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A Cross-Country Index of Intellectual Property Rights in Pharmaceutical Innovations

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1. Introduction

Cross-country studies of the impact of intellectual property rights (IPRs) on innovation have usually relied upon broad measures of the strength and scope of a country's patent system (Gadbaw and Richards, 1988; Rapp and Rozek, 1990; Ginarte and Park, 1997). More focused measures of IPR protection of innovations in a specific industry could also be useful to social scientists, as IPR coverage often varies substantially across industries due to differences in the scope, term, and strength of IPR instruments available to protect innovations in a particular industry. The pharmaceutical industry meets these criteria. Numerous studies have found that intellectual property rights are important for the development of new pharmaceutical innovations, as new drugs or improvements to existing drugs are costly to develop and can usually be imitated within a short time at relatively low cost (Mansfield and Wagner, 1981; Cockburn, *et al.*, 2007; DiMasi et al., 2003; Adams and Brantner, 2010). Numerous surveys of R&D managers in the pharmaceutical industry show that they believe product patent protection for new drugs is highly effective in protecting against imitation and important in firm decisions on location of manufacturing plants and R&D facilities (Levin *et al.*, 1987; Mansfield, 1994; Cohen *et al.*, 2000).

Many countries with strong patent protection for other industrial products and processes have not always provided strong protection for pharmaceutical innovations. For example, in 1970, all 22 OECD countries had functioning industrial patent systems, but only four allowed new pharmaceutical products to be patented.[1] Over the last five decades, the extent of IPR protection for pharmaceutical innovations has increased dramatically, as more than 90 percent of the world's countries now offer pharmaceutical product patents to both resident and foreign inventors. At the same time, the types of intellectual property available to protect new drugs and improvements to existing drugs have also expanded rapidly, with countries protecting innovations via product patents,

[1] The four countries are the United States, United Kingdom, France, and Germany.

process patents, formulation patents, new medical indication patents, and marketing exclusivity measures. The proliferation of new types of IPRs has made it more difficult to compare IPR protection of pharmaceuticals across countries and has increased the need for an index summarizing each country's property rights in pharmaceutical innovations.

In this article, we develop an annual index summarizing the presence, term, and strength of various types of patents that can be claimed for pharmaceutical innovations. The Pharmaceutical Intellectual Property Protection (PIPP) Index covers 154 countries over the period 1960 to 2005 and includes all countries with more than one million residents in 2005. The index is an aggregation of three component sub-indexes: the Pharmaceutical Patent Rent Appropriation (PPRA) Index, which measures the presence of different types of pharmaceutical patents that provide protection for different types of pharmaceutical inventions; the Pharmaceutical Patent International Agreements (PPIA) Index, which aggregates country membership in three international agreements that extend patent protection to foreign innovators; and the Pharmaceutical Patent Enforcement (PPE) Index which aggregates various statutory measures that either enhance or detract from public and private enforcement of patent rights.

The PIPP Index has many potential uses in econometric studies of how the scope and strength of pharmaceutical property rights affect firm choice of R&D expenditures, investment, geographic location, and corporate strategies as well as aggregate production, trade, and foreign direct investment in pharmaceuticals by country.

2. Literature Review

2.1. Methodology

Quantification of the strength and scope of patents and other property rights protecting inventions is important, as such measures can contribute to the characterization of the overall set of rules that affect the legal operation of business enterprises. Other measures characterizing the legal environment faced by business firms include indexes of

economic freedom, environmental policies, and competition policies (Maskus, 2000). They summarize a multitude of policy and institutional indicators in each of these general areas, thereby providing analysts and decision makers with a more integrated and informative overview than would otherwise be possible (Hammond *et al.*, 1995; Niemeijer, 2002). The main task of developers of such indexes is to identify critical policy and institutional indicators and to aggregate them using a methodology that produces a single summary measure of their scope and strength. Most indexes are constructed as an application of Keeney and Raifa's (1993) multi-attribute utility via a four-step procedure.

First, general categories of interest are specified, and variables that provide information about important attributes of each general category are identified. For example, the Economic Freedom of the World Index (Gwartney, Lawson, and Hall, 2012) assigns 42 variables to five categories; the IMD's benchmark index in the World Competitiveness Yearbook (IMD, 2012) assigns 333 variables to 20 categories; Ginarte and Park (1997)'s patent index assigns 17 variables to five categories; and Knack and Kiefer's (1995 and 1997) index of civic cooperation aggregates answers to five questions from the World Value Survey. Researchers typically must balance two factors when they select the number of variables for each category: (1) Index accuracy, which increases as the number of variables increases, and (2) country coverage, which falls as the number of variables increases due to a rise in the number of missing observations.

Once the categories and component variables have been identified, the second step is to determine weights to aggregate variables within a category as well as to aggregate categories. When possible, weights should reflect the importance of each variable for the particular category and each category for the overall index. Researchers have used a variety of weighting methodologies to generate indexes. Commonly used methods include equal weights; weights determined by experts or public surveys; and

weights based on the revealed importance of the variable or category.[2]

For indexes that incorporate time series data, a third step is to determine whether to use fixed or time-varying weights. Time-varying weights allow for the specification of a more accurate index but are more costly to calculate than fixed weights and are less likely to be available for any given set of countries. Time-varying weights are mainly applied in fiscal, financial, and price indexes (Bhandari and Hanson, 1986; Lalonde and Parent, 2006).

A final and fourth step is to conduct sensitivity tests to determine whether the index's ordinal rankings change appreciably in response to small changes in category and variable weights. For example, Ginarte and Park (1997) calculated the Spearman rank-order correlation coefficient to test whether changes in the component weights of categories and variables in their patent index produced statistically significant changes in its ordinal rankings.

2.2. General Indexes of Patent Protection

Economists have only recently begun to develop indexes of IP protection. Gadbaw and Richards (1988) produced one of the first indexes of IP protection and applied it to annual data from seven developing countries: Argentina, Brazil, India, Mexico, South Korea, Singapore and Taiwan for the 1984-1988 period. Rapp and Rozek (1990) measured the extent and strength of patent protection across countries. Their index covered 159 countries in 1984 and was scaled from zero to five. Seyoum (1996) used survey methods to generate new measures of the strength of IP in developing countries. Survey results were collected from IPR practitioners for 30 countries. After aggregating the results regarding attributes of various IPRs, Seyoum constructed four variables measuring the extent and strength of protection provided by each country for patents,

[2] The Joint Research Centre of the European Commission provides detailed descriptions and examples of construction of composite indicators for each weighting method. See http://composite-indicators.jrc.ec.europa.eu/ s6_weighting.htm. (Last access on 29 June 2013).

copyrights, trademarks, and trade secrets. Sherwood (1997) combined his own observations and experience with professional interviews and generated indexes for 18 countries, mostly from Latin American. His IP protection score is scaled to range from 0 to 103 and is an aggregate of nine components.

Ginarte and Park (1997) constructed an index of patent rights that covers 110 countries over the 1960 to 1990 time period. Park later extended its coverage through 2005 (Park 2008). Ginarte and Park identified five general categories of statutory attributes that affect the extent and strength of national patent laws: (1) extent of coverage; (2) membership in international patent agreements; (3) restrictions or limitations on the use of patent rights; (4) enforcement provisions; and (5) the patent's term. For each of the five categories, a country is awarded a score ranging from zero to one. To aggregate the five measures, they experimented with a range of possible weights. Results indicated that ordinal rankings across countries were not very sensitive to the choice of weights. Given these findings, they decided to weight each category equally and to add them together to form their index. Their index has a scale of zero to five.

The Ginarte-Park Patent Index is superior in virtually all respects to previous IPR measures, as it incorporates more detailed measures of index components while including enough components to span virtually all important features relevant to patent rights and their enforcement (Kanwar and Evenson, 2003). Their index has been widely used and cited in the rapidly expanding empirical literature analyzing the impact of stronger patent rights on a wide range of aggregate variables, including innovation, exports, foreign direct investment, and output growth.[3]

Ginarte and Park's index provides a good measure of overall patent protection for a national economy but is, by design, less informative regarding the extent and strength

[3] Researchers in economics, law, sociology, political science, and history have cited the Ginarte-Park Patent Index over 1,000 times. See, for example, Grossman and Lai, 2004; Smith, 1999; Lerner, 2002; Maskus, 2000; Nunnenkamp and Spatz, 2003; Ivus, 2010; Branstetter et al. 2016; Kanwar, 2012; and Lai and Yan, 2013.

of intellectual property protection for innovations in specific industries. IPR coverage can vary substantially across industries due to differences in the availability, scope, term, and strength of IPR instruments available to protect innovations in a particular industry. As we argued in the introduction, the pharmaceutical industry should receive special attention due to the perceived importance of patent protection for pharmaceutical innovations and specific patent laws designed for the industry.

3. Construction of an Index of Property Rights in Pharmaceutical Innovations

Using the same general methodology as Ginarte and Park, Pugatch (2006) developed the first cross-country index of intellectual property right protection for pharmaceutical innovations.[4] His index is an aggregation of scores from five categories: Term of exclusion, scope of exclusivity, strength of exclusivity, barriers to full IP exploitation, and enforcement (p. 380). Scores for each category range between zero and one, and are added together to form the index value, which ranges between zero and five as in Ginarte and Park. Each category's score is the weighted sum of between three and six variables, each of which is scored either "zero" or "one" (p. 381). Together, the five categories contain 22 variables. Pugatch's methodology differs in three key respects from the one used by Ginarte and Park: (1) The index incorporates other forms of intellectual property beyond patents, such as trademarks; (2) different weights are assigned to variables depending on whether they are categorized as a core component (40 percent weight), a significant component (20 percent weight), or an added-value component (5-10 percent weight); and (3) the index incorporates country regulatory restrictions on pharmaceutical pricing, advertising, and profits. Pugatch reports values of the index for one year, 2005, for four countries—the United States, the United Kingdom, Singapore and Israel (p. 383). For these four countries, there are substantial differences

[4] La Croix and Liu (2008) independently proposed an earlier version of this article's PIPP Index during the same time period.

between scores of Pugatch's Pharmaceutical IP Index and the Ginarte-Park Patent Index.

The Pharmaceutical Intellectual Property Protection (PIPP) Index proposed in this article uses the same general methodology used by Ginarte and Park to construct their index and incorporates some of the pharmaceutical-specific variables used in the Pugatch Index. It is a composite of three component sub-indexes: Pharmaceutical Patent Rent Appropriation (PPRA) Index, Pharmaceutical Patent International Agreements (PPIA) Index and Pharmaceutical Patent Enforcement (PPE) Index. Our index differs in four major respects from the Pugatch IP Pharmaceutical Index. First, we use just 15 rather than 22 variables to construct the index. We only include variables related to pharmaceutical patents and do not include variables for trademark protection, data exclusivity, or regulation of pharmaceutical company pricing, profits, or advertising.[5] This more focused approach enables us to expand index coverage to a broad spectrum of

[5] Many countries provide new drug developers with limited-duration property rights in pharmaceutical registration files, i.e., the data submitted by pharmaceutical companies to regulatory authorities, such as the U.S. Food and Drug Administration (FDA) and the European Agency for Evaluation of Medicinal Products (EMEA), for the purpose of obtaining marketing approval for new drugs. These files include data from clinical trials establishing a drug's safety and efficacy, its physical and chemical characteristics, and quality and reliability of the firm's manufacturing process for the drug. The time-limited property rights to these data files vary across countries and are typically referred to as "data exclusivity." We do not include data exclusivity in the PPRA Index because it has an ambiguous effect on protection of pharmaceutical innovations. In some cases, data exclusivity was designed to prevent generic entry for a limited period, thereby increasing expected profits from bringing a drug to market, and increasing intellectual property protection (IFPMA, 2000; von Braun and Pugatch, 2005). But in other cases, data exclusivity was designed to increase entry by generic competitors. Data exclusivity in the United States, as established in 1984 by the Hatch-Waxman Act, was designed to limit the market power of pharmaceutical patent owners. The Act's five-year period of data exclusivity meant that data exclusivity expires well before the product's patent expires, thereby expediting entry by generic producers and decreasing the strength of protection provided by pharmaceutical patents.

154 developed, developing, and least developed countries over a 46-year period, 1960-2005. Second, we use the same weights as Ginarte-Park for our three component sub-indexes to facilitate comparison between our index and the Ginarte-Park Index.[6] Third, we assign equal weights to variables within each component index, as we have not identified adequate empirical foundations to justify assignment of particular values as differential weights. We note that equal weighting of variables is standard practice when indexes are aggregations of binary variables. Fourth, we aggregate component indexes multiplicatively as this allows the PIPP Index to satisfy three essential properties, discussed below in Section 3.2. Finally, we follow Ginarte and Park by including a component sub-index consisting of three important international trade agreements that provide national treatment for foreign inventors, reduce the cost of obtaining patent rights in foreign countries, and expand the strength, scope, and enforcement of pharmaceutical patent rights available to inventors in signatory countries.

Below we discuss the specific variables included in each of our sub-indexes.

3.1 Extent of Patent Protection

Which types of pharmaceutical inventions can be awarded a patent or be protected by another type of intellectual property right? We identify five types: (1) New chemical entities; (2) new pharmaceutical production processes; (3) new medical indications for existing pharmaceuticals; (4) new formulations of a medicine, e.g. new dosing schedule, new dosage form, new strength and new time-release variations; and (5) exclusive marketing rights and patent extensions for orphan drugs, biologics, and drugs tested on

[6] Ginarte and Park (1997) assigned equal weights (20 percent) to each of their five categories. We assign a 40 percent weight to our PPRA Index because it combines variables from their "patent coverage" and "duration" categories. We also assign a 40 percent weight to our PPE Index because it combines variables from their "patent enforcement" and "loss of protection measures against losses" categories. We assign a 20 percent weight to our PPIA Index, which uses variables from their "membership in international agreements" category.

pediatric populations.[7]

3.1.1 Patents Covering New Products and New Processes

Process patents have two functions: To provide protection for new production processes and to provide short-term protection for a new pharmaceutical product. If a country does not grant product patents to inventors of new drugs, then a process patent can often provide indirect protection for a new drug during the interval between the initial marketing of the drug and the development and implementation by competitors of a new production process for the drug. Since most drugs can be produced by more than one method and new methods are often relatively inexpensive to develop and implement, a process patent typically provides a much shorter period of protection than a product patent (Kawaura and La Croix 1995; Correa 1998).

In 1960, only the United States and Great Britain granted patents covering new drugs. Since the passage of its first Patent Law in 1790, the United States has continuously provided patents for new drugs and new production processes to manufacture drugs.[8] Britain issued pharmaceutical product patents between 1630 and 1919.[9] From 1883 Britain took advantage of the newly concluded Paris Convention's provisions allowing countries to issue compulsory licenses (known as "licenses of right") for non-worked patents in pharmaceuticals and foodstuffs. After World War I, Britain passed the Patent Act of 1919, which abolished product patents for chemicals and pharmaceuticals and allowed any manufacturer to license any pharmaceutical and foodstuff process patent as a matter of right, regardless of whether the process patent was

[7] We include various types of patents and exclusive marketing provisions in the PIPP Index if they provide increased protection to inventors for pharmaceutical inventions. We do not mean to imply that these patents provide optimal incentives to agents or that their existence improves social welfare.

[8] See Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (April 10, 1790) and also Patent Act of 1793, Ch. 11, 1 Stat. 318-323 (February 21, 1793).

[9] See Corley (2003) for a brief history of the U.K. pharmaceutical industry.

already being worked in Britain.[10] Changes in 1949 to Britain's patent law re-established chemical and pharmaceutical product patents, but did not alter its licenses of right in products and processes. Testimony against licenses of right by pharmaceutical companies before the Banks Committee in 1969 was a major factor behind Parliament's decision to abolish them in 1977.

In France, the 1844 Patent Law specified that pharmaceutical inventions could not be patented. France introduced pharmaceutical process patents in 1883 but it took 76 years before it started the process of establishing property rights in new pharmaceutical products with an executive order on February 4, 1959. France amended its patent law in 1966 to provide some protection for pharmaceutical products, and further amendments in 1978 established a pharmaceutical product patent (Boldrin and Levine, 2010; WIPO, 1988).

Other industrialized countries introduced pharmaceutical and chemical process patents in the nineteenth century but only began to issue pharmaceutical product patents from 1968, including Australia in 1990,[11] Canada in 1987,[12] Finland in 1995, Germany in

[10] The British Patent Act of 1919, Section 38 A (1): "In the case of inventions relating to substances prepared or produced by chemical processes or intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by special methods or processes of manufacture described and claimed or by their obvious chemical equivalents." During World War I, British firms used patented German pharmaceutical processes without payment of royalties, and the 1919 Act allowed them to continue this practice (Pitkethly 1999).

[11] We follow WIPO's categorization and consider Australia to have established pharmaceutical process and product patents in 1990 (WIPO, 1988 and Nogues, 1990).

[12] From 1919 to 1993, Canada followed the practices of the British Patent Act of 1919 by only allowing pharmaceutical processes to be patented. From 1919 to 1969, Canada also issued compulsory licenses allowing Canadian firms to manufacture drugs using patented foreign processes. From 1969 to 1987 Canada also issued compulsory licenses allowing a company to import a drug protected by process patents. In 1983 Canada established a pharmaceutical product

1968, Norway and Spain in 1992, Sweden and Italy in 978, Switzerland in 1977, and Japan in 1976[13] (Nogues, 1990).

A few developing countries—Brazil, India, and some African and Latin American countries—started to grant pharmaceutical process patents from the early 1950s.[14] However, until 1963, not a single developing country issued or recognized pharmaceutical product patents.[15] Some of the earliest developing country adopters were 15 former British colonies that are members of the African Regional Intellectual Property Organization (ARIPO) and 16 former French colonies that are members of the Organisation Africaine de la Propriete Intellectuelle (OAPI). OAPI members have allowed pharmaceutical products to be patented since the Bangui Agreement of 1977 and ARIPO members (except Ghana and Malawi) have gradually introduced product patents from 1984.

Beginning in the early 1980s the United States imposed strong pressure on developing countries with weak IPR laws and institutions through its Special 301 provision of the U.S. Trade Act 1974. Special 301 directs the U.S. Trade Representative to investigate foreign protection of U.S. intellectual property holders, negotiate higher intellectual property standards, and retaliate with trade sanctions if these negotiations fail.

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patent, and in 1987 Canada amended the Canada Patent Act to sharply restrict compulsory licenses (Bill C-22, Patent Act Amendment 1987).

[13] From the passage of its first patent law in 1885, Japan allowed process but not product patents for new drugs. As in Great Britain, shifting interests among Japan's domestic drug manufacturers drove change. After a 1971 survey found support among manufacturers for product patents, the Diet passed enabling amendments to the patent law in 1975, which took effect in 1976 (Kawaura and La Croix, 1995).

[14] Smaller developing countries have frequently imported generic versions of drugs protected by product patents in the United States or Great Britain from larger developing countries, such as Brazil and India.

[15] Rwanda (1963 Patent Act) and Burundi (1964 Patent Act) were the first two developing countries to recognize pharmaceutical product patents (Thorpe, 2002).

Using a number of designated threat levels—for example countries could be placed on a watch list, a priority list, or designated for such lists but not placed on them, the United States initiated Special 301 investigations of numerous Asian and Latin American countries. In response to the U.S. investigations and E.U. diplomatic pressure, a number of Asian and South American countries strengthened their patent laws and institutions, agreeing, among other things, to establish patent protection for new pharmaceutical products.[16] Malaysia and Taiwan in 1986 and South Korea in 1987 were among the first developing economies in Asia to issue pharmaceutical product patents and were followed just a few years later by Thailand in 1992 and China in 1993.[17] Some developing countries in Asia did not even have patent laws when the United States and the European Union began to lobby other countries to strengthen patent protection for pharmaceutical innovations. For example, Indonesia passed its first patent law in 1991 and amended it in 1997 to allow pharmaceutical product patents to be issued. In South America, U.S. pressure was a major factor behind the introduction of pharmaceutical product patents in Chile in 1991, the Andean countries in 1994,[18] and Argentina in 1996.

The adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement as part of the 1995 WTO Agreement was a watershed for the global protection of pharmaceutical inventions. TRIPS required that all member countries provide pharmaceutical product and process patents. By 2006, 101 developing countries had changed their laws to provide pharmaceutical product patents (La Croix and Liu, 2008).[19] In 2013, 16 countries in our sample did not provide pharmaceutical process

[16] See La Croix (1995), Konan, *et al.* (1995) and Blakeney (1996) for a discussion of changes in intellectual property rights in the ASEAN countries between 1980 and 1993.

[17] China's patent law was enacted in 1992 and took effect in 1993.

[18] The Andean countries are Colombia, Ecuador, Peru, Bolivia and Chile.

[19] The TRIPS Agreement contains several provisions that specify transition periods for WTO members to adapt their legislation and practices to fit their TRIPS obligations. The Doha Declaration extended the transition period for pharmaceutical patents and data protection to 2016.

patents and 24 countries did not provide pharmaceutical product patents.[20] These countries are either least-developed countries or Middle Eastern countries. With the exceptions of Cuba, Pakistan, Haiti, Jordan and Tunisia, they are not WTO members. Some of these countries have been plagued by civil wars, e.g., Afghanistan and Nepal.

3.1.2 New Medical Indication Patents

Some countries issue patents covering a new medical indication of a known medical product.[21] Provision of a new medical indication patent is one variable in the PPRA index. In the United States, for example, the April 2013 edition of *The Orange Book*[22] listed 664 new medical indication patents that had received marketing approval from the FDA and were in force at the time.

Consider, the case of Wellbutrin XL, the first norepinephrine and dopamine reuptake inhibitor (NDRI) for the treatment of depression in adults available in a single daily dose. Biovail Company patented Wellbutrin XL for this use. Doctors and researchers observing patients under treatment with Wellbutrin XL noticed that their cigarette smoking had declined markedly (Perrine *et al.*, 2000). In 1997, Glaxo Wellcome patented the active ingredient in Wellbutrin—bupropion hydrochloride—for a second medical use, the treatment of nicotine addiction. It markets the compound when it is

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Sixty-three developing countries provided pharmaceutical product patents prior to the WTO agreement.

[20] The 24 countries are Afghanistan, Algeria, Angola, Cambodia, Cuba, Eritrea, Haiti, Iran, Jordan, Kuwait, Laos, Lebanon, Myanmar, Mongolia, Namibia, Nepal, Oman, Pakistan, Saudi Arabia, Somalia, Tunisia, United Arab Emirates, Yemen and Syria. Among them, Algeria, Angola, Haiti, Iran, Pakistan, Tunisia and Syria provide process patents.

[21] They are also known as second medical indications or second medical uses.

[22] The USFDA publishes *The Orange Book for the Approved Drug Products with Therapeutic Equivalence Evaluations* (widely known as *The Orange Book)* for the purpose of informing market participants as to the number and term of all patents adhering to a particular pharmaceutical.

prescribed for this use as Zyban.

Prior to the 1980s, European countries did not issue product patents for new medical indications (Eversheds, 2000). In 1984, Switzerland amended its patent law to include "Swiss type patent claims" in which a patent could be issued governing the "use of compound X as a medicament for the treatment of disorder Y".[23]

The European Patent Convention (EPC) adopted the Swiss type patent claim in 1984,[24] India in 2005, and New Zealand in 2006. Under the TRIPS Agreement, WTO Members are free to decide whether to allow patentability of new uses of known products, including for therapeutic use, and are certainly free to adopt the "Swiss type claim" approach. In the United States, "method-of-use" patents cover both new medical indications[25] and methods of medical treatment.[26]

3.1.3 Formulation Patents

In 2005, only two countries, Australia and the United States, issued formulation patents covering improvements in existing products, such as new combinations, new dosage forms, new dosage schedules, and new dosage strength.[27] Dosage and dosing

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[23] The term is from Swiss Federal Intellectual Property Office (1984).

[24] Article 54(5) EPC 2000. In 2013 members of the European Patent Organization included all EU members as well as Albania, Croatia, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey.

[25] One famous example of a new use for a known drug is AZT, which was synthesized in 1964 by the Michigan Cancer Foundation as a possible anti-cancer drug. In 1984, Burroughs Wellcome scientists discovered AZT's ability to slow the progression of HIV disease; it filed a patent application for a second medical use of AZT in 1985. The FDA approved AZT as the first AIDS treatment and Burroughs Wellcome marketed AZT as Retrovir in 1987.

[26] No other country provides a patent covering method of medical treatment.

[27] Regarding the history of formulation patents in the United States, see Eastman (1949). According to EU Regulation 1768/92/EEC (Dec, 2005), supplementary protection certificates (SPCs) are granted to protect selected improvements to medicines under patent. They extend the lifetime of such patents by a maximum of five years. In its *Regulations Amending the Patented*

patents cover innovations regarding different administration routes (e.g., oral to injection), new specific functionality and delivery systems (e.g., from an immediate release tablet to a time-release tablet), and different dosage forms of the same administration route (e.g., capsule to tablet, solution to suspension). For example, Lipitor, the all-time highest grossing patent medicine, registered six patents covering different dosage forms in 2013 despite the expiration of its product patent in November 2011. [28]

Combination patents are awarded to claims on combinations of previously known active ingredients that constitute a new treatment. If claims on combinations are accepted prior to patent expiry on the relevant active ingredients, the patent owner may be able to indirectly extend the term of protection granted under the basic patent. Combination patents are particularly important for HIV therapy, as most therapies are based upon combinations of three or more drugs. In the United States, combination therapies must undergo the same FDA safety and efficacy testing as mono-drug therapies, thereby posing the same rationale for patent protection as mono-drug therapies.

Pharmaceutical companies in the United States and Australia have used formulation patents as part of their strategies to "evergreen" their blockbuster patented drugs, and their use has been criticized as providing too much compensation to pharmaceutical companies for relatively small improvements in their products.[29] We note that the TRIPS Agreement does not require members to issue formulation patents.

Medicines (Notice of Compliance) Regulations, SOR/2006-242 (entered into force October 5, 2006), Canada changed its rules for recognizing formulation patents. With its 2005 revision of its patent law, Japan began to provide formulation patents but with strict case-by-case examination. See Japan Patent Office, Examination Guidelines for Patent and Utility Model in Japan. English-language version. May 18, 2005.

[28] USFDA (2013, 1080-1081).

[29] Some countries provide formulation patents on a case-by-case basis. For example, India protects combination patents but excludes patentability by dosage, dosing schedule, etc. We code these countries as not providing a formulation patent.

3.1.4 Pediatric, Orphan, and BioPharmaceutical Marketing Exclusivity

Our index also accounts for exclusive marketing rights or patent term extensions for three types of pharmaceuticals: (1) a new drug, a new medical indication of an already authorized drug, or a new route of administration of an already authorized drug tested for a pediatric population; (2) an "orphan" drug developed and tested for a market with a small number of patients, e.g., "small" defined by the United States as less than 200,000 U.S. patients with the disorder; and (3) original biologic products approved for marketing. The United States was the first to provide market exclusivity for approved orphan drugs from January 1983, followed by Japan in 1993, Australia in 1998, and the European Union in 2000. In 1997, the United States was also the first to provide marketing exclusivity for drugs tested on pediatric populations, followed by Canada in 2006, the European Union in 2007 and Japan in 2009. The European Union was the first to provide marketing exclusivity for biologics in 2006, followed by the United States in 2010 with the passage of the Biologics Price Competition and Innovation Act of 2009 (BPCIA).[30] We code a country as "one" if it provides an exclusive marketing right or patent extension for orphan drugs or drugs tested on a pediatric population or biologics, and "zero" otherwise.[31]

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[30] BPCIA also allows an additional six-month period for having the biological product tested and approved for use in pediatric populations (Heled, 2012).

[31] The United States has a *sui generis* form of property rights protection for pharmaceuticals: the efficacy supplement. A catch-all category, it encompasses labeling changes to an approved drug based, among other reasons, changing the formulation; adding a new indication or other condition of use, including a change in route of administration; changing the dosing strength; altering the intended patient population; or changing the drug's marketing status from prescription to over-the-counter use. FDA approval of an efficacy supplement based on firm-sponsored clinical tests triggers three years of data exclusivity for this use of the pharmaceutical. The United States

3.1.5 Membership in International Agreements

We construct the Pharmaceutical Patents International Agreements (PPIA) Index to provide a measure of how well a particular country protects the pharmaceutical patent rights of foreigners and facilitates international patenting by domestic innovators. The index equally weights each country's participation in three major international agreements governing patent rights: The Paris Convention of 1883 (and subsequent revisions), the Patent Cooperation Treaty (PCT) of 1970, and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of 1995. By participating in international IPR agreements, signatories indicate a willingness to provide national, nondiscriminatory treatment to foreign patent applicants and foreign patent holders, to provide minimum standards of patent protection and enforcement, and to reduce the costs to home inventors of filing patent applications in multiple countries.

The Paris Convention was signed in 1884 by eleven members.[32] In 1960 just 41 of the 154 countries in our sample belonged to the Paris Convention while in 2005, 136 countries in our sample were members. By 2013, the ranks of members had grown to 174 countries.[33] Two provisions of the agreement are particularly important for protection of pharmaceutical inventions: the national treatment principle and restrictions on compulsory licensing. The national treatment principle requires equal treatment for nationals and foreigners by each member's patent laws. This principle is particularly important in the pharmaceutical industry because pharmaceutical innovation occurs

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established efficacy supplements from 1981, but no other country has followed suit. We do not include efficacy patents in the PIPP Index.

[32] The 11 countries are Belgium, Brazil, France, Italy, Netherlands, Portugal, Spain, Switzerland, Tunisia, the United Kingdom and Guatemala. Guatemala left the Paris Convention in 1885 and did not rejoin until 1998.

[33] Taiwan is not a party to the Convention. However, according to Article 27 of its Patent Act, Taiwan recognizes priority claims from contracting members.

primarily in a few developed countries.

The Paris Convention requires each member to prevent the abuses of compulsory licensing.[34] The main argument over compulsory licenses concerns whether a country can issue a compulsory license on the grounds that a patent has not been exploited in the country. The 1958 Lisbon Agreement revised the Paris Convention to restrict the issuance of compulsory licenses for non-working for a limited period after the issuance of the patent.[35] A compulsory license based on failure to work the patented invention may only be granted pursuant to a request filed after three or four years of failure to work or insufficient working of the patented invention and it must be refused if the patentee gives legitimate reasons to justify his inaction.[36] This provision is particularly important for protection of pharmaceutical innovations, as some countries have required compulsory licensing of pharmaceutical patents when the patented drug has not been sold or produced in the country.

The Patent Cooperation Treaty was signed in 1970 and entered into force in 1978

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[34] The Treaty was revised at Brussels, Belgium in 1900; at Washington D.C., United States in 1911; at The Hague, Netherlands in 1925; at London, United Kingdom in 1934; at Lisbon, Portugal in 1958; at Stockholm, Sweden in 1967; and amended in 1979. The Lisbon Act of 1958 amended its compulsory licensing requirements. Compulsory licensing is a separate category in Ginarte and Park's Patent Index. We exclude this category from the PIPP Index to avoid double counting, as limits on compulsory licensing are part of the Paris Convention, as amended by the Lisbon Act of 1958.

[35] Paris Convention, Article 5.A.4. It states that:

> A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction with legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

[36] Paris Convention, Article 5.A.4.

initially with 18 contracting states.[37] The first international applications were filed on June 1, 1978. In 2013, the PCT had expanded to 147 contracting states. The main objective of the PCT is to harmonize and simplify administrative procedures. Applicants can seek patent protection for an invention in each of many countries by filing one international patent application, designating those nations in which the inventor wishes the application to have effect. Pharmaceutical companies file large number of PCT applications each year. Consider, for example, applications filed in 2003. Merck was the first named applicant on 197 published PCT applications, followed by AstraZeneca (193); Novartis (187); Glaxo Group Limited (178); Bristol-Myers Squibb (143); Isis Pharmaceuticals (130); Eli Lilly (113); Pfizer (113); Pharmacia (100); and 12 other pharmaceutical firms each filing an average of 79.9 applications.[38]

The TRIPS Agreement was established to harmonize some standards of intellectual property rights across countries, thereby providing basic international "rules of the game" for IPR protection. As summarized by Charnovitz (1998), TRIPS has nine major provisions regarding patents, all of which strengthen protection of pharmaceutical innovations. First, it requires parties to comply with the Paris Convention.[39] Second, it requires parties to provide national treatment with respect to patents.[40] Third, it requires that parties make patents available in all fields of technology.[41] This provision requires member countries to grant patents for both pharmaceutical products and processes.

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[37] Patent Cooperation Treaty, TIAS 8733; 28 UST 7645; 9 I.L.M. 978 (1970). Contracting states initiated the Patent Cooperation Treaty in Washington, D.C. on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and October 3, 2001 (as in force from April 1, 2002).

[38] PCT applications for some of the major pharmaceutical companies would be higher if we added PCT applications filed by their affiliates and acquired companies. These are listed separately on the Most Frequent PCT Users list. See Most Frequent PCT Users (2004).

[39] TRIPS Article 2.1.

[40] TRIPS Article 3.1.

[41] TRIPS Article 27.1.

Fourth, it requires that patent rights be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[42] Fifth, it places restrictions on the use of the patent's subject matter "without the authorization of the right holder, including use by the government or third parties authorized by the government".[43] Sixth, it requires that the term of patent protection shall not end before a period of twenty years from the filing date.[44] Seventh, it mandates national enforcement of private patent rights.[45] Eighth, it provides a robust dispute settlement process.[46] And ninth, it allows developing countries to delay implementation of certain provisions.[47]

Developing countries who are WTO members had four years after TRIPS went into effect in 1995 to implement some of its provisions, and had five more years to provide a pharmaceutical product patent. Least-developed countries had ten years to fulfil some of its requirements. The Doha Declaration extended the deadline for least-developed countries to fully implement TRIPS provisions, including provision of pharmaceutical patents, to 2016.

3.1.6 Enforcement Provisions and Restrictions on Patent Rights

We construct the Pharmaceutical Patent Enforcement (PPE) Index to evaluate the strength of enforcement provisions and restrictions on patent rights. Five of its six components are also used by Ginarte and Park (1997) in their patent index.[48] Our enforcement variables are preliminary injunctions, contributory infringement pleadings, burden-of-proof reversals, and national exhaustion. Our restrictions variables are

[42] TRIPS Article 27.1.

[43] TRIPS Article 31.

[44] TRIPS Article 33.

[45] TRIPS Part iii.

[46] TRIPS Part v.

[47] TRIPS Articles 65 and 66.

[48] Ginarte and Park did not include national exhaustion in their index.

working requirments and revocation of a patent for nonworking.

A preliminary injunction, sometimes called interlocutory injunction or temporary injunction, is a common tool for protecting patent rights. In short, preliminary injunctions are pre-trial actions that require individuals to cease an alleged infringement (Shapiro, 1993). Under TRIPS Article 50.1,[49] a preliminary injunction is interpreted to mean that the courts of WTO members must have the authority to order "prompt and effective provisional measures" to prevent infringements from occurring and preserve evidence relevant to the alleged infringements. Only 29 countries in our sample provided for a preliminary injunction in 1960. The number slowly grew to 45 in 1990 and took off after the 1995 TRIPS agreement, reaching 95 in 2005.

Patents can be directly or indirectly infringed, and contributory infringement is one type of indirect infringement of a patent. Generally, patent infringement means an encroachment upon the domain belonging to a patent owner that is described by the claims of the patent. By direct infringement, we mean the performance of an act, such as manufacture, sale, or use, which falls directly within the ambit of a patent's claims. Induced or indirect infringement involves the active inducement (encouragement) of infringement of a patent by others. Contributory infringement occurs when an essential element (which is not itself an infringement of the patent at issue) of a product, or method, is supplied to any person with the knowledge that the essential element will be used in an infringing product, or method.

In U.S. law, a patent owner has the exclusive right to make, use, or sell, the invention, including the right to refrain from doing so. Anyone who without permission

[49] TRIPS Article 50.1. It states that:

> The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

makes, uses, offers for sale, or sells, the patented invention, or imports the invention into the United States is a direct infringer. If a person actively induces, or encourages another to infringe the patent, the person is liable for direct infringement. One who knowingly sells, or supplies, a non-staple item for which the only or predominant use is in connection with a patented invention may be guilty of contributory infringement.[50] The concept of contributory infringement varies from country to country, and the law is not well developed in some countries.[51] Neither TRIPS nor the Paris Convention provide much guidance regarding the nature and scope of contributory infringement. We code the variable as 1 if a country restricts actions that do not in themselves infringe a patent right but cause or otherwise result in infringement by others.

The doctrine of contributory infringement first emerged in 1886 in the judge's decision in the U.S. case of *Harper v. Shoppel*.[52] In 1977 only 16 countries in our sample had statutory or case law establishing contributory infringement. By 2005, 63 of 154 countries in our sample had established the doctrine.

Burden-of-proof reversals are procedures that force a defendant to prove that the process he is using to produce a pharmaceutical product differs from a patented process used to produce the same product.[53] This procedure is applicable if the patent holder is unable through reasonable efforts to determine the process actually used (Straus, 2000, 2005). Burden-of-proof reversals pertain to infringement claims on process patents. They are a response to the "*probatio diabolica*",[54] in which a process patent holder observes

[50] 35 U.S.C. § 271 (a), (b) and (c).

[51] The law of contributory infringement in the United Kingdom is codified in Sections 60(2) and 60(3) of The Patents Act 1977.

[52] 28 F. 613 (S.D.N.Y. 1886). Contributory infringement "exists to protect patent rights from subversion by those who, without indirectly infringing the patent themselves, engage in acts designed to facilitate infringement by others." *Dawson Chem. Co. v. Rohm & Haas Co.,* 448 U.S.176, 188 (1980).

[53] TRIPS Article 34.

[54] *Probatio diabolica*, "the devil's proof," is a legal requirement to reach an impossible proof.

that a second firm has marketed a product identical to the product produced by the process patent holder and suspects that the second firm is making the product with the patented process. Since the second firm's factory is not likely to be publicly accessible and its owner may not respond to inquiries, the burden of proof reversal requires that in an infringement proceeding, the second firm proves to the court that it has not infringed on the first firm's process.

In 1891, Germany became the first country to add a reversal of burden of proof to its patent law (Article 139). Italy, Belgium and Spain were among the early countries that adopted burden of proof provisions into their patent law. In 1989, the European Union adopted the provision in its Community Patent Convention (Article 35) but in 1990 only 44 of the 135 countries in our sample had adopted it. The use of the rule dramatically increased when it was incorporated into Article 34(1) of the 1995 TRIPS Agreement; 92 of 154 countries had adopted it by 2005.[55]

Finally, according to TRIPS and the Doha Declaration, the principle of exhaustion holds that once patent holders or other authorized parties have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights for that market are "exhausted" by the act of selling it. Thus, from the moment the product is marketed, the patent holder can no longer control its subsequent sale or use. On the basis of the exhaustion principle, it would be possible for another party (apart from the patent holder or its authorized agents) to import the patented product from the market where the product has been sold. TRIPS allows WTO members to decide whether the exhaustion principle should be applied within their national territory.[56] "National" exhaustion only

[55] TRIPS Article 34.1.

[56] TRIPS Article 4 allows each country the right to choose its own system:

> For the purposes of dispute settlement under this Agreement, […] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

This principle was re-emphasized in the Doha Declaration:

allows the patented products to be consumed or resold within the territory of a national market. We follow Ginarte and Park (1997) in coding countries with national exhaustion with a score of "one" and "zero" otherwise.[57] In 2006, only the United States, Australia, Botswana, Brazil, China, Madagascar, Sudan, and Trinidad and Tobago had adopted national exhaustion, i.e., complete bans on parallel imports.

Some provisions of national patent laws weaken the rights of patent holders post-grant. Ginarte and Park call such provisions "restrictions on patent rights" and we adopt their terminology. This category includes compulsory licensing (already accounted for in our Paris Convention variable), working requirements, and revocation of patents for non-working.

A working requirement states that a domestic patent holder must manufacture a patented product or apply the patented process within the patent-granting country. A foreign patent holder has the additional option of importing the product. A country is considered to have a local working requirement if a compulsory license could be issued or the patent could be revoked if the patentee does not exploit the patent within the country. In 1960 all but nine of 135 countries in our sample had a local working requirement. By 2005, all but thirteen countries of 154 countries in our sample had a local working requirement.

Article 5A of the Paris Convention allows a patent to be revoked under certain circumstances. Article 32 of the TRIPS Agreement addresses revocation issues indirectly

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> The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge.

[57] Some WTO member countries in our sample provide for regional exhaustion. In 2005, the European Union and ARIPO allowed for regional exhaustion within their member countries. Between 1977 and 1999, OAPI required a national exhaustion system in each member country; in 1999 it switched to a regional exhaustion system. Because countries with regional exhaustion allow some parallel imports, we score the national exhaustion variable for these countries as "zero". See Heath (1999) and UNDP (2007).

by requiring judicial review of administrative decisions to revoke or forfeit patents.[58] We consider a country to have a revocation provision if a patent can be revoked because the patent holder did not manufacture the patented product within the patent-granting country. In 2005, there were 65 countries in our sample that did not allow revocation of a patent because the patent is not being worked. Countries were coded as allowing revocation if the country had statutory or case law provisions to that effect or did not specify the particular circumstances that would allow a patent to be revoked.

3.2. Construction of the PIPP Index

The PIPP index is a composite of three sub-indexes: The Pharmaceutical Patent Rent Appropriation (PPRA) Index, the Pharmaceutical Patent International Agreements (PPIA) Index, and the Pharmaceutical Patent Enforcement (PPE) Index. Equal weights are assigned to each sub-index and they are aggregated multiplicatively:

$$PIPP\ Index = PPRA\ Index \cdot PPIA\ Index \cdot PPE\ Index. \quad (1)$$

Multiplicative aggregation ensures that the PIPP Index satisfies three essential properties. First, the PIPP Index equals zero if a country does not issue patents for new pharmaceutical innovations. Second, increases in the extent of protection provided to foreign patent holders apply to all types of pharmaceutical patents issued by the country. Protection of foreign patent holders is more valuable when the country provides protection for a broad range of pharmaceutical innovations, i.e., when the PPRA and PPE Indexes register higher values. Third, measures available to enforce (or weaken) patent rights are more valuable when the country provides property rights protection for a broader range of pharmaceutical innovations and to a broader range of patent holders, i.e., when the PPRA and PPIA Indexes register higher values.[59]

[58] Most analysts interpret the TRIPS Agreement's provision on revocation as providing each WTO member with discretion to determine grounds for revocation.

[59] Increases in a country's PIPP Index do not necessarily lead to increases in a country's income, wealth, or welfare.

3.2.1 Construction of the PPRA Index

The PPRA index is specified as:

$$PPRA\ Index = \sum_{i=1}^{5} w_{PPRA,i} \cdot patent_i \cdot \frac{duration_i}{std.term} \qquad (2)$$

where $patent_i$ is a binary variable for the i^{th} patent and $w_{PPRA,i}$ is the weight assigned to patent *i*. $Duration_i$ measures the term of each type of patent *i* and *std.term* represents the standard term for a pharmaceutical product patent.

The standard term differs according to whether the start of the patent term is set from the date of the patent application or from the date of the patent grant. Following Ginarte and Park (1997), we use 20 years as the standard term for patents effective from the date of application and 18 years for patents effective from the date of the grant.[60] Exclusive marketing rights for biologics, orphan drugs, and pediatric population-tested drugs tend to be shorter. Orphan drugs receive 7 years of exclusive marketing rights in the United States and 10-11 years in the European Union; biologics receive 12 years in the United States and 10-11 years in the European Union; and pedriatic population-tested drugs receive 6 months in both the European Union and the United States.

As described above, our index accounts for the presence of the following types of patents in pharmaceutical innovations: Product patents, process patents, new medical indications, formulation patents, and patents for efficacy supplements. For each type of patent, a country scores "one" if its case or statutory law allowed this type of patent to be

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[60] Ginarte and Park (1997) set the standard duration as 17 years for this type of system. However, the average time from the filing of a pharmaceutical patent to the patent grant is only about 2 to 2.5 years (Grabowski and Vernon, 2000). This implies that 17 years from the date of the grant provides less protection than 20 years from the date of application. To account for this difference, we adjust the standard duration to 18 years for a patent that takes effect from the date of the grant. For example, if a country provides 15 years of protection from the date of the patent application, it receives a score of 15/20 in the category of $duration_i/sd.term$; if a country provides 17 years from the date of the patent grant, it receives a score of 17/18.

issued at any time during the calendar year and scores "zero" otherwise. See the Appendix for a complete listing of sources for each country.

In their index of overall patent protection, Ginarte and Park assigned equal weights to each type of patent included.[61] Equal weighting is common for many composite indicators, particularly when there are no solid empirical grounds for choosing a different scheme. We also assign equal weights to each patent category.[62] In Section 4, we conduct sensitivity tests to determine whether ordinal rankings of the PPRA Index change very much as weights assigned to each type of product patent are varied.

3.2.2 Construction of the PPIA Index

The PPIA Index incorporates country membership in three international agreements that extend pharmaceutical patent protection to foreigners: the Paris Convention, the Patent Cooperation Treaty, and the World Trade Organization. Each variable is scored as "one" if the country is a member of the international agreement and "zero" otherwise. The PPIA Index is calculated as:

$$PPIA\ Index = 1 + w_{PPIA} \sum_{i=1}^{3} agreement_i \qquad (3)$$

where w_{PPIA} is the weight assigned to each international agreement.

3.2.3 Construction of the PPE Index

The PPE Index incorporates six variables ($enforce_i$) that either facilitate or restrict patent enforcement. If a country allows for four enforcement measures—preliminary injunction, contributory infringement, burden of proof reversal and national exhaustion, we code each variable as "one" and "zero" otherwise. Two other variables restrict patent enforcement. We code a country with working requirements as "zero" and "one" otherwise, and code a country that allows revocation of a patent for non-working

[61] They also conducted sensitivity tests to determine whether the ordinal rankings of their index were sensitive to variations in the weights assigned to each patent category.

[62] Pugatch (2006) argued that some types of pharmaceutical patents were far more important than others and assigned greater weight to them.

purposes as "zero" and "one" otherwise. The PPE index is specified as:

$$PPE\ Index = 1 + w_{PPE} \sum_{i=1}^{6} enforce_i \quad (4)$$

where w_{PPE} is the weight assigned to each patent enforcement or restriction measure. Table 1 summarizes the values assigned to each of the variables used to construct the PPE, PPIA, and PPRA sub-indexes.

<Table 1 here>

3.2.4 Weights and Aggregation

We set weights on variables in each of the three sub-indexes to satisfy two conditions. First, when all 14 variables score "one", each sub-index should have the same value and contribute equally to the PIPP Index. Each of the sub-indexes is equally weighted because alternative weighting schemes are difficult to justify by substantive criteria and equal weights are the norm in the absence of such substantive criteria. Second, to facilitate comparison of the PIPP Index with the Ginarte-Park Patent Index, we normalize the variable weights such that the bounds of the PIPP and Ginarte-Park Indexes [0,5] are identical. The formula for the PIPP Index is:

$$PIPP\ Index = [\sum_i w_{PPRA_i} \cdot p_i \cdot \frac{duration_i}{std\,term}] \cdot [1 + w_{PPIA} \sum_{i=1}^{3} agreement_i] \cdot [1 + w_{PPE} \sum_{i=1}^{6} enforce_i] \quad (5)$$

Solving for sub-index bounds that satisfy the first condition yields [0,1.71] for the PPRA Index and [1,1.71] for the PPE and PPIA Indexes. The sub-indexes aggregate to zero at the minimum bound and to five at the maximum bound, thereby satisfying the second condition. Solving for weights consistent with the upper bound of each index yields $w_{PPIA} = 0.237$, $w_{PPE} = 0.118$, and $w_{PPRA,i} = 0.342$.

4. Sensitivity of the PIPP Index to Different Component and Sub-Index Weights

Using the methodology set out in Section 3, we calculate annual values for the PIPP Index for 154 countries from 1960 to 2005 (Table 2). We only include countries

that were independent in the year 2000 and had a population of at least one million in the year 2005. Before we discuss the PIPP Index in depth, we test its sensitivity to changes in the weights assigned to each sub-index and component variables. The Spearman rank-order correlation coefficient has been widely used for testing the sensitivity of an index to different weights, in part because it is a nonparametric measure of correlation (Swidler and Ketcher, 1990; Ginarte and Park, 1997; de Haan, 2003; Schmid and Schmidt, 2007).

<Table 2 here>

Our analysis proceeds by considering three different changes to the weights of variables composing each sub-index and one change in the method for aggregating the three sub-indexes. Our first sensitivity test assigns a range of [1,1.221] to the PPIA Index and [1, 1.491] to the PPE Index. We calibrated w_{PPIA} =0.0737 for each variable in the PPIA Index to ensure that when a country enters into all three specified agreements, then the PIPP Index increases by 20 percent. Similarly, we calibrated w_{PPE} = 0.082 for each variable in the PPE Index to ensure that when a country has provisions for all six enforcement measures, then the PIPP Index increases by 40 percent. This 20 percent – 40 percent contributions of the PPIA and PPE sub-indexes correspond to the weights assigned to these sub-indexes in the Ginarte-Park Patent Index. The range of the PPRA Index is set to [0, 2.744] to ensure that sub-index aggregation at the minimum and maximum bounds yields a range of [0,5]. Table 3, row 1, reports the Spearman rho between the PIPP Index and the reweighted PIPP Index for five-year intervals between 1960 and 2005. The Spearman rho equals or exceeds 0.98 in each of the five-year time intervals.

Our second sensitivity test compares the PIPP Index with a reweighted PIPP Index in which the pharmaceutical product patent in the PPRA Index is assigned more weight. Given the importance assigned to the basic pharmaceutical product patent by researchers, the World Trade Organization, and the pharmaceutical industry, we experiment with 50 percent of the total weight provided to pharmaceutical patents in the PPRA Index assigned to the basic pharmaceutical product patent. The weights assigned

to new medical indications, formulation patents, process patents, and efficacy improvements are equal and account for the other 50 percent of the PPRA Index. Table 3, row 2, reports the Spearman rho for five-year intervals. The Spearman rho equals or exceeds 0.99 in each five-year interval.[63]

Our third sensitivity test assigns weights to variables in the PPRA, PPIA, and PPE Index such that the upper bounds of the PPRA and PPE Indexes (2.155) are twice the upper bound of the PPIA Index (1.075) and the upper bounds of the sub-indexes aggregate to 5.0. This corresponds to a 40-20-40 scheme for the sub-indexes at their maximum bounds. Table 3, row 3, shows that the Spearman rho equals or exceeds 0.98 in each five-year interval.

Our fourth sensitivity test uses the weights and aggregation method used by Ginarte and Park (1997) and constructs a reweighted PIPP-Ginarte-Park (GP) Index. Ginarte and Park specify five categories ("sub-indexes")—patent coverage, international agreements, enforcement, restrictions, and duration—and weight each variable within each category by 1/N, with N the number of variables in each category. The duration of patent protection is represented by a fraction factor, f, of the actual protection term over the standard term, with $0 \leq f \leq 1$ (pp. 284, 288, 300). This yields a range of [0,1] for each category. The categories are aggregated additively, yielding an index with range [0,5]. The PIPP-GP Index is calculated as:

$$PIPP-GP\ Index = \frac{1}{5}\sum_{i=1}^{5} patent_i + \frac{1}{3}\sum_{i=1}^{3} agreement_i + \frac{1}{4}\sum_{i=1}^{4} enforcement_i + \frac{1}{2}\sum_{i=1}^{2} restrictions_i + f_i \quad (6)$$

[63] We also compare the PIPP Index with an earlier version of the index (reported in Liu and La Croix, 2013) in which a 50 percent weight was assigned to the basic pharmaceutical product patent and data exclusivity served as a proxy for patent protection for selected countries without patent protection. The Spearman rho equals 1.00 from 1960 to 1977, exceeds 0.99 from 1978 to 1990, and exceeds 0.95 from 1991 through 2004.

where $patent_i$ and $agreement_i$ correspond to the variables used in the earlier PIPP Index calculation (eq. 4) and the four variables in $enforcement_i$ (preliminary injunction, contributory infringement, burden of proof reversal, and national exhaustion) and the two variables in $restrictions_i$ (working requirements and patent revocation) are the six variables used in $enforce_i$ in the earlier PIPP calculation (eq. 4). Table 3, row 4, reports the Spearman rank-order correlation coefficients between the PIPP Index and the reweighted PIPP Index for five-year intervals. The Spearman rho registers 0.79 in 1960 and increases over time, reaching 0.94 in 2005.

5. Comparisons between the PIPP Index and Other Measures of Patent Strength

How closely correlated are the PIPP Index and the Ginarte-Park Patent Index? The PIPP Index and the Ginarte-Park Index share 114 countries. As shown in Table 4, row 1, in 1960 the Spearman rho between the PIPP Index and the Ginarte-Park Index is 0.46. The Spearman rho is less than 0.57 for each of the five-year intervals through 1985. After 1985, the Spearman rhos fluctuate before increasing to 0.65 in 2005. One reason for the somewhat closer relationship after 1980 is that during the 1960s and 1970s, some countries with substantial patent protection for a typical invention provided little protection for pharmaceutical innovations. This relationship changed during the 1980s and 1990s as countries with otherwise strong patent protection substantially increased protection for pharmaceutical product patents.

We also checked the correlation between the PIPP Index and two binary variables that are components of the PIPP Index and have been independently used as measures of protection for pharmaceutical innovations: the pharmaceutical product patent and the pharmaceutical process patent. As shown in Table 4, in 1960, the Spearman rho for the PIPP Index and the process patent (0.92 in row 2) was much higher than the Spearman rho for the PIPP Index and the product patent (0.26 in row 3). Because only two countries provided a product patent in 1960, a positive score on the PIPP Index was primarily

determined by the presence of a process patent. As more countries began to provide product patents, the Spearman rho between the PIPP Index and the process patent decreased, while the Spearman rho between the PIPP Index and the product patent increased. By 1995, the Spearman rho between the PIPP Index and the process patent had fallen to 0.62 (row 2), while the Spearman rho between the PIPP Index and the product patent increased to 0.83 (row 3). After 1995, most countries in our sample were WTO members and were bound by TRIPS requirements to provide both pharmaceutical product and process patents. As a result, the importance of the product and process patents in PIPP Index ordinal rankings decreased. By 2005 the Spearman rho had fallen to 0.62 for the product patent and to 0.52 for the process patent (Table 4, rows 2 and 3).

6. Global PIPP Index, Regional PIPP Indexes and Their Properties

We aggregate individual country PIPP indexes to calculate two versions of a Global PIPP Index. One is a simple arithmetic average of PIPP indexes for all countries in our sample in any given year, while the other weights each country's annual PIPP Index by its share in global population during that year. Figure 2 displays the two indexes from 1960 to 2005.

<Figure 2 here>

Over the 1960-1999 period, both indexes rose in tandem, with some small differences emerging after 1990 due to the increased weight provided in the population-weighted Global PIPP Index to the increasing PIPP scores of the two most populous countries, China and India. In 1960, the unweighted Global PIPP Index stood at just 0.18 and the weighted Global PIPP Index at just 0.24. Both scores reflect the near absence of protection for pharmaceutical innovations in all but a few countries. Between 1960 and 1982, growth in the population-weighted Global PIPP Index averaged 0.63 percent annually. Growth in the unweighted Global PIPP Index was somewhat higher, averaging 1.33 percent annually between 1960 and 1982. Both indexes then grew at a higher rate,

with the unweighted Global PIPP Index growing at 4.92 percent annually between 1982 and 2005 and the population-weighted Global PIPP Index growing at 7.79 percent annually between 1982 and 2005.

After 1999, a considerable gap emerged between the weighted and unweighted Global PIPP Indexes. This was primarily due to the strengthening of pharmaceutical property rights in China and India, two countries with over 37 percent of global population in 2005.

We also calculate regional PIPP Indexes. Figures 3 and 4 display unweighted and population-weighted indexes for OECD countries, Africa, South America, Asia, Other Europe, and Middle East regions. Regional PIPP Indexes all grew at positive rates over the 1960-2005 period but displayed different patterns in both timing and rate of growth. Two regions, the OECD and Africa, display substantial growth in their regional indexes from the late 1970s, while three other regions—South America, Other Europe[64], and Asia—did not grow at high rates until the early 1990s. The regional PIPP Index for the Middle East remained extremely low throughout the 1960-2005 period, with its unweighted value reaching just 0.23 in 2005.

<Figure 3 and Figure 4 here>

7. Convergence of the PIPP Index across Countries

Over our sample period, the PIPP Indexes for all but two of the 154 countries in our sample increase monotonically.[65] Is there, however, any tendency for the scores of countries with lower PIPP Index scores to converge with the scores of countries with higher PIPP Index scores? Following Phillips and Sul (2007; 2009), we calculate relative

[64] The slight decrease in the Other European Index in 1990s is due to entry into the sample of newly independent countries from the former Soviet Union that did not protect pharmaceutical innovations.

[65] Exception is xxx.

transition coefficients for each country *i* and year *t*. The relative transition coefficient, h_{it},

$$h_{it} = \log\left(PIPP\ Index_{it} + 1\right) / [1 / N \sum_{i=1}^{N} \log\left(PIPP\ Index_{it} + 1\right)] \quad (7)$$

measures the transition element for each country's PIPP Index relative to the annual unweighted Global PIPP Index. If there is an underlying mechanism pushing PIPP Index scores to converge, i.e., requirements of the TRIPS, TRIP-plus bilateral trade agreements, or diplomatic pressure from the U.S. or E.U., then the following condition should hold (Phillips and Sul, 2009, p. 1159):

$$h_{it} \to 1, \text{ for all } i, \text{ as } t \to \infty . \quad (8)$$

To see whether there is a tendency for h_{it} to approach 1.0, we first examine visual evidence. Figure 5 displays annual relative transition coefficients for the PIPP Index for 154 countries over the 1960-2005 period. The coefficients represent country deviations from the unweighted Global PIPP Index which is monotonically increasing. Not only is there considerable heterogeneity in transition paths across countries, but we also note a tendency for some countries with PIPP scores far below the Global PIPP Index to jump to scores well above the Global PIPP Index, particularly after 1982. Figure 5 displays some tendency for transition paths to converge pre-1982, diverge through the early-to-mid 1990s, and converge once again through the end of the sample in 2005.

For a more formal test of convergence in the overall sample, we follow a simple regression-based test of convergence based on a nonlinear time-varying factor model developed by Phillips and Sul (2007, 1). We estimate the "log t" regression model of convergence:

$$\log\left(H_1 / H_t\right) - 2\log(\log t) = a + \gamma \log t + \mu_t, \text{ for } t = T_0, \ldots, T \quad (9)$$

where $H_t = N^{-1}\sum_{i=1}^{N}\left[(h_{it}-1)^2\right]$ and γ provides a test of both absolute and conditional convergence. Phillips and Sul (2007, p. 1802) recommend that T_0 be set such that the first 30 percent of observations for H_t are dropped when $T \leq 50$. We use an autocorrelation and heteroskedasticity robust one-sided *t*-test to test whether $\hat{\gamma} > 0$ (Phillips and Sul 2007, p. 1789). The sign and magnitude of $\hat{\gamma}$ matter. If $\hat{\gamma} > 2$, this is consistent with convergence in the levels of the PIPP Index; if $2 > \hat{\gamma} > 0$, this is consistent with convergence of growth rates of country PIPP indexes in the global sample.

Regression results for global and regional samples are reported in Table 5. Estimates of $\hat{\gamma}$ for the overall global sample and four of the six regional samples—Africa, Asia, South America, and the Middle East—reject convergence of country PIPP Indexes either in levels or growth rates. Estimates of $\hat{\gamma}$ for the OECD countries are, consistent with convergence in levels of OECD country PIPP Indexes. Estimates of $\hat{\gamma}$ for Middle East region are statistically significant at the five percent level and are consistent with divergence in the growth rates of Middle East country PIPP indexes. We conclude that monotonic increases in the levels of PIPP Indexes observed in all countries over our sample period have not been accompanied by convergence in growth rates or levels of the PIPP Index in the overall or regional samples. Convergence in the values of country PIPP Indexes has been confined to members of the OECD club.

8. Pharmaceutical Patent Strength and Innovation

La Croix and Liu (2014) used the PIPP Index to investigate whether increases in the strength of a country's pharmaceutical patent rights are associated with increases in pharmaceutical innovation in developed and developing countries. For both developing and developed countries, we estimate dynamic Poisson panel regressions to investigate

whether increases in the PIPP Index are associated with grants of pharmaceutical patents by the U.S. Patent and Trademark Office (USPTO) to the country's residents and firms. Explicitly modeling the PIPP Index as an endogenous regressor, our instrument is a measure of cumulative pressure from the United States Trade Representative on a country to upgrade its intellectual property laws or enforcement activities. Since the USTR instrument is only available from 1985, we restrict our regression analyses to the 1985-2005 period. First-stage regressions on the PIPP Index for both developing and developed country samples yield valid instruments in linear, quadratic, and cubic specifications. In the second-stage dynamic Poisson regressions, we account for unobserved heterogeneity and endogeneity of the PIPP Index by using a control function approach that incorporates residuals from the first-stage regression and initial values of the dependent variable in the second-stage regression (Wooldridge 2005; Giles and Murtazashvili 2013). We estimate partial effects of the PIPP Index evaluated at sample means as well as average partial effects (APEs) of the PIPP Index on patent counts for both samples.

For the developing country sample, results from dynamic Poisson panel regressions found no evidence for a relationship between the PIPP Index and pharmaceutical patent counts for either partial effects evaluated at the sample means or average partial effects (Liu and La Croix 2014, Tables 3 and 4). For the developed country sample, we found different results for partial effects and APEs. Partial effects for two interaction variables, the PIPP Index with secondary education attainment and the PIPP Index with a measure of openness, have positive signs and are statistically significant at the five percent level (Liu and La Croix 2014, Table 8). These results support the conclusion that the PIPP Index has a positive effect on pharmaceutical patenting that is magnified when countries have more human capital and more open economies. However, APEs for the PIPP Index tell a different story. Although the APEs

are positive in all six specifications, they never reach statistical significance (Liu and La Croix 2014, Table 9).

In the developing country sample, APEs for three covariates—log of GDP per capita, secondary education attainment, and the log of population—are all positive and statistically significant at least at the ten percent level in specifications with linear and quadratic PIPP Index variables (Liu and La Croix 2014, Table 5). In the developed country sample, APEs for all four covariates have positive signs in all specifications and the log of population and a measure of openness are statistically significant at least at the ten percent level in specifications with the linear PIPP Index variable (Liu and La Croix 2014, Table 9). While placing too much emphasis on estimates of control variables is always to be resisted, the results tentatively point towards links between innovation in pharmaceuticals and a country's innovative capacity, size, and integration with global markets in both developed and developing country samples.

9. Conclusion

We develop an annual index summarizing the presence, term, and strength of various intellectual property rights that can be claimed for pharmaceutical inventions in 154 countries over the period 1960 to 2005. Country ranking is robust to changes in weighting of component variables used to construct the index. While most countries scored close to zero on the Pharmaceutical Intellectual Property Protection (PIPP) Index in 1960, scores increased monotonically for virtually all countries over the next 45 years and the average value of the PIPP Index increased from 0.23 in 1960 to 1.98 in 2005. We find visual and econometric evidence for convergence of growth rates in PIPP scores across countries for the full samples and within most regions.

An initial application of our index investigates whether stronger pharmaceutical patent rights are associated with more patenting activity by country's residents and firms at the USPTO. For the developing country sample, we find little evidence that a

country's adoption of stronger pharmaceutical patent rights leads to increases in patenting by its residents at the USPTO. For the developed country sample, we find some evidence for a relationship between the PIPP Index and pharmaceutical patent counts from partial effects evaluated at the mean but no evidence from APEs. While these findings are at odds with previous literature emphasizing the importance of patents for the pharmaceutical industry, we note that it corresponds closely to results from empirical studies of other industries spanning the eighteenth to the twentieth centuries (Bessen and Mauer, 2008-2009).

There may, of course, be other reasons why pharmaceutical patent rights are important for the pharmaceutical industry. In the context of the nineteenth-century United States, Lamoreaux and Sokoloff (1999) showed that establishment of property rights in new products via patenting allowed inventors to contract with firms that had comparative advantages in production and marketing of new products. We note that small pharmaceutical firms focused on developing new drugs have frequently sold their new product and/or the firm to larger pharmaceutical firms with larger production and distribution networks. Pharmaceutical patent rights could also be important for trade, foreign direct investment, and technology licensing. Yang and Maskus's (2009) general equilibrium model shows how both developed and developing countries can both gain from stronger patent rights if this facilitates technology licensing. The development of the PIPP Index should facilitate future research on these topics for the pharmaceutical industry.

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Figure 1. Number of Countries with Patent Enforcement and Restriction Measures, 1960-2005

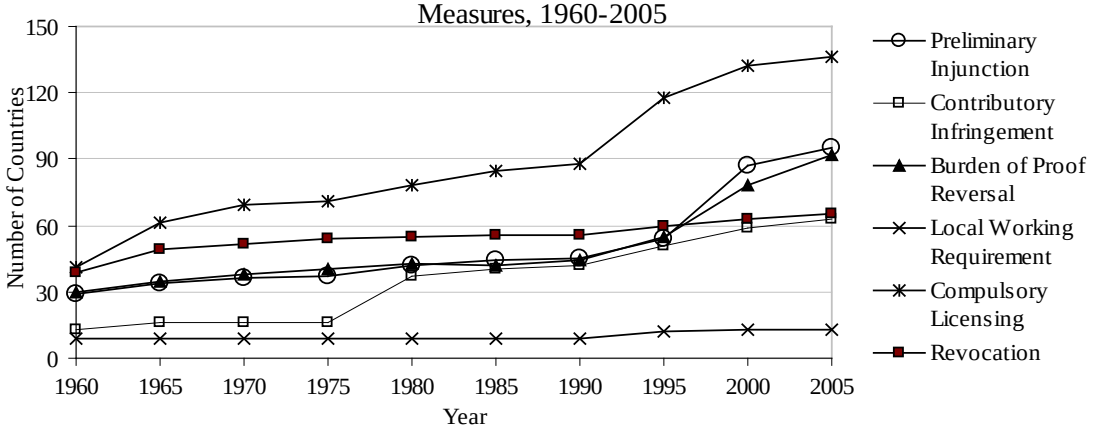

Figure 2. Global PIPP Index, 1960-2005

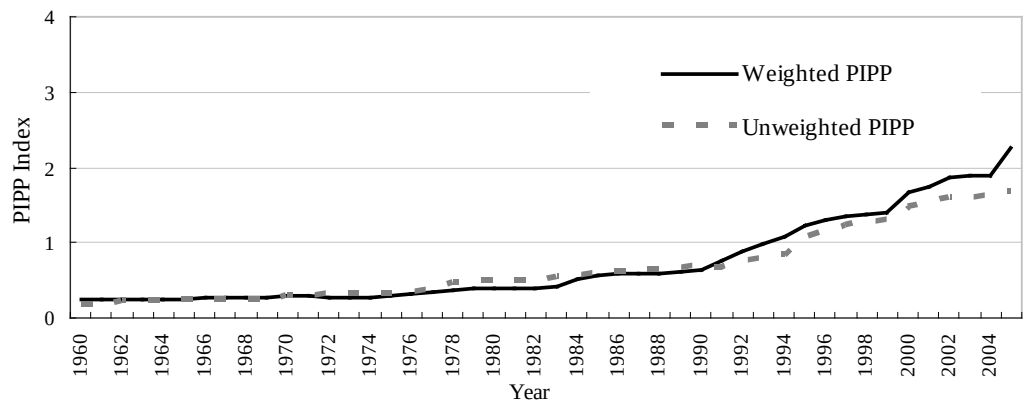

Figure 3. Unweighted Regional PIPP Indexes, 1960-2005

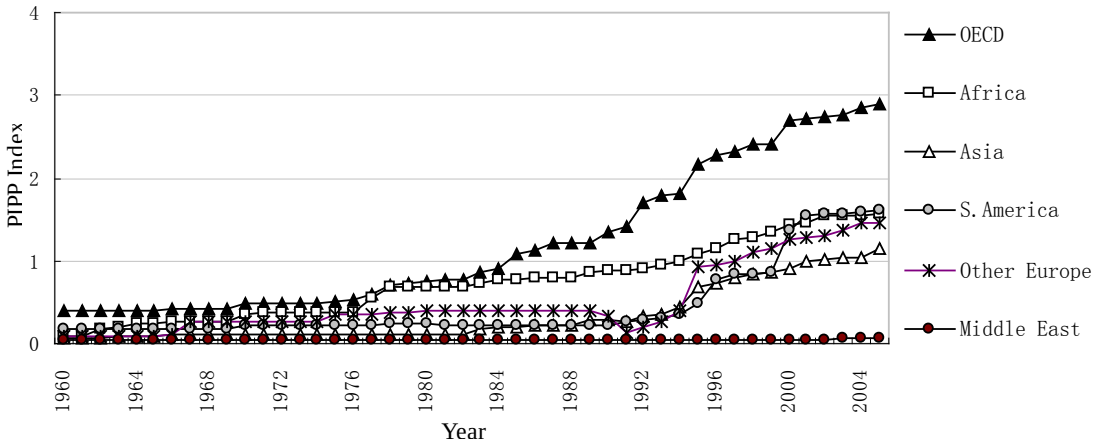

Figure 4. Population-Weighted Regional PIPP Indexes, 1960-2005

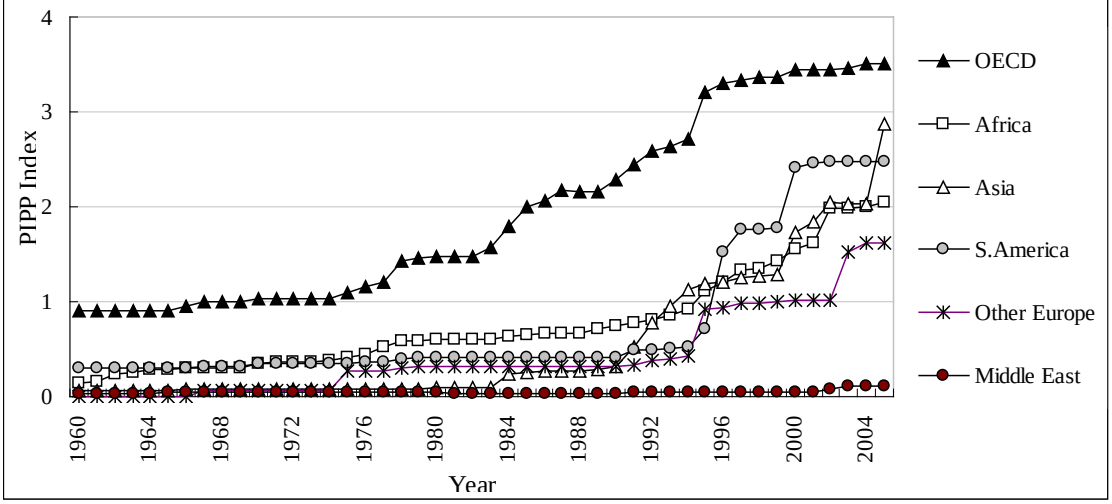

Figure 5. Transition Paths for 154 Countries, 1960-2005

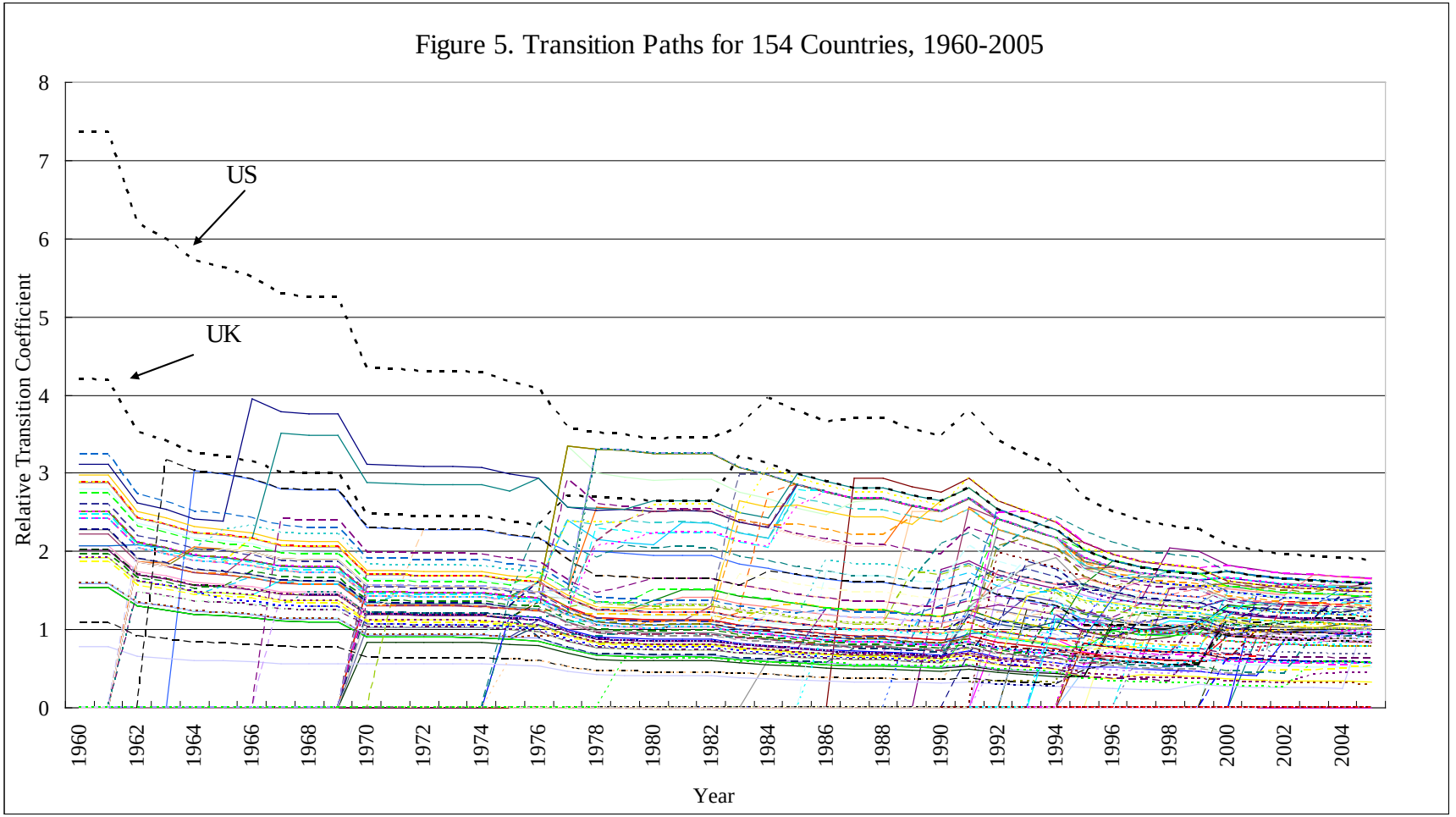

Table 1. Values Assigned to Variables in the PIPP Index

Sub-Indexes	Variables	If yes	If no
PPRA	Process Patent	1	0
	Product Patent	1	0
	New Medical Indication Patent	1	0
	Formulation Patent	1	0
	Orphan, Biologic, or Pediatric Exclusive Marketing Rights	1	0
PPIA	Member of Paris Convention	1	0
	Member of PCT	1	0
	Member of TRIPS	1	0
PPE	Preliminary Injunction	1	0
	Contributory Infringement	1	0
	Burden of Proof Reversal	1	0
	National Exhaustion	1	0
	Local Working Requirement	0	1
	Revocation for Non-Working	0	1

Table 2. PIPP Index Scores, 1960-2005

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
Afghanistan	Asia	0	0	0	0	0	0	0	0	0	0
Algeria	Africa		0	0	0	0	0	0	0.57	0.66	0.68
Angola	Africa				0.29	0.29	0.29	0.29	0.29	0.35	0.35
Argentina	S. America	0.32	0.32	0.39	0.39	0.47	0.47	0.47	0.65	2.38	2.38
Armenia	O. Europe								1.01	1.25	1.58
Australia	OECD	0	0	0	0	0	0	1.19	1.72	3.45	3.45
Austria	OECD	0	0	0	0	0	0	2.4	2.79	2.79	2.79
Azerbaijan	O. Euro								0.69	1.01	1.01
Bangladesh	Asia				0	0	0	0	0	0	1.13
Barbados	S. America			0	0	0	0	0	0	0	2.38
Belarus	O. Euro								1.01	1.01	1.01
Belgium	OECD	0.52	0.52	0.52	0.52	1.05	2.05	2.05	2.38	2.38	2.38
Belize	S. America						0	0	0	1.95	2.17
Benin	Africa	0	0.38	0.47	0.47	1.72	1.72	2.05	2.05	2.38	2.38
Bhutan,	Asia	0	0	0	0	0	0	0	0	0.75	0.85
Bolivia	S. America	0	0	0	0	0	0	0	0	1.87	1.87
Bosnia and Her.	O. Europe								0.85	1.01	1.01
Botswana	S. America			0	0	0	0	0	0.35	1.13	1.45
Brazil	S. America	0.35	0.35	0.35	0.35	0.42	0.42	0.42	0.49	2.58	2.58
Bulgaria	O. Europe	0	0	0	0	0	0	0	1.48	1.72	1.72
Burkina Faso	Africa	0	0	0.47	0.47	0.57	0.57	2.05	2.05	2.38	2.38
Burundi	Africa		0.76	0.76	0.76	0.95	0.95	0.95	1.04	1.13	1.13
Cambodia	Asia	0	0	0	0	0	0	0	0	0	0
Cameroon	Africa		0	0.47	0.47	2.05	2.05	2.05	2.06	2.38	2.38
Canada	OECD	0.54	0.54	0.54	0.54	0.54	1.76	2.23	2.58	2.58	2.58
Central Africa	Africa	0	0	0.47	0.47	2.05	2.05	2.05	2.24	2.38	2.38
Chad	Africa	0	0.47	0.47	0.47	1.37	1.37	2.05	2.05	2.38	2.38
Chile	S. America	0	0	0.29	0.29	0.29	0.29	0.29	1.05	1.15	1.58
China	Asia	0	0	0	0	0	0.31	0.35	1.69	2.58	3
Colombia	S. America	0.25	0.25	0.25	0.25	0.32	0.32	0.32	0.89	1.25	1.45
Congo	Africa	0	0	0.47	0.47	2.05	2.05	2.05	2.05	2.38	2.38
Costa Rica	S. America	0	0	0.23	0.23	0.23	0.23	0.23	0.29	1.96	2.17
Croatia	Other Europe								0.85	1.14	1.58
Cuba	S. America	0	0	0	0	0	0	0	0	0	0
Cyprus	O. Europe	0.38	0.38	0.47	0.47	0.47	0.47	0.47	0.51	2.67	3.18
Czech Republic	OECD	0.26	0.26	0.26	0.26	0.34	0.34	0.34	1.17	1.76	2.67
D.R. Congo	Africa	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.29	1.25	1.45
Denmark	OECD	0.44	0.44	0.44	0.44	0.68	1.37	2.05	2.05	2.92	3.18
Dominican	S. America	0	0	0.47	0.47	0.47	0.47	0.47	0.55	1.13	1.13
Ecuador	S. America	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.62	1.87	2.17
Egypt	Africa	0	0	0	0.35	0.35	0.35	0.35	0.39	0.42	1.31
El Salvador	S. America	0.32	0.32	0.32	0.32	0.32	0.32	0.32	1.39	1.48	1.48
Eritrea	Africa								0	0	0
Estonia	O. Europe								1.01	1.58	2.32
Ethiopia	Africa	0	0	0	0	0	0	0	0.68	0.68	0.68
Finland	OECD	0.44	0.44	0.44	0.44	0.6	0.68	0.68	1.72	3.18	3.18
France	OECD	0.57	0.57	1.15	1.15	1.37	2.05	2.05	2.38	2.92	2.92
Gabon	Africa	0	0.47	0.47	0.47	2.05	2.05	2.05	2.38	2.38	2.38
Gambia	Africa		0.34	0.34	0.34	0.34	0.34	0.68	0.85	1.17	1.17

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
Georgia	O. Europe								1.01	1.35	1.45
Germany	OECD	0.52	0.52	1.03	1.03	1.48	2.23	2.23	2.58	3.18	3.18
Ghana	Africa	0	0	0.34	0.34	0.52	0.52	0.52	0.52	1.45	1.45
Greece	OECD	0.39	0.39	0.39	0.39	0.39	0.39	0.41	2.17	2.17	2.38
Guatemala	S. America	0.26	0.26	0.26	0.26	0.26	0.26	0.26	0.38	1.69	1.69
Guinea	Africa	0	0.38	0.38	0.38	0.46	0.57	0.57	2.1	2.38	2.38
Guinea Bissau	Africa				0.38	0.46	0.46	0.57	0.64	2.38	2.38
Haiti	S. America	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.59	0.59
Honduras	S. America	0.34	0.34	0.34	0.34	0.34	0.34	0.34	0.5	1.69	1.69
Hungary	OECD	0.52	0.52	0.52	0.52	0.57	0.62	0.62	1.86	2.5	3.43
Iceland	OECD	0.35	0.44	0.44	0.44	0.44	0.44	0.44	0.76	2.13	2.92
India	Asia	0.12	0.12	0.15	0.15	0.15	0.15	0.15	0.18	0.25	2.38
Indonesia	Asia	0	0	0	0	0	0	0	0.79	1.31	2.17
Iran	Middle East	0	0	0	0	0	0	0	0	0	0
Iraq	Middle East	0	0	0	0	0	0	0	0	0	0
Ireland	OECD	0	0	0.42	0.42	0.42	0.42	0.42	2.79	3.43	3.43
Israel	O. Europe	0.42	0.42	0.52	0.52	0.52	0.52	0.52	0.59	2.58	2.58
Italy	OECD	0.43	0.43	0.43	0.43	1.15	1.97	2.05	2.05	2.92	2.92
Ivory Coast	Africa	0	0	0.38	0.38	1.39	1.39	1.39	2.05	2.05	2.05
Jamaica	S. America		0.44	0.44	0.44	0.44	0.44	0.44	0.53	0.65	1.31
Japan	OECD	0	0	0	0.43	1.02	1.02	1.54	3.18	3.18	3.18
Jordan	Africa	0	0	0	0	0	0	0	0	0.68	0.68
Kazakhstan	Asia								1.01	1.01	1.01
Kenya	Africa		0.34	0.38	0.42	0.52	0.52	1.05	1.45	1.58	2.38
Korea	OECD	0	0	0	0	0	0	1.02	1.72	2.08	2.08
Kuwait	Middle East	0	0	0	0	0	0	0	0	0	0
Kyrgyzstan	Asia								1.01	1.17	1.17
Laos	Asia	0	0	0	0	0	0	0	0	0	0
Latvia	O. Europe								1.13	1.31	1.15
Lebanon	Asia	0	0	0	0	0	0	0	0	0	0
Lesotho	Africa	0	0	0.34	0.34	0.34	0.34	0.85	0.97	1.17	1.17
Liberia	Africa	0.42	0.42	0.42	0.76	0.76	0.76	0.76	1.13	1.13	1.13
Libya	Africa	0.26	0.26	0.26	0.26	0.32	0.32	0.32	0.32	0.32	0.32
Lithuania	O. Europe							0	1.01	1.1	1.45
Luxembourg	OECD	0	0	0.52	0.52	1.25	1.87	1.87	2.17	2.58	2.58
Macedonia	O. Europe								0.68	0.68	0.68
Madagascar	Africa	0	0	0	0.47	0.56	0.56	1.13	1.14	1.45	1.45
Malawi	Africa			0.42	0.42	0.5	0.68	0.68	0.75	1.58	1.58
Malaysia	Asia		0.34	0.34	0.34	0.46	1.51	1.87	2.23	2.23	2.23
Mali	Africa	0	0.38	0.38	0.38	0.46	2.05	2.05	2.24	2.38	2.38
Mauritania	Africa	0	0	0.47	0.47	0.57	2.05	2.05	2.24	2.38	2.38
Mauritius	Africa			0.3	0.3	0.37	0.37	0.37	0.44	0.44	2.05
Mexico	OECD	0	0	0.35	0.35	0.26	0.26	0.37	1.72	1.72	1.72
Moldova	O. Europe								0.85	0.85	1.01
Mongolia	Asia	0	0	0	0	0	0	0	0	0	0
Morocco	Africa	0.34	0.34	0.34	0.34	0.42	0.42	0.42	0.5	1.31	1.31
Mozambique	Africa					0	0	0	0	1.24	1.31
Myanmar	Asia	0	0	0	0	0	0	0	0	0	0
Namibia,	Africa	0	0	0	0	0	0	0	0	0	0
Nepal	Asia	0	0	0	0	0	0	0	0	0	0
Netherlands	OECD	0	0	0.52	0.52	1.37	2.05	2.05	2.79	2.79	2.79

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
New Zealand	OECD	0.46	0.46	0.46	0.46	0.46	0.46	1.15	1.58	2.38	2.38
Nicaragua	S. America	0.17	0.17	0.17	0.17	0.17	0.17	0.17	0.36	1.51	1.76
Niger	Africa	0	0.47	0.47	0.47	0.57	0.57	0.57	2.05	2.38	2.38
Nigeria	Africa	0.52	0.52	0.52	0.52	0.52	0.52	0.57	0.68	0.74	2.46
Norway	OECD	0.49	0.49	0.49	0.49	0.68	0.68	0.68	2.58	2.58	2.58
Oman	Middle East	0	0	0	0	0	0	0	0	0	0
Pakistan	Asia	0.31	0.31	0.31	0.31	0.31	0.31	0.31	0.47	0.47	0.62
Panama	S. America	0.42	0.42	0.42	0.42	0.42	0.42	0.42	0.42	0.63	0.69
Papua N.G.	Asia				0	0	0	0	0	0	1.17
Paraguay	S. America	0	0	0	0	0	0	0	0	1.87	1.87
Peru	S. America	0	0	0	0	0	0	0	0.94	1.25	1.25
Philippines	Asia	0.33	0.34	0.4	0.4	0.4	0.4	0.4	1.13	1.37	1.58
Poland	OECD	0.39	0.39	0.39	0.39	0.52	0.52	0.52	1.6	1.72	3.18
Portugal	OECD	0.44	0.44	0.44	0.44	0.44	0.39	0.44	1.87	2.67	2.92
Romania	O. Europe	0	0	0.63	0.63	0.76	0.76	0.76	1.19	2.13	2.13
Russia	O. Europe	0	0	0	0.32	0.38	0.38	0.38	0.47	0.47	1.25
Rwanda	Africa		0.76	0.76	0.76	0.76	0.95	0.95	0.95	1.13	1.13
Saudi Arabia	Middle East	0	0	0	0	0	0	0	0	0	0
Senegal	Africa	0	0	0.47	0.47	2.05	2.05	2.05	2.38	2.38	2.38
Serbia-Mont.	O. Europe								0.85	1.01	1.01
Sierra Leone	Africa				0.38	0.38	0.38	0.38	0.43	1.31	1.31
Singapore	Asia		0.34	0.34	0.42	0.42	0.85	0.85	1.75	2.17	2.17
Slovak Rep.	OECD	0.26	0.26	0.26	0.34	0.34	0.34	0.34	1.61	2.16	2.67
Somalia	Africa	0	0.29	0.29	0.29	0.29	0.29	0.29	0.29	0.76	0.76
Somaliland	Africa								0	0	0
South Africa	Africa		0.42	0.42	0.42	0.52	0.52	0.52	0.52	2.17	2.17
Spain	OECD	0.6	0.6	0.6	0.6	0.6	0.6	0.78	2.58	3.18	3.18
Sri Lanka	Asia	0	0	0	0	0.24	0.24	0.26	0.26	0.26	0.68
Sudan	Africa	0	0.42	0.42	0.42	0.42	0.62	0.62	0.62	1.25	1.37
Swaziland	Africa			0.34	0.34	0.34	0.34	0.34	0.59	1.31	1.31
Sweden	OECD	0.44	0.44	0.44	0.44	1.16	1.74	2.05	2.38	2.92	3.18
Switzerland	OECD	0.52	0.52	0.52	0.52	1.44	2.16	2.16	2.6	2.79	2.79
Syria	Middle East	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.5
Taiwan	Asia	0	0	0	0	0	0	0.51	0.68	0.85	1.41
Tajikistan	Asia								1.01	1.01	1.01
Tanzania	Africa		0.34	0.34	0.34	0.34	0.34	0.34	1.57	1.72	1.72
Thailand	Asia	0	0	0	0	0	0	0	1.87	1.87	1.87
Togo	Africa	0	0.29	0.35	0.35	2.05	2.05	2.05	2.24	2.38	2.38
Tri. and Tobago	S. America		0.3	0.3	0.3	0.3	0.3	0.3	0.97	2.38	2.38
Tunisia	Africa	0.42	0.42	0.42	0.42	0.42	0.42	0.42	0.48	0.65	0.65
Turkey	OECD	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.45	2.38	2.38
Turkmenistan	Asia								1.01	1.01	1.01
Uganda	Africa		0.29	0.29	0.29	0.29	0.29	0.29	1.64	1.67	1.94
UK	OECD	0.84	0.84	0.84	0.84	1.48	2.23	2.23	2.58	3.18	3.18
Ukraine	O. Europe								1.01	1.01	1.37
United Arab Emirates	Middle East				0	0	0	0	0	0	0
Uruguay	S. America	0	0	0	0	0	0	0	0.38	0.42	1.13
USA	OECD	1.91	1.91	1.91	1.91	2.27	3.41	3.67	4.48	4.51	4.51
Uzbekistan	Asia								1.01	1.01	1.01
Venezuela	S. America	0	0	0	0.17	0.17	0.17	0.17	0.52	1.45	1.45
Vietnam	Asia	0	0	0	0	0	0	0.63	1.01	1.87	2.05

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
Yemen	Middle East							0	0	0	0
Zambia	Africa		0.54	0.57	0.57	0.57	0.57	1.15	1.37	1.37	1.58
Zimbabwe	Africa					0.54	0.57	0.57	1.33	1.58	1.58
Mean		0.18	0.23	0.30	0.32	0.49	0.60	0.70	1.06	1.48	1.67
S.D.		0.27	0.27	0.28	0.27	0.54	0.71	0.77	0.88	0.98	0.98
Max		1.91	1.91	1.91	1.91	2.27	3.41	3.67	4.48	4.51	4.51
Min		0	0	0	0	0	0	0	0	0	0

Table 3. Sensitivity Tests Using Different Variable Weights and Sub-Index Aggregation Methods

Weighting Method *Aggregation Method*	Spearman Rank Correlation Coefficients (rho)									
	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
1. Weights on PPE and PPIA component variables set to increase PIPP by 20% and 40% when variables score 1.0. *Multiplicative aggregation.*	0.99	0.99	0.99	0.98	0.99	0.99	0.99	0.99	0.99	0.99
2. Product patent weight twice as much as other type of patent in PPRA. *Multiplicative aggregation.*	1.00	1.00	1.00	1.00	1.00	1.00	0.99	0.99	0.99	0.99
3. Upper bounds of PPRA and PPE Indexes are set at twice the upper bound of PPIA Index. *Multiplicative aggregation.*	0.99	0.99	0.98	0.98	0.99	0.99	0.99	0.99	0.99	0.99
4. Equal weights for five Ginarte-Park sub-indexes. *Additive aggregation.*	0.79	0.77	0.85	0.86	0.90	0.91	0.95	0.92	0.93	0.92

Table 4. Comparisons between PIPP Index and Alternative Measures of Protection

Spearman Rank Correlation Coefficients (rho)

Alternative Measures	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
PIPP Index and Ginarte-Park Index	0.46	0.44	0.49	0.49	0.54	0.57	0.66	0.62	0.62	0.71
PIPP Index and Process Patent	0.92	0.86	0.76	0.73	0.73	0.73	0.70	0.62	0.56	0.52
PIPP Index and Product Patent	0.26	0.33	0.41	0.42	0.66	0.72	0.80	0.83	0.72	0.62

Table 5. Convergence Tests

Sample	$\hat{\gamma}$	SE($\hat{\gamma}$)	*t*-statistic
Overall 154 countries	-0.41	0.24	0.17
OECD Countries (30 countries)	8.18**	2.26	1.81
Africa Countries (49 countries)	-0.83	0.18	1.30
Asia Countries (26 countries))	0.72	0.40	0.90
South America Countries (24 countries)	0.38	0.48	0.40
Other Europe Countries (16 countries)	1.72	0.67	1.28
Middle East Counties (9 countries)	-0.89**	0.13	2.30

Note: *t*-statistic is a one-sided *t*-test. ** denotes statistical significance at the five percent level.