# Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries

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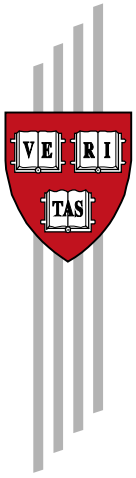
CID Working Paper No. 92
May 2002






Working Papers

Center for International Development
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Preliminary version
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# Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries

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May 30, 2002

[*] We thank Victor Aguirregabiria, Amir Attaran, Pierre Azoulay, Eli Berman, Ernie Berndt, Richard Caves, Ian Cockburn, Paul Farmer, Rebecca Henderson, Jim Kim, Markus Mobious, Ariel Pakes, Dani Rodrik, Albert Saiz, Frederic M. Scherer, and Elena Zoido for helpful comments and suggestions. We gratefully acknowledge the comments from many participants at Harvard and NBER Seminars. We also thank Lilith Haynes for patiently reading and providing helpful comments on early versions of this manuscript. While working on this paper Watal was Visiting Fellow at the Center for International Development (CID) at Harvard University and Borrell was Post-doctoral Fellow at Harvard Economics Department. We thank our respective hosts. We gratefully acknowledge funding from the CID. Borrell gratefully acknowledges unrestricted educational grants from Fundacion Ramon Areces (Madrid, Spain) and The Merck Foundation, the philanthropic arm of Merck & Co. Inc., Whitehouse Station (New Jersey, USA). Borrell thanks the faculty of the Department of Economic Policy at the University of Barcelona for taking care of his duties while he was in the US. Research assistance from Friederike Hesse (Kennedy School of Government) and Jimmy Liu (Harvard College) is also gratefully acknowledged. The opinions stated are only those of the authors, and any error or omission remains only under the authors' responsibility. In particular the views expressed in this paper do not implicate in any way either the WTO Secretariat or WTO Members. E-mails: Jayashree.Watal@wto.org, borrell@eco.ub.es

Abstract

This paper uses sales data on HIV/AIDS drugs in a sample of 34 low and middle income countries between 1995 and 1999 to assess empirically the impact of patents on unsubsidized access to a new drug therapy. There can be two possible effects of patents on access to new drugs in developing countries. On the one hand, patents may constrain access to new drugs through less competition and higher prices. On the other hand, patents may promote access to new therapy by encouraging innovators to launch new drugs in low and middle-income countries soon after introducing them in high-income countries. The net effect is theoretically ambiguous and, therefore, it is an empirical matter to evaluate. Our main finding is that patent rights do have a negative effect on unsubsidized access to HIV/AIDS drugs. Between 1995 and 1999, switching all HIV/AIDS drugs from a patent regime to a no patent regime would have actually increased access to therapy at least by 30%. However, we also find that the negative impact of patents on access differs strongly over time, and across countries with different income levels. Patents hurt access most in the early period from the date the drug is launched in the US, and in the countries of our sample with the relatively higher per capita income levels.

*Keywords*: Patents; Entry; Pricing; Access; Pharmaceuticals.

JEL Codes: L65; K11; O34.

## 1 Introduction

Millions of patients living with the Human Immunodeficiency Virus (HIV) in low and middle income countries lack access to effective and safe drugs that change the late stage of that infection, the Acquired Immune Deficiency Syndrome (AIDS) from a death sentence to a chronic disease. Those drugs are called antiretrovirals (ARVs).[1] Patent rights are at the center of the public debate on access to ARV therapy. Patents allegedly impede the access of a vast majority of patients in poor countries to ARV therapy. However, this statement has not been assessed empirically. This paper tackles the question of whether patent rights constrain access to new drug therapies in low and middle-income countries.

[1] According to UNAIDS/WHO (2001), 31.6 million people were living with HIV worldwide by December 2000 and 3 million people died suffering AIDS during 2000. The epidemic has spread fiercely in poor countries. The three regions with the largest number of adults and children living with HIV are Sub-Saharan Africa (25.3 million), South-East Asia (5.8 million), and Latin America and the Caribbean (1.79 million).

Some papers estimate the impact of patents on drug markets. Most study 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). A common finding of these papers is that drug prices are lower the larger the number of competitors, and that brand name products might even increase prices after the introduction of generics -- what Scherer (1993) named the 'generic paradox'. 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. In his later work, Hudson shows that generics are more likely to enter drug markets that generate large revenues during the patent term.

Very little attention has been devoted to studying the impact of patent rights on drug availability, pricing, and access in developing countries. Some papers attempt to simulate the likely effects of product patents on average drug prices. 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, 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. Other studies, using less detailed data, obtain maximum price increases of up to 67% due to the introduction of pharmaceutical product patent rights -- Maskus and Eby-Konan (1994), and Subramanian (1995). Lanjouw (1998) discusses more generally the socio-economic effects of the introduction of patents in India, and Lanjouw and Cockburn (2001) study empirically the positive impact of patent protection on research on drugs that address the needs of patients in poor countries (a point raised formally by Diwan and Rodrik, 1991).

This paper tries to fill part of the gap in the empirical literature on drug markets. It investigates the impact of patents on unsubsidized access to ARV therapy in a sample of low and middle-income countries in the late 1990s. We will use the more popular term "access" and the more technical name "market coverage" as equivalents referring to the percentage of AIDS patients that do actually consume any ARV drug.

We hypothesize that patents have two possible and counterbalancing effects on access to drugs in low and middle-income countries. On the one hand, patents may have a negative impact on market coverage because of less competition and higher prices. Patents legally

prevent unauthorized manufacture, sale or offering for sale, importation and use of the patented product during the patent term. This prevents competition between the innovator of the drug (or any of its licensees) and unauthorized providers of products that contain the same therapeutically active substance or of products that only differ trivially from these. The lack of close competitors is expected to shift prices up and decrease demand in market equilibrium.

On the other hand, patents could have a positive impact on market coverage. Exclusivity could mean higher prices and greater profits, which in turn, could encourage patent holders to launch new drugs in low and middle income countries soon after they are launched in high income countries.[2] Imitators usually require some time after a drug is launched for the first time by the innovator to produce that drug in countries where patent rights are not granted. This is because imitators do not have detailed information on the characteristics of the new drug until the content of the patent is disclosed through publication of the patent application and more importantly after the product is available in any market round the world.[3] Without the innovator's technical assistance, imitators usually lack the expertise to produce the new drug immediately after it has been marketed for the first time. The actual time lag between the worldwide launch of a product by the innovator and the fastest imitator depends on several factors, including the technological complexity of the product and the skill level of the domestic pharmaceutical industry.

The net effect of these two forces of patents on access to new drug therapy across countries and time is a matter for empirical investigation. It depends largely on how much patents constrain competition and shift prices up and demand down in market equilibrium and on whether patents encourage the introduction of new drugs across markets. This paper uses sales data on HIV/AIDS drugs in a sample of 34 low and middle income countries

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[2] Lanjouw and Cockburn (2001) report that interviewed drug firm executives believed that 'faster introductions of new products and greater investments in marketing and educating the local medical community about new therapies' were the major benefits from the introduction of product patents in developing countries.

[3] Most countries, other than the United States, provide for publication of patent applications 18 months from the date of their filing. The American Inventor's Protection Act of 1999 required for the first time in the US publication of all non-provisional patent applications filed after November 29, 2000. It also allowed publication of earlier-filed pending applications on request. However, the

between 1995 and mid-2000, and estimates a selection model using instrumental variable techniques to assess empirically the impact of market exclusivity on access to new drug therapy.

Our main finding is that the patent regime has a negative effect on unsubsidized access to HIV/AIDS drugs in the countries of our sample. Switching all drugs subject from a patent regime to no-patent regime would have actually increased unsubsidized access to therapy by 30%. However, such increase only shifts market coverage up from 0.88% to 1.15%. Thus, even with such a patent regime change, 98.85% of AIDS patients would have been excluded from ARV therapy.

The plan of the paper is the following: in section 2 (data and method), we describe how we test whether patents have a positive or negative effect on access to ARV therapy, and the characteristics of the data set. In section 3 (descriptive statistics), we offer summary statistics on the distribution of exclusivity rights, drug availability, pricing, and market coverage by country and by year. In section 4 (results), we estimate the impact of patents on access to ARV therapy and we obtain some out-of-sample and in-sample predictions of market coverage in different patent regimes. Finally, we conclude in section 6.

## 2 Data and Method

### 2.1 Data

The first five ARVs were launched in the US market before 1995. They were of the type called Nucleoside Reverse Transcriptase Inhibitors (NRTI). However, treatment of AIDS in rich countries changed dramatically after 1995, when new, more effective, and safer drugs were approved. These new ARVs are called Protease Inhibitors (PI) and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI). 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 drugs containing one molecule, and one

TRIPS Agreement does not require that Patent Offices provide for such publication prior to patent

drug combining two molecules (i.e. a total of 15 drugs), were available in the US by June 2000: 7 NRTIs, 5 PIs, and 3 NNRTIs.

IMS, the leading collector of data on drug sales world-wide, provided us with annual sales data for these 15 ARVs in 21 different countries and two country groupings, viz. French West Africa and Central America, between January 1995 and June 2000.[4] According to the World Bank (2000b) standards, five are low income (ordered from lower to higher GNP per capita): Bangladesh, French West Africa, India, Pakistan and Indonesia.[5] Ten are lower-middle income: the Philippines, Morocco, Ecuador, Egypt, Central America, Dominican Republic, Thailand, Tunisia, Colombia and Peru. And, eight are upper-middle income: South Africa, Malaysia, Venezuela, Mexico, Brazil, Chile, Uruguay and Argentina.[6]

IMS data consist of unsubsidized annual wholesale sales and revenues 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, nor do they include any donations of drugs. This is particularly important in Brazil. The Brazilian government provides free access to ARV therapy to HIV patients and produces many of the ARVs in public facilities or imports them directly from the manufacturers. Thailand also has a substantial public distribution programme. However, except for Brazil and Thailand, it seems that such programmes were treating a tiny number of patients in our sample of countries and during our sample period, 1995-2000.

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grant.

[4] 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.

[5] Bangladesh and four out of the six countries of French West Africa (Benin, Democratic Republic of Congo, Guinea and Senegal) are included in the group of "Least Developed Countries" that benefit from some preferential treatment under the rules of the WTO.

[6] UNAIDS/WHO (2000a) estimates that 12.9 million people were living with HIV in the countries of our sample by the end of 1999. Those patients accounted for 37.6% of the estimated total number of people living with HIV worldwide in 1999.

Unfortunately, we do not have data on such drug subsidized or free distribution of ARV drugs. It is worth emphasizing that the results of our research refer only to actual unsubsidized sales of ARVs.

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, nor in daily doses.

Using the strength and pack size information provided by IMS, we computed a measure of active ingredient concentration per standard unit (i.e. per tablet, vial, or teaspoon). Then, multiplying that by standard unit sales, we obtained 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). Using this information, we were able to compute sales in terms of the number of annual single-drug minimum treatment dose. Using the physical sales observations, we summed across products to obtain the number of equivalent annual single-drug treatments by country and year. We also computed the price per annual single-drug treatment dose by dividing revenues in $US by sales in terms of the number of annual treatment doses.

### 2.2 Method

We estimate a selection model using instrumental variable techniques to study how the outcome of interest – access or market coverage – changes due to the indicator under study, the country-drug specific patent regime. Having large enough sample of observations, a selection model and instrumental variable (IV) regression analysis is a simple and parsimonious way of assessing empirically the impact of the patent regime on the expected outcome of interest.

The IV approach for studying the impact of patents relies on four key assumptions: (1) that we have sample variation not only on the outcome of interest, but also on the indicator under study across observations; (2) that we include control variables in the regressions to avoid bias from omitted variables; and, (3) that the changes in the indicator

under study and the control variables are exogenous to the outcome of interest; (4) that we appropriately instrument any endogenous variable.

First, the IV approach relies on having enough sample variation not only with respect to access to therapy across observations, but also with respect to the patent regime across observations. Each drug-country-year specific patent regime depends on two dates: (1) whether patent protection is locally available and for how long it lasts; and, (2) whether and when the innovator can apply for patent protection in any of the World Trade Organization (WTO) member countries. The differences in drug patent regimes across countries and time, 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.

Second, the IV approach also relies on controlling for variables affecting the outcome apart from the indicator under study. In the regression analysis, we take care of omitted variables by controlling for relevant country characteristics, and also country, drug, pharmaceutical form, and year fixed effects. Additionally, the empirical literature on drug markets draws our attention to the additional need for controlling for differences in observed drug qualities such as dosage, efficacy, and side-effects.[7]

Third, an underlying key assumption in our study is that the patent regime, that is the patent status attainable for each drug in each country at any time, is exogenous with respect to the outcomes in the market for ARVs. We show below that patent law changes in the countries of our sample were driven mainly by bilateral or international agreements and national political developments, rather than by concerns related to the treatment of HIV patients with ARVs. It is an indicator that avoids the problem of endogeneity between firm's decisions to actually apply for patent protection in any country and the firm's decisions on entry and pricing.

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[7] The empirical literature that studies specific drug markets shows that we should control for 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 antiulcer 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 ARVs 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.

Finally, when some of our regressors are endogenously determined we need to use instruments conveniently to identify the system of equations and avoid the endogeneity bias from the least square estimates.

### 2.3 Selection Model

We are interested in studying the expected market coverage by each ARV drug, that is, the percentage of AIDS patients that have access to each one of the 15 ARV drugs in the 23 countries or country groupings across 1995 and 1999 conditional on the patent regime. As noted earlier, a patent regime has two possible effects on access: (1) a direct negative effect on access through less competition and higher prices; (2) an indirect positive effect on access through more availability in countries where without patents there might be no entry at all. For studying the net impact of patents on market coverage, we use a selection model that includes a selection equation (the drug availability equation) and a regression equation (the market coverage equation) that includes the number of firms offering the same drug as an endogenous explanatory variable.

*Drug Availability Equation*

The selection equation of the model is specified following the models of entry proposed by Bresnahan and Reiss (1987, 1990, 1991a and 1991b). Let $a^i_{jt}$ be a binary indicator that equals one when any drug *j* is available in any country *i* at any given observed year *t*, and zero otherwise. The unconditional expected share of AIDS patients that had access to any ARV drug, $E(s^i_{jt})$, is equal to the probability of having that drug locally available ($a^i_{jt}=1$) times the expected share of patients that access to the drug conditional on having the drug available locally, $E(s^i_{jt} \mid a^i_{jt}=1)$ as shown below:

$$E(s^i_{jt}) = \Pr(a^i_{jt}=1) \cdot E(s^i_{jt} \mid a^i_{jt}=1).$$

We model the probability of having any ARV drug locally available using a model of entry. We denote $n^i_{jt}$ the number of competitor drug firms that supply drug *j* in country *i* at time *t*. Any ARV drug is available locally if and only if the ex-ante expected value of offering that drug by at least one potential firm is positive. That is, if the present discounted value of

the flow of profits minus the fixed costs of entering the market for at least one firm is positive,

$$E[V(n^i_{jt} \geq 1)] = V(x, r; \theta_1) - F^i{}_{jt} > 0, \quad (1)$$

where $V$ denotes the value function (the present discounted value of the flow of profits of selling drug $j$ in country $i$ at time $t$) as a reduced form function of a set of market shifters and profit drivers ($x^i_{jt}$) and the patent regime indicator ($r^i_{jt}$) that is equal to one if the government of country $i$ offers a patent right option to the developer of drug $j$ at time $t$, and zero otherwise, and a set of parameters ($\theta_1$). We expect the reduced form value function ($V$) to be increasing with respect the patent regime indicator ($r^i_{jt}$). Patents prevent competition from imitators during the patent term, and therefore patents increase the flow of net profits in those markets in which other firms would otherwise enter and compete with the innovator at some point of the patent term. Even in markets and years in which at most one firm would enter in a no-patent regime, the patent owner will be more prone to enter if patents are granted than in a no-patent regime because the marketing efforts of the patent owner will not spill over other potential entrants that would eventually come into the market at some point of patent term. The patent regime shifts the average marketing costs of the patent owner up when there is the expectation that another firm would enter the market during the patent term. This spill-over effect within products that contain the same drug is important because drugs are experience goods in which firms invest heavily in informing doctors and patients about the characteristics of each drug.

$F^i_{jt}$ is the annual fixed cost of marketing drug $j$ in market $i$ at time $t$ : for instance, annual fixed production costs, annual fixed distribution costs, annual fixed promotional costs, annual fixed surveillance costs, and expected annual fixed damage and liability costs.

Let us assume that $F^i_{jt}$ is a log normal random draw corresponding to the annual fixed cost of marketing drug $j$ in country $i$ at time $t$ that faces any potential entrant firm.

$$\ln F^i_{jt} = \mu^i_j + \sigma_\varepsilon \upsilon^i_{1jt}, \quad (2)$$

$$\upsilon^i_{1jt} \sim N(0,1).$$

From the natural log of inequality 1 and from equation 2 we find that any drug $j$ will be available at any country $i$ at time $t$ if and only if inequality 3 holds:

$$\ln V(x,r;\theta_1) - \mu^i_{jt} - \sigma_\varepsilon \upsilon^i_{1jt} > 0 . \qquad (3)$$

Let us denote $V^*(x,r,; \theta_2)$ the new reduced form expected net value function that takes into account the mean and the variance of the cost of introducing a new drug as follows,

$$V^*(x,r;\theta_2) = \frac{1}{\sigma_\varepsilon}\left[\ln V(x,r;\theta_1) - \mu^i_{jt}\right].$$

Then, any potential competitor will make available a new drug if and only if the following inequality holds,

$$V^*(x,r,y;\theta_2) - \upsilon^i_{1jt} > 0 .$$

And then, the probability of having drug *j* available at country *i* at time *t* is the following,

$$\Pr\left(V^*(x,r;\theta_2) - \upsilon^i_{1jt} > 0\right) = \Phi\left(V^*(x,r;\theta)\right),$$

where $\Phi$ denotes the cumulative distribution of the standard normal.

That new reduced form inequality and the corresponding probability of having a new drug available can be used as the selection or participation inequality in a Heckman selection model. Heckman (1976) outlines the estimation of parameters of equations with dependent variables that are only observed and then selected if an underlying inequality holds.

*Market Coverage Equation*

We model the market coverage, that is, the percentage of patients that have access to ARV therapy ($s^i_{jt}$) as a function of our set of observable exogenous drivers ($x^i_{jt}$), the endogenous number of competing firms offering different versions of the same drug ($n^i_{jt}$) and an unobservable mean zero and normally distributed random variable $\sigma_s \upsilon^i_{2jt}$,

$$s^i_{jt} = D(x,n;\beta) + \sigma_s \upsilon^i_{2jt} .$$

In this equation, $\upsilon^i_{2jt}$ is also a standard normal random draw, but that we allow to be potentially correlated with $\upsilon^i_{1jt}$, with correlation coefficient equal to $\rho_s$. The correlation

coefficient takes into account that the unobservable random part of the fixed cost of introducing a new drug in a particular country and year might be correlated with the unobservable random variable that defines the percentage of patients with access to that drug. For instance, the fixed costs of setting up the new facilities and training the new personnel at entry in the drug availability equation might be correlated with the unobservable demand drivers of the drug in the market coverage equation.

*Entry in No-Patent Regimes Equation*

The number of competing firms that will offer different versions of the same drug in no-patent regimes is an endogenous variable in the market coverage equation which we should instrument conveniently using a set of instruments ($z^i_{jt}$). As Bresnahan and Reiss (1987, 1990, 1991a and 1991b) put it, we know that in any equilibrium that satisfies the non-negative profit condition, the number of firms that any market can sustain ($n^i_{jt}$) is the number that satisfies the following restriction:

$$V^*(x,z,n,r;\theta_2) - \upsilon^i_{1jt} > 0 > V^*(x,z,n+1,r;\theta_2) - \upsilon^i_{1jt}.$$

Therefore probability of having $n^i_{jt}$ competing firms offering different versions of the same drug *j* at country *i* at time *t* is the following,

$$\Pr\left(V^*(x,z,n+1,r;\theta_2) - \upsilon^i_{1jt} > 0\right) - \Pr\left(V^*(x,z,n,r;\theta_2) - \upsilon^i_{1jt} > 0\right) =$$

$$= \Phi\left(V^*(x,z,n+1,r;\theta_2)\right) - \Phi\left(V^*(x,z,n,r;\theta_2)\right)$$

where $\Phi$ denotes the cumulative distribution of the standard normal.

We estimate the parameters of the ordered probit model that relates the expected number of competing firms as a function of $x^i_{jt}$, $z^i_{jt}$, and $r^i_{jt}$ by maximum likelihood. We use the sum of the characteristics of the drugs already marketed at each time t in the US as instruments that account for the characteristics of the potential competition that faces any version of a drug from versions of other drugs. Those instruments are correlated with $n^i_{jt}$ but not with $s^i_{jt}$.

We estimate the parameters of the market coverage equation by two stage least squares, that is, using the predicted value of the number of competing firms as an

explanatory variable to study the impact of exogenous changes in competition on market coverage in no-patent regimes.

We estimate the selection equation and the access equation simultaneously using maximum likelihood techniques to obtain consistent and asymptotically efficient estimates of the unconditional expected censored dependent variable.

## 3 Descriptive Statistics

### 3.1 Distribution of Exclusive Rights

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: Argentina, Bangladesh, Brazil, Colombia, Egypt, Guatemala, India, Morocco, Pakistan, Peru, Tunisia, Uruguay and Venezuela.[8] Between 1996 and 2000, eight of those countries introduced patent protection for pharmaceuticals: Colombia, Ecuador, Peru and Venezuela in 1996; Brazil in 1997; Argentina in 1999; Guatemala and Morocco in 2000.[9]

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 5-year exclusive marketing rights or until the patent is granted or rejected for eligible pharmaceutical products.[10] Developing countries were allowed up to 1st January

[8] Pakistan had a patent law in force, but an executive order disallowed pharmaceutical patents.

[9] We focus on product patents (exclusivity related to therapeutically active ingredient) rather than process patents (exclusivity related to the method of obtaining such 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.

[10] When product patents are not available as for 1st January1995, WTO members have to provide a system whereby drug patent applications can be filed (often referred to as a "mailbox" system). "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 takes a decision on whether granting a patent right or not, the following special rule applies:

2005, and 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) to formally change patent laws to introduce pharmaceutical product patent protection.

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 on as on the date of filing in that country or as on the date of priority accorded to them upon request. 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. 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. [11]

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

Balasubramaniam (2000) provides date of filing of the patent application which the US Patent and Trademark Office reports as the key patent for each ARV.[12] According to

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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.

[11] 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 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 on or after January 1995), but we believe that this is unlikely to happen in practice.

[12] The US Federal Food, Drug, and Cosmetics Act requires 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

that information, the key patent applications corresponding to the 14 ARV molecules were filed between September 17th 1985 (Zidovudine, AZT) and June 2nd 1995 (Efavirenz). 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. Additionally, TRIPS provisions on EMRs[13] affect four of the 14 ARV molecules. These four ARVs fall into the "TRIPS-net". 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 option indicator 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.

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, to the best of our knowledge. So, the patent regime is exogenous to firm decisions. 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.

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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.

[13] See Articles 70.8 and 70.9 of the TRIPS Agreement.

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 ARVs could apply for patents.[14]

In a second set of countries, patent laws have changed recently to make product patents available for pharmaceuticals: Mexico (1991), Thailand (1992), 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 EMRs for the 4 drugs affected by the TRIPS rules on 'mailbox applications'.

### 3.2 Distribution of Drug Availability

Local availability of ARVs in the local unsubsidiazed sector varies substantially across countries and years. The most striking feature of the distribution of the data is that only seven countries or country groupings had 11 or more ARVs available by mid-2000: Argentina, Colombia, Thailand, Chile, Mexico and South Africa. Except for Chile, this set of countries had most ARVs available soon after they were available in the US. A second group of seven countries or country groupings had only between 6 and 10 ARVs by mid-2000: French West Africa, Malaysia, Brazil, Central America, Ecuador, India and Uruguay. The remaining ten countries had only 5 or fewer ARVs available by mid-2000.

[14] 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. Product patents for drugs were granted also in all French West African nations of our sample since the 1960s, except in Guinea where product patents were also introduced in 2000. We set the patent regime indicator to be equal to 1 in all the country-drug-pairs corresponding to the two supranational entities.

### 3.3 Distribution of Market Coverage

Table 8 shows the distribution of ARV sales in terms of equivalent annual single-drug therapies by country and year. By the year ending in June 2000, Thailand was leading the table of countries by sales: 7,790 out of the 20,143 total single-drug therapies were sold in Thailand. We note that Brazil ranks 9th in this table although most HIV/AIDS patients needing therapy were able to access free ARVs through the public sector. Sales in South Africa reached 3,371 between July 1999 and June 2000, and sales in India increased sharply during the last year of our sample reaching 2,414 annual single-drug therapies. IMS report zero sales for Bangladesh, Morocco, Pakistan or Tunisia during this period.

Using the sales data, we estimated how many patients actually in need of therapy had access to for-profit ARV treatment. As Henkel (1999) pointed out, 'some HIV-infected patients progress to AIDS quickly while others can remain healthy for 10 years or more'. We used the estimated numbers of patients living with HIV in each country to turn the access problem into a relative measure. Data on HIV infections are not still available for 2000, therefore we computed the relative measures only for the 1995 to 1999 period.

WHO (1995) offers estimates of the number of adults (15 to 49 years old) living with HIV by country at the end of 1994, and UNAIDS/WHO(1998 and 2000b) offers the number of adults and children (0 to 49 years old) living with HIV by country at the end of 1997 and 1999. Using this data, we estimated the number of adults and children living with HIV between 1995 and 1999 by country at the end of each year.[15]

Assuming that about 10% of those living with HIV are in need of HAART, we divided the number of annual single-drug therapies sold by the number of patients in need of HAART.[16] By 1999, only the equivalent of 1.21% patients in need of HAART had access to a single-drug annual therapy in our sample. Only Argentina (19%), Malaysia (17%) and

[15] We first estimate the number of adults and children living with HIV by country at the end of 1994 assuming that by the end of 1994 the proportion of infected children to adults was the same as that estimated by UNAIDS/WHO (1998) at the end of 1997. Then we assume that the number of infected adults and children at the end of 1995, 1996 and 1998 lay between the estimates at the end of 1994, 1997 and 1999.

Colombia (15%) had percentages of access of 15% or more. Thailand, including retail and hospital sales, reached 9.25% in 1999, and Chile (6.21%) and Mexico (4.98) had figures close to 5%. The Philippines (2.07%) and Indonesia (1.36%), both including retail and hospital sales, had figures slightly above the weighted average (1.21%), and the remaining countries had percentages below that average.

The estimates for Brazil show that unsubsidized sales increased from 1995 to 1996 and then decreased. This data is consistent with the increasing number of patients treated within the public ARV program. According to the Brazilian Ministry of Health (2001), 73,000 of the estimated 540,000 HIV Brazilian patients or roughly 13% had access to the public ARVs in 1999, thus exceeding our standard of 10%.

## 4 Results

We show the results from estimating two different specifications of the model, one in Table 6, and the other in Table 7. Although our data set might cover 1,695 country-drug-year triplets, we have only 1,273 country-drug-year triplets that correspond to cases in which the year of observation is posterior to the date the new drug was launched in the US, and 363 triplets with positive sales.

In the market coverage equation (column 1), the dependent variable is the log of the percentage of AIDS patients that consume an annual single-drug ARV treatment in each drug-country-year market. The explanatory variable in the market coverage equation (column 1) named "competitors if no patent" is the predicted value of the dependent variable in the entry in no-patent regimes equation (column 3). In the drug availability equation (column 2), the dependent variable is the probability that the ARV drug is available at any country-drug-year triplet. We estimate by maximum likelihood the parameters of the drug availability and the market coverage equations simultaneously allowing for correlation between the error terms as explained above. In the entry in no-patent regimes (column 3), the dependent

[16] Dr. Paul Farmer suggested to the authors that at least around 10% of the HIV patients in the Central Plateau of Haiti should be treated using the directly observed therapy of HAART, see Farmer et al (2001).

variable is the number of competing firms offering different versions of the same drug in a given country and year.

We control for drug heterogeneity in the three equations by including a set of drug characteristics (drug type, dosage, efficacy, adverse reactions, and the first order and the second order effect of the number of years since the drug was launched in the US). We also control for country heterogeneity in two alternative ways. In Table 6 we control only for per capita income and income inequality differences across countries and years in all equations. However, in column 1 of Table 7 we include instead country fixed effects for taking care of other country specific variations (such as tariffs, prices regulations, access to health care, and so on). In the drug availability and the entry equations, we use also our instruments to identify the model. As explained above, we control for the sum of the characteristics of all alternative drugs already launched in the US (heterogeneity of potential competition). Tables 8.A and 8.B offer summary statistics of the main variables used in the analysis.

## 5 Predictions

The parameter estimates of the access model shown in Tables 6 and 7 allow us to predict the impact of any change in the patent regime. We obtain an estimate of the unconditional expected access to ARV therapy by multiplying the estimates of the probability of having an ARV drug available (column 2 in Table 6), by the conditional expected access to that ARV drug (column 1 in Table 6):

$$E(s_{jt}^{i}) = \Pr(a_{jt}^{i} = 1) \cdot E(s_{jt}^{i} \mid a_{jt}^{i} = 1)$$

We use the results of Table 6 of the market coverage equation with controls that do not include country fixed effects to predict the effect of any change in the patent regime on the following variables: (1) the probability of having any sample mean ARV available; (2) the expected number of competitors offering the same sample mean ARV; (3) the expected access to a sample mean ARV conditional on having the drug available; and, (4) the unconditional expected access to any sample mean ARV.

According to our estimates, the patent regime has a negative impact on drug availability during the first 3 years of a drug's introduction in a high-income market (in this

case in the US market) (see Graph 1). After 3 years, the patent regime has a strong positive impact that lasts 10 years. Graph 1 also shows how the probability of having a sample mean ARV drug locally available changes when we switch from a no-patent to a patent regime. That impact is convex with respect to the number of years of the drug in the high-income market.

Additionally, Graph 1 shows that the absolute value of the impact of patents on availability decreases as per capita income increases. The graph shows the effect of switching from a no-patent to a patent regime on availability for our actual sample of data on per capita income, and for simulated data fixing the per capita income at the 5$^{th}$, 25$^{th}$, 75$^{th}$ and 95$^{th}$ percentile of our distribution of per capita incomes that correspond to $1339, $3007, $7056, and $9288 at PPP.

The estimates also suggest that, as can be expected, the patent regime has a negative impact on the expected number of firms offering different versions of the same drug for the countries of our sample. Graph 2 shows the negative impact of the patent regime on the expected number of competitors for the actual sample of data on per capita income, and for simulated data fixing the per capita income at the 5$^{th}$, 25$^{th}$, 75$^{th}$ and 95$^{th}$ percentile of our distribution of per capita incomes as before. The negative impact of patents on the number of firms offering the same drug decreases as per capita income decreases. Patents have even a positive impact on the expected number of firms in the 5$^{th}$ and 25$^{th}$ percentile after three years from the date of launch of the drug in the US. That positive impact is due to the fact that patents encourage the patent owner to launch the drug in countries where there would not have any firm providing that drug otherwise. In very low income countries, exclusivity implies a larger value function and a larger probability of having the drug locally available. That will be the case for instance if the patent holder faces smaller average marketing costs in the case of exclusivity than otherwise. Exclusivity implies that the marketing efforts will not spill-over the sales of any other competitor during the patent term. By contrast, no exclusivity means that the patent holder is not willing to launch the drug because it expects another entrant to benefit from its marketing efforts during the patent term.

Graph 3 shows that patents have a negative impact on access conditional on availability for the countries of our sample. Using the estimates of Table 6, each extra competitor that enters the market in no-patent regimes increases access to therapy by 66%.

Access to therapy is smaller under a patent regime across all 15 years after the date any ARV is launched in a high-income market. This negative effect of the patent regime is larger for countries with a larger per capita income. On the other hand, the patent effect gets smaller as per capita income decreases, and patents have no significant effect on access for very poor countries such as those with per capita income under the 25th percentile of our distribution.

Finally, Graph 4 shows that patents have a negative effect on expected access to therapy in our sample countries. The negative effect is the largest during the initial years of the period after the date any drug is launched in a high-income market. The negative effect is also the largest for the countries with the largest per capita income in our sample such as Argentina and South Africa. In those countries the net effect is negative i.e. increase in the probability of having the drug available due to the patent regime is not compensated by the decrease in competition that patents cause.

On the other end, Graph 4 shows that patents appear to have a positive effect on access for countries around the 25th percentile of our sample such as Egypt, Ecuador, Indonesia and Morocco in between the 3rd year and the 11th year after the date of launch in a high-income market. And, patents appear to have practically no effect[17] on the poorest countries in our sample such as Bangladesh, French West Africa, India and Pakistan.

We use the results of Table 7 of the access model that do include country fixed effects to predict the effect of any change in the patent regime on total unconditional expected access to ARV therapy by country. Table 9 shows the change in the predicted number of single-drug annual treatment doses when we switch all drugs in the sample that are actually subject to a patent regime to a no-patent regime. This is like waiving the patent rights actually in place, as for example, through the systematic grant of compulsory licenses.

The impact of changing to a no-patent from a patent regime would have been an increase total access for the 5-year period by as much of 12,320 annual therapies. As Table 9 shows, this is an increase by 30% in market coverage, that is, an increase of 0.26% in the market coverage, from the tiny 0.88% of actual coverage to a bit larger market coverage of 1.15%. The largest impact of patents on access was in 1999 where without patents access would have been larger by 43%. It appears that patent rights do matter but patents cannot be

blamed for the lack of access of the vast majority of patients in developing countries because even without patents market coverage would have only reached 1.74% in 1999.

Table 10 shows the impact on total access by country when we switch all drugs under patent regime to a no-patent regime. The results are heterogeneous by country. A set of countries comprising Bangladesh, Dominican Republic, Egypt, Ecuador, India, Morocco, Pakistan, Peru, Tunisia and Uruguay would have not benefited from switching all ARV from patent to a no-patent regime.

By switching all ARV actually subject to patent regime to a no-patent regime access to ARV drugs would have increased strongly in South Africa (5,272 annual treatments) and Thailand (4,263), and slightly in Argentina (295), Mexico (323), the Philippines (217) and Malaysia (202).

## 6 Conclusions

This paper offers for the first time an estimate of exclusion from unsubsidized access to ARV therapy in poor countries. Only the equivalent of 1.21% of the patients in need of HAART therapy were able to afford the high local prices of even a single-drug ARV therapy through unsubsidized channels in 1999. The vast majority of patients suffered from not having the new drugs locally available. Only in a very select group of poor countries were ARVs locally available soon after they were launched in a high-income market.

The main finding of the paper is that patents do constrain access to unsubsidized ARV therapy in developing countries. We found that the net impact of having patent regimes on expected access to ARV in the developing countries of our sample is significant. Patents reduced access by 30% between 1995 and 1999: from 1.15% to only 0.88%. However, even switching all ARVs from patent to no-patent regime would have excluded the vast majority of patients (98.85%) from therapy if access is not subsidized.

This evidence suggests that apart from the effects of patents on producer surplus and incentives to innovate, patents have a strong negative impact on availability of drug therapy and access to unsubsidized drug therapy in developing countries. We find that while

[17] Only a very slight or insignificant positive effect was found.

patents have a negative effect on mean access to therapy, they have a positive effect on the mean probability of having drugs available locally. We find that the negative impact of patents differs strongly over time from the date of launch of a new drug in a high-income market, and across countries with different income levels.

Our policy analysis concludes that patents hurt access most in the early period from the date the drug is launched in a high-income market, and in the countries of our sample that are not in the lower end of our distribution of per capita income. And, we also find that patents have a small positive effect on access to therapy in countries with per capita income around $3007 at PPP (such as Egypt, Ecuador, Indonesia and Morocco), the 25$^{th}$ percentile of our distribution of per capita incomes after three years from the date the drug is launched in a high-income market . And, patents appear to have no practical effect on access to drugs in the poorest countries in our sample such as Bangladesh, French West Africa, India and Pakistan.

## 7 References

Balasubramaniam T. (2000) 'Background Information on Fourteen FDA Approved HIV/AIDS Drugs', Consumer Project on Technology. Published online: http://www.cptech.org/, version 1.41, June 8 2000.

Berndt, E.R, Z. Griliches and J. Rosett (1993) 'Auditing the Producer Price Index: Micro Evidence from Prescription Pharmaceutical Preparations, *Journal of Business & Economic Statistics*, 11(3), 251-64.

Berndt E.R., *et al.* (1995) 'Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market', *American Economic Review*, 85(2), 100-105.

Berndt E.R, I.M. Cockburn and Z. Griliches, Zvi (1996) 'Pharmaceutical Innovations and Market Dynamics: Tracing Effects on Price Indexes for Antidepressant Drugs' *Brookings Papers on Economic Activity*: *Microeconomics,* 133-88.

Berndt E.R., Pindkyck R.S. and Azoulay P. (1999) 'Network Effects and Diffusion in Pharmaceutical Markets: Antiulcer Drugs, *NBER Working Papers*, 7024.

Berndt E.R., Pindkyck R.S. and Azoulay P. (2000) 'Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs', *NBER Working Papers*, 7772.

Bresnahan T. F. and Reiss P. C. (1987) 'Do Entry Conditions Vary across Markets?', *Brookings Papers on Economic Activity*, 3(0), 833-71.

Bresnahan T. F. and Reiss P. C. (1990) 'Entry in Monopoly Markets', *The Review of Economic Studies*, 57(4), 531-53.

Bresnahan T. F. and Reiss P. C. (1991a) 'Empirical Models of Discrete Games', *Journal of Econometrics,* 48 (1-2), 57-81.

Bresnahan T. F. and Reiss P. C. (1991b) 'Entry and Competition in Concentrated Markets', *Journal of Political Economy,* 99 (51), 977-1009.

Boulet P., J. Perriens and F. Renaud-Thery (2000) 'Patent situation of HIV/AIDS-related drugs in 80 countries', UNAIDS/WHO, Geneva (Switzerland).

Brazilian Ministry of Health (2001) 'Acesso Universal e Gratuito', Coordenacao Nacional de DST e AIDS, Secretaria de Politicas de Saude, Ministerio da Saude. Published on-line at: http://www.aids.gov.br

Caves R.E., M.D. Whinston MD and M.A. Hurwitz MA (1991) 'Patent expiration, entry and competition in the US pharmaceutical industry', *Brookings Papers on Economic Activity: Microeconomics*, 1-48.

Challu P. (1991) 'The Consequences of Pharmaceutical Product Patenting', *World Competition*, 15(2), 65-126.

Cockburn I.M. and A.H. Anis (1998) 'Hedonic Analysis of Arthritis Drugs', *NBER Working Paper*, 6574.

Diwan I. and Rodrik D. (1991) 'Patents, Appropriate Technology, and North-South Trade', *Journal of International Economics*, 30, 27-48.

Farmer *et al.* (2001) 'Community-Based Approaches to HIV Treatment in Resource-Poor Settings', *The Lancet*, 358, 404-409.

FDA(2000) *Electronic Orange Book. Approved Drug Products with Therapeutic Evaluations,* US Department of Health and Human Services, Federal Drug Administration, Rockville, (MD, USA). Published online: http://www.fda.gov/cder/ob.

Fink, C. (2000) 'How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries', *World Bank Policy Research Paper*, 2352.

Fisher F.M. and Z. Griliches (1995) 'Aggregate price indices, new goods, and generics', *Quarterly Journal of Economics*, 110(1), 229-244.

Frank R.G. and D.S Salkever (1992) 'Pricing, patent loss and the market for pharmaceuticals', *Southern Economic Journal*, 59(2), 165-179.

Frank R.G. and D.S. Salkever (1997) 'Generic entry and the pricing of pharmaceuticals', *Journal of Ecnomics and Management Strategy*, 6(1), 75-90.

Grabowski H.G. and J.M. Vernon (1992) 'Brand loyalty, entry, and price competition in pharmaceuticals after the 1984 drug act', *Journal of Law and Economics*, 35, 331-350.

Griliches Z. and I. Cockburn (1994) 'Generics and new goods in pharmaceutical price indexes', *The American Economic Review*, 84(5), 1213-1232.

Hellerstein JK (1994) 'The demand for post-patent prescription pharmaceuticals', *NBER Working Paper*, 4981.

Henkel, J. (1999) 'Attacking AIDS with a "Cocktail" Therapy', *FDA Consumer Magazine*, July-August 1999.

Hudson J. (1992) 'Pricing dynamics in the pharmaceutical industry', *Applied Economics*, 24, 103-112.

Hudson J. (2000) 'Generic Take-up in the Pharmaceutical Market Following Patent Expiry: A Multi-Country Study', *International Review of Law and Economics*, 24, 103-112.

Hurwitz M.A. and R.E. Caves (1988) 'Persuasion or Information? Promotion and shares of brand name and generic pharmaceuticals', *Journal of Law and Economics*, 31(2), 299-320.

IMF (2001) *International Finance Statistics*, CD-Rom edition, Produced by Joint IMF and World Bank CD-ROM Project, Washington, D.C.

Lanjouw J.O.(1998) 'The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering?"', *NBER Working Paper*, 6366.

Lanjouw J.O. and I.M. Cockburn (2001) 'New Pills for Poor People? Empirical Evidence after GATT', *World Development,* 29(2), 265-89.

Mankiw N.G. and M.D. Whinston (1986) 'Free entry and social inefficiency', *RAND Journal of Economics*, 17(1), 48-58.

Maskus, K.E and D. Eby-Konan (1994) 'Trade-Related Issues of Intellectual Property Rights: Issues and Exploratory Results', in A.V. Deardorff and R.M. Stern (Eds.) *Analytical and Negotiating Issues in the Global Trading System*, University of Michigan Press, Ann Arbor (MI, USA)

PDR (2000) *Physicians' Desk Reference: PDR*, 54th Edition, Medical Economics, Oradell (NJ, USA).

PDR-Generics (1997) *Physicians Desk Reference Generics*, 3rd Edition, Medical Economics, Montvale (NJ, USA).

PDR-CG (1998) *Physicians Desk Reference Companion Guide*, 54th Edition, Medical Economics, Montvale (NJ, USA).

PDR-CG (1999) *Physicians Desk Reference Companion Guide*, 54th Edition, Medical Economics, Montvale (NJ, USA).

PDR-CG (2000) *Physicians Desk Reference Companion Guide*, 54th Edition, Medical Economics, Montvale (NJ, USA).

Qian, Yi (2001) 'Do Additional National Patents Law Stimulate Domestic Innovation in a Global Patenting Environment. A Cross-country Analysis of Pharmaceutical Patent Protection: 1978-1999', unpublished dissertation, Harvard College.

*Red Book* (1995) *Drug Topics Red Book.*, Medical Economics, Montvale (NJ, USA).

*Red Book* (1996) *Drug Topics Red Book.*, Medical Economics, Montvale (NJ, USA).

*Red Book* (1998) *Drug Topics Red Book.*, Medical Economics, Montvale (NJ, USA).

*Red Book* (1999) *Drug Topics Red Book.*, Medical Economics, Montvale (NJ, USA).

Scherer FM (1993) 'Pricing, profits and technological progress in the pharmaceutical industry', *Journal of Economic Perspectives*, 7(3), 97-115.

Scherer F.M. and J. Watal (2001) 'Post-TRIPS options for access to patented medicines in developing countries', a paper repared for Working Group 4, Commission for Macroeconomics and Health, World Health Organization, mimeo.

Subramanian, A. (1995) 'Putting Some Numbers on the TRIPS Pharmaceutical' Debate, *International Journal of Technology Management*, 10, 252-68.

UNAIDS/WHO (1998) 'AIDS Epidemic Update Report - June 1998', Joint United Nations Program on HIV/AIDS (UNAIDS) and World Health Organization (WHO). Published on-line: http://www.unaids.org.

UNAIDS/WHO (2000a) 'AIDS Epidemic Update Report - June 2000', Joint United Nations Program on HIV/AIDS (UNAIDS) and World Health Organization (WHO). Published on-line: http://www.unaids.org.

UNAIDS/WHO (2000b) 'Epidemiological Fact Sheets by country- June 2000', Joint United Nations Program on HIV/AIDS (UNAIDS) and World Health Organization (WHO). Published on-line: http://www.unaids.org.

UNAIDS/WHO (2001) 'AIDS Epidemic Update - December 2000', Joint United Nations Program on HIV/AIDS (UNAIDS) and World Health Organization (WHO). Published online: http://www.unaids.org.

UNDP/UNU/WIDER (2000) 'World Income Inequality Database', Joint Project of the United Nations Development Program (UNDP) and the United Nations University/World Institute for Development Economics Research (UNU/WIDER). Published online: http://www.wider.unu.edu, version 1.0, updated September 12 2000.

USDHHS/HKFF (2000) 'Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents', US Department of Health and Human Services and Henry J. Kaiser Family Foundation. Published online: http://www.hivatis.org, January 28, 2000.

Watal, J. (2000) 'Pharmaceutical Patents, Prices and Welfare Losses: A Simulation Study of Policy Options for India under the WTO TRIPS Agreement', *The World Economy*, 23(5), 173-752.

Watal, J. (2001) 'Workshop on Differential Pricing and Financing of Essential Drugs: Background Note', WTO, mimeo, available at www.wto.org/english/tratop_e/trips_e/wto_background_e.doc.

WHO (1995) 'Provisional Working Estimates of Adult HIV Prevalence as of End of 1994, by Country', *Weekly Epidemiological Record*, 50, 355-57.

WHO (2000) 'ATC classification index with Daily Defined Doses 2000', Excel file, World Health Organization Collaborating Center for Drugs Statistics Methodology, Oslo (Norway).

World Bank (2000a) *World Development Indicators 2000*, Washington DC. World Bank (2000b) *World Development Report 2000-2001: Attaching Poverty*, Washington DC.

## 8 Tables

Table 1.- ARVs 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: Authors' calculations based on local legislation, Balasubramaniam (2000) and Qian (2001).

Table 3.- Number of drugs available by country and year

| | 1995 | 1996 | 1997 | 1998 | 1999 | June 2000 |
|---|---|---|---|---|---|---|
| **US** | **6** | **9** | **12** | **13** | **15** | **15** |
| ARGENTINA | 4 | 7 | 10 | 12 | 14 | 15 |
| COLOMBIA | 1 | 4 | 6 | 10 | 12 | 13 |
| THAILAND R&H | 3 | 6 | 8 | 10 | 12 | 13 |
| CHILE | 0 | 1 | 5 | 9 | 12 | 12 |
| MEXICO | 3 | 3 | 5 | 8 | 10 | 11 |
| SOUTH AFRICA R&H | 3 | 4 | 6 | 9 | 10 | 11 |
| FRENCH WEST AFRICA | 2 | 2 | 4 | 8 | 9 | 10 |
| MALAYSIA | 1 | 2 | 5 | 6 | 7 | 9 |
| BRAZIL | 1 | 4 | 4 | 5 | 7 | 7 |
| CENTRAL AMERICA | 1 | 1 | 4 | 5 | 5 | 7 |
| ECUADOR | 0 | 1 | 1 | 1 | 3 | 6 |
| INDIA | n.d. | n.d. | 1 | 2 | 5 | 6 |
| URUGUAY | 1 | 1 | 1 | 5 | 7 | 6 |
| PHILIPPINES R&H | 1 | 2 | 2 | 3 | 4 | 5 |
| VENEZUELA | 0 | 0 | 2 | 3 | 5 | 5 |
| DOMINICAN REPUBLIC | 0 | 0 | 0 | 0 | 3 | 3 |
| INDONESIA R&H | 1 | 3 | 4 | 2 | 2 | 2 |
| PERU | 0 | 0 | 1 | 3 | 3 | 2 |
| BANGLADESH | 0 | 0 | 0 | 0 | 0 | 0 |
| EGYPT | 0 | 0 | 0 | 0 | 0 | 0 |
| MOROCCO | 0 | 0 | 0 | 0 | 0 | 0 |
| PAKISTAN | 0 | 0 | 0 | 0 | 0 | 0 |
| TUNISIA | 0 | 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.- Sales of equivalent full year single-drug ARV treatment doses (in actual numbers)

| | 1995 | 1996 | 1997 | 1998 | 1999 | 2000[1] |
|---|---|---|---|---|---|---|
| THAILAND R&H | 653 | 1,533 | 5,028 | 5,502 | 6,986 | 7,790 |
| SOUTH AFRICA R&H | 78 | 81 | 195 | 511 | 2,196 | 3,371 |
| INDIA | n.a. | n.a. | 88 | 45 | 417 | 2,414 |
| ARGENTINA | 305 | 748 | 2,102 | 2,622 | 2,481 | 2,284 |
| MEXICO | 288 | 337 | 506 | 1,148 | 747 | 1,528 |
| COLOMBIA | 2 | 36 | 405 | 704 | 1,056 | 937 |
| MALAYSIA | 1 | 13 | 103 | 582 | 848 | 706 |
| FRENCH WEST AFRICA | 8 | 14 | 30 | 165 | 434 | 528 |
| BRAZIL | 83 | 1,020 | 413 | 164 | 124 | 163 |
| INDONESIA R&H | 5 | 15 | 11 | 8 | 71 | 110 |
| CHILE | 0 | 0 | 5 | 65 | 93 | 93 |
| CENTRAL AMERICA | 2 | 4 | 23 | 22 | 82 | 91 |
| PHILIPPINES R&H | 6 | 11 | 25 | 40 | 58 | 63 |
| VENEZUELA | 0 | 0 | 120 | 83 | 42 | 32 |
| ECUADOR | 0 | 0 | 0 | 1 | 21 | 25 |
| PERU | 0 | 0 | 1 | 6 | 8 | 7 |
| DOMINICAN REPUBLIC | 0 | 0 | 0 | 0 | 1 | 2 |
| URUGUAY | 0 | 0 | 0 | 1 | 2 | 1 |
| BANGLADESH | 0 | 0 | 0 | 0 | 0 | 0 |
| MOROCO | 0 | 0 | 0 | 0 | 0 | 0 |
| PAKISTAN | 0 | 0 | 0 | 0 | 0 | 0 |
| TUNISIA | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 1,430 | 3,810 | 9,055 | 11,669 | 15,666 | 20,143 |

[1] July 1999 to June 2000.

n.a.: no data available.

R&H: Retail & Hospital sales. Otherwise, retail sales only.

Source: Authors' calculations based on IMS, WHO (2000) and PDRCG (2000).

Table 5.- Sales of full year single-drug treatment doses out of AIDS patients (%)

| Country | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|
| ARGENTINA | 4.03 | 7.85 | 17.52 | 20.99 | 19.08 |
| MALAYSIA | 0.03 | 0.24 | 1.51 | 10.08 | 17.30 |
| COLOMBIA | 0.03 | 0.60 | 5.62 | 9.85 | 14.88 |
| THAILAND R&H | 0.90 | 2.04 | 6.45 | 7.17 | 9.25 |
| CHILE | 0.00 | 0.01 | 0.32 | 4.20 | 6.21 |
| MEXICO | 1.49 | 1.81 | 2.81 | 6.98 | 4.98 |
| PHILIPPINES R&H | 0.31 | 0.49 | 1.03 | 1.56 | 2.07 |
| INDONESIA R&H | 0.10 | 0.29 | 0.21 | 0.15 | 1.36 |
| ECUADOR | 0.00 | 0.01 | 0.01 | 0.05 | 1.09 |
| VENEZUELA | 0.00 | 0.00 | 1.46 | 1.17 | 0.68 |
| SOUTH AFRICA R&H | 0.07 | 0.05 | 0.07 | 0.15 | 0.52 |
| CENTRAL AMERICA | 0.02 | 0.03 | 0.21 | 0.15 | 0.42 |
| URUGUAY | 0.01 | 0.04 | 0.04 | 0.19 | 0.32 |
| BRAZIL | 0.15 | 1.79 | 0.71 | 0.29 | 0.23 |
| FRENCH WEST AFRICA | 0.00 | 0.01 | 0.01 | 0.07 | 0.17 |
| PERU | 0.00 | 0.00 | 0.01 | 0.10 | 0.16 |
| INDIA | n.a. | n.a. | 0.02 | 0.01 | 0.11 |
| DOMINICAN REPUBLIC | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| Total | 0.20 | 0.43 | 0.78 | 0.96 | 1.21 |

n.a.: no data available.
R&H: Retail & Hospital sales. Otherwise, retail sales only.
Source: Authors' calculations based on IMS, WHO (1995), UNAIDS/WHO (1998 and 2000a).

Table 6.- Access Model 1 – Instrumental Variables
Coefficient (Standard Errors)
Censored Observations: 910. Uncensored Observations: 363.

| | (1) Market Coverage | (2) Drug Availability | (3) Competitors in No-Patent Regime |
|---|---|---|---|
| Competitors in No-Patent Regime | .51 (.17)** | -- -- | -- -- |
| Patent | -- -- | -1.49 (.21)** | -- -- |
| Patent * Years in the US | -- -- | .58 (.09)** | -- -- |
| Patent * Years in the US ^2 | -- -- | -.03 (.007)** | -- -- |
| Years in US | -.16 (.22) | .27 (.05)** | .27 (.14)+ |
| Years in US ^2 | -.006 (.01) | -.009 (.004)* | -.01 (.01) |
| Mean Income | .65 (.37)+ | .20 (.02)** | .36 (.07)** |
| Income Inequality | -4.32 (1.05)** | .05 (.01)** | .07 (.02)** |
| Dosage | 2.88 (1.04)** | -.56 (.18)** | -.05 (.39) |
| Efficacy | .76 (.36)* | .03 (.03) | .04 (.04) |
| Adverse Reactions | .56 (.24)* | -.10 (.03)** | -.01 (.04) |
| Characteristics Other Drugs | -- | Yes | Yes |
| Drug Type Fixed Effects | Yes | Yes | Yes |
| Country Fixed Effects | -- | -- | -- |
| Time Trend | Yes | Yes | Yes |
| Country Specific Time Trend | -- | -- | -- |
| Observations | 363 | 1,273 | 669 |
| Log Likelihood | | -1,183.02 | -321.62 |
| Pseudo $R^2$ | | -- | .39 |

The hypothesis that each coefficient is zero is rejected at the two-sided 1% (**), 5% (*), or 10% (+) significance level respectively.
Hospital sales fixed effects included.
Mean Income and Income Inequality in Logs in the Access Equation (1) and in levels (thousands of PPP$ and Gini percentage respectively) in the others equations (2, 3, 4).
Dosage, Efficacy and Adverse Reactions in Logs in the Access Equation (1) and in levels in the others equations (2, 3, 4).
Years in US in logs in the Availability Equation (2) and in levels in the other equations (1, 3, 4).
Bootstrapped Standard Errors in (1) and (2).
Robust Standard Errors Clustered on Country in (2) and (3).
Significant at 1% (**), at 5% (*).

Table 7.- Access Model 2 – Instrumental Variables
Coefficient (Standard Errors)
Censored Observations: 910. Uncensored Observations: 363.

| | (1) Market Coverage | (2) Drug Availability | (4) Competitors in No-Patent Regime |
|---|---|---|---|
| Competitors in No-Patent Regime | .26 (.16)+ | -- -- | -- -- |
| Patent | -- -- | -1.75 (.27)** | -- -- |
| Patent * Years in the US | -- -- | .74 (.11)** | -- -- |
| Patent * Years in the US | -- -- | -.04 (.01)** | -- -- |
| Years in US | .13 (.17) | .21 (.06)** | .27 (.14)+ |
| Years in US ^2 | -.02 (.01)+ | -.004 .005 | -.01 (.01) |
| Mean Income (PPP$ 1,000) | -- -- | .22 (.02)** | .36 (.07)** |
| Income Inequality (% Gini) | -- -- | .03 (.01)** | .07 (.02)** |
| Dosage | 3.08 (.83)** | -.80 (.20)** | -.05 (.39) |
| Efficacy | .81 (.24)** | .05 (.03) | .04 (.04) |
| Adverse Reactions | .66 (.20)** | -.15 (.03)** | -.01 (.04) |
| Characteristics Other Drugs | -- | Yes | Yes |
| Drug Type Fixed Effects | Yes | Yes | Yes |
| Country Fixed Effects | Yes | -- | -- |
| Time Trend | Yes | Yes | Yes |
| Country Specific Time Trend | Yes | -- | -- |
| Observations | 363 | 1,273 | 669 |
| Log likelihood | | -1,031.43 | -321.61 |
| Pseudo $R^2$ | | -- | .39 |

The hypothesis that each coefficient is zero is rejected at the two-sided 1% (**), 5% (*), or 10% (+) significance level respectively.
Hospital sales fixed effects included.
Dosage, Efficacy and Adverse Reactions in Logs in the Access equation (1) and in levels in the other equations (2, 3, 4).
Years in US in logs in the Availability equation (2) and in levels in the other equations (1, 3, 4).
Bootstrapped Standard Errors in (1) and (2).
Robust Standard Errors Clustered on Country in (2) and (3).
Significant at 1% (**), at 5% (*).

Table 8.A..- Summary Statistics (1)

| | N | Mean | Std. Dev. | Min | Max |
|---|---|---|---|---|---|
| | Panel A. All Observations | | | | |
| Available ($a^i_{jt}$) | 1,273 | .28 | .45 | .00 | 1.00 |
| Patent Regime ($r^i_{jt}$) | 1,273 | .43 | .49 | .00 | 1.00 |
| Mean Income ($PPP) | 1,273 | 5,051.95 | 2,687.76 | 1,092.00 | 11,844.00 |
| Income Inequality (Gini, %) | 1,273 | 47.70 | 7.57 | 33.92 | 64.33 |
| Years since US Launch ($y^i_{jt}$) | 1,273 | 3.49 | 3.04 | .03 | 12.78 |
| Competitors | 1,273 | .36 | .80 | .00 | 8.00 |
| Dosage | 1,273 | 2.32 | .54 | 1.00 | 3.00 |
| Efficacy | 1,273 | 6.50 | 3.56 | 2.84 | 13.50 |
| Adverse Reactions | 1,273 | 5.97 | 3.68 | 1.00 | 11.87 |
| | Panel B. Drugs Available ($a^i_{jt}$ =1) | | | | |
| Market Coverage (%) | 363 | .56 | 1.06 | .00012 | 9.55 |
| Patent Regime ($r^i_{jt}$) | 363 | .48 | .50 | .00 | 1.00 |
| Mean Income ($PPP) | 363 | 6,669.07 | 2,876.64 | 1092.00 | 11,844.00 |
| Income Inequality (Gini, %) | 363 | 51.16 | 6.91 | 36.45 | 64.33 |
| Years since US Launch ($y^i_{jt}$) | 363 | 5.32 | 3.39 | .71 | 12.78 |
| Competitors | 363 | 1.28 | 1.03 | 1.00 | 8.00 |
| Dosage | 363 | 2.31 | .50 | 1.00 | 3.00 |
| Efficacy | 363 | 6.99 | 3.55 | 2.84 | 13.50 |
| Adverse Reactions | 363 | 6.32 | 3.85 | 1.00 | 11.87 |

Table 8.B.- Summary Statistics (2)

| | N | Mean | Std. Dev. | Min | Max |
|---|---|---|---|---|---|
| | Panel A. Drugs Available ($d^i_{jt}$ =1) & Patent Regime ($r^i_{jt}$=1) | | | | |
| Market Coverage (%) | 190 | .40 | .95 | 1.17e-4 | 9.55 |
| Mean Income ($PPP) | 190 | 6,316.59 | 2,871.26 | 1,092.00 | 11,844.00 |
| Income Inequality (Gini, %) | 190 | 51.96 | 7.00 | 36.45 | 64.33 |
| Years since US Launch ($y^i_{jt}$) | 190 | 4.75 | 2.95 | .79 | 12.78 |
| Competitors | 190 | 1.01 | .12 | 1.00 | 2.00 |
| Dosage | 190 | 2.35 | .54 | 1.00 | 3.00 |
| Efficacy | 190 | 6.98 | 3.67 | 3.12 | 13.50 |
| Adverse Reactions | 190 | 6.08 | 3.90 | 1.00 | 11.87 |
| | Panel B. Drugs Available ($d^i_{jt}$ =1) & No-Patent Regime ($r^i_{jt}$=0) | | | | |
| Market Coverage (%) | 173 | .73 | 1.14 | 6.29e-4 | 5.94 |
| Mean Income ($PPP) | 173 | 7,056.18 | 2,840.63 | 1,956.00 | 11,844.00 |
| Income Inequality (Gini, %) | 173 | 50.27 | 6.72 | 36.45 | 60.10 |
| Years since US Launch ($y^i_{jt}$) | 173 | 5.94 | 3.73 | .71 | 12.78 |
| Competitors | 173 | 1.57 | 1.43 | 1.00 | 8.00 |
| Dosage | 173 | 2.27 | .45 | 2.00 | 3.00 |
| Efficacy | 173 | 6.99 | 3.41 | 2.84 | 10.28 |
| Adverse Reactions | 173 | 6.59 | 3.79 | 1.00 | 11.13 |

Table 9.- Impact of Switching All Drugs Currently in Patent Regime to No-Patent Regime

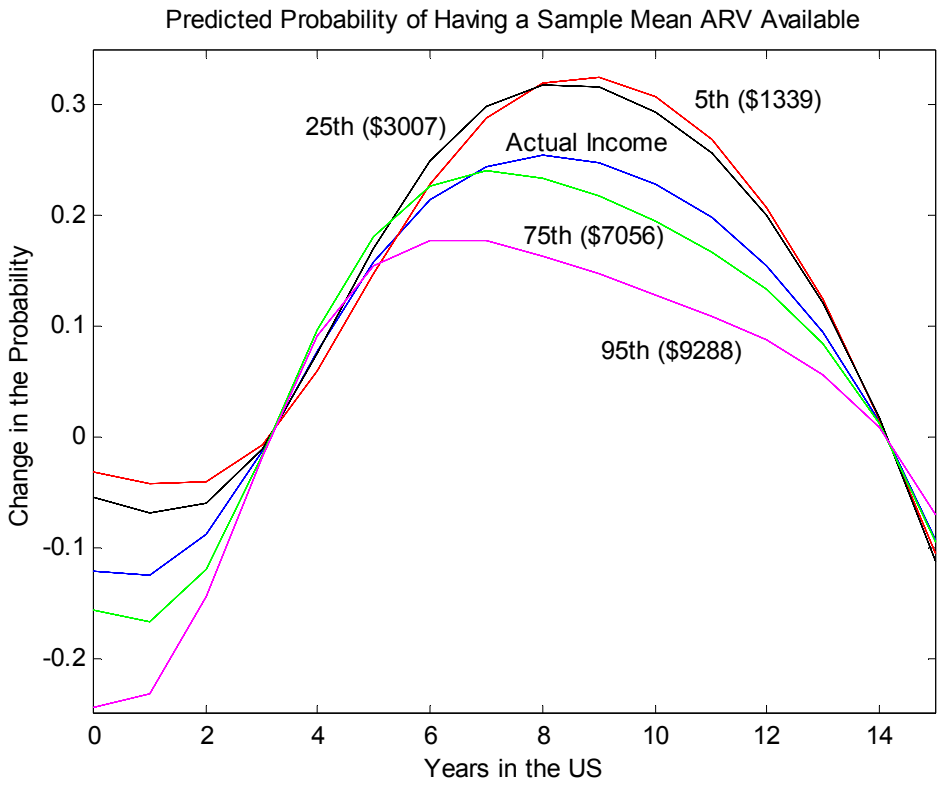
| | 1995 | 1996 | 1997 | 1998 | 1999 | Total |
|---|---|---|---|---|---|---|
| Absolute Increase: | | | | | | |
| In Annual Doses | 138 | 547 | 1,583 | 3,337 | 6,715 | 12,320 |
| In Market Coverage | 0.03% | 0.09% | 0.14% | 0.28% | 0.52% | 0.26% |
| Relative Increase: | | | | | | |
| In Market Coverage | 10% | 14% | 17% | 29% | 43% | 30% |
| Pro-memoria: | | | | | | |
| AIDS Patients | 471,388 | 581,956 | 1,155,960 | 1,212,596 | 1,289,388 | 4,711,288 |
| Current Market Coverage | 1,430 | 3,810 | 9,055 | 11,669 | 15,666 | 41,630 |
| Predicted Market Coverage (No Patent) | 1,568 | 4,357 | 10,638 | 15,006 | 22,381 | 53,950 |
| Current Market Coverage | 0.20% | 0.43% | 0.78% | 0.96% | 1.21% | 0.88% |
| Predicted Market Coverage (No Patent) | 0.33% | 0.75% | 0.92% | 1.24% | 1.74% | 1.15% |

Table 10.- Change in Annual Treatment Doses When We Switch
All Drugs Currently Under Patent Regime to No-Patent Regime

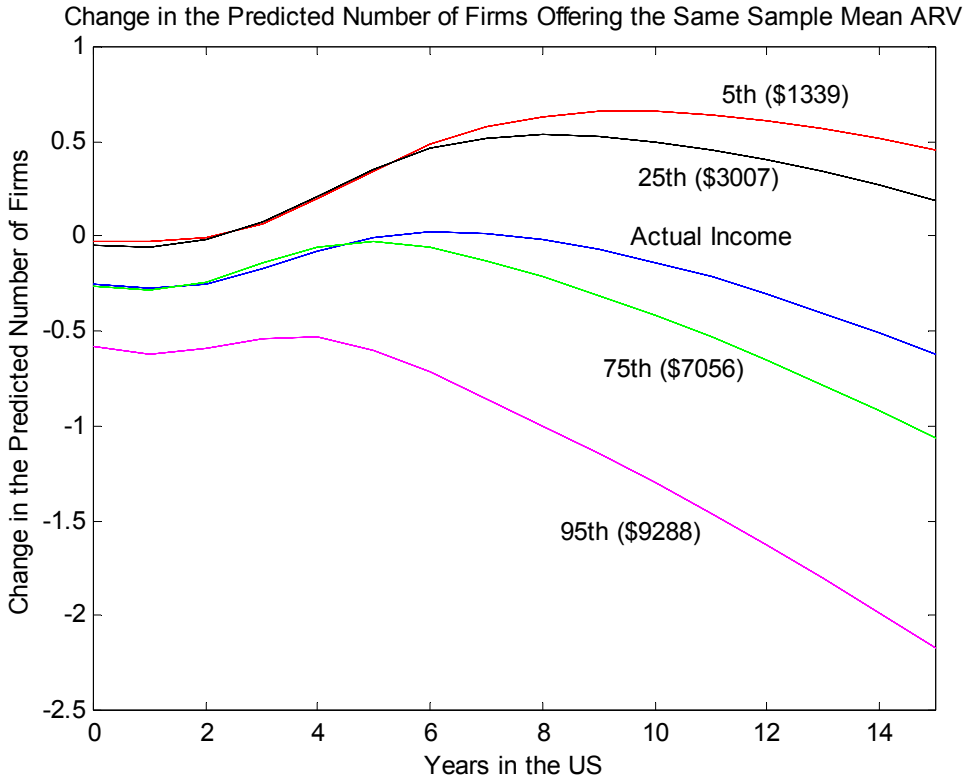
| | 1995 | 1996 | 1997 | 1998 | 1999 | Total |
|---|---|---|---|---|---|---|
| ARGENTINA | 0 | 0 | 17 | 89 | 190 | 295 |
| BANGLADESH | 0 | 0 | 0 | 0 | 0 | 0 |
| BRAZIL | 0 | 0 | 1 | 4 | 3 | 8 |
| CENTRAL AMERICA | 0 | 0 | 1 | 1 | 4 | 6 |
| CHILE | 0 | 0 | 0 | 1 | 10 | 12 |
| COLOMBIA | 0 | 0 | 0 | 4 | 25 | 29 |
| DOMINICAN REPUBLIC | 0 | 0 | 0 | 0 | 0 | 0 |
| EGYPT | 0 | 0 | 0 | 0 | 0 | 0 |
| EQUADOR | 0 | 0 | 0 | 0 | 0 | 0 |
| FRENCH WEST AFRICA | 0 | 0 | 0 | 0 | 2 | 2 |
| INDIA | | | 0 | 0 | 0 | 0 |
| INDONESIA R&H | 0 | 0 | 0 | 2 | 2 | 4 |
| MALAYSIA | 0 | 3 | 18 | 62 | 119 | 202 |
| MEXICO | 4 | 18 | 40 | 89 | 173 | 323 |
| MOROCCO | 0 | 0 | 0 | 0 | 0 | 0 |
| PAKISTAN | 0 | 0 | 0 | 0 | 0 | 0 |
| PERU | 0 | 0 | 0 | 0 | 0 | 0 |
| PHILIPPINES R&H | 2 | 7 | 20 | 59 | 129 | 217 |
| SOUTH AFRICA R&H | 78 | 268 | 723 | 1467 | 2736 | 5272 |
| THAILAND R&H | 30 | 168 | 641 | 1249 | 2175 | 4263 |
| TUNISIA | 0 | 0 | 0 | 0 | 0 | 0 |
| URUGUAY | 0 | 0 | 0 | 0 | 0 | 0 |
| VENEZUELA | 0 | 0 | 0 | 0 | 1 | 1 |

## 9 Graphs

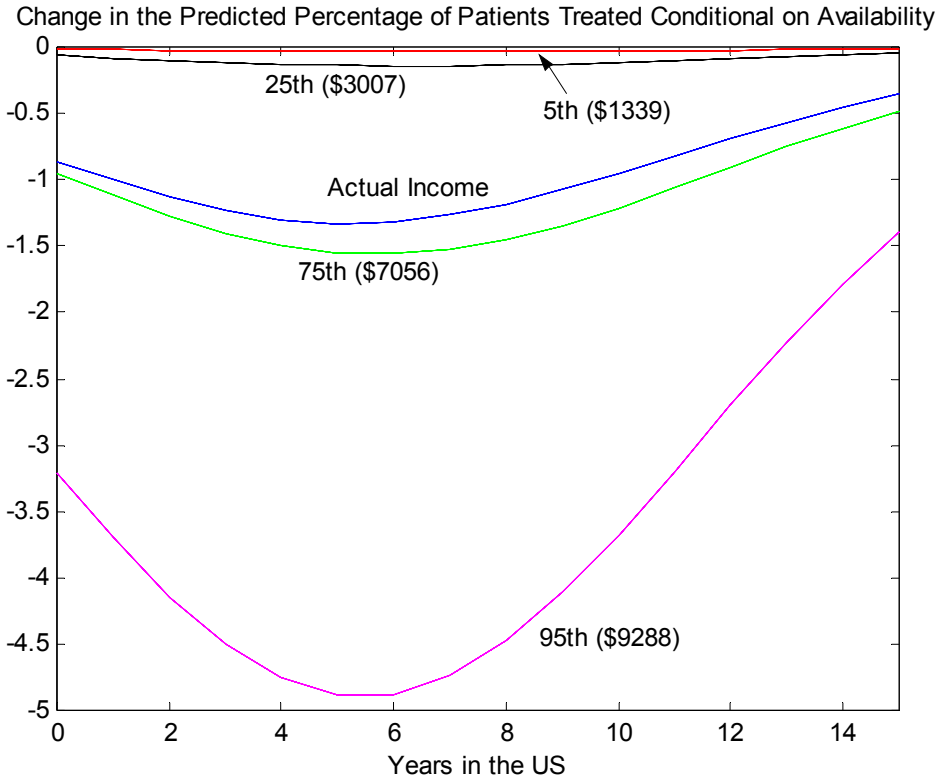
Graph 1.- Change in the Probability of Having a Sample Mean ARV drug Available Locally When We Switch from a No-Patent to a Patent Regime



Graph 2.- Change in the Expected Number of Firms Offering a Sample Mean ARV Drug When We Switch from a No-Patent to a Patent Regime



Graph 3.- Change in Market Coverage by a Sample Mean ARV Drug When We Switch from a No-Patent to Patent Regime Conditional on Having the Drug Available



Graph 4.- Change in Market Coverage by a Sample Mean ARV Drug When We Switch from a No-patent to Patent Regime