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Pricing and Patents of HIV/AIDS Drugs in Developing Countries

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Abstract

This paper provides empirical evidence on the impact of patents on drug prices across developing countries. It uses sales data on HIV/AIDS drugs in a sample of 34 low and middle-income countries between 1995 and mid-2000. The main findings are that patents do shift drug prices up, that drug prices are correlated to per capita income levels, and that drug firms follow a skimming strategy when pricing new HIV/AIDS drugs. That is, there is across country and intertemporal price discrimination in the global drug markets.

Keywords: Patents; Pricing; Pharmaceuticals; AIDS.

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1 Introduction

The impact of patents on drug prices has emerged as a controversial issue in the face of the Human Immunodeficiency Virus (HIV) public health crisis. Activists blame patents for keeping prices out of the reach of those who badly need new drugs called antiretroviral drugs (ARV), and lobby strongly for letting generics compete with original brand products protected by patents in developing countries. ARV drugs are effective and safe drugs that have changed the late stage of the HIV infection, the Acquired Immune Deficiency Syndrome (AIDS), from a death sentence to a chronic disease. Drug firms argue that patents are not a barrier to access to the new drug therapy, because of tiered or compassionate pricing, and that patents are key mechanisms to encourage research and development of new medicines and vaccines.

Most of the studies on patents and pricing focus on the effect of patent expiration on drug pricing and shares in the US: Hurwitz and Caves (1988); Caves, Whinston and Hurwitz (1991); Grabowski and Vernon (1992); Frank and Salkever (1992, 1997); Griliches and Cockburn (1994); Hellerstein (1994) and, Fisher and Griliches (1995). Hudson (1992 and 2000) analyzes drug pricing dynamics and patent expiration not only in the US, but also in the UK, Germany, France, and Japan. A common finding

of these papers is that the larger the numbers of competitors, the lower drug prices are, and that brand name products might even increase in price after the introduction of generics. This is what Scherer (1993) named the "generic paradox."

Very little attention has been devoted to studying the impact of patent rights on drug pricing in developing countries. Some papers attempt to simulate the likely effects of product patents on average drug prices in developing countries. In the cases of Argentina and India, Challu (1991), Fink (2000), and Watal (2000) obtain impacts of patents on average prices of a different order. Impacts of about 200% are obtained by using the assumptions that yield the highest impact and of 26% (Watal, 2000), or as low as 12% (Fink, 2000), with the assumptions that yield the lowest impact. Using less detailed data, Maskus and Eby-Konan (1994) and Subramanian (1995) obtain maximum price increases of up to 67% due to the introduction of pharmaceutical product patent rights.

Another stream of works has focused on studying the dynamics of drug pricing. Lu and Comanor (1998) described that there are two different pricing strategies in the drug markets. The pricing strategy named "skimming strategy" corresponds to what Lu and Comanor (1998) found to be the pricing strategy for the subset of drugs which represent important therapeutic gains, as opposed to the "penetration strategy" that Lu and Comanor (1998) found to be the pricing strategy for the subset of drugs which largely duplicate the actions currently available products.

In the skimming strategy cases, drug firms introduce their products at high price which later on declines. In the penetration strategy cases, drug firms introduce their products at low price which later on increases. The literature on experience goods (those whose users determine product attributes only by using the product) explains when pioneering brands try to build up their consumer base and their reputation by a low/high

pricing sequence (Schmalensee, 1982), and also when monopolists prefer instead to "milk its reputation" using a high/low pricing sequence (Shapiro, 1983). The key issue in this literature is the buyer's perceptions of the new product quality. When consumers are pessimistic regarding the product quality, the firms needs to build the reputation of the product largely by setting a low introductory price followed by a higher regular price. When consumers overestimate product quality, the firm will optimally set a high launch price but then lower its price over time.[1]

This paper tries to fill part of the gap in the empirical literature on drug pricing. It investigates the impact of patents on pricing of HIV/AIDS drugs in a sample of low and middle-income countries in the late 1990's. This is a companion paper to that by Borrell and Watal (2002) on studying patents and access to HIV/AIDS drugs. The hypothesis is that drug prices are higher under patent regimes. Patents legally prevent unauthorized manufacture, sale, importation, and using or stocking for sale of the patented product during a limited term. Patents prevent competition between the innovator of the drug (and any of its licensees) and the imitators (unauthorized providers). Patents prevent competition between providers of products that contain the same therapeutically active substance, and that only differ slightly in other characteristics. The lack of such close competitors is expected to shift prices upward.

Additionally, this paper studies how the pricing dynamics differ across patent regimes. We expect pricing strategies to differ strongly across patent regimes. Patents allow drug firms to get the most from skimming and penetration strategies. By contrast, pricing in no-patent regimes will be more closely linked to the dynamics of production costs and competition.

[1] Bagwell and Riordan (1991) analyze the case in which the firms signal high quality new products with prices that are above full information profit maximizing prices. As information about the prices diffuses, the price distortion disappears.

This paper uses sales data on HIV/AIDS drugs in a sample of 34 low and middle- income countries, between 1995 and mid-2000, and reduced form regressions to empirically assess the impact of market exclusivity on pricing of clinically tested ARV drug bundle (so called "cocktail therapy").

Our main finding is that the daily dose price of any "cocktail therapy" differs significantly in two dimensions: (1) drug bundles are on average more expensive when they include products under patent regime, and (2) drug bundles are on average more expensive when they include products under licenses from the firm that originally developed the drug. We also find a positive relationship between drug prices and per capita income in both patent and non-patent regimes. This finding suggests, that not only competition under non-patent regimes drives drug prices to be related to per capita income across countries, but also that multinational drug firms have effectively tiered their prices to per capita income across countries when drugs are under patent regime.

Finally, we find that drug firms set a very high initial price and then lower it over time during the 9-year period after the date the drug bundle was available on the US market only in patent regimes. This pricing strategy, named skimming pricing (as opposed to penetration pricing), corresponds to what Lu and Comanor (1998) found to be the pricing strategy for drugs, which represent important therapeutic gains. Competition prevents price discrimination in no-patent regimes.

This paper is organized in the following way: section 2 describes the method we follow to test whether patents have a positive or negative effect on pricing, and the characteristics of the data set. Section 3 offers some descriptive statistics on patents and prices. Section 4 shows the results of estimating the impact of patents on pricing. Section 5 concludes.

2 Methodology and Data

2.1 Methodology

There are large number of studies in economics that use natural experiments or quasi-experiment designs to examine outcome measurements for observations in treatment groups and comparison groups. Meyer (1995) describes the strengths and weaknesses of using quasi-experiments in economics. Among good natural experiments, Meyer (1995) cites those induced by policy changes that may allow a researcher to obtain exogenous variation in the main explanatory variables.

This paper uses the difference approach in a quasi-experiment to study how the outcome of interest – i.e. drug pricing, – differs for treatment groups and comparison groups that are not randomly assigned. The treatment group contains all the country-drug pairs for which any ARV drug, in the country of a sample of developing countries, is under a patent regime, while the comparison group contains all the country-drug pairs for which the drug is not under a patent regime. Quasi-experiments allow us to distinguish the effects of exogenous variation in an explanatory variable that is, in other situations, endogenously related to the outcome of interest. The estimates of the effect of patents on drug prices are usually biased because drug firms apply for patent status across countries and drugs in a non-random way. Drug firms apply and renew the patent status of a particular drug in a given country only when both of the two following conditions hold: (1) when the firm may legally obtain a patent right from the government of that particular country (what we will refer to as the "patent regime") for the drug and (2) when the present discounted value of the expected cash flow of patenting that drug in that country is positive (what we will refer to as the firm "patenting decision").

This paper overcomes the bias by studying the effect of a policy change on the patent regime of a set of HIV/AIDS drugs and country pairs on the outcome of interest – i.e. drug pricing. The key identifying assumption in the study is that differences in patent regimes across drug-country pairs are exogenous with respect to the outcomes in the market for ARV drugs. The paper sustains that patent law changes in the countries sampled were driven mainly by bilateral or international agreements and national developments, rather than by concerns related to the treatment of HIV patients.

As Meyer (1995) highlights, three of the main goals of the research design should be: (1) having a large enough variation in the key explanatory variables so that it is exogenous, (2) finding comparison groups that are comparable, (3) probing the implications of the hypotheses under test.

With respect to the first issue, this paper identifies the factors that drove changes in the patent regime to rule out obvious sources of endogeneity. Each drug-country patent regime indicator depends on two data: (1) whether patent protection is locally available and, (2) when the innovator can apply for patent protection in any of the World Trade Organization (WTO) member countries. The differences in patent regimes across countries, and the timing of the invention of the 14 different ARV molecules (from 1985 to 1995) lead to an appropriate mix of patent regimes across drug-country-pairs.

With respect to the second issue, this paper uses different regression specifications including different sets of controls to avoid the possibility of omitted variables, trends in outcomes and omitted interactions to examine the comparability of treatment groups and comparison groups. In the regression analysis, we treat omitted variables, trends in outcomes and omitted interactions by controlling for relevant country characteristics, and also country, brand licensing status (licensed brands versus non-licensed brands), pharmaceutical form, and annual fixed effects, and country and year

interactions. Additionally, the empirical literature on drug markets draws our attention to the additional need for controlling differences in observed drug qualities such as dosage, efficacy, and side effects.[2]

The following regression equation provides a simple and parsimonious way to control observable differences in the observations of different groups,

$$p_{jt}^{i} = \alpha + \alpha_{t}^{i} + \beta r_{j}^{i} + z_{t}^{i}\delta_{1} + z_{j}\delta_{2}$$

where p_{jt}^{i} is the price of the daily dose of a single, double or triple drug bundle j in country i in year t, α_{t}^{i} are fixed effects for country i and year t, r_{j}^{i} is the patent regime of the drugs of the bundle j in country i, and β is the true causal effect of the treatment on the outcome. The regression controls for country and year characteristics (z_{t}^{i}), and also for drug bundle characteristics (z_{j}). The regression equation adjusts for observable differences between the observations in the different groups.

With respect to the third issue, the paper further probes for hypotheses by testing whether the causal effect of the patent regime holds in different settings: for single, double and triple drug bundles separately, and for countries with variation in drug patent

[2] The empirical literature that studies specific drug markets shows that we should control dosage, efficacy, toxicity, and side effects among other observed qualities: Berndt, Griliches and Rosset (1993) study antihypertensive drugs; Berndt *et al.* (1995), and Berndt, Pindkyck and Azoulay (1999 and 2000) focus on anti-ulcer drugs; Berndt, Cockburn and Griliches (1996) analyze antidepressant drugs; and Cockburn and Anis (1998) arthritis drugs. We do not have enough data on differences in drug toxicity among ARV's although higher life-threatening toxicity has been related to the use of a type of ARV, the so-called Nucleoside Reverse Transcriptase Inhibitors (NRTI). Therefore, at least drug fixed effects take care of fixed differences in toxicity across drug types.

regimes separately. In any regression equation, the restriction that δ_1 and δ_2 are equal across groups is important because otherwise the regression equation will not adjust for differences in control variables across groups.

Scherer and Watal (2001) estimated reduced form pricing equations across countries and time by using this same data set. They found a significant negative impact of patent rights on average leading multinational prices. They qualified this result as 'anomalous' and driven by: (1) measurement error, or (2) complex interrelationships between patent and other variables.

This study of the impact of patent on prices differs from that conducted by Scherer and Watal (2001) in three aspects. First, we study the effect of the patent regime indicator on all firms pricing, not only on multinationals. Second, the patent regime indicator has been improved with respect to that used by them. It includes data on patent rights, exclusive marketing rights (EMR), and 'pipeline protection' available to innovators across countries and drugs as explained below. Finally, instead of regressing the price of each product on a set of country and drug effects, we regress the price of each clinically tested bundle of drugs available in any given country and year, on a set of characteristics including the patent regime indicator. This is important because ARV drugs have strong complementarities in consumption. Effective therapies are usually cocktail therapies combining two or three different drugs. Equilibrium prices are likely to be related to the dosage, efficacy and adverse reactions of each bundle of drugs that is actually available to the AIDS patients in a given country and year.

2.2 Data

Treatment of AIDS in rich countries changed dramatically after 1995, when new, more effective, and safer drugs were approved. According to Henkel (1999), the combination

of the new ARV drugs with the older ones ("cocktail therapy") "has helped change AIDS in the last three years from being an automatic death sentence to what is now often a chronic, but manageable, disease." As Table 1 shows, 14 different products containing one molecule, and one product combining two molecules (i.e. a total of 15 products), were available in the US by June 2000.

IMS, the leading collector of data on drug sales world-wide, provided us with annual sales data for the 15 ARV's in 21 different countries and two country groupings, viz. French West Africa and Central America, between January 1995 and June 2000.[3] IMS data consist of unsubsidized annual wholesale sales and revenue estimates corresponding to each particular drug presentation sold at retail outlets between 1995 and mid-2000, except in 4 cases. IMS reports total aggregated retail and hospital sales (R&H) in South Africa, Thailand, the Philippines, and Indonesia. IMS data refer only to unsubsidized sales. They do not include subsidized distribution of drugs to patients (particularly important in Brazil and Thailand), nor do they include any donations of drugs.[4] Using

[3] IMS provided us with aggregated sales data for two supranational entities: French West Africa, comprising aggregate sales in Benin, Cameroon, Democratic Republic of Congo, Ivory Coast, Gabon, Guinea and Senegal; and, Central America, including Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama. All economic indicators for those two supranational entities are population weighted averages of the national indicators. The data set includes annual data referring to the calendar years from 1995 to 1999, and also to the year from July 1999 to June 2000.

[4] For each drug presentation, IMS reports data by year, country, molecule, firm, brand name, pharmaceutical form, strength, and pack size. Sales revenues obtained from each package or presentation at the wholesale level are reported in current $US. Physical sales are reported in standard units (number of tablets, vials or teaspoons). IMS did not provide us with sales of the active ingredient in milligrams, or in daily doses.

IMS data, we compute sales in milligrams for each presentation. We collected data on the minimum recommended milligrams for completing a daily dose of our 15 drugs from WHO (2000) and PDR-CG (2000). Combining this information, we computed sales in terms of the number of daily single-drug treatment dose. We then obtained the price per daily single-drug treatment dose by dividing revenues in $US by sales in the number of daily treatment doses.

Patent protection on pharmaceuticals changed substantially in the countries of our sample due to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Before January 1st 1995, 14 countries in our sample did not grant product patents.[5] Between 1996 and 2000, eight of those countries introduced patent protection for pharmaceuticals.[6]

Under TRIPS, WTO member countries were obliged to allow for the filing of product patents for pharmaceuticals by 1st January 1995 and the subsequent grant of either product patents or exclusive marketing rights for eligible pharmaceutical products.[7]

[5] These were Argentina, Bangladesh, Brazil, Colombia, Egypt, Guatemala, Guinea, India, Morocco, Pakistan, Peru, Tunisia, Uruguay and Venezuela. Pakistan had a patent law in force, but an executive order disallowed pharmaceutical patents.

[6] Colombia, Ecuador and Venezuela introduced product patents in 1996; Brazil in 1997; Argentina in 1999; Guinea, Guatemala, and Morocco in 2000. We focus on product patents (exclusivity related to therapeutically active ingredient) rather than process patents (exclusivity related to the method of obtaining such an active ingredient). Process patents, like other type of patents on therapeutic uses, pharmaceutical forms, and so on, are important but accessory ways of protecting the main and broader exclusivity right of the innovator, that protecting the therapeutic active ingredient from being copied and sold.

[7] When product patents are not available as of 1st January1995, WTO members have to provide a system whereby drug patent applications can be filed (often referred to as a "mailbox" system).

Developing countries were allowed up to 1st January 2005, and the least-developed countries up to 1st January 2006 (and now up to 2016 under the Doha Ministerial Declaration on the TRIPS Agreement and Public Health) so as to formally change patent laws to introduce pharmaceutical product patent protection. Furthermore, those lesser-developed countries may obtain further extensions from WTO on a case-by-case basis.

In the countries not providing patents to eligible drugs before 1st January 1995, TRIPS obligations do not affect drugs that were no longer "new" for patenting purposes as of the date of filing in that country, or as of the date of priority accorded to them upon request. Therefore, we can conclude that all WTO Members would be obliged to make patents (or exclusive marketing rights) available to inventions for which the first patent application was made in any WTO member on or after 1st January 1994. [8]

"Mailbox" applications do not have to be examined until the local patent law is passed. However, when a drug subject to a "mailbox application" obtains marketing approval before the local patent office makes a decision on whether granting a patent right or not, the following special rule applies: An Exclusive Marketing Right (EMR) of up to five years (or until the patent is granted or rejected, whichever is shorter) must be granted from the date of local marketing approval, provided that a patent has been filed for that drug and a patent and marketing approval obtained in another WTO member country after 1st January 1995.

[8] An invention is considered to be new if it does not form part of the state of the art. The "state of the art" is generally defined, as everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the patent application. Under WTO rules, incorporating existing WIPO (World Intellectual Property Organization) conventions, for purposes of determining novelty, patent applicants may claim the priority of an earlier application made during the period of 12 months from the date of filing. It is theoretically possible to have a patent applicant not to claim priority from the date of an earlier filing and to claim that products for which patent applications were filed elsewhere from say, mid-1993 are

We lacked direct data on patents granted for each of the 14 different ARV molecules in each country. Therefore, we assessed instead the patent regime for each drug-country pair. We gathered information on whether product patents for pharmaceuticals were available in each country for a year after each ARV product patent application was filed in according to the key priority date given in the US.

Balasubramaniam (2000) provides the date of filing of the patent application, which the US Patent and Trademark Office reports as the key patent for each ARV.[9] Using a variety of sources, including local legislation and the complete cross-country data-set compiled by Qian (2001), we obtained the hypothetical date from which patent protection for pharmaceuticals could have been granted for each drug in each one of the 34 countries of our sample.

We built up the patent regime indicator using the key patent priority date and the date from which each country could have granted patent protection. For each drug-country-pair, we assessed whether product patents would have been available locally within a year from the key priority date of each molecule. TRIPS provisions on exclusive

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novel (since later than this date the application would then be published by another patent office after 18 months and so would no longer be novel as of or after January 1995), but we believe that this is unlikely to happen in practice.

[9] The US Federal Food, Drug, and Cosmetics Act required that drug firms provide patent information with all new drug applications. Taking into account this information, the FDA sets the exclusivity term during which an abbreviated new drug application is not granted (a generic is not approved). The *Electronic Orange Book* (FDA, 2000) publishes the number of the appropriate patents claimed by the firms when the drugs are subject to approval. Using the patent numbers, Balasubramaniam (2000) obtained each ARV key priority date from the US Patent and Trademark Office online database (http://www.uspto.gov). We thank Mike Palmedo from the Consumer Project on Technology for explaining to us how this data was gathered.

marketing rights (EMR's) affect four of the 14 ARV molecules. For the following four molecules, patent applications could have been filed after January 1st 1995 in all WTO countries apart from the country where the priority date was set: Nelfinavir (key patent priority date - February 2nd 1994); Delavirdine (key patent priority date – February 22nd 1994); Ritonavir (key patent priority date - April 25th 1995); Efavirenz (key patent priority date - June 2nd 1995). We set the patent regime dummy variable to be 1 for these four drugs in all countries in our sample because local governments would be obliged to provide EMR or product patents to the innovators of these molecules under TRIPS rules.

Remember that the patent regime indicator does not report whether the innovator was granted or had even applied for patent protection for each drug-country-pair of our sample. In other words, it does not reflect the actual patent status of the drug. It only shows that patent or other market exclusivity status was attainable for some years, to the best of our knowledge. So, the patent regime is arguably exogenous to any firm decision. Taking into account the value of patent protection, innovators may decide whether or not it pays to apply in each one of the countries that make available such rights.

Table 2 shows that Central America, French West Africa, Malaysia and South Africa led the sample in the number of drugs for which patents could have been granted by 2000. In these four countries or country groupings, the patent holders of all 15 ARV's could apply for patents.[10] In a second set of countries, patent laws have changed recently to make product patents available for pharmaceuticals: Mexico (1991), Thailand (1992),

[10] Product patents for drugs have been granted in all Central American countries since the 1950s, except in Guatemala where product patents were introduced in 2000. We set the patent regime indicator to be equal to 1, in all the country-drug-pairs corresponding to Central America.

Chile (1991) and Indonesia (1993). Mexico and Thailand led this second group of countries because they granted the so-called 'pipeline' protection when introducing legislation on product patents. In these countries, innovators could apply for patent protection for drugs in the 'pipeline', i.e. drugs not already marketed although not 'new' for patenting, when the new law came into force. Finally, in 14 countries in our sample, innovators could only apply for patents or EMR's for the 4 drugs affected by the TRIPS rules on 'mailbox applications'.

Local prices of ARV drugs differ substantially from US prices across countries and time. Table 4 shows the wholesale minimum price per year of a set of clinically tested ARV therapies in any oral solid form (tablets, capsules, and the like): single-drug therapy; double-drug therapy and the so-called Highly Active Antiretroviral Therapy (HAART) three-drug therapy. At the top end, the lowest priced annual triple drug bundle per patient in 1999 was higher in Mexico (US$ 8,149), Colombia ($US 7,728), Chile ($US 6,853) than in the US ($US 6,770). At the bottom end, the minimum price per annual triple drug bundle is $US 4,366 in South Africa and $US 3,025 in Brazil. The last column in Table 4 shows that the minimum price per annual triple drug bundle in 1999 was higher than the per capita income in $PPP in all the countries of the sample except in Brazil (47% of per capita income), Argentina (58%) and Chile (81%), while the minimum price was 21% of the per capita income in the US. All minimum prices of single and double drug bundles are smaller than the minimum price in the US, particularly in India, Thailand, Brazil, and South Africa.

We also matched each local product to an equivalent product in the US using data on the minimum list price in the US.[11] In 1995, sales weighted mean prices were

[11] As reported in the Red Book (1995, 1996, 1997, 1999 and 2000), the PDR-Generics (1997), and PDR-CG (1998, 1999 and 2000). We matched each local price with the US minimum

quite close to US wholesale list prices in current $US in all countries for which data is available. However, by mid-2000, prices dropped to one-half or less of US prices in five countries: India, South Africa, Brazil, Malaysia and Thailand. Note that patents were available for all drugs in S. Africa and in Malaysia and for most in Thailand. In eight countries, prices dropped to levels of between 53% and 73% of the US prices. In contrast, prices increased in Mexico and Venezuela, and did not decrease much in Argentina and Colombia.

Table 5 also shows that local prices in terms of purchasing power parity (PPP) were well above their US counterparts for all countries in 1995 (ranging from 118% to 394%). Between 1995 and 1999, relative local to US prices dropped in all countries except in Mexico and Venezuela. However, by 1999, mean local prices in PPP terms were higher than US prices in all countries (ranging from 106% to 286%) except Brazil (60%).

What are the drivers of the pricing dynamics? Table 6 shows that the cumulative annual decrease in the sales weighted mean price in current $US between 1995 and 1999 (column 1) is driven by three factors: (1) the introduction of cheaper new products particularly in India, Uruguay, French West Africa, and Malaysia (column 2); (2) the drop in nominal prices in current $US for the drugs already on the market, particularly in Central America, the Philippines, South Africa, and Peru (column 3); which in turn is mainly driven by (3) the depreciation of the exchange rate between the local, and the US currency, particularly in the Philippines, South Africa, and Peru (column 4).

Table 7 shows that relative price indices in local currency (column 1) decreased in all countries except Thailand, Malaysia, and Argentina. Patients benefited from lower

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wholesale list price for each particular drug and pharmaceutical form pair between 1995 and 2000.

prices in local currencies because many firms were not able to increase nominal prices (column 2) to offset the negative impact of local inflation (column 3).

3 Results

Table 8 shows summary statistics of the variables used in the regression analysis. The dependent variable in the pricing regressions is the log of the price per daily dose of any clinically tested drug bundle available to patients in any country, in any year. There are 2,459 clinically proven one-drug, two-drug, or three-drug bundles available to AIDS patients in our data set. The right hand side variables of interest in the pricing regressions are the dummies that are equal to 1 when (1) the bundles include at least one original drug in a patent regime, (2) when the bundles includes at least one original drug in a no-patent regime, and (3) when the bundles includes at least a generic in a patent regime. The omitted category is the case when all the drugs in the bundle are local copies introduced in no patent regimes.

We control for different vectors of price shifters. Table 9 shows the results from estimating different specifications of the pricing equation. In column (1) we include the country mean income, the country income inequality, the dosage, the efficacy, the adverse reactions of each bundle, and the fixed effects related to the number of years since the drug bundle was available in the US (1…12), the number of drugs contained in each bundle (1, 2 or 3), pharmaceutical form (oral solid, oral liquid, vials), years (1995…1999), and a fixed effect for controlling when the data also includes hospital sales. In column (2) we add a set of country fixed effects. In column (3), we add to this latter specification a set of country-year pair effects. Table 10 shows the results of this specification including country-year pair effects for single drug, double drug and triple drug therapy separately. It is important to check the robustness of the results to the type

of drug therapy because when including double and triple therapies in the regression, we might be introducing heterocedasticity of unknown form.

Results in table 9 and 10 do not differ much. As a larger number of drugs of the bundle are under a patent regime, expected prices increase. This result becomes more significant as we include country, year, and country-year pair fixed effects. The effect of the patent regime variable grows as we go from single therapy to triple therapy.

Results in column 3 of table 9 allow us to compare expected prices. Panel A in Table 11 shows that drug bundles containing at least one original drug in a patent regime are on average priced 70% higher than drug bundles containing only local copies marketed in no patent regimes.

Table 11 also shows that drug bundles containing at least one generics marketed in a patent regime (probably when the drug goes off patent in country-drugs previously under patent regime) are on average priced 22% higher then drug bundles containing only local copies. Moreover, drug bundles containing at least one original drug are priced 16% higher than local copies even when it is introduced in no-patent regimes. Panels B, C and D show the estimates of these price differences using the results in Table 10.

These results show that patients have access to cheaper drug bundles, and to a wider range of prices in no-patent regimes i.e., drug bundles containing only cheaper local or generic non-licensed brands rather than bundles containing more expensive big pharma brands. That is the expected result from the competition among different firms offering drugs that contain the same chemical entities on the market. For instance, we observe that in a no-patent regime such as the corresponding to the country-drug pair Argentina-Zidovudine eight firms compete offering close substitute brands.

Results also show that competition of just one generic firm at the end of the patent term also induces a reduction of prices. For instance, a generic Canadian firm

introduced Zidovudine in Central America as a non-licensed brand after the exclusivity term of the original developer ended. These results suggest that drug prices flatten out only gradually as new competitors come in. Furthermore, these price differentials also show that big pharma licensed brands are priced differently across patent regimes.

Tables 9 also show that the prices across countries are closely related to each country per capita income and income inequality. More importantly, the positive link between prices and mean income is persistent across patent regimes, and gets stronger for drug bundles containing more drugs. The relationship between prices and income inequality is ambiguous, probably because the functional form is too restrictive to handle the non-linearity relationship between prices and income distribution. However, these results are consistent with the assumption that price relatives depend not only on the degree of differentiation among products on the market, but also on the income distribution of each country, the characteristics of the outside good, and the marginal and fixed costs of production.

Finally, tables 9 and 10 show that launch prices are very high, and that drug bundle prices adjust down strongly. Figure one uses the results of a regression using country-year fixed effects and allowing for different time trends for single, double and triple therapies to predict the evolution of mean prices across the life cycle of the products. The figure shows that drug firms use the so called "skimming strategy" when pricing new drug in the case of original drugs in patent-regimes. This is the pricing strategy named "skimming strategy." More should be studied to understand the fundamentals of this strategy, particularly, whether and why drug firms are discriminating prices intertemporally and across countries.

4 Conclusions

Our main finding is that the average daily dose price of any ARV "cocktail therapy" differs significantly between the treatment group of country-drug pairs in which pharmaceutical firms may apply for product patent rights, and the comparison group of country-drug pairs in which pharmaceutical firms may not apply for product patent rights. We find that on average cocktail therapies are more expensive when they include big pharma licensed brand products.

Additionally, we find evidence of a persistent relationship between drug prices and per capita income under patent and no-patent regimes, and a strong decreasing trend in prices. Sales-weighted average ARV prices were quite close to US average prices in all countries by 1995. By mid-2000, these prices had dropped significantly in current $US. However, ARV prices were still well above US prices in PPP terms in all poor countries throughout the period under study. Prices in $US decreased due to two factors: (1) the introduction of cheaper local and generic brands in local markets; and (2) firms' difficulties in increasing nominal prices when local currencies depreciated. Patients do not, however, benefit from decreasing prices in nominal local currency terms, but benefit from decreasing prices in real terms because of firms' inability to increase nominal prices to offset the negative impact of local inflation. Drug firms appear to use the "skimming strategy" when pricing new drugs in patent regimes.

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6 Tables

Table 1. ARV's approved in the US by June 2000 (from older to newer in the US)

Molecule generic name	Drug type	Brand name in the US	Firm name in the US	Year of key patent application	Launch Year in the US
ZIDOVUDINE (AZT)	NRTI	Retrovir ®	Glaxo Wellcome	1985	1987
DIDANOSINE (DDI)	NRTI	Videx ®	Bristol-Myer	1987	1991
ZALCITABINE (DDC)	NRTI	Hivid ®	Roche Labs	1987	1992
STAVUDINE (D4T)	NRTI	Zerit ®	Bristol-Myer	1986	1994
LAMIVUDINE (3TC)	NRTI	Epivir ®	Glaxo Wellcome	1989	1995
SAQUINAVIR	PI	Invirase ® and Fortovase ®	Roche Labs	1990	1995
INDINAVIR	PI	Crixivan ®	Merck	1993	1996
NEVIRAPINE	NNRTI	Viramune ®	Roxane	1993	1996
RITONAVIR	PI	Norvir ®	Abott Pharm	1995	1996
DELAVIRDINE	NNRTI	Rescriptor ®	Agouron	1994	1997
LAMIVUDINE & ZIDOVUDINE	NRTI	Combivir ®	Glaxo Wellcome	1989	1997
NELFINAVIR	PI	Viracept ®	Agouron	1994	1997
ABACAVIR	NRTI	Ziagen ®	Glaxo Wellcome	1989	1998
EFAVIRENZ	NNRTI	Sustiva ®	Du Pont Pharm.	1995	1998
AMPRENAVIR	PI	Agenerase ®	Glaxo Wellcome	1993	1999

Source: PDR (2000), Balasubramaniam (2000), and FDA (2000).

Table 2. - Number of drugs for which the innovator could obtain patent or EMR rights

	1995	1996	1997	1998	1999	2000
US	**6**	**9**	**12**	**13**	**15**	**15**
CENTRAL AMERICA	6	9	12	13	15	15
FRENCH WEST AFRICA	6	9	12	13	15	15
MALAYSIA	6	9	12	13	15	15
SOUTH AFRICA R&H	6	9	12	13	15	15
PHILIPPINES R&H	6	9	12	14	15	15
MEXICO	5	8	11	12	13	13
THAILAND R&H	4	7	10	11	13	13
INDONESIA R&H	2	5	8	10	11	11
CHILE	1	4	6	7	8	8
BRAZIL	0	1	4	4	4	4
ARGENTINA	0	1	4	4	4	4
BANGLADESH	0	1	4	4	4	4
COLOMBIA	0	1	4	4	4	4
DOMINICAN REPUBLIC	0	1	4	4	4	4
EGYPT	0	1	4	4	4	4
ECUADOR	0	1	4	4	4	4
INDIA	0	1	4	4	4	4
MOROCCO	0	1	4	4	4	4
PAKISTAN	0	1	4	4	4	4
PERU	0	1	4	4	4	4
TUNISIA	0	1	4	4	4	4
URUGUAY	0	1	4	4	4	4
VENEZUELA	0	1	4	4	4	4

n.d.: no data.

Source: Author's calculations based on local legislation, Balasubramaniam (2000) and Qian (2001).

Table 3. - Number of drugs available by country and year
(of which under patent regime)

	1995	1996	1997	1998	1999
US	**6 (6)**	**9 (9)**	**12 (12)**	**13 (13)**	**15 (15)**
ARGENTINA	4 (0)	7 (1)	10 (2)	12 (3)	14 (4)
CHILE	0	1 (0)	5 (0)	9 (3)	12 (5)
COLOMBIA	1 (0)	4 (1)	6 (1)	10 (2)	12 (3)
THAILAND R&H	3 (1)	6 (4)	8 (6)	10 (8)	12 (10)
MEXICO	3 (2)	3 (2)	5 (4)	8 (7)	10 (9)
SOUTH AFRICA R&H	3 (3)	4 (4)	6 (6)	9 (9)	10 (10)
FRENCH WEST AFRICA	2 (2)	2 (2)	4 (4)	8 (8)	9 (9)
BRAZIL	1 (0)	4 (0)	4 (0)	5 (0)	7 (0)
MALAYSIA	1 (1)	2 (2)	5 (5)	6 (6)	7 (7)
URUGUAY	1 (0)	1 (0)	1 (0)	5 (1)	7 (2)
CENTRAL AMERICA	1 (1)	1 (1)	4 (4)	5 (5)	5 (5)
INDIA	n.d.	n.d.	1 (0)	2 (0)	5 (0)
VENEZUELA	0	0	2 (0)	3 (0)	5 (0)
PHILIPPINES R&H	1 (1)	2 (2)	2 (2)	3 (3)	4 (4)
DOMINICAN REPUBLIC	0	0	0	0	3 (0)
ECUADOR	0	1 (0)	1 (0)	1 (0)	3 (0)
PERU	0	0	1 (0)	3 (0)	3 (0)
INDONESIA R&H	1 (0)	3 (0)	4 (1)	2 (1)	2 (1)
BANGLADESH	0	0	0	0	0
EGYPT	0	0	0	0	0
MOROCCO	0	0	0	0	0
PAKISTAN	0	0	0	0	0
TUNISIA	0	0	0	0	0

n.d.: no data.
R&H: Retail & Hospital sales. Otherwise, retail sales only.
Source: Author's calculations based on IMS.

Table 4. - Wholesale minimum price for an annual ARV therapy in 1999 (tablets only)

	Single Therapy	Double Therapy	Triple Therapy (HAART)	Per Capita Income (PPP$)
US	2533	5114	6770	31910
ARGENTINA	1567	3845	6632	11324
CHILE	1513	4825	6853	8370
SOUTH AFRICA R&H	835	2023	4366	8318
URUGUAY	1533	7941	..	8280
MALAYSIA	1247	3153	..	7963
MEXICO	1195	2589	8149	7719
BRAZIL	757	1982	3025	6317
COLOMBIA	1431	2862	7824	5709
THAILAND R&H	593	2029	4345	5599
VENEZUELA	1869	4432	6301	5268
DOMINICAN REPUBLIC	1290	4161	..	4653
PERU	1476	4061	..	4387
PHILIPPINES R&H	1915	4770	6685	3815
CENTRAL AMERICA	1181	3019	..	3545
EQUADOR	954	2692	..	2605
INDONESIA R&H	1299	3408	..	2439
INDIA	634	1319	7728	2149
FRENCH WEST AFRICA	1411	3363	6624	1092

HAART: Highly Active ARV Therapy

Source: Author's computations on the price of single double and triple clinically tested drug bundles that can be combined using the drugs available in each country in 1999 based on IM. Per capita incomes from World Bank (2000).

Table 5. - Sales weighted local to US price ratios

	At current $US						At purchasing power parity				
	1995	1996	1997	1998	1999	2000	1995	1996	1997	1998	1999
URUGUAY	2.68	0.99	0.60	1.07	1.62	1.15	3.94	1.40	0.84	1.48	2.26
VENEZUELA	..	..	0.52	0.66	1.01	1.11	..	..	0.81	0.94	1.45
MEXICO	0.67	0.70	0.71	0.66	0.74	0.91	1.18	1.36	1.42	1.24	1.29
ARGENTINA	0.95	0.97	0.86	0.87	0.91	0.83	1.38	1.42	1.25	1.27	1.36
COLOMBIA	1.18	1.45	1.00	0.97	0.88	0.79	3.01	3.51	2.31	2.32	2.24
CHILE	..	1.13	0.90	0.76	0.79	0.73	..	1.92	1.57	1.25	1.41
INDONESIA R&H	1.06	0.89	0.70	0.33	0.68	0.69	2.91	2.36	2.01	1.88	2.86
CENTRAL AMERICA	0.78	0.79	0.87	0.66	0.67	0.66	1.89	1.87	1.94	1.41	1.50
EQUADOR	..	0.84	0.74	0.57	0.62	0.59	..	1.66	1.45	1.13	1.24
FRENCH WEST AFRICA	1.15	1.10	0.88	0.63	0.60	0.57	3.31	3.08	2.55	1.80	1.72
DOMINICAN REPUBLIC	..	..	..	..	0.65	0.56	..	..	..	..	1.59
PERU	..	..	0.77	0.69	0.57	0.53	..	..	1.32	1.17	1.06
PHILIPPINES R&H	1.02	0.98	0.89	0.54	0.58	0.53	3.42	3.11	2.96	2.22	2.17
THAILAND R&H	0.81	0.77	0.62	0.52	0.55	0.50	1.78	1.68	1.56	1.57	1.57
MALAYSIA	0.86	0.81	0.67	0.53	0.50	0.47	1.65	1.51	1.31	1.32	1.17
BRAZIL	0.88	0.73	0.64	0.55	0.42	0.44	1.31	1.02	0.87	0.78	0.60
SOUTH AFRICA R&H	0.87	0.73	0.69	0.53	0.44	0.38	1.94	1.81	1.68	1.40	1.17
INDIA	n.d.	n.d.	0.63	0.42	0.30	0.20	n.d.	n.d.	2.91	1.99	1.43

n.d.: no data.

..: no drug available.

Author's calculations based on IMS, WHO (2000), *Red Book* (1995, 1996, 1997, 1998, 1999, 2000), PDR-Generics (1997) and PDR-CG (1998, 1999, 2000).

Table 6. - Drivers of Pricing Dynamics in $US
(annual cumulative change between 1995 and 1999)[1]

	Mean price in $US	Entry & Mix	ARV price index in $US	Local Currency
INDIA	-30.50%	-22.36%	-8.14%	-8.16%
SOUTH AFRICA R&H	-16.45%	-4.81%	-11.65%	-12.22%
URUGUAY	-15.29%	-13.76%	-1.53%	-7.65%
PERU	-15.23%	-3.60%	-11.63%	-11.26%
FRENCH WEST AFRICA	-14.81%	-11.10%	-3.72%	-26.22%
MALAYSIA	-14.72%	-11.96%	-2.75%	-9.90%
BRAZIL	-10.87%	-0.01%	-10.86%	-15.67%
PHILIPPINES R&H	-8.36%	2.67%	-11.03%	-9.94%
COLOMBIA	-7.91%	-8.29%	0.38%	-15.09%
CHILE	-7.13%	0.79%	-7.92%	-9.22%
THAILAND R&H	-6.96%	-2.26%	-4.70%	-9.90%
CENTRAL AMERICA	-6.86%	10.67%	-17.53%	-6.14%
ECUADOR	-5.78%	-5.78%	..	..
INDONESIA R&H	-2.08%	4.46%	-6.54%	-33.19%
ARGENTINA	2.08%	0.93%	1.14%	0.01%
MEXICO	3.45%	-0.51%	3.96%	-9.48%
VENEZUELA	27.33%	28.57%	-1.24%	-10.18%

[1] Or between the first year when any of the ARV's is locally available and 1999.
..: not available.
Source: Author's calculations based on IMS, WHO (2000), PDR (2000), IMF (2001).

Table 7. - Drivers of Pricing Dynamics in Local Currency
(annual cumulative change in the following factors)

	Relative Price Index in Local Currency	Nominal Price Index in Local Currency	Inflation Shocks on Relative Prices in Local Currency
FRENCH WEST AFRICA	-49.95%	22.51%	-72.46%
CENTRAL AMERICA	-20.65%	-11.39%	-9.27%
VENEZUELA	-15.96%	8.95%	-24.91%
PHILIPPINES R&H	-9.00%	-1.09%	-7.90%
INDIA	-7.15%	0.03%	-7.18%
SOUTH AFRICA R&H	-7.09%	0.58%	-7.67%
MEXICO	-5.98%	13.43%	-19.41%
INDONESIA R&H	-5.03%	26.65%	-31.68%
PERU	-4.73%	-0.36%	-4.37%
BRAZIL	-4.52%	4.81%	-9.33%
CHILE	-3.26%	1.29%	-4.55%
URUGUAY	-1.08%	6.12%	-7.20%
COLOMBIA	-0.82%	15.47%	-16.29%
THAILAND R&H	1.66%	5.21%	-3.54%
MALAYSIA	2.01%	7.15%	-5.13%
ARGENTINA	2.28%	1.14%	1.14%
ECUADOR	..	..	..

..: drugs available only two in 1998 and 1999.
Source: Author's calculations based on IMS, WHO (2000), PDR (2000).

Table 8. - Summary Statistics
Observations: 2,459 single, double and triple drug bundles in 23 countries or regions that combine 14 different drugs between 1995 and 1999

Variable	Mean	Std. Dev.	Min	Max
Price per minimum daily dose	20.66	20.59	0.13	141.97
Drugs in Patent Regimes (%)	0.37	0.39	0.00	1.00
Original Brands (%)	0.71	0.34	0.00	1.00
Original drugs in patent regimes (%)	0.32	0.38	0.00	1.00
Country Mean Income	8684.47	3023.32	1092.00	11844.00
Country Income Inequality (Gini, %)	49.28	5.61	36.45	64.33
Including an oral liquid	0.37	0.48	0.00	1.00
Including a vial	0.04	0.19	0.00	1.00
2 drugs	0.58	0.49	0.00	1.00
3 drugs	0.18	0.39	0.00	1.00
Number of Doses a Day	4.47	1.87	1.00	12.00
Efficacy	0.21	0.24	-0.14	0.90
Adverse Reactions	0.09	0.05	0.00	0.29
Retail and Hospital sales	0.21	0.41	0.00	1.00
First year on the US market	0.04	0.19	0.00	1.00
Second year on the US market	0.24	0.43	0.00	1.00
Third year on the US market	0.17	0.38	0.00	1.00
Fourth year on the US market	0.14	0.34	0.00	1.00
Fifth year on the US market	0.14	0.35	0.00	1.00
Sixth year on the US market	0.03	0.17	0.00	1.00
Seventh year on the US market	0.04	0.19	0.00	1.00
Eighth year on the US market	0.06	0.23	0.00	1.00
Ninth year on the US market	0.08	0.27	0.00	1.00
Tenth year on the US market	0.01	0.12	0.00	1.00
Eleventh year on the US market	0.02	0.13	0.00	1.00
Twelfth year on the US market	0.02	0.14	0.00	1.00

Table 9. - Drug Bundle Pricing Regressions – OLS
Coefficient (Standard Errors)
Single, Double and Triple Therapy (n=2,459)

	Log of Price per Daily Dose of a Drug Bundle		
	(1)	(2)	(3)
Local copies in no-patent regime	-- --	-- --	-- --
Original drug in patent regime	.34 (.17) +	.56 (.07) **	.53 (.08) **
Original drug in no-patent regime	.12 (.12)	.16 (.12)	.15 (.12) +
Generics after patent expiration	.09 (.16)	.06 (.07)	.19 (.07) **
Log of Country Mean Income	.23 (.08) **	.23 (.51)	.32 (.06) **
Country Income Inequality (Gini, %)	-.15 (.48)	5.96 (1.56) **	
Number of Doses per Day	.17 (.04) **	.13 (.04) **	.13 (.04) **
Efficacy	.42 (.10) **	.20 (.15)	.17 (.14)
Adverse Reactions	-1.63 (.63) *	-.84 (.23) **	-.73 (.23) **
Years in the US market:			
First	-- --	-- --	-- --
Second	-.12 (.04) **	-.19 (.07) *	-.15 (.26)
Third	-.14 (.07) *	-.18 (.08) *	-.13 (.08)
Fourth	-.31 (.09) **	-.27 (.07) **	-.10 (.11)
Fifth	-.33 (.09) **	-.27 (.09) **	-.21 (.07) **
Sixth	-.18 (.10) +	-.19 (.12)	-.22 (.05) **
Seventh	-.25 (.10) **	-.22 (.11) +	-.13 (.08) +
Eighth	-.30 (.14) +	-.28 (.11) **	-.16 (.08) *
Ninth	-.36 (.12) **	-.36 (.10) **	-.25 (.09) **
Tenth	.17 (.10)	.06 (.11)	-.32 (.08) **
Eleventh	.11 (.08)	.03 (.09)	.16 (.08) +
Twelfth	.05 (.07)	.05 (.08)	.13 (.06) *
Fixed Effects:			
Pharmaceutical Form	Yes	Yes	Yes
Number of Drugs	Yes	Yes	Yes
Year	Yes	Yes	
Country		Yes	
Country-Year			Yes
R^2	.64	.71	.73

Hospital sales fixed effects included.
Robust Standard Errors Clustered on Country.
Significant at 1% (**), 5% (*), or 10% (+).

Table 10. - Drug Bundle Pricing Regressions – OLS
Coefficient (Standard Errors)

	Log of Price per Daily Dose of a Drug Bundle								
	Single Therapy (n=586)			Double Therapy (n=1,428)			Triple Therapy (n=445)		
Local copies in no-patent regime	--	--		--	--		--	--	
Original drug in patent regime	.62	(.11)	**	.48	(.06)	**	.63	(.05)	**
Original drug in no-patent regime	.29	(.15)	+	.11	(.08)	+			
Generics after patent expiration	.25	(.09)	*						
Number of Doses per Day	.14	(.08)	+	.20	(.07)	**	-.01	(.01)	
Efficacy	.33	(.24)		-.01	(.13)		1.02	(.18)	**
Adverse Reactions	.07	(.88)		.88	(.62)		-.66	(.50)	
Years in the US market:									
First	--	--		--	--		--	--	
Second	-.04	(.09)		-.22	(.15)		-.36	(.02)	**
Third	.03	(.13)		-.25	(.16)				
Fourth	-.15	(.10)		-.34	(.20)		-.06	(.05)	
Fifth	-.15	(.07)	*	-.40	(.27)		-.02	(.05)	
Sixth	-.15	(.10)		-.21	(.18)				
Seventh	-.30	(.10)	**	-.21	(.21)				
Eighth	-.39	(.15)	*	-.30	(.22)				
Ninth	-.49	(.15)	**	-.43	(.28)				
Tenth	.16	(.11)							
Eleventh	.13	(.11)							
Twelfth	.06	(.13)							
Fixed Effects:									
Pharmaceutical Form	Sí			Sí			Sí		
Number of Drugs	Sí			Sí			Sí		
Country-Year	Sí			Sí			Sí		
R^2	.51			.41			.27		

Hospital sales fixed effects included.
Robust Standard Errors Clustered on Country.
Significant at 1% (**), 5% (*), or 10% (+).

Table 11. – Mean Price Differences by Patent Regime and Licensing Status

A. - All sample: Single, Double and Triple Therapy (n=2,459)			
Local copies in no-patent regime	100		
Original drug in patent regime	170	(**)	100
Original drug in no-patent regime	116	(+)	
Generics after patent expiration	122	(**)	72
B. - Single therapy (n=586)			
Local copies in no-patent regime	100		
Original drug in patent regime	186	(**)	
Original drug in no-patent regime	135	(+)	
Generics after patent expiration	127	(*)	
C. - Double therapy (n=1428)			
Local copies in no-patent regime	100		
Original drug in patent regime	162	(**)	
Original drug in no-patent regime	112		
Generics after patent expiration			
D. - Triple therapy (n=445)			
Local copies in no-patent regime	100		
Original drug in patent regime	188	(**)	
Original drug in no-patent regime			
Generics after patent expiration			

From the estimates including country-year fixed effects. Price differences with respect to the no-patent and unlicensed brand (local firm) are statistically significant at 1% (**), 5% (*), or 10% (+).

Fig 1. Daily Price Across Time Since US Launch Date
Bands: 95% prediction conf. interval