

Online Appendix: Patents and the Global Diffusion of New Drugs

Iain M. Cockburn and Jean O. Lanjouw and Mark Schankerman

Data Sources and Construction

New Drug Launches

The phenomenon of interest here is the dating of the launch of each new drug in each country. This was derived from the dating of launches of drug products, which contain the new drug, in combination with inactive ingredients and potentially other active ingredients. The distinction between ‘drug’ and ‘drug product’ is significant. Not all new drugs are launched as exactly the same product in all countries. A given ‘active moiety’ may be approved as different salts or esters in different countries (as sulfate, hydrochloride, maleate etc.) or in different galenical forms (tablet, injectable, topical cream etc.), or may be sold in combination with different sets of other active ingredients.

Drug launches were identified from two sources of data, in which the unit of observation is a drug product. The first is the December 2002 version of the *LifeCycle: Drug Launches* database obtained from IMS Health, Inc. This file contained 187,725 observations on retail drug product launches for the period 1982-2002. The unit of observation is product-country-year, with each observation recording: (1) the trade name (proprietary product name, or brand name); (2) a listing of active ingredients using non-proprietary generic chemical name; (3) the composition, listing the formulation (capsule, syrup, powder etc.) and amounts, strength or concentration of the active ingredient(s); (4) the date the product goes on sale; and (5) the therapeutic class of the product using the World Health Organization’s Anatomical Therapeutical Chemical classification system at the third level. This database covers all therapeutic classes, but not all countries. Coverage of countries increased over time, with product launches observed in 45 countries in 1982, increasing to 66 in the early 1990s, and to 76 by the end of the sample. In two cases country was coded by IMS as a region: French West Africa, consisting of Benin, Cameroon, Congo, Cote d’Ivoire, Gabon, Guinea, and Senegal; and Central America consisting of Costa Rica, El Salvador, Guatemala, Honduras, and Panama. Notably, India was not included in this database during this period.

The drug launch data for India were obtained from a second source, the *FirstIndia* dataset of product sales compiled by ORG MARG, a market research company. This covers the period 1967 to 1997 but only for a partial set of therapeutic classes, namely antibiotics, cancer, and antiulcer. This dataset contained 498 observations on brand name, active ingredient(s), therapeutic class, and launch date.

Identifying drug launches in these data consistently across countries and over time was a significant challenge. In the data, 14 percent of records had no listing of active ingredients, only a brand name, for about one fifth of which the active ingredient could be recovered through lookup of the brand name or through parsing of the composition field. Moreover, 24 percent of records were for multi-ingredient or combination products: in some cases more than 20 ingredients were listed. About 20 percent of products fell into categories in which active ingredients were prohibitively difficult to identify consistently (vaccines, biologics, hormones, allergens, immune globulins etc.), appeared to be for non-prescription

products such as nostrums, over-the-counter, or proprietary formulations, herbal and homeopathic medicines, or were for 'non-drug' medical products, such as blood-testing strips, imaging contrast agents, non-medicinal or inactive ingredients or excipients, diagnostics, and surgical solutions.

As a preliminary step, we therefore excluded 17,452 records for products whose ingredients could not be identified. After a very careful effort to identify brand names of known drugs, we believe that no instances of launches of new drugs were excluded for this reason. We further excluded 37,199 records in therapeutic classes largely populated with non-prescription or hard to identify products,¹ and 2,274 records for vaccines.

Remaining records were 'unpacked' to give one observation per ingredient per product, with the exception of 29 combination drugs given a distinct non-proprietary name in the British Pharmacopeia where ingredients were combined.² This created an additional 29,784 observations, and was done to be 'over-inclusive' in identifying drug launches: while many drug products combine active ingredients, treating all combinations of new and old chemical entities as distinct products would result in spuriously high counts of new products, and under-identification of launches of new entities.

In principle each active ingredient is unambiguously identified by the generic name, in practice these are not fully standardized, or may use spelling variations from different languages, or may not have been assigned. After excluding non-drug or hard-to-identify products and ingredients, we observe 9,065 distinct active ingredients in the remaining 115,123 observations on country and ingredient. The great majority of these compounds were not directly relevant to this study, since they were first introduced before 1983, or are nonprescription drugs such as aspirin. Considerable effort was nonetheless invested in coding this list of active ingredients consistently, to avoid miss-identification of drugs and consequent under-identification of drug launches. A variety of online and hardcopy reference sources were consulted, including: the *ChemIDplus* database maintained by the US National Library of Medicine, the *WHO-MedNet* database, the University of Alberta *DrugBank* database, the *DrugBase* database published by Wissenschaftliche Verlagsgesellschaft Stuttgart, the Health Canada *Non-Medicinal Products Database*, the FDA's *Inactive Ingredients Database*, the Kyoto University and University of Tokyo *KEGG DRUG* database, and current and historical editions of the *Martindale Complete Drug Reference* published by The Pharmaceutical Press, the *Merck Index*, the *Index Nominum* published by the Swiss Pharmaceutical Society, and the *USP Dictionary of United States Adopted Names (USAN) and International Drug Names*

¹ Products in the following therapeutic classes: toothpaste and dentifrices, digestives, vitamins, mineral supplements, tonics, laxatives, anti-anemics, topical antihemorrhoidals, certain dermatologicals (emollients and protectives, wound and ulcer preps, anti-pruritics, disinfectants, medicated dressings, acne, miscellaneous), parenteral nutrition, bacterial immunostimulants, smoking cessation, herbal cough and cold, ophthalmics, otologicals, allergens, herbal and homeopathic medicines. These were identified through the ATC codes (A1A, A9, A11, A12, A13, A6, B3A, B3B, C5A, D2, D3, D4, D8, D9, D10, D11, K, L3X, N7B, R5F, S, T, V) or through manual examination. Vitamins and non-prescription or OTC drugs were identified from reference sources such as the *Physicians' Desk Reference for Nonprescription Drugs and Dietary Supplements*. Herbal and homeopathic products were identified by hand inspection, lookup in *Physicians' Desk Reference for Herbal Medicine*, or being manufactured by a company specializing in herbal products e.g. Arkopharma, Weleda.

² These are the drug combinations with demonstrated synergistic effects: co-amoxiclav, co-amilofruse, co-amilozide, co-amoxiclav, co-beneldopa, co-bucapap, co-careldopa, co-climasone, co-codamol, co-codaprin, co-cyprindiol, co-drydamol, co-erynsulfisox, co-fluampicil, co-flumactone, co-hycodapap, co-methiamol, co-oxycodapap, co-phenotrope, co-proxamol, co-simalcite, co-spiroozide, co-tenidone, co-tetroxazine, co-triamterzide, co-trifamole, co-trimazine, co-trimoxazole, and co-zidocapt.

published by the U.S. Pharmacopeial Convention. When possible, generic chemical names were matched to the WHO's listing of International Nonproprietary Names (INNs); when an INN was not available, the USP USAN, British Approved Name, or Japanese Approved Name was used.

As a further measure to avoid under-identification of country launches, the parts of active ingredient names corresponding to salts, esters or non-covalent derivatives were removed to arrive at the 'active moiety'. This corresponds roughly to the New Chemical Entity in U.S. usage. Treating different salts, esters and derivatives as distinct entities would result in a significantly larger number of new drugs. For each of the 2,265 such chemical entities in the source dataset we determine the first worldwide launch date, based on the earliest of (1) the first date it appears in the IMS or ORG MARG datasets, (2) the first date it appears in the FDA's drugs@fda approvals database, (3) the first date it was listed as approved for marketing in any country in the *Pharmaprojects* database compiled by PJ Publications. To avoid problems with left-censoring of launch dates in 1982 in the IMS data, we exclude any drugs for which the first worldwide launch date defined this way was before 1983. We also exclude drugs that were only launched in Japan and Taiwan and/or Korea, which appear to reflect medical practice idiosyncratic to this region. This leaves us with 642 drugs, for which we observe 17,189 drug-country observations on the timing of launches.

To prepare this dataset for survival analysis, we use the first worldwide launch date to determine $t=0$ for each molecule, and then for each drug-country combination create annual observations for the time-varying and non-time varying covariates described below for each year until either the drug is launched in that country or is censored. Care was taken to exclude country-years where a drug was not at risk of launching (as observed in these data), for example if data were not reported for that country until after the first worldwide launch date, or if the drug were in a therapeutic class not covered in these data for that country, for example anti-hypertensives in India. This gives a total of 298,605 observations on 38,180 drug-country combinations, with the launch date censored for 20,991 drug-country combinations.

Collectively, these choices about data construction result in a data set which differs from that in Kyle (2006) and Kyle (2007), making exact comparisons difficult to draw. Kyle's studies cover a similar time period to ours (1980-2000 whereas as we use 1983-2000), but use a different source for data on launch status (the *Pharmaprojects* database) and focus on smaller sets of countries: the G7 in Kyle (2006) and 28 countries, largely the membership of the OECD, in Kyle (2007), compared to our 76 countries. The exact basis for determining launch status in the *Pharmaprojects* database is unclear, but appears to be primarily regulatory approvals, whereas IMS combines regulatory approvals, announcements by manufacturers, local media reports, and active surveillance of distribution channels announcements to determine when a product becomes commercially available. Kyle uses a significantly narrower product definition, with over 1400 distinct new chemical entities appearing her data sets compared to our 642 more broadly defined drugs, and also defines markets as drug-country-therapeutic class combinations where we look at broader drug-country tuples. Overall, we observe a similar rate of entry to that reported by Kyle, with 4.8 percent of 298,605 opportunities filled in our sample compared to 3.9 percent of 86,755 drug-country-class-year opportunities in Kyle (2006) and 2.5 percent of 299,567 opportunities in Kyle (2007). Within the same sets of countries, our broader market definition results in entry rates that, although still quite low, are roughly double those reported by Kyle: 6.9 percent of opportunities filled for the G7 and 5.7 percent for the 28 countries in Kyle (2007).

Explanatory variables

Patent Protection

We construct measures of the availability and duration of patent protection for (a) pharmaceutical products and (b) chemical processes, which are coded for each country-year, along with presence of enforcement mechanisms.

Two sources were used. Data compiled by Ginarte and Park (1997) and Park (2008) who give dummy variables coded every 5 years 1960-2000 for up to 120 countries on (1) Coverage---i.e., availability of patent protection for different classes of subject matter, here the relevant category is chemicals and pharmaceuticals, process and product; (2) patent term, measured as years from filing or years from grant; (3) treaty membership in PCT, Paris Convention and UPOV; and (4) presence of various enforcement mechanisms and other factors impacting the scope of rights, such as preliminary injunctions, requirements to work, contributory infringement, compulsory licensing etc. This information was cross-referenced against the text of relevant statutes and treaties, published in *World Patent Law and Practice: Patent Statutes, Regulations, and Treaties* by John P. Sinnott and William J. Cotreau (New York: M. Bender, 1974, serialim), and *Patents Throughout the World*, an annually updated looseleaf publication (New York: West Group). *The Statutes, Regulations, and Treaties* information is taken as definitive regarding dating of changes in patent term, coverage of pharmaceuticals and chemical processes, patent term extensions, duration of term for foreign versus domestic applicants, and provides some ability to back fill the Ginarte-Park data to identify more precisely changes in the patent regime. There are occasional inconsistencies and conflicts between national law and multinational treaties such as the Andean Pact, the Bangui Agreement etc. In these cases, the provisions of the national law are taken as definitive.

Using these data we define: $Patent_Term = \text{Max}(\text{Years from grant} + 2, \text{Years from filing})$. The distribution of country/year observations by patent term is as follows:

<i>Patent_Term</i>	0	3	7	10	12	14	15	16	17	18	19	20	22
No. obs	9	17	21	77	59	15	83	35	175	39	38	694	12

Using the patent term, we define the following process and product patent regimes:

- $Short_Process=1$ if chemical processes patentable and $0 < Patent_Term \leq 12$
- $Short_Product=1$ if pharmaceutical products patentable and $0 < Patent_Term \leq 12$
- $Medium_Process=1$ if chemical processes patentable and $13 \leq Patent_Term \leq 17$
- $Medium_Product=1$ if pharmaceutical products patentable and $13 \leq Patent_Term \leq 17$
- $Long_Process=1$ if chemical processes patentable and $Patent_Term > 17$
- $Long_Product=1$ if pharmaceutical products patentable and $Patent_Term > 17$

Pro patent Index = sum of dummies for whether:

- a. patent term is the same for domestic and foreign applicants
- b. preliminary injunctions are available

- c. infringer can be liable for contributory infringement
- d. burden of proof of infringement is reversed for process inventions
- e. patents cannot be revoked for failure to work
- f. there is no requirement to work the patent, or can be satisfied by importation
- g. there is no compulsory licensing
- h. term extensions are available for pharmaceuticals

Price Controls

Each country's price control regime was coded as None/Some/Extensive from the sources listed in Lanjouw (2005). The designation 'Some' means that the country has formal price control regulation but it covers only a subset of drugs. 'Extensive' means that the regulation covers most drugs and/or is viewed in the sources as particularly restrictive. In the regressions a dummy variable for price control regime = Extensive is used.

Demographic and Income Variables

Age distribution: For each country-year, the total population, and percentage of the population over 65 years old are taken from the World Bank, *World Development Indicators*. We also used the percentage of the population under 5 years old, but found no effect in the regressions.

Income per capita: For each country, annual values of real GDP per capita (RGDPCH) are taken from the Penn World Table version 6.2

Income inequality: We use the Gini coefficient as reported in the World Bank's *World Development Indicators*. Since there are rarely more than two observations per country 1975-2005, missing values are interpolated using first-observation-carried-back for years prior to the first observed value, and then last-observation-carried-forward subsequently.

Health care expenditures: For each country, total health care expenditure as percent of GDP is taken from the World Bank's *World Development Indicators*. This is only consistently available 1990 onwards, and missing data are interpolated using first-observation-carried-back for years prior to 1990.

Health Institutions

We use the following dummy variables:

- EDL = 1 if the country has adopted an Essential Drug List
- NDP = 1 if the country has adopted a National Drug Policy
- NF = 1 if the country has adopted a National Formulary

Each of these variables varies across countries and time, and were taken from sources listed in Lanjouw (2005).

Local Technical Capacity

Chemicals Patents is a count of U.S. patents (in 10,000s) by application date in any of the IPC classes corresponding to chemical engineering and manufacturing, as indexed by the American Chemical Society. These include Pesticides, Medicinal Preparations, Chemical Methods and Processes, Inorganic Chemistry, Fertilizers, Organic Chemistry, Macromolecules, Dyes and Paints, Petrochemicals, Soaps and Oils, Beverages and Vinegar, Microbiology and Fermentation, Sugar, and Analyzing Materials; plus Chemical or Physical Laboratory Apparatus, Biocides and Pest Repellants, and Apparatus for Enzymology or Microbiology. This count is constructed for each country/year, based on the country of the inventor(s) listed on the patent, and then converted to a stock using a 15 percent depreciation rate and an assumed pre-sample growth of 10 percent to initialize the stock. If a patent has multiple inventors listed, we count the patent in each of the listed countries.

Governance

Rule of Law and Regulatory Quality index values and rank order (for 181 countries) published in World Bank, *Worldwide Governance Indicators* for 1996, 1998, 2000, 2002 (not available before 1996). We use first-observation-carried-back for years prior to 1996, then last-observation-carried-forward.

Instrumental Variables

Political_Constraints: a measure of credible policy commitment (the degree of political constraints on policy change). It is derived from a spatial model of political interaction and is based on the number of independent veto points in the different branches of the political system and the distribution of political preferences both across and within these branches. Higher values represent greater political constraints (and thus greater policy commitment). For details see Henisz (2000).

Executive_Orientation: a dummy variable that codes whether the executive comes from a right, left or center party with respect to its orientation on economic policy. Source: World Bank Database of Political Institutions: Changes and Variable Definitions (Philip Keefer, December 2009).

Ethnolinguistic_diversity: a measure commonly used as an indicator of difficulty in reaching and committing to political decisions. For details, see La Porta et al. (1999).

Legal_Origin: The historical origins of the legal system for each country is coded as either common law (U.K.), French law, German law, Socialist, or Scandinavian. For details, see La Porta et al. (1999).

Regional Trade Agreements (RTA): the cumulative number of regional trade agreements that the country has entered as of a given year. These data were compiled from Table 3 of Baier and Bergstrand (2007), supplemented with information from the WTO's online Regional Trade Agreements Information System (RTA-IS). We thank Keith Head for providing a clean version of these data.

All of these instruments vary across countries and over time, with the exception of *Legal_Origin*.

Ancillary Regressions for Policy Regime Choice

Table A.3 reports the FIML parameter estimates for the price controls and patent policy regime equations. A Probit is used for price controls (=1 if price controls are in place in a given country/year). Ordered Probits are used for process and product patent regimes, ordered by increasing duration (the reference category is no protection). The regressions include the instruments and all covariates from the launch equation reported in the body of the paper. A random country effect is included in all equations with the coefficient normalized in the launch equation.

We present the results for two sets of instruments (labeled narrow and broad). The narrow set includes two instruments: 1) *Political_Constraints*, which measures the degree to which voting rights within the political structure constrains policy change (this is used in the political science literature as a proxy for credible policy commitment; higher values correspond to greater commitment); and 2) *Executive_Orientation*, coded as Left, Right or Center based on the ruling party with respect to its orientation on economic policy (Center is the reference category). The second, broad set includes the first two instruments plus three additional ones: 1) *Ethnolinguistic_diversity*, commonly used in the economics and political science literature as an indicator of difficulty in reaching and committing to political decisions; 2) *Legal_Origin*, coded as UK (common law), French law, German law, or Socialist/Other (the reference category); and 3) *RTA* which is the cumulative number of regional trade agreements that the country has entered. With the exception of *Legal_Origin*, all of the instruments vary both across counties and time.

Columns (1)-(3) are based on the narrow set of instruments; columns (4)-(6) use the broader set. The instruments are all statistically significant both individually and jointly (p-values < 0.001 in all cases). We briefly summarize the qualitative results for the instruments as follows. Price controls are more likely when there are weaker *Political_Constraints* (less policy commitment), a left-leaning *Executive_Orientation*, French legal origins (followed by common law countries), greater *Ethnolinguistic_diversity*, and (weakly) higher RTA indicating greater trade openness. Process patent protection is more likely to be longer when there are weaker *Political_Constraints*, a centrist *Executive_Orientation* (both Left and Right- leaning executive orientation favor shorter protection), German legal origins (followed by UK and French), lower *Ethnolinguistic_diversity*, and higher *RTA*. Finally, product patents are longer when there are weaker *Political_Constraints*, a centrist *Executive_Orientation*, German (followed by UK and French) legal origins, higher *Ethnolinguistic_diversity*, and higher *RTA*.

The noteworthy conclusions from the other covariates are: larger countries (population and GDP/capita), and those with greater income inequality and older populations are less likely to have price controls and more likely to have longer process and product patent protection. Countries which have adopted the Essential Drug List are less likely to have price controls and more likely to have longer patent regimes, while those with a National Formulary are more likely to have both price controls and longer patent regimes. Finally, the coefficient on the random country effect is negative in the price control equation, and positive in the process and product patent equations. Recalling that the coefficient is normalized in the drug launch equation, this indicates that unobserved country factors that promote earlier launch of new drugs also make it more likely that the country adopts longer process and patent policy regimes, but less likely to adopt strong price controls.

While these results are descriptively intriguing, we emphasize that these regressions do not have a structural interpretation because they are not based on any formal model of how price regulation and patent policy are determined. The economics and political science literature has not reached any consensus on how to model policy-making in general (including these policy regimes), and the challenges to formulate such models that are applicable to widely diverse countries are formidable.

References

- Baier, Scott and Jeffrey Bergstrand (2007), "Do Free Trade Agreements Actually Increase Members' International Trade?" *Journal of International Economics*, 71: 72-95}
- Ginarte, Juan and Walter Park (1997), "Determinants of Patent Rights: A Cross-National Study," *Research Policy*, 26:283-301
- Henisz, Witold (2000), "Institutional Environment for Economic Growth," *Economics and Politics*, 12(1): 1-31
- Kyle, Margaret (2006), "The Role of Firm Characteristics in Pharmaceutical Product Launches," *RAND Journal of Economics*, 37(3):602-618
- Kyle, Margaret (2007), "Pharmaceutical Price Controls and Entry Strategies," *Review of Economics and Statistics*, 89(1):88-99
- La Porta, Rafael, Florencio López-de-Silanes, Andrei Shleifer and Robert Vishny (1999), "The Quality of Government," *Journal of Law, Economics and Organization*, 15(1): 222-279
- Lanjouw, Jean O. (2005), "Patents, Price Controls, and Access to New Drugs: How Policy Affects Global Market Entry," NBER Working Paper No. 11321
- Park, Walter (2008), "International Patent Rights: An Update," *Research Policy*, 37: 761-766}

Table A.1. Summary Statistics (country-year observations)

Variables	Mean	Std. Dev	Minimum	Maximum
Policy Regimes				
Short_Process	0.11	0.31	0.00	1.00
Medium_Process	0.22	0.42	0.00	1.00
Long_Process	0.60	0.49	0.00	1.00
Short_Product	0.07	0.25	0.00	1.00
Medium_Product	0.16	0.37	0.00	1.00
Long_Product	0.59	0.49	0.00	1.00
Propatent Index	0.42	0.23	0.00	1.00
Price Controls	0.40	0.49	0.00	1.00
Health Institutions				
National Drug Policy	0.82	0.39	0.00	1.00
Essential Drug List	0.74	0.44	0.00	1.00
National Formulary	0.83	0.38	0.00	1.00
Other Variables				
Population (millions)	49.44	119.05	0.41	1034.17
GDP/cap (thousands)	12.58	8.83	1.12	48.59
Health/GDP (percent)	4.48	8.83	0.20	15.78
Gini Coefficient	39.25	10.05	19.49	63.00
% Pop Age 65+	8.40	4.95	1.40	18.07
Bureaucratic Quality	67.96	24.71	16.67	100.00
Rule of Law index	4.25	1.50	1.00	6.00
Chemical patents (10,000s)	0.10	0.46	0.00	5.20

NOTES: 1,228 observations on variables measured at the country-year level. Up to 76 countries observed 1983-2002. Data form an unbalanced panel based on availability of launch data, with not all countries observed for the full time period.

Table A.2: Policy Regimes and Drug Launches by Country

Country	Product Patent Regime	Process Patent Regime	Price Control Regime	Percent of Drugs		Country	Product Patent Regime	Process Patent Regime	Price Control Regime	Percent of Drugs	
				Launched Within 5 Yrs	Launched & FDA approved					Launched Within 5 Yrs	Launched & FDA approved
Argentina	N,S,M,N	S,M,L	S,N	45.3	56.5	Kuwait	N,L	S,L	S	21.5	25.4
Australia	M,L	M,L	N	27.3	38.2	Latvia	L	L	N	20.1	23.2
Austria	N,L	L	S	44.4	58.0	Lebanon	N,L	M,L	S	19.7	22.3
Bangladesh	M	M	N	9.7	11.0	Luxembourg	L	L	S	25.4	29.5
Belgium	L	L	S	36.3	47.5	Malaysia	L,M	L,M	N	20.2	27.1
Benin	S,L	S,L	S	12.2	14.0	Mexico	N,L	N,L	N,S,N	37.4	48.7
Bolivia	L	L	N	8.6	10.1	Morocco	L,N,L	N,L	S	13.7	16.1
Brazil	N,M,S	N,S	S,N	31.6	42.0	Netherlands	L	L	N	39.4	50.4
Bulgaria	L	L	N	18.3	21.1	New Zealand	L	L	N	28.8	39.0
Cameroon	S,L	S,L	S	12.2	14.0	Norway	L	L	N	47.0	53.5
Canada	L	L	N	37.5	54.6	Pakistan	M,L	M,L	S	14.8	16.9
Chile	M	N,M	N	28.8	36.6	Panama	M	M	N,S	28.5	36.6
Colombia	N,M,L	N,M,L	S,N	31.5	42.5	Paraguay	N	M	S	19.4	23.7
Costa Rica	N,S,L	L,S,L	N	28.5	36.6	Peru	N,M,L	N,M,L,N	S,N	20.6	26.4
Cote D'Ivoire	S,L	S,L	S	12.2	14.0	Philippines	L	L	N	31.8	40.4
Czech Republic	L	L	N	41.9	46.9	Poland	L	L	N	34.2	39.6
Denmark	M,L	M,L	N	44.9	59.4	Portugal	N,L	M,L	N	24.6	28.3
Dominican Republic	M	M	N	21.3	26.8	Puerto Rico	L	L	N	48.7	59.6
Ecuador	N,M,L	M,L	S	22.1	28.5	Russia	L	L	N	14.3	16.7
Egypt	N	M	S	10.3	13.8	Saudi Arabia	L,M	L,M	S	13.7	19.5
El Salvador	M	M	N	28.5	36.6	Senegal	S,L	S,L	N	12.2	14.0
Finland	L,N,L	L	S,N	43.5	59.1	Singapore	L	L	N	25.5	33.3
France	L	L	S	37.5	44.2	Slovak Republic	L	L	N	34.4	39.5
Gabon	S,L	S,L	S	12.2	14.0	Slovenia	L	L	N,S	28.7	33.8
Germany	L	L	N	55.0	67.9	South Africa	L	L	N,S	28.8	39.0
Greece	M,L	M,L	S	35.7	46.8	South Korea	M,L	M,L	S,N	42.6	46.9
Guatemala	N	M,S	S,N	28.5	36.6	Spain	N,L	L	S	39.1	47.5
Guinea	S,L	S,L	N	12.2	14.0	Sweden	L	L	S,N	38.9	53.0
Honduras	L,M	L,M	N,S	28.5	36.6	Switzerland	L	L	N	44.4	58.4
Hong Kong	L	L	N	27.7	37.3	Taiwan	L	L	N	28.3	35.1
Hungary	N,L	L	N	36.6	41.2	Thailand	N,L	M,L	N	30.4	40.9
India	N	S	S,N	8.2	10.9	Tunisia	N	L	S	8.2	9.2
Indonesia	N,M,L	N,M,L	N	19.5	25.9	Turkey	M,L	M,L	S	25.1	33.5
Ireland	L	L	N	38.5	50.8	UK	L	L	N	50.6	66.5
Israel	L	L	S	24.0	34.0	UAE	N	S	N	21.1	25.0
Italy	L	L	S,N	52.3	60.3	Uruguay	N,M	M	N	37.6	43.9
Japan	L	L	N	31.9	34.4	USA	L	L	N	53.1	80.0
Jordan	L	L	S	12.9	15.8	Venezuela	N,M,L	N,M,L	N	24.6	32.1

Price Controls: N=None/Weak S=Strong; Patents: N=None S=Short M=Medium L=Long

Table A.3. Probit and Ordered Probit Regressions for Policy Regimes

Equation	1a			2a		
	Price Controls	Proc Pat	Prod Patents	Price Controls	Proc Patents	Prod Patents
Dependent variable		Ordered	Ordered		Ordered	Ordered
Specification	Probit	Probit	Probit	Probit	Probit	Probit
Political Constraints	-0.728** (0.041)	-0.631** (0.042)	-0.401** (0.038)	-0.239** (0.042)	-1.702** (0.038)	-1.914** (0.039)
Executive Left	0.346** (0.018)	-0.227** (0.021)	-0.244** (0.024)	0.368** (0.022)	-0.244** (0.025)	-0.315** (0.027)
Executive Right	0.131** (0.016)	-0.582** (0.014)	-0.670** (0.018)	0.146** (0.016)	-0.500** (0.012)	-0.576** (0.016)
Ethno-linguistic Diversity				0.786** (0.046)	-0.880** (0.031)	0.213** (0.035)
Legal Origins Germany				-0.038 (0.036)	2.731** (0.074)	4.346** (0.055)
Legal Origins UK				0.545** (0.037)	1.449** (0.076)	2.986** (0.062)
Legal Origins France				1.358** (0.036)	0.580** (0.074)	2.291** (0.054)
RTAs				0.002* (0.001)	0.089** (0.001)	0.092** (0.001)
log(Population)	-0.166** (0.007)	0.011 (0.007)	0.094** (0.007)	-0.345** (0.010)	0.190** (0.007)	0.394** (0.008)
Log(GDP/cap)	-0.602** (0.021)	0.742** (0.016)	0.994** (0.018)	-0.528** (0.029)	0.503** (0.018)	1.152** (0.020)
Log(Health/GDP)	0.370** (0.016)	0.253** (0.015)	0.305** (0.015)	0.638** (0.019)	-0.025 (0.016)	0.168** (0.016)
Gini Coefficient	-0.053** (0.001)	0.006** (0.001)	0.032** (0.001)	-0.098** (0.002)	0.057** (0.001)	0.096** (0.001)
% Pop Age 65+	-0.076** (0.004)	0.248** (0.003)	0.189** (0.003)	-0.164** (0.005)	0.187** (0.004)	0.134** (0.005)
Bureaucratic Quality	0.007** (0.001)	0.016* (0.001)	0.011** (0.001)	0.015 (0.001)	0.016* (0.001)	0.017* (0.001)
Rule of Law	-0.203** (0.008)	0.093** (0.016)	0.187** (0.008)	-0.179** (0.007)	-0.153** (0.005)	-0.273** (0.007)
National Drug Policy	0.396** (0.002)	-0.132** (0.020)	0.440** (0.021)	0.369** (0.023)	-0.010 (0.019)	-0.359** (0.022)
Essential Drug List	-0.200** (0.018)	0.583** (0.021)	0.963** (0.022)	-0.296** (0.019)	0.317** (0.021)	0.816** (0.025)
National Formulary	0.395 (0.018)	0.354** (0.021)	0.136** (0.026)	0.334** (0.020)	0.448** (0.019)	0.140** (0.026)
Country random effect	-0.405** (0.009)	1.140** (0.012)	1.150** (0.012)	-0.619** (0.013)	1.070** (0.009)	1.490** (0.015)

NOTES: * significant at 5 percent and ** significant at 1 percent. Heteroskedasticity-robust standard errors are reported in parentheses. Parameter estimates from are FIML estimation of each group of three policy regime equations jointly with a hazard model for drug launch: equations 1a, 1b, 1c were estimated jointly with the model in column 4 of Table 5, and 2a, 2b, and 2c with column 5 in Table 5. In the Ordered Probits, the process and product patent regimes are ordered according to increasing duration (the reference category is no protection). The last coefficient is on the country random effect which is common to all three equations (and the hazard of launch equation not reported here).