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Abstract

This paper quantifies the effects of drug monopolies and low per-capita income on pharmaceutical prices in developing economies using the example of the antiretroviral drugs (ARVs) used to treat HIV.

Key words: intellectual property rights, international price discrimination, TRIPS agreement, pharmaceutical industry, markups

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1 Introduction

How much do drug monopolies increase prices in developing economies? The 1995 World Trade Organization's *TRIPS* agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), with subsequent amendments, requires enforcement of intellectual property rights (*IPR's*) in most developing countries by the year 2016. These *IPR's* include pharmaceutical patents that grant monopolies to produce and market a drug for a limited number of years. While there has been much public debate about the possible effects of the *TRIPS* agreement, there is little empirical evidence on how granting monopoly rights will impact prices in developing countries, particularly in the pharmaceutical sector, because of the difficulty in gaining access to accurate price and cost data.[1] On the face of it, the answer to this question of whether (patent-supported) monopolies will lead to higher markups – and so prices – appears obvious. In the context of developing economies, however, it is not as straightforward as one may initially surmise, as their lower per-capita incomes may discourage firms from charging higher prices. This paper tackles this question, developing an empirical approach to parse out the countervailing effects of low per-capita income and of drug monopolies on prices in developing economies, and applying it to the example of the antiretroviral (ARV) drugs used to treat the HIV virus.[2]

Recent developments make antiretrovirals a good case by which to gauge the impact of these two factors on drug prices. The unit costs to produce the drugs appear low enough for many individuals in developing countries to afford them. Production of generic variants of these drugs existed in some countries over the sample period (Brazil, India). Other countries had no or very limited access to generic variants from 2000 to 2003 (Tanzania, Uganda). These differences provide an opportunity to examine firms' markups in the presence and absence of competition, which is proxied for by the absence or presence of generic variants of each ARV. In addition, in the other features of their health expenditure systems, these two groups of countries appear quite similar, which facilitates identifying the effect of their different competitive environments on prices.

The paper introduces a new cross-country data set of ARV prices and uses it to estimate the drugs' price-cost markups without observing cost data. The price data come from a collaboration with the *Campaign for Access to Essential Medicines* run by the NGO *Médicins Sans Frontières* (MSF). The campaign gathers information on drug prices in developing countries for their own

[1] Notable exceptions include Chaudhuri, Goldberg, and Jia (2006); Challu (1991); Nogues (1993); Scherer and Watal (2001); and Watal (2000).

[2] HIV stands for Human Immunodeficiency Virus.

procurement needs and to produce policy reports. I find that markups are 50 cents higher per capsule in monopolistic than in competitive countries – compared to an average price of about 65 cents per capsule – after conditioning on cross-country variation in consumers' purchasing power. The next section reviews the *MSF* data, Section 3 introduces the model used to estimate markups, and Section 4 reports results. Section 5 concludes.

2 Data and Setting

The data include the import prices for each product sold over a period of four years, from 2000 to 2003, with a product defined as one unit (a single capsule) of a drug. Antiretrovirals inhibit the actions of enzymes *HIV* needs to reproduce, extending the length and quality of life of infected people. They are comprised of two classes, reverse transcriptase inhibitors and protease inhibitors (*PI*'s). The first class can be further divided into two sub-classes: Nucleoside Reverse Transcriptase Inhibitors (*NRTI*'s) and Non-Nucleoside Reverse Transcriptase Inhibitors (*NNRTI*'s). Therapies that combine drugs from both classes suppress the virus most effectively.

The price data fall into one of two country groups. The first includes African countries that did not have widespread availability of generic *ARV*'s over the sample period and so faced markups set by monopolistic firms: Originator firms were their only suppliers. Ethiopia, Kenya, Rwanda, Tanzania, and Uganda comprise this group. The second group includes countries with widespread availability of generic *ARV*'s in their domestic market over the sample period. This availability may have resulted from domestic generics manufacturing, as in Brazil, India, and Thailand, or from a permissive generics import policy, as in Cameroon. These countries faced markups set by competitive firms – firms operating in markets characterized by relatively free entry. These two country groups proxy best for monopolistic and competitive markets for the *NRTI*'s class of the *ARV*'s as generics firms manufactured all the drugs in this class over the sample period. Although the competitive countries extracted price reductions from originator firms for the *NNRTI*'s and *PI's* with the threat of generics production, over the sample period only the *PI's Indinavir* and *Nevirapine* were produced by generics manufacturers.

Table 1 reports the mean and standard deviation of the *ARV* prices across all the countries in the sample. The mean price of a capsule is \$0.67 (two capsules make up a daily dose for most of the sample *ARV's*), with a standard deviation of \$0.71, indicating significant price dispersion across countries. Given monopolistic and competitive countries' average per-capita annual incomes of 272 and 1411 dollars, respectively, holding the degree of competition constant one would expect

markups, and so prices, to be somewhat lower in the former than the latter.[3] So it is puzzling that the sample's average prices are roughly at par across the two groups – $0.69 per capsule in monopolistic countries and $0.65 in competitive countries. If purchasing power (per-capita income) were the only metric used by firms to set their prices, one would expect average prices to be much lower in the monopolistic countries given their significantly lower purchasing power.

In their reporting of such price comparisons, public-health advocates have tended to focus on the more counterintuitive country-pair price differentials for individual drugs, such as that for *Stavudine*, with an average sample price of $0.84 per capsule in monopolistic countries compared with $0.30 in competitive countries, an almost 200-percent difference, or *Nevirapine*, with an average price almost 50-percent higher in monopolistic than in competitive countries. In a sense, these types of price differentials are the crux of the policy debate over the relative effects of purchasing power and monopoly power in developing economies. Do originator firms account for these cross-country differences in consumers' purchasing power in setting their prices? Or do they exhibit insufficient price discrimination across countries with different per-capita incomes, as some public-health advocates charge?

For the sake of the empirical analysis, one would ideally like these two groups of countries to be nearly indistinguishable in their other characteristics, particularly those likely to affect drug prices, such as the nature of price regulation and the structure of health expenditure, and so the bargaining power of consumers – a government purchasing drugs for an entire population naturally has more bargaining power than do individuals each negotiating on his or her own behalf, for example. Over the sample period, there is no price regulation of antiretrovirals in any of the sample countries. (Some of the countries, such as India, do have price ceilings for a limited number of drugs over the sample period, but these do not cover antiretrovirals.) Regarding the structure of health expenditure, the *WHO*'s annual *World Health Report* compiles country-level indicators for major health-expenditure aggregates, breaking down each country's total health expenditure into government and private insurance (and other prepaid) programs and households' out-of-pocket expenditure.[4] Fortunately for the empirical analysis, these indicators either appear

[3] The GDP data come from the World Bank's *World Development Indicators*.

[4] The *WHO* data are collated from national and international sources and harmonized into a single framework using standard national accounts procedures, with a focus on low to middle-income countries. General government health expenditures is the "sum of outlays by government entities to purchase health care services and goods: notably by ministries of health and social security agencies" and private health expenditures include "total outlays on health by private entities" which include prepaid plans, private insurance, and the like. Household out-of-pocket spending is defined as the "direct outlays of households, including gratuities and in-kind payments made to health practitioners and to suppliers of pharmaceuticals, whose primary intent is to contribute to the restoration or the enhancement of

nearly identical across the two groups of countries, or differ in such a way as to promote *lower* prices in monopolistic countries. For example, total health expenditure as a share of GDP is 5.4 and 5.8 percent in the competitive and monopolistic countries, respectively, and the share of government health expenditures in total health expenditures is 33 and 38 percent, respectively. The key indicator to gauge consumers' bargaining power, the share of total health expenditure paid out of pocket, is 58 and 41 percent in competitive and monopolistic countries, respectively. Among competitive countries, India is a clear outlier, with an out-of-pocket share of 82.1 percent. If one excludes India, the average out-of-pocket share in competitive countries falls to 48 percent. In either case, the greater out-of-pocket share in competitive countries should result in higher prices there owing to consumers' lower bargaining power. This, in turn, suggests that the model's results will understate any differences in markups across monopolistic and competitive countries that may be attributed to their competitive environment, and so that its estimates may plausibly be regarded as lower bounds on those differences.

3 Model

This section describes the model used to estimate the price-cost markups. Suppose we observe demand for a product in two countries, country 1 and country 2. Let a market be the total demand for the product in one time period and in one country. Each country's demand is characterized by a representative individual. Let there be a monopolist that produces the market's only product and that chooses its price in each country to maximize its profits:

$$\Pi_t = (p_{1t} - mc_t)\, x_{1t}\,(p_1) + (p_{2t} - mc_t)\, x_{2t}\,(p_{2t}) \tag{1}$$

where p_{jt} is the price of the product in country j at time t, x_{jt} is the quantity demanded of the product in country j at time t, and mc_t is the marginal cost to produce the product which does not vary across countries. Assuming the firm sets prices to maximize profits, the price p_{jt} must satisfy the first-order conditions:

$$0 = x_{1t} + (p_{1t} - mc_t)\frac{\partial x_{1t}}{\partial p_{1t}} \tag{2}$$

$$0 = x_{2t} + (p_{2t} - mc_t)\frac{\partial x_{2t}}{\partial p_{2t}} \tag{3}$$

the health status of individuals... This includes deductibles and copayments but excludes contributions to pre-paid pooling schemes and the like," (*The World Health Report 2006*, p. 160).

This gives us a set of two equations, one for each product where $\frac{\partial x_{kt}}{\partial p_{jt}}$, j,k=1, 2, ..., J, is the change in demand for the kth country's product given a change in the jth country's price for the product. If markets are perfectly segmented, each market's price is a function of the marginal cost and the demand elasticity (or other features) of that market alone. One can rearrange equations (2) and (3) to express the price as a function of the marginal cost and a markup term:

$$p_{jt} = mc_t \left(\frac{\eta_j}{(\eta_j - 1))} \right) \text{ for } j = 1, 2. \tag{4}$$

where $\eta_{_1} = \frac{\partial x_1}{\partial p_1} \frac{p_1}{x_1}$ is the demand elasticity for the product in country 1. If one takes logs of this expression, one can identify the marginal-cost and the common cross-country component of the markup separately from the country-specific component of the markup in a simple fixed-effects regression model:[5]

$$lnp_t = \theta_t + \lambda_j + \zeta_{c,m} + Y_j + \varepsilon_{jt} \tag{5}$$

where θ_t is a time effect, λ_j is a country effect, $\zeta_{c,m}$ is a dummy that equals 1 if a country has a monopolistic market and 0 otherwise, Y_j is the average per-capita income in country j, and ε_{jt} is a regression disturbance. If one assumes imperfectly competitive firms, a reasonable model for the pharmaceutical industry, then the time effects capture common cross-country movements in the product's marginal cost and markups (the latter possibly due to non-constant price elasticities of demand) and the country fixed effects the country-specific component of the markup relative to the average, which is of most interest to policymakers. (Note that both the marginal cost and the markup terms can be estimated for each product without observing cost data.) In addition to these fixed effects, the model includes the average (over-the-sample-period) per-capita GDP, Y_j, to assess how the purchasing power of each country's resident affects prices, *conditional on* the degree of competition in the domestic pharmaceutical market. Likewise, it includes the competition/monopoly dummy $\zeta_{c,m}$ to gauge the effect competition has on markups in each country, *conditional on* its resident's average income. This model thus parses out the role of monopoly power versus purchasing power in determining each country's prices.

[5] The model adapts a methodology developed by Knetter (1989).

4 Results

Table 1 reports the results from estimation of the model as defined in equation (5): Its first four columns report results for each drug in the *NRTI* class, columns (5) and (6) for each in the *NNRTI* class, column (7) for these two classes pooled, and column (8) for all three classes together. The two pooled specifications constrain the marginal cost and markup terms to be common across drugs, and the coefficients have all been transformed to dollar terms from elasticities to facilitate the reader's intuition regarding their interpretation.[6] As reported in the second panel of Table 1, the estimated per-capsule marginal cost for each *NRTI* and *NNRTI* is positive and significant at the 1-percent level, ranging from \$0.15 for *Stavudine* to \$0.64 for *Efavirenz,* averaging \$0.28 across all the *NRTI*'s and *NNRTI*'s, and a bit more, \$0.33 in the final specification that includes the *PI*'s. The next set of coefficients report the markup per capsule that can be attributed to cross-country variation in purchasing power or in monopoly power. The per-capita GDP variable appears to be a significant determinant of prices for only about half the drugs in the sample – a finding which is consistent with the weak relationship others have found between *ARV* prices and per-capita income, e.g. Scherer and Watal (2002). Each \$100 increase in per-capita income results in about a 1 to 1.5 cent increase in the price of a capsule of *Didanosine*, *Lamivudine*, or *Efavirenz*. Similarly, as reported in column (7), the results for the pooled *NRTI*'s and *NNRTI*'s suggest that each \$100 increase in per-capita income increases the average per-capsule price by 1.1 cent (about 1.5 percent), a modest effect that is, however, significant at the 1-percent level. These results, in turn, imply that the average price of an *ARV* capsule is 12.5 cents higher in competitive countries due to their greater purchasing power than in monopolistic countries. Including the *PI*'s in the pooled sample reduces this difference to 11.4 cents.

This modest effect of purchasing power on prices contrasts somewhat with the fairly striking effect of monopoly power. The monopoly dummy is significant for five of the six *ARV*'s for which the model is estimated individually (the exception being the *NNRTI Efavirenz)*: It increases the

[6] As noted previously, the model cannot be estimated individually for each drug in the Protease Inhibitor (*PI*) class: These drugs were generally introduced later than those in the *NRTI* and *NNRTI* classes, and so were available in fewer markets over the sample period. As a result, there simply aren't sufficient observations (and so degrees of freedom) to include both the monopoly dummy and the country fixed effects in the model. One can, however, include the *PI* data as part of the final specification, whose results are reported in column (8) of Table 1. This specification imposes a single marginal cost and country-specific markup across all the drugs in the sample, which enables one to estimate the model even with the limited *PI* observations: The same assumption is made in the pooled *NRTI* and *NNRTI* specification reported in column (7), so the two sets of results are comparable. This does not appear to be an unreasonable assumption, given the similar magnitude of the marginal cost and markup estimates for most of the drugs for which these parameters can be estimated individually.

per-capsule markup from \$0.16 in the case of *Didanosine* to \$0.98 in the case of *Nevirapine*. The basic message from the two pooled specifications is of monopolistic countries paying a 50-cent higher average markup per capsule than competitive countries after conditioning on each country's purchasing power.

To the extent that policymakers are ultimately interested in whether *ARV*'s are affordable for residents of developing economies, it may be informative to use the model's results to compute the share of each country's per-capita income required to purchase an annual dose of each *ARV priced at its marginal cost and common international markup*. The last two lines of Table 1 reports this average share across monopolistic or competitive countries based on the most common treatment regimen for each *ARV*. Although the results vary considerably across individual drugs, the common message is of marginal costs (and common markups) that amount to about 20 percent of per-capita income in competitive countries, a substantial chunk of annual income, but one that may be manageable for many households. This contrasts with the over 90 percent share of per-capita income for monopolistic countries – which rises to almost 200 percent once one includes *PI*'s in the pooled specification, compared to a 37 percent share for competitive countries – and which, in turn, suggests that *ARV*'s do not lie within the means of an average household in monopolistic countries when they are priced at their marginal cost and common international markup.

5 Conclusion

This paper compares markups on *ARV*'s in countries with monopolistic drug markets to those with more widespread availability of generics. It finds that for *ARV*'s with an average per-capsule price of \$0.65, consumers in competitive countries paid \$0.12 more per capsule due to their greater purchasing power than did consumers in monopolistic countries and, more generally, that every \$100 increase in per-capita income corresponded to a 1-cent (about a 1.5-percent) increase in the average per-capsule price. The paper also finds that consumers in monopolistic countries paid on average \$0.50 more per capsule owing to firms' exercise of their monopoly power than did consumers in competitive countries. These results suggest a fairly modest responsiveness of *ARV* prices to consumers' purchasing power and a somewhat more robust responsiveness to firms' monopoly power. In the end, richer nations may pay a little more for drugs, but a lot more if a monopolist is supplying them. Finally, the paper's empirical approach and markup estimates may be useful for other researchers as they evaluate the impact of granting monopoly rights on prices, and consumers, in developing countries.

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	NRTIs				NNRTIs		NRTI's and	
	Didanosine	Lamivudine	Stavudine	Zidovudine	Efavirenz	Nevirapine	NRTI's	All
Summary statistics per capsule	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Average price ($)	0.46	0.50	0.48	0.29	0.95	1.30	0.64	0.67
standard deviation	(.45)	(.51)	(.69)	(.28)	(.64)	(1.39)	(.78)	(.71)
Regression results per capsule								
Marginal cost ($)	0.24	0.27	0.15	0.16	0.64	0.57	0.28	0.33
	(.04)***	(.03)***	(.05)***	(.03)***	(.15)***	(.16)***	(.03)***	(.03)***
Markup:								
per-capita GDP ($)	0.008	0.009	0.012	0.003	0.015	0.021	0.011	00.10
	(.004)**	(.005)*	(.009)	(.004)	(.008)**	(.018)	(.004)***	(.003)***
monopoly ($)	0.16	0.42	0.56	0.35	0.46	0.98	0.49	0.50
	(.05)***	(.16)***	(.26)**	(.10)***	(.32)	(.55)*	(.20)***	(.25)**
R^2	0.86	0.89	0.73	0.83	0.79	0.86	0.75	0.73
Per annual dose								
Marginal cost ($)	350	195	112	120	699	416	255	1125
as share of per-capita GDP								
monopolistic (%)	129	72	41	44	257	153	94	190
competitive (%)	25	14	8	9	50	29	18	37

Table 1: *A comparison of costs and markups for antiretrovirals in countries with and without widespread availability of generics.* Notes: Starred coefficients are significant at the *10-, **5-, or ***1-percent level. Annual figures marked with an "*ns*" are derived from daily coefficients that are not significant at the 10-percent level. Sources: Médicins Sans Frontières; World Development Indicators, World Bank; Author's calculations. Per capsule dosages are as follows: Didanosine, 100 mg; Lamivudine, 100 mg; Stavudine, 40 mg; Zidovudine, 100 mg; Efavirenz, 200 mg; Nevirapine, 200 mg.