Adjustment	Total
<i>Withdraw:</i>				
C only	-4.98	+0.06	-2.40	-7.32
O only	-0.08	+0.00	-0.15	-0.23
C,O,N	-7.52	+0.12	-5.13	-12.53
C,O,S	-6.14	+0.11	-4.55	-10.58
C,O,N,S	-11.77	+0.41	-6.45	-17.81

**Table 5. The Pharmaceutical Market in Sweden 1995-1998**

Sweden	1995	1996	1997	1998
Gross Domestic Product (MSEK)	1,649,922	1,688,200	1,738,859	1,816,042
Total pharmaceutical sales (MSEK)	13,393	15,808	14,263	16,567
Sales of top 50 molecules (MSEK)	4,576	5,977	5,201	6,203
Top 50 as share of total sales	34%	38%	36%	37%
Parallel imports (MSEK)	0	>0	269	1,007
Parallel imports of top 50 (MSEK)	0	>0	269	920
Parallel imports/Total sales	0%	0%	2%	6%
Parallel imports/Top 50 sales	0%	0%	5%	16%
Total number of PI approvals	0	1	45	226
PI approvals for top 50 molecules	0	1	31	131
Total number of PI firms	0	1	4	10

Sources: SCB, LIF, MPA

*Taken from: Ganslandt and Maskus, JOURNAL OF HEALTH ECONOMICS (2004).*

**Table 6. Estimated Impacts of PI Entry on Original Manufacturers' Prices Using Instrumental Variables Estimation**

Variable	IV-FE (5)	IV-RE (6)	IV-FE (7)	IV-RE (8)	IV-FE (9)	IV-RE (10)	IV-FE (11)	IV-RE (12)	IV-FE (13)	IV-RE (14)
DENTRYHAT	-0.1890 (-11.3)***	-0.1796 (-11.0)***	-0.1913 (-11.4)***	-0.1735 (-10.8)***	-0.1715 (-10.3)***	-0.1663 (-10.1)***	-0.1300 (-10.2)***	-0.1208 (-9.84)***	-0.1661 (-9.03)***	-0.1386 (-8.33)***
D1995	-0.0172 (-7.99)***	-0.0163 (-7.70)***	-0.0175 (-8.06)***	-0.0157 (-7.51)***	-0.0157 (-7.35)***	-0.0152 (-7.20)***	0.0033 (1.32)	0.0047 (1.93)*	-0.0047 (-1.15)	-0.0001 (-0.02)
TREND	0.0010 (26.5)***	0.0010 (26.5)***	0.0010 (26.6)***	0.0010 (26.6)***	0.0010 (25.7)***	0.0010 (25.7)***	0.0008 (16.0)***	0.0007 (15.8)***	0.0011 (14.2)***	0.0010 (14.0)***
CONSTANT	0.9844 (763.0)***	0.9726 (113.6)***	0.9843 (760.4)***	0.9733 (175.7)***	0.9848 (775.2)***	0.9730 (91.6)***	0.9875 (631.4)***	0.9745 (110.0)***	0.9763 (356.1)***	0.9628 (103.5)***
Observations	24751	24751	24751	24751	24601	24601	13138	13138	7234	7234
Products	196	196	196	196	196	196	196	196	196	196

Notes: in Models (5) and (6) the instruments are LAUNCHPER, QUANTLAG, and bilateral exchange rates with Italy, Spain, and Greece. In Models (7) and (8) the instruments are LAUNCHPER, SALES LAG, and the same exchange rates. In Models (9) and (10) the instruments are LAUNCHPER, QUANT1995, and the same exchange rates. In Models (11) and (12) the instruments are LAUNCHPER, MINRELPR, and the same exchange rates. In Models (13) and (14) the instruments are LAUNCHPER, SALES LAG, the relative prices in Italy and Spain, and the same exchange rates.

*Taken from Ganslandt and Maskus, JOURNAL OF HEALTH ECONOMICS (2004).*