Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry[1]

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Abstract

We consider how patent rights and price regulation affect whether new drugs are marketed in a country, and how quickly. The analysis covers a large sample of 68 countries at all income levels and includes all drug launches over the period 1982-2002. It uses newly compiled information on legal and regulatory policy, and is the first systematic analysis of the determinants of drug launch in poor countries. Price control tends to discourage rapid product entry, while the results for patents are mixed. There is evidence that local capacity to innovate matters and that international pricing externalities may play a role.

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I. Introduction

The pharmaceutical industry faces a rapidly evolving legal and regulatory environment. Governments, drug companies and advocacy groups continue to engage in a decade-long battle over the type of patent rights that will be available to industry, particularly in poor countries. Particular criticism has focused on the intellectual property standards required of members of the World Trade Organization—standards known as Trade-Related aspects of Intellectual Property, or TRIPS, rules. International drug pricing is also coming under the spotlight. Americans have accused the Europeans and Canadians of using their price control systems to free-ride on U.S. consumers, and the United States is starting to push for regulatory changes in bilateral trade negotiations.[2] These pressures may well generate future reforms on a broad scale.

The choices made by each country about its patent system and price regulation will have many ramifications – influencing the size of future investment in medical research, the availability of the resulting therapies, how the financial burdens are distributed across countries, and finally the health of consumers. We focus here on how policy choices affect whether new drugs are marketed in a country, and how quickly. Because there are fixed costs associated with launching new products, it would seem intuitive that both weaker price regulation and stronger intellectual property would facilitate entry by virtue of increasing firm profit.[3] However, what makes this an interesting economic problem is that intellectual property can have a second important effect. While patents indeed make local markets more attractive, they also convey control over launch decisions to multinational firms with global interests.[4] Multinationals may delay or even avoid launching drugs in lower-priced countries because they are concerned about the implications for pricing in *other* markets. If they hesitate, and patent rights block otherwise willing local entrants, then strong patent rights may actually reduce product entry.

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[2] See, for example, the speech by Mark McClellen, then Commissioner of the U.S. FDA, before the First International Colloquium on Generic Medicine. September 25, 2003, Cancun, Mexico. Available at http://www.fda.gov/oc/speeches/2003/genericdrug0925.html (accessed 12/28/03). Most recently, the U.S. insisted that reforms to Australia's domestic price and reimbursement system be a part of the AUS Free Trade Agreement (see www.aph.gov.au/Senate/committee/freetrade_ctte for details and discussion. Accessed 1/24/05). Suggesting a future agenda, see "Ten Questions," Pfizer Annual Review 2004: "We believe Americans carry an unfair share of the global cost of biomedical research. We think that's a serious issue that should be near the top of the global trade agenda."

[3] Local fixed costs include obtaining marketing approval from the country regulatory authority and educating doctors and patient groups about the drug's benefits. These costs can be sizeable, particularly for the first entrant.

[4] While in principle smaller local firms could develop new drugs, in fact multinationals hold almost all product patents. Some 86% of the applications for product patents in India in 1995 were submitted by inventors with a non-Indian address (CDRI, 1996) and in most developing countries the share is far higher. As firms based in developing countries also begin to invest in the development and patenting of new products they will have the same global marketing incentives and constraints faced by the current multinationals.

Although the pricing of patented pharmaceuticals has attracted a great deal of attention recently, the question of whether new drugs are marketed at all, remarkably, has not.[5] This is significant given that less than one-half of the new pharmaceutical molecules marketed worldwide are sold in any given country – whether rich or poor. Even those drugs that are eventually marketed in one country frequently appear on pharmacy shelves only six or seven years after becoming available to consumers elsewhere.[6] Both price regulation and intellectual property rights influence these outcomes. The CEO of Pfizer, Hank McKinnell, frankly acknowledged this point some years ago when he threatened that the company would withhold new treatments from France unless the government allowed higher drug prices (*Financial Times*, December 10, 2001).

When considering the effect of patent rights it is important to distinguish two main types: those that protect of methods of manufacture ("process patents") and those that protect pharmaceutical products ("product patents").[7] Process patents are relatively weak. While one firm's patents on methods for producing a molecule might give it a monopoly for a time, a second firm can legally devise (and patent) a new method and come into the market. Indeed, countries have purposefully chosen a "process-only" patent regime for pharmaceutical innovations in order to foster a domestic industry based on inventing around originators' manufacturing processes.[8] Although relatively weak, process patents may nevertheless encourage product entry by slowing down the arrival of competitors, allowing firms to cover fixed entry costs.

The ambiguity arises with product patents because these concentrate control in the hands of a single innovating firm. In the debate preceding the TRIPS Agreement it was argued that countries refusing to grant product patents were failing to get many newer drugs precisely because of the threat of follow-on imitative competition. If innovator firms could be assured of a local monopoly, it was suggested, they would find it attractive to launch more products. In the presence of externalities, however, this argument is no longer obvious.

Several mechanisms can generate international pricing externalities. Some developed country price regulators explicitly use cross-country comparisons to establish ceiling prices. U.K. drug prices, for example, are used as an international reference by regulators in Austria, Canada, Greece, Ireland,

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[5] Although when Gilead Sciences recently offered to expand to 95 the number of countries eligible to receive its key anti-retroviral drug "at cost", the offer was called "disingenuous" by the NGO Doctors without Borders because the firm has been supplying only 22 of the original 68 eligible countries. *San Francisco Chronicle*, March 18, 2005.

[6] A "drug" refers to a chemical entity in any of its presentations – e.g. tablets, capsules, liquid.

[7] Some countries also give additional protection to new formulations and new uses of existing products.

[8] India's rejection of its adopted colonial British patent code in 1972 in favor of a system allowing only short (5-7 year) process patents for drugs provides an example. With only process patents available, the multinational subsidiary Glaxo India faced several local competitors from the first day that it marketed its blockbuster drug ranitadine (Zantac); while Cipla was manufacturing a version of the Pfizer drug Viagra shortly after the drug's global launch (*Wall Street Journal*, July 10, 1998).

Italy, Luxembourg, Netherlands and Portugal (Bloom and van Reneen, 1998; see also Jacobzone 2000). Physical arbitrage across country borders can also erode prices in higher-priced markets. Arbitrage is legal among E.U. member countries, which pushes prices in the direction of uniformity although it has not resulted in a single price across markets (Kanavos, *et. al*., 2004; Ganslandt and Maskus, 2004). Arbitrage between most countries is illegal. Nevertheless there are concerns about black market movements, with occasional high-profile stories involving developing countries and a soaring trade between the U.S. and Canada.[9]

The behavior of political interest groups can also push prices toward uniformity. Consumers forcefully object to paying prices that are higher than those they see being charged to consumers elsewhere, giving firms and their regulators reason to fear a political backlash if obviously different prices are in place. A growing literature examines how firms may distort behavior to avoid the imposition of regulation or soften its effect. Glazer and McMillan (1990), for example, model pricing by a monopolist where the firm may choose to forestall regulation by setting a price closer to that desired by the regulator. Erfle and McMillan (1990) find that oil firms limited their price increases during the 1979 oil crisis. Price restraint was more pronounced on more visible fuels like home heating oil and more likely among large and visible firms. Ellison and Wolfram (2004) show that pharmaceutical firms acted collectively to limit price increases during a period of intensive political discussion of health care reform in the U.S. Firms identified as particularly vulnerable to regulation were more likely to engage in price restraint and lobbying. Examining the stock prices of credit card firms, Stango (2003) finds that announced rate cuts were less damaging to returns when the announcements followed a regulatory threat. Again this result was more pronounced for politically visible firms.[10]

Identifying the precise mechanisms generating pricing externalities across markets is not the goal of this paper. Rather, the concern here is whether product patents can reduce access to new drugs by making firms that care about externalities – whatever the source – more important players. Whether access is, in fact, limited is also a key question for interpreting the welfare implication of firms' inability to fully price discriminate across countries.[11]

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[9] For example, "HIV Drugs For Africa Diverted to Europe," *The Washington Post*, October, 2002; "Europeans Investigate Resale of AIDS Drugs," *New York Times*, October 29, 2002.

[10] Behavior beyond pricing may also be affected. For example Maxwell, Lyon, and Hackett (2000) examine firm efforts to deter consumer mobilization, and thereby government-imposed regulation, by voluntarily limiting their pollution output.

[11] Maleug and Schwartz (1994) show that uniform pricing by a monopolist yields lower global welfare than third-degree price discrimination when demand dispersion is such that many markets are left unserved under uniform pricing. See also Scherer and Watal (2002). This result is accentuated if one allows for global equity concerns and differences in the marginal utility of income across consumers (See Jack and Lanjouw, 2005, where they apply many-person Ramsey pricing to the problem of global pharmaceutical pricing.)

Two examples of firm behavior in this environment are instructive. In the late 1980s, Bayer chose not to introduce its new antibiotic ciprofloxacin in India. To do so it would have needed to price the product very low to be competitive in that market, at a time when the firm was negotiating prices in its more important markets. Instead, ciprofloxacin was introduced in India three years after its world launch by the Indian firm Ranbaxy. However, eight years after the drug's global launch and long after the entrance of a multitude of local producers, Bayer finally entered the Indian market (interview with Bayer executive, India, 1997). More recently, GlaxoSmithKline and Pfizer have cut back supplies of their products to Canada to prevent drugs from leaving for the United States – where they damage the higher prices that the firms enjoy in that country.[12] In both of these situations the multinationals found it profitable to engage in a local market at a low price. Their reluctance to do so clearly stemmed from the potential implications for their profits in other markets. What is particularly notable in the story of ciprofloxacin is the further suggestion that pricing externalities may become less acute later in the product lifecycle.[13]

Given the considerations raised here, one would expect to see three types of entry into poorer country markets. Firms interested in producing only for the local or regional market should be willing to enter at any time, assuming that expected returns in the local market at least cover the fixed costs of entry. Multinationals might enter poorer markets quickly in situations where they can set a price that is close to their target price in the major markets. Sales would then be limited to the local elite. Finally, one might see multinationals waiting for some time after the global launch of a new product, and then entering developing country markets with a low price that allowed them to capture market share. Which of these strategies are feasible and likely will be influenced by price regulation and the intellectual property regime.

To date there has been little analysis of the determinants of international drug launches. Danzon, Wang and Wang (2005) examine launch data from 25 major markets for the years 1994-1998, and a selected sample of 85 new chemical entities (NCE). They are specifically concerned with the effects of price regulation. Rather than summarizing differences in price control systems directly, they use the price for a standard unit in a drug's therapy class in an earlier year as indicator of the intensity of regulation. A similar variable is constructed for expected market size. Both higher prices and larger markets are found to have a significantly positive effect on the likelihood and speed of launch.

Kyle (2004a and 2004b) analyzes 21 OECD countries and much larger set of drug launches, including 1577 molecules developed during the period 1980-2002. She focuses primarily on how firm

[12] *Wall Street Journal*, January 22, 2003; "Pfizer Cuts Supplies to Canadian Drugstores," *The Washington Post*, April 5, 2005.

[13] One candidate explanation is the fact that controlled prices set in high-income countries in the early entry years are typically not renegotiated over time (Jacobzone, 2000).

characteristics affect launch timing and finds, for example, that domestic firms have a 5 times higher probability of launching at home (with domestic status most important in Japan and Italy). A dummy for price regulation has a significantly negative effect and she finds that firms are less likely to follow launch in a low-price country with launch in a high-price country.

None of these papers consider intellectual property (IP) as a determinant of marketing decisions. McCalman (2004) provides an econometric analysis of how intellectual property might influence launch decisions – of American Hollywood movies. His data are from 1997-99 covering 37 countries, and he estimates hazard models for the effect of IP strength on the speed of film launches across countries. He finds a non-monotonic relationship with moderate IP associated with the most rapid diffusion. There is, in his context however, no scope for pricing spillovers across countries.

This paper analyzes launch patterns across a very large sample of 68 countries over the period 1982-2002. The paper provides descriptive statistics; and probit and hazard analyses of the likelihood and speed of launch. Explanatory variables include those related to the attractiveness of markets and local technical capacity. Those of primary interest are newly constructed policy variables for the availability and strength of patent protection and the stringency of price control. This is the first analysis of pharmaceutical launch patterns that includes developing countries. Their experience is of independent interest and provides more variation in the policy variables than is found among OECD members.

II. The Drug Launch Data

The launch data are drawn primarily from the December 2002 "LifeCycle: Drug Launches" database constructed by the private vendor IMS Health. The database identifies the month and year that a product first has retail sales in a given country, and indicates which entries represent first world launches of new chemical entities (NCE).[14] For each product launched, it gives the tradename, the Anatomical Therapeutic Classification (ATC) code, active ingredient, composition, and firm making the launch. Coverage includes entry during the 21 years 1982-2002 in the retail sector and, for some countries, the hospital sector also. The Indian market was not covered by IMS during this period so we incorporate similar information obtained from the Indian market research company, ORG-MARG. The Indian data cover a partial, but broad, set of therapeutic classes – including launches of all antibiotics, ulcer and cancer drugs – and includes all products in those classes launched in the Indian market during the period 1986-98. The combined dataset covers 68 countries or country groups, 60%

[14] In some cases the same chemical was indicated as being 'new' more than once, or was identified as 'new' at a country launch later than the first launch in the world. In these cases the first appearance is taken as the global launch date.

of which have at least twenty years of information.[15] Further details regarding data construction are available in Lanjouw (2005).

III. Description of Global Launch Patterns

Table 1 gives the number of NCE's with a first appearance (global launch date) in each year. The first column indicates the number of new "blockbusters". These are drugs that were found among the top 200 in terms of world revenue in 1998 or 2003, or among the top 100 U.S. revenue earners in 1995 and 1993 (Med Ad News, various issues). The second column includes all drugs. There was an increase in the number of new chemical entities launched in the mid-1980's, with some fall off in the numbers in the early 2000's (perhaps due in part to data processing delays). On the whole, however, the number of NCE's appearing each year was fairly similar over the period.

There were 836 new pharmaceuticals first marketed during the period 1982 – 2002. Table 2 indicates the location of these first launches. The table includes countries having at least one first launch, ordered by income class.[16] Two points stand out. First, firms almost invariably launch products first in rich country markets. Second, a very large share of all drugs is launched first in Japan (and only there – see below).

Figure 1 gives an idea of the number of countries that an NCE typically reaches. It is based only on the 300 NCEs with global launch dates early in the period (1982-1988) to avoid truncation. We see that just a very few drugs from that time period were launched worldwide. The mean number of countries is 20, the median is 9, and almost 20% of new drugs are marketed in just a single country. Of the 54 single-market drugs represented in this figure, 23 were sold only in Japan, 13 only in Italy, with the rest scattered across countries. Japan is clearly distinctive – it is the location of 24% of all drug launches, but 43% of those marketed in a single country. From 1995 there was a marked increase in the number of countries reached within a short span after global launch, so it is likely that today the distribution shown in Figure 1 has shifted rightward.

Table 3 indicates how long it takes for a drug to become available to a country's consumers. Calculations in this table are restricted to the 122 NCEs first launched 1986-92 and assigned to therapy classes for which the Indian data are available. There is some truncation for drugs entering after a long delay because the data end at 2002, but each NCE has at least 120 months of information. It is evident that lags tend to lengthen as one goes down the income rankings. The group summary at the bottom of the table shows that differences are most pronounced between the high-income countries

[15] French West Africa (Benin, Cameroon, Congo, Cote d'Ivoire, Gabon, Guinea, Senegal) and Central America (Costa Rica, El Salvador, Guatamala, Honduras, Panama) are aggregated by IMS because they are very small markets.

and the rest.[17] However, there is also clearly a great deal of variation across individual countries: median launch lags range from months (Japan, Switzerland) to over eight years (Latvia, Lebanon). There is also considerable variation across products within countries: For example, the difference between the 10th and 90th percentile of the lag distribution is over 10 years in Morocco and Peru and over 7 years in some of the OECD countries.

To avoid differing degrees of truncation across years, Table 4 restricts attention to launches that occur within 10 years of the first global launch of each NCE. The ten-year span includes most market entry, as shown in the previous table. Table 4 includes the 91 "blockbuster" and 462 total drugs in all therapy classes first launched during 1982-92 (so India is dropped). The first column, on the left side of the table gives the percentage of all drugs that was eventually launched in the row country at any point within a ten-year lag. The second column gives the percentage of blockbusters eventually launched in each country.

Considering the first column, the percentage of drugs launched within a ten year lag ranges from lows of 19% and 22% (Egypt, Malaysia) to highs of 49% and 53% (Italy, Japan). Thus, no consumers anywhere have access to more than about one-half of the new pharmaceuticals that enter the world market. The mean (unweighted) percentage is 34.8% for the high-income countries, and 29.9% and 28.4% for the middle- and low-income countries, respectively. As expected, "blockbuster" drugs that experience high sales revenues in the developed world are also launched more frequently in the poorer countries than drugs overall, although in no country is the rate for even this more select group close to 100%. The fact that drugs are not launched more widely can be due to the availability of substitutes, differences in disease patterns across countries, and rejection by some local regulatory authorities.

The remaining columns of Table 4 give the cumulative distribution of drug launches at different lags from one year to nine years. Thus the column headed "3" indicates the percentage of all NCE launched within ten years in a given row country that arrived in that market within three years. Countries are listed by income group and, looking down this column, we again see that drugs are more likely to be launched within three years in the richer countries than in the poorer countries. This is highlighted in Figure 2, which shows unweighted averages for each income group. However, the pattern is not strong. Israel, at 27%, for example, has a smaller share on the market this quickly than either the Philippines or Thailand (44% and 41% respectively). Again we see the large range of

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[16] The income classes follow those in the World Bank 2002 *World Development Indicators Report*. The ranges for GNI per capita measured in 1999 U.S. dollars are: Low ≤ $755 < Lower ≤ $2995 < Middle ≤ $9265 < High.

[17] The difference for high income countries is not driven by the fact that Japan has a large number of unique drugs. Dropping Japan lowers the average number of drugs to 40 and increases the median lag to 28 months.

experience overall. Germany has 75% of its drugs on the market within three years of the global launch, Saudi Arabia just 16%.

Most global market entry is done by the "first" firm, defined as the firm that makes the first global launch of an NCE in a high-income country, or any country for the few NCE launched exclusively in the poorer countries. This firm almost surely holds most of the patents associated with an NCE and is typically a multinational. A smaller share is done by "other" firms – which may in many cases be entry done under license as part of a marketing arrangement and thus effectively controlled by the first firm (the data do not allow one to distinguish). "Other" firms may also be multinationals.

Shares for the low- and middle-income countries are shown in Table 5, broken down by type of patent regime. Moving from left to right, a stronger patent regime is associated with more of the drug launch in a country being done by the first firm. Overall, two-thirds of all drug launches and three-quarters of blockbuster launches are done by the first firm. These firms are responsible for about 80% of the new drug launches in the poorer countries that occur within the first 3 years. That these firms enter markets more rapidly is also clear in Figure 3, which shows the timing of drug entry in high or lower-income countries conditional on launch being done by the "first" or "other" firm.

IV. The Explanatory Variables

Annual series were constructed to describe each of the main policy areas:

Intellectual Property Protection: These include indicator variables for the availability of patents on innovative methods of manufacture for pharmaceuticals (process patents), and on new pharmaceutical compounds (product patents). Historically, countries have offered either no protection in the area of pharmaceuticals, process patents only, or both process and product patents. The data include the statuary term of each form of protection, and information about whether a country allows for an extension to the patent term to compensate for time spent in the marketing approvals process.

How a country interprets and enforces its patent laws clearly affects how meaningful any patent "rights" are to their owners. Unfortunately this is a difficult characteristic to capture in data. We use one variable, "strong," falling between 0 and 1, which takes on a higher value as a country limits how patent rights can be curtailed. Specifically, it is the average of non-missing values for three other 0/1 indicators: the first equals one if a country will not impose compulsory licensing until three years after patent grant; the second equals one if the country has no formal obligation to "work" a patent (supply the market); and the third equals one if the country does not revoke patents for failing to work if there is such a requirement. This variable was devised by Walter Park, who provided the data required for its construction for most countries for each five years beginning in 1980 (see Ginarte and

Park, 1997, for details). For missing countries, his data were supplemented assuming current values throughout the period based on the legal texts. A similar variable composed of enforcement-related indicators was not found to have any explanatory power and therefore was not included in the estimations.

Price Control: Countries approach the control of pharmaceutical prices in a bewildering variety of ways. We consider systems of explicit price regulation and summarize the variation across countries with two dummy variables – one for the existence of "some" price control regulation and the second for "extensive" price control. A price regime is label "extensive" if all drugs are regulated, rather than just a subset of the market, or if a country's price regulation is identified by commentators as being particularly rigorous. The set of reports consulted in making this determination, and legal texts sourced for relevant IP law, are given in Lanjouw (2005).

The legal and regulatory policies of a country result from some process, and this makes endogeneity an obvious concern when trying to understand the effects of any policy regime. In our case, one might expect firms to lobby hardest to obtain strong patent protection in countries viewed as attractive markets for entry, potentially creating a positive bias in estimated relationships.[18] However, a consideration of history suggests that substantive within-country changes in the patent law can reasonably be treated as exogenous for our purpose – certainly in their timing. Such changes tend to be forced by the rules of entry into new political groups (e.g., Portugal and Spain joining the EU in 1992); by newly negotiated standards created at an international level (e.g., many poor countries and TRIPS, Mexico and NAFTA); or a vulnerability to trade pressure and the political dynamic of bilateral negotiations (Korea, Brazil, and Jordan in the 1980s and 1990s). (See Sell, 2003.) The link to the dynamic of trade negotiations is reflected in comments by the body that advises the U.S. Congress and administration on IPR and trade, the Industry Functional Advisory Committee on IPR for Trade Matters (IFAC-3), in its reports to the US Trade Representative:

> CAFTA (the Central American Free Trade Agreement) "mirrors, as closely as possible, the Singapore and Chile FTAs in order to establish clear precedents in most key areas of intellectual property protection for *future* FTA negotiations."

And

> "IFAC-3 is particularly gratified that….with high-level agreements with both small developing countries in the CAFTA and a strong and mature developed country like Australia, it will prove much easier to convince future FTA countries that strong intellectual property

[18] And lobby they do. For a candid discussion see historical issues of the PhRMA annual report.

protection is in the interests of all countries *regardless of their economic circumstances*." (Italics mine).[19]

Price regulation is more likely to be endogenous. While patent laws change only rarely, and then in fairly specific and major ways, governments may more flexibly adjust price controls. In particular, a government might be willing to limit the scope or intensity of an existing system even where it would not dismantle it altogether. Weaker regulation might be associated with pressure from an industry with an eye on entry for other reasons. There are, however, strong countervailing forces that limit industry influence, such as budgetary pressures and vigorous lobbying by patient groups and the retired elderly.

Control Variables: To mitigate potential endogeneity concerns and remove noise, we construct controls for other characteristics that one might expect to influence pharmaceutical marketing. Some of these control variables are of independent interest. Given our hypothesis that multinationals might be reluctant to launch in poor countries when they face price competition, and that local firms could be an alternative source of new drug entry, the presence of a competitive local industry should be relevant. The finding in Section 3 that innovator firms are responsible for most global marketing suggests that the price effect of local competition could be particularly important. Country R&D expenditure (in all areas) as a share of GDP is included as a regressor to capture local technical capacity and thus the potential for imitative competition. High tariffs in a country may also make entry less attractive to multinationals that would anticipate importing supplies from centralized production facilities. High-income countries have zero rates on pharmaceuticals, but in the poorer countries there is considerable variation, with rates as high as 35%.[20]

Differences in market opportunities are captured by the demographic indicators population size and the percentages of the population aged 0-14, 15-64, 65+ years. Economic variables include the level of GDP per capita. The Gini coefficient of inequality, and asset ownership, provide some measure of differences in income distributions. We also control for the share of health expenditure in GDP, and the share of health expenditure that is private, and the share of doctors in the population.

Characteristics of the regulatory process can also influence market entry. Health authorities differ in their standards and some may reject a new drug even when it is on the market elsewhere. Delays in the marketing approvals process can take the speed of drug launch at least partially out of

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[19] Industry Functional Advisory Committee on IPR for Trade Matters (IFAC-3) in reports to the USTR: http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA-DR/CAFTA_Reports/asset_upload_file571_5945.pdf and http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_FTA/Reports/asset_upload_file164_3139.pdf (both accessed 12/06/04).

[20] The data used here were drawn from the UNCTAD database and kindly supplied by Adrian Otten. See European Union (2003) in the policy references for a description of these regulations.

the hands of firms.[21] The observed timing of market entry reflects some combination of the decisions of firms and the complexity and efficiency of a country's regulatory process. Thus, the estimations include other elements of government policy that might directly affect or proxy for other conditions that influence entry timing, beyond our key variables of interest. These include whether a country has adopted an essential drug list, standard treatment guidelines or a national formulary. For E.U. members we include an indicator for the 1995 establishment of the European Medicines Evaluation Agency. This agency offers a centralized, and thus potentially more rapid, approvals procedure within the European Union.

Many of the explanatory variables are available annually and others are in one or several cross-sections. Variables are defined in Appendix Table A1 with summary statistics in Table A2.

V. Econometric Analyses of Launch Determinants

This section describes the probit and hazard model estimations used to analyze the probability and speed of drug launch. Results are discussed in the following section.

Because the data are sufficiently rich to allow disaggregation, all estimations are done separately for the high-income countries and for a combined low-and middle-income grouping. We consider four different subsets of the NCE in the data. The base estimations include all drugs. However, some drugs launched in one location fail to reach other county markets because they do not meet those countries' local health standards for safety or efficacy. We want to distinguish between firm's decisions not to launch, and a failure to fulfill marketing requirements. Thus, for the high-income countries we also estimate the models on a "high quality" subset of NCEs, defined as those that obtain marketing approval and are launched in either the U.S. or the U.K within 2 years. This follows Danzon, *et. al.* (2005), who argue that these two countries have the most stringent regulation and that therefore approval for their markets implies a minimum quality standard.[22]

For the low- and middle-income group we focus on the set of "blockbuster" drugs – those of greatest commercial importance as measured by sales revenue. The group includes drugs of great medical importance and also some major "lifestyle" drugs. We examine the launch of blockbuster

[21] Firms are able to influence how quickly a given drug moves through the approvals process. They can work with more institutions and offer greater compensation to participants in order to rapidly reach required sample sizes for clinical trials. They can direct more resources to interacting with the authorities during the approvals process. Dranove and Meltzer (1994) provide evidence from the United States that firm work harder to speed the approval of drugs that are later successful in the market.

[22] Unlike Danzon, *et. al.*, we drop the U.S. and the U.K. as launch countries when analyzing this subset since their launch probabilities are biased upwards by construction. Another way to approach the quality issue is to restrict attention to drugs known to satisfy a given country's standards because they are observed entering its market within ten years, and analyze the probability that those drugs are launched within two years (analogous to Table 4). Unreported estimates on this subset support the results discussed below.

drugs in the low and middle-income group only, because one could expect drugs in this group to be launched extensively in the rich countries (although see the second column of Table 4.)

Finally, when examining launch in the lower-income group we consider separately NCE in therapy classes that have sales relatively more concentrated in developing countries: class A (alimentary tract and metabolism) and class J (systemic anti-infectives). The sales of drugs in class A and J were 23.6% and 23.0% of all sales in India in 2000, while only 10.4% and 18.1% of the NCE in our data fell in these therapy classes (sales figures from Chaudhuri, *et. al.*, 2004). Firms might have stronger incentive to enter poorer markets with products in these classes.[23]

Tables 6-8 and Tables 10-11 contain the estimation results for probit models of the probability that a new drug is launched in a given country within either two years or ten years of the drug's first appearance in the global market. Observations are at the level of a country/NCE and the dependent variable takes on the value one if the NCE was marketed within the indicated period of time. A 24-month lag is below the median lag for high-income countries, and below the 10th percentile for low- and middle-income countries (see Table 3). Thus, product entry within this timeframe represents relatively rapid launch, particularly in the poorer countries. The procedural steps associated with market entry should not typically require a delay longer than two years, particularly for the originator firm.[24] Thus, if a launch fails to happen within two years one can fairly assume that this failure involved at least some element of firm choice to delay, or that a decision was made to enter but the product was rejected by the health authority. The descriptive statistics presented above suggest that a lag of ten years is a reasonable indicator of whether a drug is "ever launched".

Table 9 contains estimation results for a log-logistic hazard model of the time path of country launches.[25] The log-logistic model implies that the probability of failing to have a new drug on the market *t* months after the global launch is

$$S(t) = \left[1 + \left(\frac{t}{\exp\{x\beta\}}\right)^{1/\gamma} \right]^{-1}.$$

This functional form allows for increasing and then decreasing hazards rates through the parameter γ and was preferred by the data over other frequently used specifications such as Cox proportional hazard or Weibull models. To accommodate unobserved heterogeneity across drugs, the estimations also allow for a multiplicative factor on individual hazards having a Gamma distribution with mean

[23] Virtually all drugs are also marketed in the high-income countries. Of the over four hundred NCE launched through 1992, only eight were launched exclusively in the low- and middle-income countries and only one of these in more than a single country.
[24] A timeline of patent application and approvals is discussed in ____(2005).
[25] Global launches are defined as being a launch in the first month to avoid those observations being dropped.

one and variance θ. This standard form yields a convenient analytical expression for the likelihood function.

In all specifications, countries enter the estimation for a given NCE only if the NCE's global launch precedes the entry of the country into the database. To avoid truncation, the hazard estimations include NCE first launched 1982-2001, the probit estimations for a two-year lag include those first launched 1982-2000, while those for the ten-year lag include only NCE with first launch 1982-1992. All estimations include full sets of dummy variables for both the date of NCE first global launch and the fourteen ATC therapeutic classes. Country fixed effects are also included in some of the probit estimations – as indicated in the column headings – and in the hazard estimations. Their inclusion implies the loss of all information available from cross-country variation in the key policy variables; but focusing on within-country changes over time has the advantage of controlling for any unobserved market characteristics that might be correlated with those variables. Appendix Table A3 indicates the countries that saw changes in their policy variables during relevant time periods. Time, therapy class, and (where included) country fixed effects are each jointly significant in all cases. Where country fixed effects are not included in the model, the estimations allow for a country random effect.

Explanatory variables are dated by the year of the first global launch. For example, if an NCE is first marketed in 1990 then it is a country's population size in the year 1990 that is considered as a determinant of drug launch in the period two or ten years after 1990. This is not obviously the right assumption – one might expect that the relevant characteristics would be those for a later period, particularly for the probability of launch within ten years. However, experimentation showed that both policy and market variables dated after the global launch (either two or four years) have weaker explanatory power in models of new product launch. It may be that worldwide launch decisions for a new drug are taken at the time of first marketing and do not readily respond to subsequent changes in the policy environment.

VI. The Estimation Results

We now examine the determinants of drug launch. Coefficient estimates on the patent regime and price control variables are discussed in detail, followed by a brief discussion of other estimates.

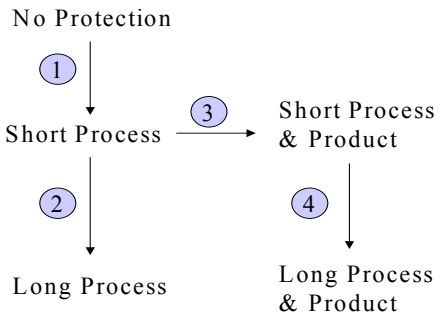
Low- and Middle-income Countries

Results of probit estimations for the low- and middle-income countries are presented in Tables 6 through 8, with corresponding hazard model estimates in Table 9.

The type of patent protection offered by a country in this income grouping is characterized by a set of five dummy variables (see the first rows of Table 6). Information on the length of protection is collapsed into indicator variables for whether the statutory patent term is short vs. long. This

distinction has explanatory power whereas the specific term length in years does not. While somewhat surprising, launch decisions are made by managers who must synthesize different types of information and it is quite plausible that the simpler breakdown is the way in which they think about country patent policies when making their choices.

The first of the five dummy variables indicates whether a country offers at least short-term process protection for pharmaceuticals versus no protection at all (see the diagram below).



For the lower-income countries "Short" refers to a statutory term of 14 years or less.[26] About 10 years pass between patent application and marketing approval on a product (see Gabrowski and Vernon, 2000). Thus a term of 14 years would imply that, on average, about four years of effective protection would be conveyed by a patent on the product molecule and perhaps a few more years by associated process patents having later application dates. Of the periods in which countries in the data offered a short term of protection, in about 25% of cases the term was 14 years. In about 50% the term was 12 years, implying an average effective patent life of only a few years. In the remaining cases the term was just 7 years.

The next two variables capture the *incremental* effect of moving to either to long process protection (≥ 15 years), or alternatively adding short product protection. The forth variable indicates the additional effect of going from short protection of both products and processes to long protection of both. (One never observes a country with short product protection and long process protection.) The final dummy variable indicates whether the country will grant an extension on product patents to compensate for marketing time lost during the approvals process.

[26] Experimenting sequentially with cutoffs from 12 to 17 years, 14 gave the highest pseudo-R^2.

Table 6 presents results for the full set of drugs. The first model, shown in column one, includes country fixed effects, while the second model does not. [27] Because the latter specification includes the Gini coefficient as a control, a number of countries are lost due to missing information.

The estimates are quite robust to the assumption of fixed or random country effects, which lends empirical support to the argument that the set of policy variables can be treated as exogeneous. As noted above, the decision whether to maintain an extensive price control system in the face of international corporate or governmental pressure is the policy choice most likely to be problematic. To test whether endogeneity in this variable might be influencing the results, we also estimate a two-stage conditional maximum likelihood version of the model in column two that includes the residual from a first-stage regression for extensive price control (Rivers and Vuong, 1988). Significant instruments in the first-stage regression include the economic orientation of the ruling executive party, its tenure in power, and the overall budget balance.[28] First-stage estimates are provided in Appendix Table A4. The exogeneity of the extensive price control variable in the probit for launch is not rejected (null hypothesis that the residual coefficient is zero: $\chi^2(1) = 0.42$, p-value = 0.52). The coefficients in the launch model change little so they are not reported.

Given the historical link between changes in patent law and trade agreements, one might also be concerned that what looks like a positive role for stronger patents could be due to other changes in the trade regime facilitating market interaction. To test this, annual exports was included as a control variable in unreported estimations. Its inclusion had little effect on the estimated coefficients on the policy variables.

The observed probability that a drug is launched in a low- or middle-income country within two years is about 9%. The estimates in Table 6 suggest that going from a regime with only short process patents to one with long process patents significantly encourages rapid entry. A long process patent regime still allows for possible generic entry and this appears to be important. The marginal effect is to raise the probability of launch within two years by 2-3 percentage points (or about 30%). There is little evidence, however, that offering any form of protection to new pharmaceutical products enhances the likelihood of quick entry into these markets. The individual incremental effects of adding short and then long product protection are insignificant in both specifications, and the joint marginal effect is weakly significant only in the random effects model (0.021 + 0.008, p-value 0.08).

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[27] Because there is limited variation in the policy variables – particularly when country fixed effects are included – a jackknife procedure was used to look for potential overfitting of the data. Countries were dropped in turn, the model re-estimated and the resulting coefficient estimates checked for stability.

[28] Budget stress could increase the stringency of price regulation as countries that cover pharmaceuticals though general expenditure strive to control costs (for many specific incidents in the E.U., see Jacobzone, 2000). Because it could conceivably have a direct effect on the government's willingness to approve relatively expensive new drugs we also run the two-stage estimations dropping this variable. The results are the same.

Extensive price control clearly lowers the probability that new pharmaceuticals reach consumers quickly in lower-income countries, as expected. The predicted effect is similar in magnitude to that of the change to a longer term on process patents – in this case lowering the probability of rapid entry by some 30%. That a country has an essential drugs list is also associated with a lower likelihood that new drugs are launched quickly and may indicate more focused efforts by the government to ensure that drug purchases are cost effective. Moderate price control, on the other hand, does not appear to have a significant influence on entry in these specifications.

The first two columns of Table 7 present the main results for estimates when additional variables are included in the random effects specification. The first adds a country's R&D share and its level of tariff protection (which together lead to a sizable drop in the number of observations due to missing data). We again find that having a long process patent regime significantly encourages rapid drug launch. A new finding is that countries with a high technical capacity as measured by R&D expenditure are far less likely to see new pharmaceuticals in the market quickly. Starting from no R&D and then increasing R&D to the mean level of one-half of one percent of GDP drops the probability of rapid launch by an estimated 13.6 percentage points. This negative effect of local capacity, however, is significantly offset if a country offers the strongest level of patent protection. Although the effect of a higher R&D share remains negative even when interacted with strong patent protection, its marginal effect is diminished by a third (joint marginal effect = -0.19, p-value = 0.01, versus -0.28).

As in the simpler specification, extensive price control has a significant negative effect on the probability of rapid launch. Moderate regulation of prices is also found to have a negative effect now that the specification allows for its interaction with GDP per capita. The impact of having any price regulation is sizable for the poorest countries, and is only fully absent at a GDP over $11,000, or higher than cutoff for this country group. That price regulation has a larger effect in the poorest countries may reflect firm choices. It might also result from low-income countries having less efficient regulatory procedures that slow price negotiations. There is some suggestion of the importance of variation in regulatory efficiency within the lower-income countries in the fact that the coefficient estimate on having a national formulary is significantly positive (which is not the case for the higher-income countries, see below). One would expect its direct effect to be negative, but within the lower-income country group this variable may be acting as a proxy for bureaucratic competence.

The specification shown in the second column of Table 7 includes interactions between short and long product patent variables and the indicator "Strong" that indicates limits on how patent rights can be curtailed. There is some weak evidence from these interactions that short product patents may encourage rapid entry when they are held in a legal environment more generally supportive of patentee

rights. It may be, for example, that in such an environment the patent holder feels able to simply import product rather than go through the time consuming process of finding local producers and/or distributors to license.

The third and forth columns of Table 7 correspond to the same random effect model as in column 2 of Table 6, but for the NCE subsets indicated in the column headings. As found for all drugs, the NCE most relevant to poor countries ("LDC concentrated") are more likely to be launched quickly when a country offers only long process patent protection. In addition, for this subset of NCE there is also evidence that offering long protection on pharmaceutical products can encourage rapid entry. The incremental effect of long product protection is positive and weakly significant and the estimated coefficient on having a patent term extension provision is both significant and sizable. Results for the other policy variables are similar to those for all drugs.

The last set of estimates given in Table 7 is for the high revenue "blockbuster" drugs. For a low- and middle-income country the probability that one of these drugs is launched within two years is considerable higher than is the probability for all NCE (24% vs. 9%). That said, there is no evidence that offering any form of patent protection – whether long or short – speeds the arrival of the worlds' blockbuster drugs to their markets. This finding does not seem to be an artifact of the smaller sample size, since other estimations showing significant effects of the patent variables have even smaller sample sizes. Further, the other policy variables remain significant and are estimated to have a similar-sized effect on the launch of blockbusters (relative to the observed probability) as they do for other sets of NCE.

Table 8 compares results for the probability of launch within two years ("rapid") and ten years ("ever") using only NCE launched globally by 1992 in both cases so as to enable comparisons across a common sample of drugs. Considering first the within 2 year results, as in the full period data there is evidence that a long process patent regime – possibly supporting generic entry – is conducive to rapid drug launch. However, unlike in the full period data, in this earlier subset of NCE a long patent regime also including products – possibly encouraging entry by innovator firms – gives significant support to rapid entry. Both patent regimes offering a long period of protection are estimated to have similar-sized marginal effects: 0.086 without product patents and 0.070 when products are included (as compared to a short process-only regime). Interestingly, the R&D share and its interaction are not significant in the earlier time period. The fact that we observe less benefit from product patents in the full period data and a more negative effect associated with local R&D activity (compare Tables 6, 7 and 8) may be due to innovator firms feeling increasingly less able to make use of patent rights in developing countries to protect against local competition.

Policy choices have remarkably different effects on whether drugs are "ever" launched. Contrary to the finding for rapid launch, there is only weak evidence that moving from a short to a long process patent regime increases the likelihood of a drug being marketed ever. Instead, there is a significant benefit in the longer term associated with giving short-term protection to innovative products, increasing the estimated probability that a drug is ever launched in a lower-income country by 7.5 percentage points or 25%.

Most interestingly, there is a significant, sizable, and now positive benefit associated with having local technical capacity. Moving from no local research activity to the mean R&D share in this sample of 0.38 increases the probability that a new NCE is ever launched in a country by an estimated 9.7 percentage points or 32%. Further, in contrast to our finding for rapid launch that strong patent protection partially and positively offsets the harmful effect of local capacity, when it comes to the question of whether new drugs are ever marketed, we find that strong patent protection negatively offsets the otherwise beneficial effect of having local capacity. Further, the offset is no longer partial. The joint marginal effect of R&D capacity when combined with extensive IP protection is a statistically insignificant 0.07 (p-value 0.256). Consistent with this contrast in the direction of effects across time lags, we also find here that offering a patent term extension has a weakly significant negative effect on whether new drugs are ever launched, whereas for rapid launch this policy was found to be either insignificant or positive.

One surprise in Table 8 is that price regulation, which has a large and consistently negative effect on the likelihood that a drug is launched quickly, is estimated to have a weakly positive effect on whether drugs are ever launched. This is difficult to explain either as a direct effect, or as the result of policy endogeneity, both of which would give a negative effect. Nor is it consistent with the idea that regulators lower price demands if firms hold out long enough to entice them into the market, since such behavior would, at best, make regulation neutral. At the very least, it does not appear that price regulation is severely limiting the ultimate entry of new products.

Taken together, the findings in column two of Table 8 suggest that innovator firms are an important source of drug entry (hence product patents matter for eventual launch) and that these firms are willing to enter poorer markets at low prices with only a few years of effective patent protection – after some delay. They also suggest that local firms can be a significant source of market entry, and that their ability to actively enter could be slowed by stronger patent rights. Given this, unless speed of access is paramount, a lower-income country would not seem to benefit in terms of greater product availability from offering a long term of product patent protection or from limiting its price control regulation.

Finally, Table 9 presents hazard model estimates. There are in an accelerated failure time form which means that a negative coefficient is associated with shorter launch lags and thus corresponds to a positive coefficient in the probit estimations. The hazard model summarizes the effect of policy on launch behavior at all monthly lags after global launch and thus incorporates - within a specific structure – both the "within two year" and "within ten year" launch probabilities. Thus it is not surprising to see in the first column of Table 9 that both increasing the term on process patents and making short protection available on new products speed drug launch.[29] We find that while extensive price regulation slows launch, moderate price regulation, on average, has no effect in this group of low- and middle-income countries.

High-income Countries

There is less variation in the patent regimes observed in the high-income countries. For example, all of the countries in this group offered at least protection on pharmaceutical processes over most of the period. Thus, for this group of countries the set of indicator variables is limited to three: a dummy for whether a country protects pharmaceutical products, another for the incremental effect of having a long statutory term on either form of protection, and finally a dummy variable indicating whether a patent term extension is available. For this group of countries, "Short" refers to a statutory term of less than 20 years, the distinction preferred by the data.

The estimations in Table 10 for the high-income countries and the full set of NCE follow the same format as Table 6. For this set of countries the estimates on the policy variables are less robust to the choice of fixed or random country effects (compare models one and two).[30] It may be that the policy variables are picking up some the effect of other country level characteristics in the random effects specification. However, it is also the case that among the high-income countries there is more limited within-country variation in the policy variables (see Table A3). As a result the countries contributing to the estimation of policy effects across the two specifications are quite different and this makes some divergence in the point estimates less surprising. We also test formally, as above, the hypothesis that the extensive price control variable is exogeneous and again cannot reject the null ($\chi^2(1) = 0.84$, p-value = 0.36). First-stage estimates are in Appendix Table A4.

The results in Table 10 consistently indicate that adding the protection of new products to an otherwise "Short" patent regime gives the greatest incremental boost to rapid market entry. For the specification with country fixed effects, shown in column one, we also find a significant additional benefit from moving to a longer patent term. However, in no specification is there any evidence that

[29] From Table 8 it is clear that a model allowing for changes in the relative effect of policy variables at different lags would be desirable. A Cox proportionate hazard specification accommodates this easily but the underlying proportionality assumption is resoundingly rejected by the data.

having a drug patent extension affects the market entry of new pharmaceuticals within high-income countries.

All price regulation – whether moderate or extensive – tends to reduce the probability that a drug is launched in a high-income country within two years. However, as for the poorer countries, the effect of moderate price regulation depends on the income level of a country. The estimates here indicate that moderate price control no longer lowers the probability of rapid entry once a country reaches a GDP per capita of about $12,088, slightly below the median level for the group.

The first column of Table 11 contains estimation results for the "high quality" subset of NCE using the country fixed-effects specification. The overall probability of a high quality drug being launched within 2 years is over fifty percent higher than for an average NCE (33% vs. 20%). As for all drugs, short-term product patent protection encourages the launch of blockbusters. In contrast to all drugs, however, there is no incremental benefit from having the longest term of protection. Having any price control lowers the likelihood of entry and extensive price control is particularly problematic. The latter lowers the probability of rapid launch by 10.7 percentage points, or 33%.

The last results in Table 11 are within 2 and within 10 year estimates for the early (1982-92) period NCE. Because of the limited within-country variation in the policy variables during this shorter period, we use the random effects specification corresponding to column three in Table 10.

A high-income country increases the probability that new drugs are available to its consumers quickly by offering at least short-term protection to pharmaceutical products, as before, but for this early period there is an even larger incremental effect from moving to a longer term of protection (column 2). Moderate price control is weakly significant and extensive price control significantly diminishes the likelihood of rapid entry.

When considering whether drugs are "ever" launched in the high-income countries both patents and price regulation continue to have a role. In this longer time span, however, it is only long-term patent protection that is found to make a positive contribution. Because later market entry shortens the effective patent life, the statutory term may need to be long if it is to create a period of exclusivity sufficient to allow a firm to cover the higher costs of entry into high-income countries. It is somewhat surprising, then, to continue to find that offering a patent term extension has no discernible effect on eventual market entry nor on its timing. Finally, and again as we found for the poorer countries, extensive price control is far less damaging to the likelihood that a drug is ever launched than it is to the likelihood that it is launched quickly.

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[30] However, the standard errors are sizable so the estimates are statistically indistinguishable at conventional levels.

Maintaining an essential drugs list was found to have a significant dampening effect on market entry in the poorer countries in most specifications. We see the same negative effect within the high-income countries when considering all drugs, and of a similar relative magnitude. Having a national formulary is also associated with less rapid entry. Finally there is some evidence that the establishment of the European Medicines Evaluation Agency in 1995 as a centralized mechanism for obtaining marketing approvals within Europe has succeeded in speeding access to new drugs for consumers there. In specifications where the estimated effect of the EMEA is significant it is also large – increasing the probability of launch within 2 years by 25-30%.

Income Distribution and Demographic Characteristics

As one would expect, having a larger population and higher level of GDP per capita increases the likelihood that a country will have more drugs on the market and that they will become available quickly. In the estimations that include the Gini coefficient as a measure of income inequality, we find that the distribution of income is always also a significant determinant of market entry. The Gini coefficient, and its interaction with the log of GDP per capita, are statistically significant and show a pronounced pattern across the two income groups. As noted in the introduction, when an innovator firm considers launching products in one of the poorer countries, it may follow a strategy of setting low prices with small profit margins in an attempt to achieve extensive market penetration. Alternatively it may opt for higher prices with the expectation of reaching just the top of the market. We find that a lower-income country is more likely to get new drugs if it is unequal – ensuring that it has a wealthy "elite". On the other hand, a high-income country is better off with a more equal distribution as this generates the largest "middle class". Equality becomes less important as average income increases. These findings are consistent with the idea that there is a threshold level of income that makes an individual a potential consumer of new drugs. For countries with an average income below that threshold, inequality increases market size. For those above, inequality decreases market size – unless average income is so high that even when it is unequally distributed most consumers are above the threshold.

The age composition of a country's population also appears as a very significant determinant of the speed and extent of drug launch. In the low- and middle-income countries, drugs are more likely to reach the market in countries with many children and those with a high proportion of elderly. In the high- income countries, having a larger proportion of children seems to be most important.

VII. Policy Simulations

This section gives a sense of the empirical implications of the econometric results discussed above. Table 12 gives the predicted probability that a drug arrives in a given country market within

two years of its global launch. The predictions are for 1995 and the anti-infectives therapy class. They are based on the estimation of country fixed-effects models, using the high quality NCE for the high-income countries (Table 10, column 1) and the blockbuster sample for the low- and middle-income countries (unreported). The columns on the left hand side indicate a range of different policy choices, while those on the right show how the predicted probabilities vary with these choices. The last row gives selected estimated standard errors – to give a sense of the precision of the predictions. Because the predictions are highly correlated across rows within a given column, and across columns within income groups, these should not be used to formally assess the statistical significance of differences. Bold typeface indicates changes that are significant.

The first three rows change the patent regime, while the last three rows change price regulation. It is apparent from this table that a country's choices regarding intellectual property and price regulation can have a substantial impact on the likelihood that new pharmaceuticals are available to consumers quickly. In both lower- and high-income countries there appears to be scope to alter the probabilities by some 20-30% or more by virtue of these policy decisions.

Figure 4 presents this finding in another form using the hazard model estimates in Table 9. It gives predicted cumulative hazard rates for India. Each line represents the time path of market launches assuming different combinations of intellectual property and price control (PC) policies. As in Table 12, the predictions are for 1995 and the anti-infectives therapy class. The pair of policies indicated in the top row change the patent term, while the pair in the second row change the degree of price regulation. These two changes generate similar-sized shifts in the cumulative hazard curves.

The vertical axis indicates the predicted share of drugs launched in the given market by the lag indicated on the horizontal axis. Considering the upper dashed and dotted lines that overlay each other, for example, we see that if India were to have some price control and also offer long (≥ 15 years) patent protection, a predicted 20% of all NCE would be marketed there within about five years of their global launch dates. Suppose that India then kept the longer term of patent protection but moved to more extensive price regulation (the lower solid line). One can ask the question: how many fewer drugs would arrive within five years with the new policy? Looking vertically at five years, the answer is that just 15% of all drugs – rather than the previous 20% - would be launched within this period as a result of the change in policy. One can also ask the question: with the new policy, how much longer would it take for 20% of all drugs to be launched? Looking horizontally, the answer is that it would take some six and a half years – rather than five – as a result of the change in policy. Irrespective of policy regime, ten years after global launch no more than 40% of all drugs are predicted to be on the Indian market.

VII. Concluding Comments

Much attention has been paid to how price controls and the patent system determine pharmaceutical prices. We find that countries' choices about how to regulate pharmaceutical prices and protect innovation also have a significant influence on whether drugs become available to their consumers and how quickly. Short-term patent protection that includes products, or long protection only of manufacturing processes, are both patent regimes that tend to encourage more or faster launches in the developing world. Increasing the strength of a patent system to include long-term protection on pharmaceutical products appears to spur market entry – among the high-income countries. For the low- and middle-income countries that are currently being encouraged to move to stronger protection through trade policy, the evidence that extending protection enhances access to new pharmaceuticals is mixed. There is some evidence that high levels of protection might encourage more frequent entry of innovative products in the short term, particularly in countries where multinationals might otherwise hesitate because local technical capacity might create competitive pressures. On the other hand, in the longer term that same domestic capacity could be an alternative source of entry, and we find that a country offering extensive patent protection may lose the benefits of that activity and have fewer new products in the market overall as a result.

The fact that patent laws in the low- and middle-income countries are shown to matter at all is also of significance. Intellectual property holders frequently assert that the poor quality of enforcement in developing countries undermines the value of their patent rights. With the patent variables significant in various estimations, and entering with different and plausible patterns across subsets of the NCE, it is evident that patent laws in these countries are at least broadly meaningful.

Like intellectual property, the standard argument regarding price regulation – that it will dissuade market entry – appears to have more relevance among the high-income countries. For these countries, extensive price control is always found to lower the probability of market entry, and moderate regulation appears to do likewise, even in the long run. Not so for the poorer countries. There we find that while price regulation makes it less likely that new drugs will be available quickly, it does not appear to prevent new products from being launched eventually.

As they stand these results might temper some of the arguments made in the course of future international negotiations. Interpreting what they imply for public health and social welfare will require further analysis. If, for example, ten percent of new drugs are no longer marketed in a country due to a policy change, this may be damaging or not depending on what was in that ten percent. Pharmaceuticals often have acceptable substitutes, and some "lifestyle" drugs may not be of great medicinal importance. Future research will explore the therapeutic significance of the pharmaceuticals

that are launched slowly, or not at all, and the extent to which this failure is associated with there being substitutes available in the market.

A very poor country may also be quite willing to accept some delay in the arrival of innovative new pharmaceuticals as a result of regulation if it means that the drugs are priced within reach of more of the population when they finally reach the market. With cross-country data on product prices, this tradeoff could be assessed. Finally, giving innovators the strongest patent protection might be viewed as worthwhile irrespective of its effect on entry, on the grounds that it might boost R&D and the discovery of new NCE.

Table 1
NCE Global Launches per Year

Year	Annual Blockbusters	Total New Drugs
1982	4	36
1983	4	29
1984	2	34
1985	8	58
1986	10	45
1987	9	55
1988	7	43
1989	6	38
1990	12	42
1991	5	39
1992	4	43
1993	6	37
1994	9	41
1995	13	39
1996	13	42
1997	13	43
1998	13	39
1999	6	44
2000	5	35

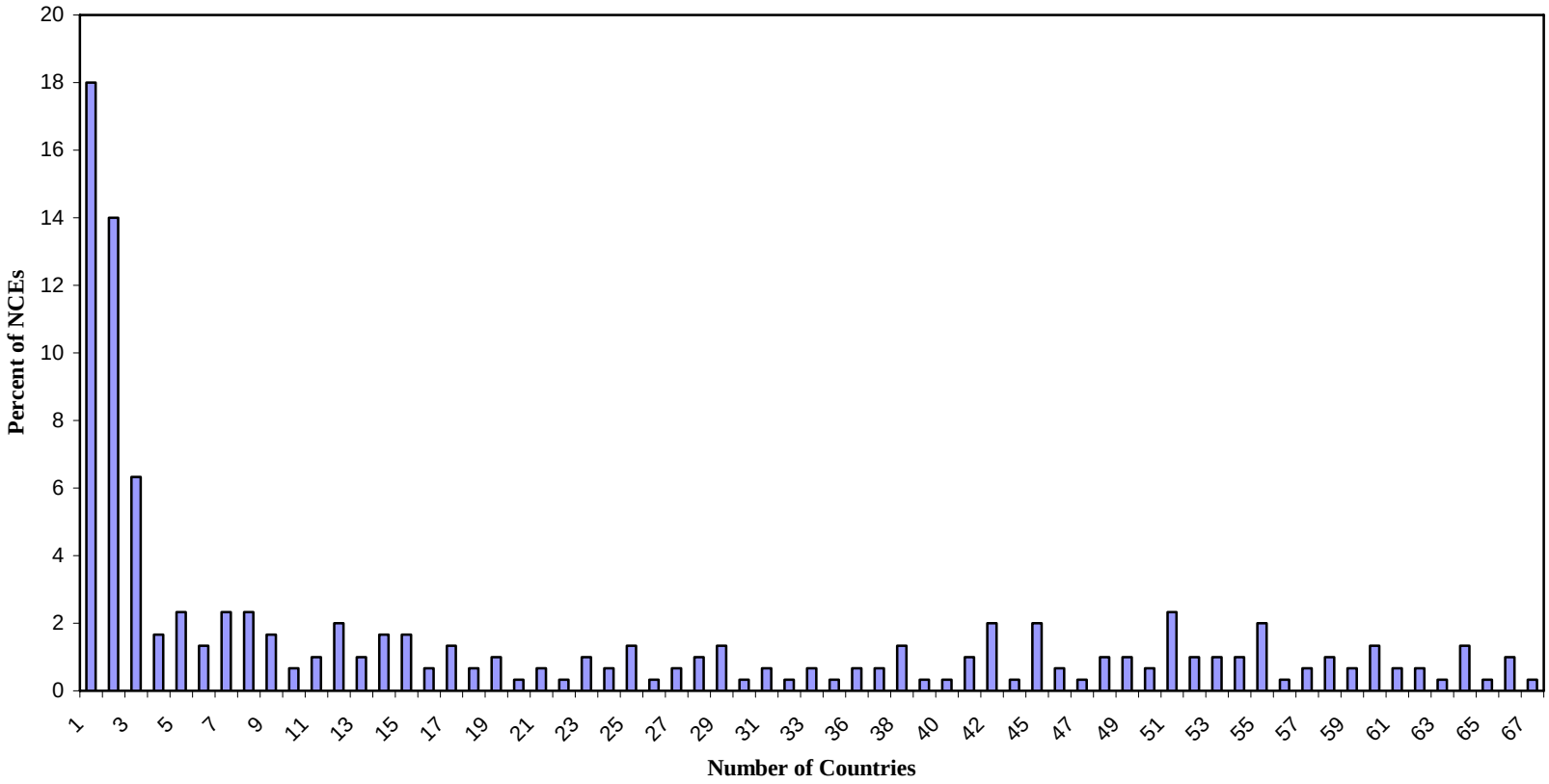
Note: Blockbuster drugs are NCE among the top 200 drugs in terms of world revenue in 1998 or 2003 or among the top 100 in U.S. revenue in 1993 or 1995.

Table 2
Location of First Launch: Distribution Across Countries

Country	No. First Launches	Years of Data	Pct. Of First Launches
High Income Countries			
AUSTRALIA	3	21	0.28
AUSTRIA	12	21	1.28
BELGIUM	6	21	0.54
CANADA	10	21	1.02
DENMARK	18	21	1.82
FINLAND	12	21	1.19
FRANCE	44	21	4.38
GERMANY	74	21	7.36
GREECE	1	21	0.10
HONG KONG	1	21	0.09
IRELAND	15	21	1.53
ISRAEL	1	21	0.10
ITALY	61	21	6.08
JAPAN	231	21	23.99
NETHERLANDS	26	21	2.89
NEW ZEALAND	7	19	0.80
NORWAY	6	10	1.33
PORTUGAL	3	21	0.30
PUERTO RICO	16	9	3.68
SINGAPORE	6	19	0.70
SPAIN	23	21	2.38
SWEDEN	26	21	2.66
SWITZERLAND	36	21	3.67
UK	72	21	7.30
USA	163	21	16.95
Upper Income Countries			
ARGENTINA	7	21	0.72
BOLIVIA	1	11	0.24
BRAZIL	3	21	0.26
CHILE	1	21	0.10
CZECH REPUBLIC	1	10	0.20
MALAYSIA	5	21	0.53
MEXICO	16	21	1.66
POLAND	1	11	0.20
SOUTH AFRICA	6	21	0.65
SOUTH KOREA	1	15	0.11
TURKEY	1	21	0.09
VENEZUELA	6	21	0.58
Lower Income Countries			
COLOMBIA	1	21	0.07
DOMINICAN REPUBLIC	1	17	0.10
PERU	1	21	0.12
PHILIPPINES	4	21	0.45
RUSSIA	2	8	0.56
THAILAND	2	21	0.19
Low Income Countries			
BANGLADESH	1	10	0.19
FRENCH WEST AFRICA	2	11	0.40
PAKISTAN	1	21	0.08

Note: Total number of drugs launched = 836; launched 1995-2001 = 337. Shares are adjusted for the differing years of coverage. See Lanjouw (2005) for details.

Figure 1
Geographic Spread of New Drugs: Number of Countries Reached



Note: This figure includes the 300 drugs first launched 1/82 through 12/88.

Table 3
Launch Lags for NCEs that were First Marketed 1986-1992
(Months)

Country	# Drugs	Percentiles 10th	Median	90th	Country	# Drugs	Percentiles 10th	Median	90th
High Income					**Upper Income**				
AUSTRALIA	28	15	46.5	111	ARGENTINA	49	8	36	110
AUSTRIA	46	12	28.5	73	BRAZIL	43	22	52	131
BELGIUM	40	6.5	23	90.5	CHILE	39	13	41	104
CANADA	34	4	32.5	69	LEBANON	26	46	106	157
DENMARK	40	0.5	18	68	MALAYSIA	26	26	50.5	138
FINLAND	38	11	27.5	85	MEXICO	44	8	29	102
FRANCE	41	0	19	62	POLAND	6	34	43.5	98
GERMANY	54	0	18.5	45	SAUDI ARABIA	29	32	51	107
GREECE	44	13	37	120	SOUTH AFRICA	37	10	30	100
HONG KONG	37	13	27	88	SOUTH KOREA	53	24	49	110
IRELAND	38	0	22.5	88	TAIWAN	5	55	83	116
ISRAEL	29	28	52	102	TURKEY	40	23	55.5	95
ITALY	57	0	24	74	VENEZUELA	38	17	35.5	115
JAPAN	77	0	0	85	**Lower Income**				
NETHERLANDS	47	4	22	49	CENTRAL AMERICA	43	18	46	136
NEW ZEALAND	36	5	26.5	79	COLOMBIA	42	17	44.5	104
PORTUGAL	33	20	49	88	DOMINICAN REPUBLIC	35	25	49	111
SINGAPORE	33	18	45	109	ECUADOR	37	20	55	118
SPAIN	37	18	30	111	EGYPT	30	37	73.5	133
SWEDEN	46	0	17	86	LATVIA	20	63	99.5	142
SWITZERLAND	46	2	14	66	MOROCCO	29	14	45	140
UK	50	0	16	51	PERU	36	24	57.5	159
USA	46	0	20	69	PHILIPPINES	49	6	35	98
					THAILAND	48	16	41.5	99

Table 3: Continued

Country	# Drugs	Percentiles 10th	Median	90th
Low Income				
FRENCH WEST AFRICA	10	19	47	131
INDIA	14	46	58	84
INDONESIA	42	22	43	97
PAKISTAN	38	23	57	118
(Unweighted) Means				
High Income	42.5	7.4	26.8	81.2
Upper Middle Income	33.5	24.5	50.9	114.1
Lower Middle Income	36.9	24.0	54.7	123.9
Low Income	26.0	27.5	51.3	107.5

Notes: The sample includes the 122 NCE from the therapy classes A2B, C, J for which Indian data are available and, for a given country, only those NCE first marketed after the country entered the database.

Table 4: The Arrival of New Drugs

Percent Released:			Percentage Marketed - Years After Global Launch:								
All	**Block-Buster**		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	9
25%	67%	AUSTRALIA	5%	18%	39%	57%	68%	74%	83%	88%	98%
38	81	AUSTRIA	13	30	51	66	74	83	87	94	98
31	67	BELGIUM	19	40	61	72	79	85	91	94	97
30	81	CANADA	19	34	56	65	78	89	91	96	97
36	81	DENMARK	26	48	65	75	84	89	93	95	97
33	78	FINLAND	11	33	54	67	74	80	87	93	96
37	71	FRANCE	35	49	62	70	79	85	91	94	100
44	86	GERMANY	32	60	75	83	87	91	94	98	94
34	84	GREECE	6	23	41	56	69	78	85	91	97
29	73	HONG KONG	13	37	62	70	76	79	86	93	97
32	75	IRELAND	28	50	60	69	77	83	88	94	98
26	75	ISRAEL	3	17	27	52	69	74	83	93	98
49	82	ITALY	33	46	60	71	78	86	92	95	97
53	68	JAPAN	64	68	73	78	83	88	91	93	98
37	79	NETHERLANDS	31	53	68	79	84	90	92	94	94
28		NEW ZEALAND	20	41	53	65	72	81	86	91	97
29	69	PORTUGAL	11	23	40	47	65	76	84	91	98
26	56	SINGAPORE	14	35	53	66	76	82	89	95	96
36	80	SPAIN	12	28	48	61	70	78	85	92	98
34	78	SWEDEN	30	48	57	70	76	83	88	94	96
36	80	SWITZERLAND	35	56	70	79	83	87	90	92	98
40	84	UK	44	60	72	79	86	91	95	97	98
38	90	USA	34	48	62	71	78	89	93	94	93
42	84	ARGENTINA	13	27	44	60	70	76	80	84	92
32	76	BRAZIL	7	20	34	50	62	70	76	85	95
30	77	CHILE	7	25	43	53	65	74	83	91	99
22	55	MALAYSIA	13	33	56	76	83	88	91	94	98
35	79	MEXICO	14	33	47	60	73	81	87	93	95
23	70	SAUDI ARABIA	1	5	16	33	50	65	75	89	98
29	74	SOUTH AFRICA	15	35	53	63	69	77	84	91	96
31	81	TURKEY	1	10	24	35	52	64	76	88	94
26	77	VENEZUELA	4	21	38	50	64	75	84	90	95
31	82	CENTRAL AMERICA	3	19	35	46	63	72	81	88	97
31	82	COLOMBIA	6	15	30	47	59	67	79	85	91
27	74	ECUADOR	3	10	25	35	53	67	78	82	90
19	62	EGYPT	0	2	7	19	29	48	63	74	94
25	67	PERU	3	11	26	37	51	62	73	80	93
36	81	PHILIPPINES	8	25	44	58	67	74	83	86	93
34	80	THAILAND	5	23	41	55	63	71	80	88	96
26	75	INDONESIA	0	9	30	45	57	68	80	88	92
26	66	PAKISTAN	2	10	18	34	49	61	69	78	95%

Notes: "Percent Released" is the share of global NCE launched in the row country within 10 years. "Upper Bound" assumes all observations with missing ingredient information are NCEs and grosses up the total launches accordingly.

Figure 2: Timing of Launch for NCEs Marketed within 10 Years

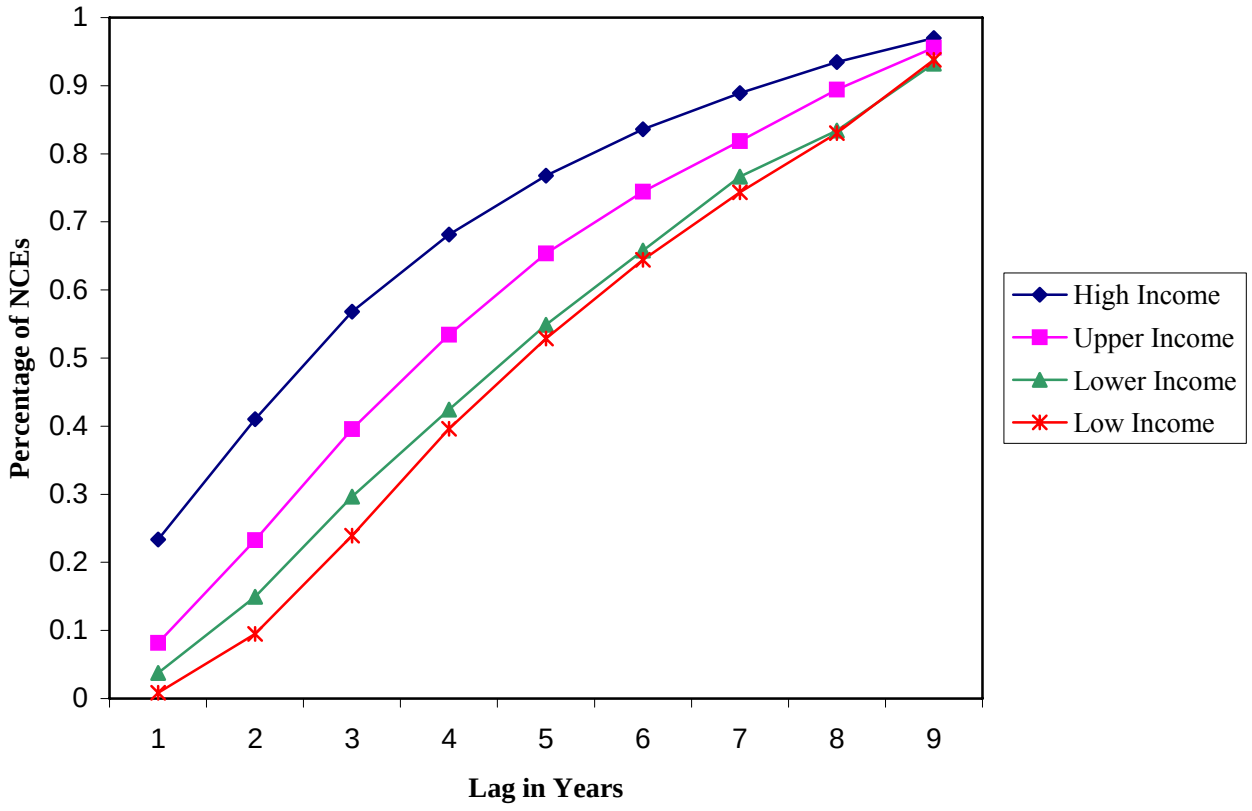


Table 5
Percent of NCE Launches 1982-92 done by "First" Firm
By Type of Patent Regime

Group (No. launches)	Short Process or None	Short Product and Process	Long Process Only	Long Product and Process	All Countries
All Drugs	54.8%	67.5%	68.0%	71.7%	61.6%
	(5,430)	(332)	(842)	(2,963)	(9,567)
Blockbusters	65.6	75.1	72.2	76.9	72.3
	(1,154)	(189)	(461)	(1,577)	(3,381)

Notes: The "first" firm is defined as the one making the first launch in a high-income country. The number of observations in each cell is in parentheses. A "short" patent regime is one with a statutory term of less than 15 years.

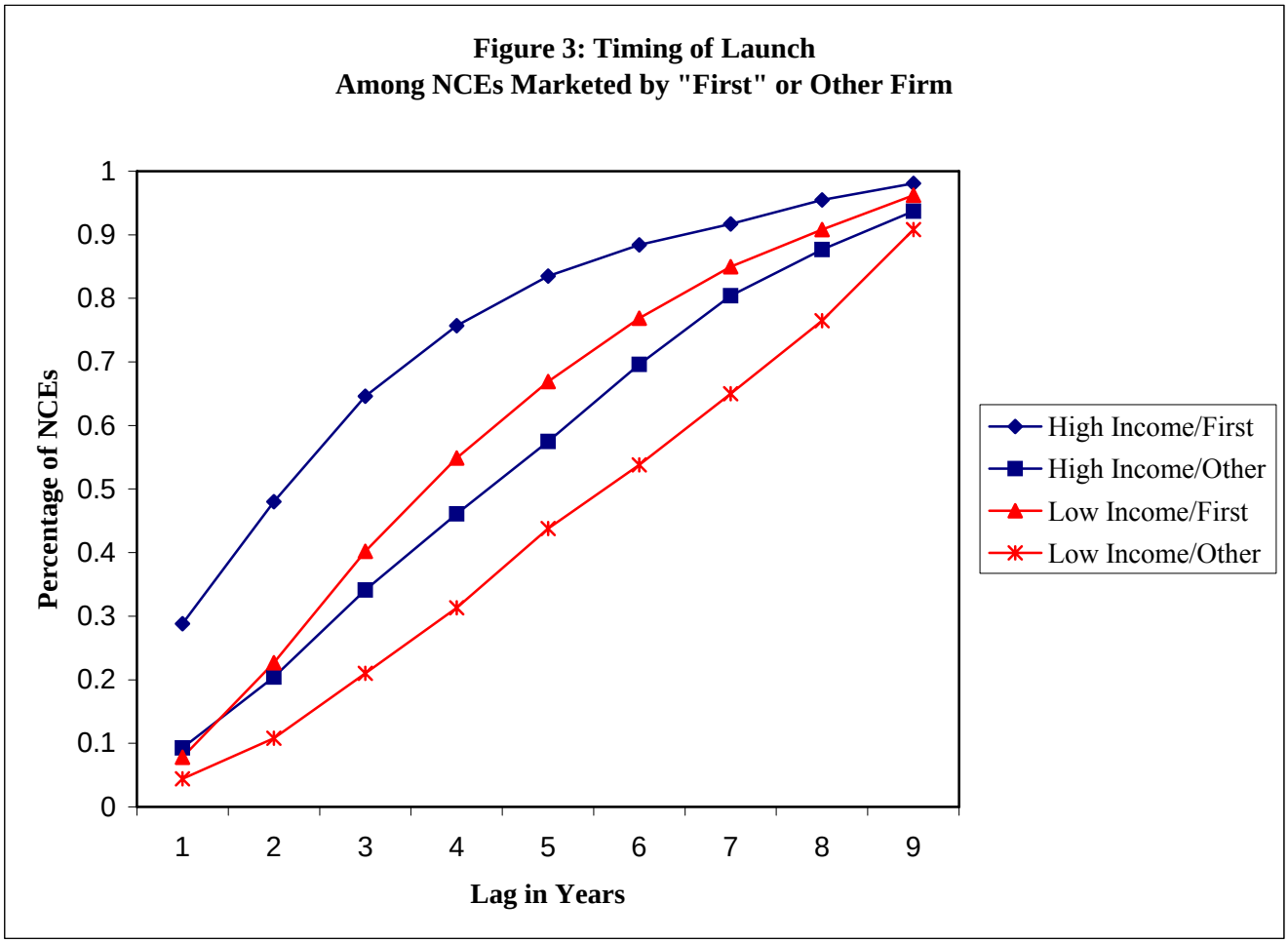


Figure 3: Timing of Launch
Among NCEs Marketed by "First" or Other Firm
Percentage of NCEs
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1
2
3
4
5
6
7
8
9
Lag in Years
High Income/First
High Income/Other
Low Income/First
Low Income/Other

Table 6: Low- and Middle-Income Countries
Probability of Launch within Two Years

	With Country Fixed Effects		Without Country FE	
Policy Variables	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**
Short process patent (< 15 years)	-0.010	0.011	-0.011	0.010
Add long process (only) patents	**0.034**	**0.015**	**0.033**	**0.016**
Add short product patents (< 15 years)	0.010	0.015	0.021	0.014
Add long process & product patents	0.006	0.012	0.008	0.009
Some price control	-0.005	0.012	0.014	0.011
Extensive price control	**-0.028**	**0.010**	**-0.029**	**0.013**
Essential Drug List	**-0.017**	**0.007**	-0.017*	0.009*
Other Variables				
Health expenditure share Of GDP 1995/97			0.272	0.246
Private share of all Health expenditure			0.041*	0.022*
LnPopulation	**-0.257**	**0.120**	**0.024**	**0.005**
LnGDPcapita	**-0.063**	**0.020**	**0.109**	**0.028**
Gini Coefficient			**0.016**	**0.006**
Gini*LnGDPcapita			**-0.002**	**0.0007**
Pct 65 yrs +	0.877	1.746	**0.567**	**0.265**
Pct 15-64 yrs	0.219	0.246	**-0.279**	**0.119**
Population Growth			-0.401	0.430
GDP Growth			0.022	0.056
Radios per capita 1990			-0.004	0.003
Growth Radios 90-95			-0.004	0.005
Doctors/1000 in 1990			**0.011**	**0.005**
Growth Doctors 90-95			-0.0007	0.002
No. Obs./ Observed P	19901/0.089		17917/0.091	
Pseudo R^2	0.155		0.132	

Notes: All specifications control for year of first launch and therapy class. Huber-White robust estimated standard errors allow for heteroscedasticity; and intra-country correlation in the disturbances in specifications without country fixed effects. Bold typeface and * indicate coefficients significant at $\alpha = 0.05$ and 0.10, respectively. Marginal effects estimated at variables means (all data) and for a discrete change in the case of dummy variables. As a result of missing inequality information, Lebanon, Puerto Rico, Saudi Arabia and Taiwan are dropped in estimations without country FE.

Table 7: Low- and Middle-Income Countries
Probability of Launch within Two Years

	All Drugs				LDC Concentrated		"Blockbusters"	
Policy Variables	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**
Short process patent (< 15 years)	-0.013	0.016	-0.003	0.011	0.004	0.019	-0.031	0.034
Add long process (only) patents	**0.021**	**0.012**	0.021*	0.013*	**0.041**	**0.024**	0.044	0.039
Add short product patents (< 15 years)	-0.001	0.013	0.003	0.015	0.002	0.021	0.048	0.044
Add short * strong			0.053*	0.030*				
Add long process & product patents	-0.012	0.019	0.018	0.014	0.024*	0.014*	0.034	0.036
Add long p & p * strong			-0.045	0.031				
Drug patent extension	-0.010	0.009	0.011	0.011	**0.057**	**0.017**	0.001	0.030
R&D share	**-0.279**	**0.100**						
long p & p * R&D share	**0.093**	**0.046**						
Some price control	**-0.466**	**0.232**	**-0.172**	**0.092**	**-0.265**	**0.121**	**-0.587**	**0.164**
Extensive price control	**-0.027**	**0.007**	**-0.034**	**0.010**	**-0.047**	**0.018**	**-0.123**	**0.035**
Some price control * lnGDPcapita	**0.050**	**0.020**	**0.023**	**0.011**	**0.033**	**0.013**	**0.088**	**0.028**
Tariff rate	**-0.003**	**0.001**						
Essential Drug List	**-0.037**	**0.010**	**-0.029**	**0.009**	**-0.038**	**0.015**	**-0.093**	**0.029**
Standard Treatment Guidelines	0.017	0.014	**0.035**	**0.011**	**0.074**	**0.019**	**0.117**	**0.037**
National Formulary	**0.027**	**0.013**	**0.015**	**0.008**	**0.023**	**0.009**	**0.061**	**0.029**
No. Obs./ Observed P	12828/0.097		17917/0.091		4499/0.110		4046/0.238	
Pseudo R^2	0.155		0.136		0.181		0.216	

Notes: See notes to Table 1 and 6. All specifications control for year of first launch and therapy class. "LDC Concentrated" includes only NCE from the therapy classes A (Alimentary tract and metabolism) and J (Systemic anti-infectives).

Table 8
Low- and Middle-Income Countries
Probability of Launch within Two and Ten Years

	Within 2		**Within 10**	
Policy Variables	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**
Short process patent (< 15 years)	-0.003	0.020	-0.012	0.035
Add long process (only) patents	**0.086**	**0.020**	0.035*	0.019*
Add short product patents (< 15 years)	0.018*	0.010*	**0.075**	**0.022**
Add long process & product patents	**0.052**	**0.033**	0.035	0.041
Drug patent extension	-0.009	0.014	-0.051*	0.026*
R&D share	0.055	0.073	**0.255**	**0.100**
long p & p * R&D share	-0.095	0.075	-0.185*	0.105*
Some price control	-0.002	0.129	0.402*	0.220*
Extensive price control	-0.018*	0.011*	0.040*	0.024*
Some price control * lnGDPcapita	-0.0002	0.016	-0.038	0.026
Essential Drug List	-0.024	0.023	-0.075*	0.042*
Standard Treatment Guidelines	0.025	0.022	**0.089**	**0.041**
National Formulary	**0.045**	**0.013**	0.032	0.029
No. Obs./Observed P	7099/0.057		6963/0.303	
Pseudo R^2	0.089		0.051	

Notes: See notes to Tables 6 and 7. These estimations include only NCE first launched in 1992 or earlier.

Table 9: Hazard Estimations
Low- and Middle-Income Countries

	All Data		"Blockbusters"	
Policy Variables	**Coefficient**	**Estimated S.E.**	**Coefficient**	**Estimated S.E.**
Short process patent (< 15 years)	0.066	0.103	0.144	0.112
Add long process (only) patents	**-0.226**	**0.103**	-0.208*	0.111*
Add short product patents (< 15 years)	**-0.243**	**0.121**	-0.125	0.127
Add long process & product patents	0.053	0.095	0.022	0.101
Drug patent extension	-0.003	0.094	-0.052	0.107
Some price control	0.133	0.103	0.024	0.115
Extensive price control	**0.343**	**0.097**	**0.345**	**0.108**
Essential Drug List	0.111*	0.061*	0.065	0.063
Standard Treatment Guidelines	0.020	0.070	0.100	0.073
Control Variables				
LnPopulation	**3.466**	**1.023**	**3.182**	**1.130**
LnConsumption	**0.526**	**0.178**	**0.154**	**0.188**
Pct 65 yrs +	22.823*	13.239*	24.838	14.982
Pct 15-64 yrs	**-6.303**	**1.996**	**-5.719**	**2.210**
γ	**0.556**	**0.012**	**0.481**	**0.012**
θ	**3.275**	**0.160**	**0.214**	**0.047**
No. Observations.	21116		4708	
Log likelihood	-17966.4		-5397.2	

Notes: See notes to Tables 1 and 6. Both specifications use a log-logistic hazard function with a gamma distributed multiplicative factor to capture unobserved heterogeneity. They include country, year, and therapy class fixed effects.

Table 10
High-Income Countries
Probability of Launch within Two Years

	With Country Fixed Effects		Without Country Fixed Effects			
Policy Variables	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**
Short product patents (< 20 years)	**0.091**	**0.013**	**0.050**	**0.020**	**0.057**	**0.020**
Add long process and/or product patents	**0.031**	**0.013**	0.064	0.039	0.059	0.045
Drug patent extension					0.006	0.021
Some price control	**-0.038**	**0.014**	**-0.053**	**0.024**	**-0.667**	**0.243**
Extensive price control	**-0.058**	**0.020**	**-0.127**	**0.025**	**-0.124**	**0.026**
Some price control * lnGDPcapita					0.071*	0.036*
Essential Drug List	-0.025	0.019	**-0.068**	**0.017**	**-0.084**	**0.033**
Standard Treatment Guidelines					0.029	0.086
National Formulary					-0.039	0.026
EMEA	**0.034**	**0.017**	0.026	0.042	0.041	0.043
Other Variables						
Health expenditure share Of GDP 1995/97			**-2.602**	**1.012**	**-2.393**	**1.038**
Private share of all health expenditure			0.205	0.178	0.184	0.179
LnPopulation	**0.436**	**0.129**	**0.041**	**0.006**	**0.043**	**0.006**
LnGDPcapita	**-0.154**	**0.056**	**-0.673**	**0.346**	**-0.766**	**0.359**
Gini Coefficient			**-0.256**	**0.111**	**-0.273**	**0.116**
Gini*LnGDPcapita			**0.025**	**0.011**	**0.027**	**0.011**
Pct 65 yrs +	**-3.519**	**0.470**	-0.617	0.572	-0.534	0.628
Pct 15-64 yrs	-0.544	0.382	**-1.610**	**0.435**	**-2.097**	**0.477**
Population Growth			-1.781*	0.987*	**-1.811**	**0.932**
GDP Growth			0.265	0.364	0.282	0.336
Doctors/1000 in 1990			-0.008	0.015	-0.012	0.016
Growth Doctors 90-95			-0.052	0.044	-0.047	0.044
No. Obs./ Observed P	18889/0.205		15383/0.225		15383/0.225	
Pseudo R^2	0.104		0.090		0.091	

Notes: See notes to Table 6. As a result of missing inequality information, Kuwait, New Zealand, Singapore and UAE are dropped from the estimations without country FE.

Table 11
High-Income Countries
Probability of Launch

	"High Quality Drugs"		**All Drugs**			
	With Country FE Within 2		**Within 2**		**Within 10**	
Policy Variables	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**	**Marginal Effect**	**Estimated S.E.**
Short product patents (< 20 years)	**0.188**	**0.025**	**0.042**	**0.013**	-0.011	0.014
Add long process and/or product patents	0.035	0.028	**0.087**	**0.022**	**0.053**	**0.021**
Drug patent extension			-0.013	0.020	0.025	0.021
Some price control	**-0.056**	**0.029**	-0.379*	0.172*	**-0.638**	**0.128**
Extensive price control	**-0.107**	**0.040**	**-0.095**	**0.017**	-0.055*	0.029*
Some price control * lnGDPcapita			0.041*	0.023*	**0.077**	**0.024**
Essential Drug List	0.005	0.039	**-0.057**	**0.023**	**-0.089**	**0.019**
National Formulary			-0.022	0.018	-0.010	0.028
EMEA	**0.088**	**0.031**				
No. Obs./ Observed P	7951/0.335		9258/0.166		9258/0.371	
Pseudo R^2	0.113		0.058		0.030	

Notes: See notes to Tables 6. "High Quality" is the subset of NCE that are marketed in either the U.S. or the U.K. within 2 years of first global launch. The U.S. and U.K. are not included in these estimations. Results for "All Drugs" are based only on NCE first launched in 1992 or earlier and do not include country fixed effects.

Table 12
Predicted Probability of Launch within Two Years
"Blockbuster" or "High Quality" Drugs

Policy Scenario				Country				
Product Patent	**"Long" Patent Term**	**Any Price Control**	**Extensive Price Control**	**Brazil**	**Egypt**	**Thailand**	**France**	**Canada**
No	No	Yes	No	**55.7**	**16.6**	**25.8**	**27.2**	**34.3**
No	Yes	Yes	No	**66.3**	**24.5**	**35.5**		
Yes	Yes	Yes	No	71.6	29.5	41.2	**54.5**	**64.2**
Yes	Yes	No	No	**73.0**	**30.9**	**42.9**	**60.7**	**68.3**
Yes	Yes	Yes	Yes	**53.0**	**15.1**	**23.8**	**42.2**	**50.3**
S.E. on final prediction				11.3	8.4	8.5	6.4	5.0

Note: All scenarios assume that at least short process patents are available. "High Quality" (high-income group) and "Blockbuster" (low-and middle-income group) are defined in notes to Tables 1 and 11. The predictions given are based on a model with country fixed effects and use time-variant country characteristics for 1995, and the anti-infectives therapy class. A "long" statutory term is > 14 years for Brazil, Egypt, and Thailand; > 19 years for France and Canada. Bold typeface indicates comparisons that likely represent statistically significant differences.

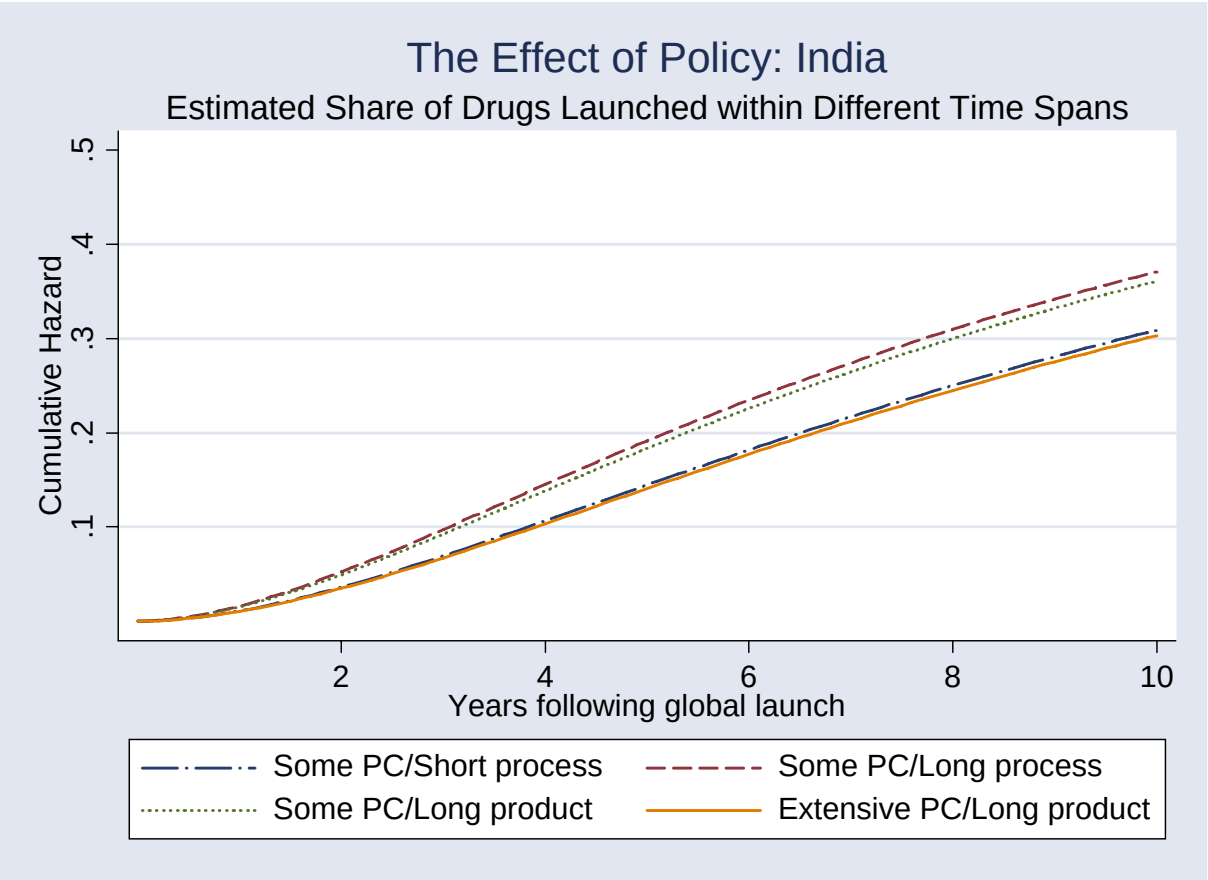

The Effect of Policy: India
Estimated Share of Drugs Launched within Different Time Spans
Cumulative Hazard
.1
.2
.3
.4
.5
2
4
6
8
10
Years following global launch
Some PC/Short process
Some PC/Long process
Some PC/Long product
Extensive PC/Long product

Figure 4

Table A1: Variable Definitions	
Short process patent (< 15 years)	Dummy = 1 if country protection only on pharmaceutical processes. When the statutory term is defined to end "X years after grant," the granting process is assumed to take 2 years. As is appropriate for some countries, we take the min or max of "years from grant" and "years from filing" to estimate the statutory term.
Short product patents (< N years)	Dummy = 1 if product patents are offered.
Long process (only) patents	Dummy = 1 if country offers only process patents with a statutory term ≥ 15 years.
Long process & product patents	Dummy = 1 if both product and process innovations covered and term is at least 15 years.
Long process and/or product patents	Dummy = 1 if either process or both process and product protection is offered and the term is at least 20 years.
Strong	"Strong" is a variable that takes on values between 0 and 1, with a higher value indicating that a country has more limits on how patent rights can be curtailed.
Drug Patent Extension	Dummy = 1 if firms may apply for an extension of the statutory term of patent protection to compensate for time taken in the marketing approvals process.
Some Price Control	Dummy = 1 if country has a formal price control mechanism but it is not extensive.
Extensive Price Control	Dummy = 1 if price control covers most of the market and/or is viewed as particularly restrictive.
Tariff	
Essential Drug List	Dummy =1 for national adoption of an EDL
Standard Treatment Guidelines	Dummy = 1 for national adoption of standard treatment guidelines
National Formulary	Dummy = 1 for having a national formulary
EMEA	Dummy = 1 for years when a country is a member of the European Medicines Evaluation Agency
Health Expenditure Share of GDP 1995/97	Mean annual total health expenditure during the years 1995-97 in 1995 U.S. $
Private Share of All Health Expenditure	Mean private health expenditure for 1995-97 as a share of mean total health expenditure 1995-97
R&D share	Country R&D expenditure in all fields as share of GDP
LnPopulation	Log of population
LnGDPcapita	Log of GDP per capita in 1995 U.S. $
Gini Coefficient	Estimated Gini coefficient of inequality (of household per-capita income in most cases) taken as close as possible to early 1990 but ranging from years 1987-99.
Pct 65 yrs +	Percentage of total population aged 65 and older
Pct 15-64 yrs	Percentage of total population aged 15 through 64
Population Growth	Pct. Growth in total population over previous year
GDP Growth	Pct. Growth in GDP over previous year
Radios per capita 1990	Average radios per person in 1990
Growth Radio 90-95	Percent increase in radios per 100 between 1990 and 1995
Doctors/1000 in 1990	Doctors per thousand people as of 1990/2 (1990 if available)
Growth Doctors 90-95	Percent increase in doctors per thousand between 1990/2 and 1995/7 (1990 and 1995 if available)

Table A2: Variable Distributions

	All Data				Early Period (1982-93)			
	Low/Middle Income		High Income		Low/Middle Income		High Income	
Policy Variables	**Mean**	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D.**
Process patent	0.853	0.345			0.752	0.422		
Short product patents (< N years)	0.536	0.492	0.880	0.326	0.334	0.463	0.837	0.370
Long process (only) patents	0.614	0.487			0.407	0.492		
Long process & product patents	0.473	0.499			0.263	0.441		
Long process and/or product patents			0.779	0.415			0.693	0.461
Drug patent extension	0.614	0.487	0.856	0.352	0.407	0.492	0.819	0.386
Some price control	0.833	0.372	0.784	0.412	0.319	0.466	0.347	0.476
Extensive price control	0.397	0.489	0.349	0.477	0.462	0.499	0.379	0.485
Tariff	9.657	8.114			7.94	5.38		
Essential Drug List	0.415	0.490	0.921	0.270	0.131	0.335	0.884	0.321
Standard Treatment Guidelines	0.178	0.373	0.972	0.164	0.082	0.272	0.957	0.204
National Formulary	0.173	0.371	0.755	0.430	0.070	0.252	0.623	0.485
EMEA Member			0.177	0.382				
Control Variables								
R&D share	0.487	0.449			0.382	0.342		
LnPopulation	17.205	1.255	16.398	1.317	17.384	1.158	16.518	1.241
LnGDPcapita	7.661	0.840	9.950	0.407	7.570	0.840	9.875	0.394
LnPop*LnGDPcapita	131.49	13.74	163.31	15.74	131.20	13.22	163.23	15.23
Gini Coefficient	43.677	10.235	32.453	6.188	45.530	9.402	32.710	6.217
Gini*LnGDPcapita	334.43	95.99	322.84	58.41	345.98	95.07	322.79	57.66
Pct 65 yrs +	0.053	0.031	0.128	0.033	0.043	0.017	0.125	0.027
Pct 15-64 yrs	0.600	0.005	0.666	0.027	0.582	0.035	0.665	0.028
Population Growth	0.018	0.010	0.008	0.012	0.021	0.009	0.007	0.010
GDP Growth	0.015	0.053	0.022	0.026	0.0109	0.0648	0.020	0.025
Radios per capita 1990	0.331	0.203	0.824	0.385	0.301	0.180	0.848	0.386
Growth Radios 90-95	0.136	0.425	0.139	0.934	0.157	0.474	0.039	0.067
Doctors/1000 in 1990	1.343	1.037	2.432	1.063	1.345	1.018	2.474	1.077
Growth Doctors 90-95	0.601	1.842	0.158	0.273	0.469	1.448	0.154	0.279
Health Expenditure Share of GDP 1995/97	0.054	0.019	0.080	0.019	0.053	0.019	0.081	0.018
Private Share of All Health Expenditure	0.531	0.170	0.309	0.146	0.551	0.152	0.311	0.127

Table A3: Changes in Price Control and Patent Protection
Early Period (1982-92) and Late Period (1993-2000)

	Any Price Control		Extensive Control		Process Patents		Product Patents		Statutory Term	
	Early	**Late**	**Early**	**Late**	**Early**	**Late**	**Early**	**Late**	**Early**	**Late**
ARGENTINA			0						+	+
BANGLADESH	+		+	0						
BOLIVIA										+
BRAZIL				0		+		+		
BULGARIA				0						
CENTRAL AMERICA	+	0	+	0	+		+	+		
CHILE					+		+			
COLOMBIA			0				+		+	+
CZECH REPUBLIC			0							
DOMINICAN REPUBLIC			0							
ECUADOR									+	+
EGYPT										
FRENCH WEST AFRICA			0							
HUNGARY			0					+		+
INDIA				0						
INDONESIA	+				+		+			
JORDAN								+		+
LATVIA	0	+	0							
LEBANON								+		+
MALAYSIA									0	
MEXICO	+		+	0	+		+			
MOROCCO								+		
PAKISTAN								+		+
PARAGUAY										
PERU			0				+		+	+
PHILIPPINES	+									+
POLAND			0					+		+
PUERTO RICO										+
RUSSIA	0	+	0							
SAUDI ARABIA					+		+			
SLOVAK REPUBLIC	0	+	0							
SOUTH AFRICA		+		+						
SOUTH KOREA				0						
TAIWAN	+									+
THAILAND							+		+	
TUNISIA										
TURKEY						+				
URUGUAY								+		+
VENEZUELA								+	+	+

	Any Price Control		Extensive Control		Process Patents		Product Patents		Statutory Term	
	Early	**Late**	**Early**	**Late**	**Early**	**Late**	**Early**	**Late**	**Early**	**Late**
AUSTRALIA										+
AUSTRIA							+			
BELGIUM										
CANADA	+								+	
DENMARK	+		+, 0				+			
FINLAND				+				+		
FRANCE										
GERMANY	+	0								
GREECE										
HONG KONG										
IRELAND									+	
ISRAEL										
ITALY				0						
JAPAN										+
KUWAIT	+		+							
LUXEMBOURG										
NETHERLANDS		+								
NEW ZEALAND	+									+
NORWAY				+			+			
PORTUGAL	+							+		+
SINGAPORE										
SLOVENIA	0	+	0	+						
SPAIN							+			
SWEDEN				0						
SWITZERLAND										
UK										
UNITED ARAB EMIRATES										
USA										+

Note: Changes are only indicated for a country during periods for which launch information is also available. + indicates and increase and 0 a decrease in the variable.

Table A4: First-stage Regression Estimations
The Probability of Extensive Price Control

	Low- and Middle-income Countries		High-income Countries	
Variables	**Coefficient**	**Estimated S.E.**	**Coefficient**	**Estimated S.E.**
LnPopulation	-0.008	0.023	**-0.059**	**0.021**
LnGDPcapita	0.024	0.158	**-3.908**	**0.563**
Gini Coefficient	-0.051*	0.031*	**-1.178**	**0.177**
Gini*LnGDPcapita	0.004	0.004	**0.115**	**0.017**
Pct 65 yrs +	**-4.789**	**1.124**	1.805	1.160
Pct 15-64 yrs	**-3.549**	**0.888**	**-5.574**	**1.291**
Instruments				
Executive_right	**0.447**	**0.063**	0.181*	0.105*
Executive_left	**0.376**	**0.064**	**0.369**	**0.105**
Executive_center	**0.391**	**0.086**	**0.359**	**0.135**
Executive_natl	**-0.412**	**0.071**		
Tenure	**0.007**	**0.003**	0.008	0.007
Military	**0.201**	**0.050**		
Budget Balance	**-0.033**	**0.006**	0.009	0.006
Adjusted R^2	0.324		0.292	
No. Obs.	435		385	

Notes: The first three instruments are dummies for the economic orientation of the party of the chief executive. The fourth indicates if it is a nationalist party. Tenure is the number of years that the chief executive has been in office. Military indicates if he is a military officer. Budget balance is overall, including grants, as a percent of GDP. All instruments save tenure are lagged two years (as preferred by data). Bold typeface and * indicate coefficients significant at $\alpha = 0.05$ and 0.10, respectively.
Sources: Political variables, the World Bank Database of Political Institutions, downloaded from http://www.worldbank.org/research/bios/pkeefer.htm; Budget, World Development Indicators Online, 2004 (both accessed April 5, 2004).

General References

Bloom, Nicholas and John van Reenen (1998) "Regulating Drug Prices: Where Do We Go from Here?" *Fiscal Studies*, Vol. 19, no. 3, pp. 321-42.

Carpenter, Daniel, Brian Feinstein, Colin Moore, Marc Turenne, Ian Yohai and Evan James Zucker (2004) "Why do Bigger Firms Receive Faster Drug Approvals?" Mimeo. Department of Government, Havard University.

CDRI (1996). "Patents: Indian," *Drugs and Pharmaceuticals: Industry Highlights*. NISSAT. 19 (3 and 6), 35-39 and 43-48.

Chaudhuri, Shubham, Penelopi Goldberg and Panle Jai (2004) "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India." Mimeo. Yale University.

Danzon, Patricia, Wang, Y. Richard and Liang Wang (2005) "The Impact of Price Regulation on the Launch Delay of New Drugs," *Journal of Health Economics*, Vol. 14, no. 3, pp. 269-92.

Dranove, David and David Meltzer (1994) "Do important drugs reach the market sooner," *RAND Journal of Economics*, Vol. 25, no. 3, pp. 402-23.

Ellison, Sara Fisher and Catherine Wolfram (2004) "Coordinating on Lower Prices: Pharmaceutical Pricing under Political Pressure." Mimeo. Haas School of Business, U.C. Berkeley.

Erfle, Stephen and Henry McMillan (1990) "Media, Political Pressure, and the Firm: The Case of Petroleum Pricing in the Late 1970s," *The Quarterly Journal of Economics,* pp. 115-34.

Gabrowski, Henry G. and John Vernon (2000) "Effective Patent Life in Pharmaceuticals," *International Journal of Technology Management.* Vol. 19, nos. ½, pp. 98-120.

Ganslandt, Matthias and Keith E. Maskus (2004) "The Price Impact of Parallel Imports in Pharmaceuticals: Evidence from the European Union," *Journal of Health Economics,* Vol. 23, no. 5, pp. 1035-57.

Glazer, Amihai and Henry McMillan (1992) "Pricing by the Firm Under Regulatory Threat," *The Quarterly Journal of Economics*, Vol. 107, no. 3, pp. 1089-99.

Jack, William and Jean O. Lanjouw (2005) "Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?" *World Bank Economic Review*, forthcoming.

Kanavos, Panos, Joan Costa-i-Font, Sherry Merkur, Marin Gemmill (2004) "The Economic Impact of Pharmaceutical Parallel Trade in European Member States: A Stakeholder Analysis," Special Research Paper, LSE Health and Social Care, the London School of Economics and Political Science.

Kyle, Margaret (2004a) "Pharmaceutical Price Controls and Entry Strategies," Mimeo. Fuqua School of Business, Duke University.

Kyle, Margaret (2004b) "The Role of Firm Characteristics in Pharmaceutical Product Launches," Mimeo. Fuqua School of Business, Duke University.

Lanjouw, J. O. (1998) "The Introduction of Product Patents in India: "'Heartless Exploitation of the Poor and Suffering'?" NBER Working Paper no. 6366.

Lanjouw, J. O. (2005) "Patents, Price Control and Access to New Drugs: How Policy Affects Global Market Entry," NBER Working Paper, forthcoming.

Malueg, David and Marius Schwartz (1994) "Parallel imports, demand dispersion, and international price discrimination," *Journal of International Economics*, Vol. 37, pp. 167-95.

McCalman, Philip (2004) "International Diffusion and Intellectual Property Rights: An Empirical Analysis," *Journal of International Economics*. (forthcoming). Department of Economics, U.C. Santa Cruz.

Rivers, Douglas and Quang H. Vuong (1988) "Limited Information Estimators and Exogeneity Tests for Simultaneous Probit Models," *Journal of Econometrics.* Vol. 39, pp. 347-66.

Sell, Susan (2003) Private Power, Public Law: the Globalization of Intellectual Property. Cambridge Studies in International Relations.

Scherer, F.M. and Jayashree Watal (2002) Post-TRIPS Options for Access to Patented Medicines in Developing Nations," *Journal of International Economic Law*, Vol. 5, pp. 913-939.