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A cross-country index of intellectual property rights in pharmaceutical inventions

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ABSTRACT

Building on the seminal work of Ginarte and Park (1997. Research Policy. 26, 283–301), we develop an index of property rights in pharmaceutical inventions, the Pharmaceutical Intellectual Property Protection (PIPP) Index, for 154 countries spanning 1960 to 2005. It incorporates five types of property rights in pharmaceuticals; six statutory measures of enforcement; and adherence to three international agreements providing for the grant and enforcement of rights to foreigners. For both developed and developed countries, the PIPP Index starts at low levels in 1960, increases slowly through the early 1990s, and then sharply increases due to minimum standards set by the 1995 TRIPS Agreement.

1. Introduction

Cross-country studies of the impact of intellectual property rights (IPRs) on invention 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 inventions 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 industry inventions. Many countries with strong patent protection for other industrial products and processes have not always provided strong protection for pharmaceutical inventions. For example, in 1970, all 22 OECD countries had functioning industrial patent systems, but only four allowed new pharmaceutical products to be patented[1]. Five decades later, more than 90 percent of all countries offered pharmaceutical product patents. Over the same period, the variety of IPRs available to protect pharmaceutical inventions expanded rapidly, with countries offering product patents, process patents, formulation patents, new medical indication patents, and marketing exclusivity measures.

Numerous studies have already recognized that pharmaceutical IPRs are important for industry innovation, as new drugs or improvements to existing drugs are costly to develop and can often be imitated within a short time at relatively low cost (Mansfield et al., 1981; Cockburn et al., 2003; 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). An index summarizing each country's property rights in pharmaceutical inventions would facilitate additional study of their impact not just on invention and innovation but also on trade, foreign investment, and industry entry and exit.

We develop an annual index summarizing the presence, term, and strength of various types of patents that can be claimed to protect pharmaceutical inventions. The Pharmaceutical Intellectual Property Protection (PIPP) Index covers 154 countries from

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

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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 (PP) Index, which measures the presence of five types of patents and marketing exclusivity provisions that provide protection for different types of pharmaceutical inventions; the Pharmaceutical Patent International Agreements (PPIA) Index, which aggregates country membership in three international agreements extending patent protection to foreign inventors; and the Pharmaceutical Patent Enforcement (PPE) Index which aggregates statutory measures enhancing or diminishing public and private enforcement of patent rights.

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. The main task of index developers 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 et al., 2012) assigns 42 variables to five categories; the Institute for Management Development's (IMD) benchmark index in the World Competitiveness Yearbook (Institute for Management Development (IMD), 2012) assigns 333 variables to 20 categories; Ginarte and Park's (1997) patent index assigns 17 variables to five categories; and Knack and Keefer's (1995) 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: index accuracy, which increases as the number of variables increases, and 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 and 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.

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 feasible as the number of countries increases. The final 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.

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, using annual data from seven developing countries from 1984 to 1988. Rapp and Rozek (1990) measured the extent and strength of patent protection across 159 countries for a single year, 1984. Seyoum (1996) used survey methods to collect information from IPR practitioners to construct rankings of patent, copyright, trademark, and trade secret protection for 30 countries. Sherwood (1997) combined his own observations and experience with professional interviews and aggregated nine components into an IPR index covering 18 countries, mostly in Latin America.

Ginarte and Park (1997) constructed an index of patent rights covering 110 countries from 1960 to 1990. 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: extent of coverage, membership in international patent agreements, restrictions or limitations on the use of patent rights, enforcement provisions, and patent term. For each category, a country is awarded a score ranging from zero to one. To aggregate the five measures, they experimented with a range of possible weights. Since ordinal rankings across countries were not very sensitive to the choice of weights, they decided to weight each category equally and to add them together to form their index. Index values range from zero to five.

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 of intellectual property protection for inventions 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 inventions in a particular industry. As we argued in the introduction, it makes sense to construct a specific index for pharmaceutical patent protection due to the perceived importance of patent protection for pharmaceutical inventions and specific patent laws designed for the industry.

3. Construction of an index of property rights in pharmaceutical inventions

Using the same general methodology as Ginarte and Park, Pugatch (2006) developed the first cross-country index of intellectual property right protection for pharmaceutical inventions[2]. 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. 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". Together, the five categories contain 22 variables. Pugatch's methodology differs in three key respects from the one used by Ginarte and Park: The index incorporates other forms of intellectual property beyond patents, such as trademarks; 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 the index incorporates regulatory restrictions on pharmaceutical pricing, advertising, and profits. Pugatch reports index values for a single year, 2005, for four countries—the United States, the United Kingdom, Singapore, and Israel. For these four countries, there are substantial differences between scores from 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 as Ginarte and Park and incorporates some of the pharmaceutical-specific variables used in the Pugatch Index. It is a

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

composite of three component sub-indexes: Pharmaceutical Patent (PP) 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 exclusive marketing rights and do not include variables for trademark protection or regulation of pharmaceutical company pricing, profits, or advertising[3]. This more focused approach enables us to expand index coverage to a broad spectrum of 154 developed, developing, and least developed countries over a 46-year period, 1960–2005. Second, we assign equal weights to each of the three component sub-indexes. We conduct sensitivity tests using Ginarte–Park's sub-index weights, which assign higher weights to patent types and enforcement measures and lower weights to international agreement, to see whether country rankings change much[4]. Third, we also 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 and sub-indexes is standard practice when indexes are aggregations of binary variables. Fourth, we aggregate the three sub-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 domestic and foreign 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 product patent or be protected by another type of intellectual property right? We identify five types: new chemical entities; new pharmaceutical production processes; new medical indications for existing pharmaceuticals; new formulations of a medicine, e.g. new dosing schedule, new dosage form, new strength, new time-release variations; and exclusive marketing rights and patent extensions for orphan drugs, biologics, and drugs tested on pediatric populations[5].

3.1.1. Patents covering new products and new processes

In 1960, only the United States and Great Britain granted product patents covering new drugs. From 1960 to 1977, Britain allowed any manufacturer to license any pharmaceutical and foodstuff process patent as a matter of right, regardless of whether the process patent was already being worked in Britain. Parliament abolished licenses of right in 1977. France introduced pharmaceutical process patents in 1883 but took 76 years to start 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; World Intellectual Property Organization (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[6], Canada in 1987, Finland in 1995, Germany in 1968, Norway and Spain in 1992, Sweden and Italy in 1978, Switzerland in 1977, and Japan in 1976 (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[7]. However, until 1963, not a single developing country issued or recognized pharmaceutical product patents. Some of the earliest developing country adopters were 15 former British colonies who are members of African Regional Intellectual Property Organization (ARIPO) and 16 former French colonies who are members of the Organisation Africaine de la Propriété 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 (Thorpe, 2002).

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 of 1974. In response to US investigations and EU 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[8]. 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 by Thailand in 1992 and China in 1993. 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, and Argentina in 1996.

The 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement required all member countries to 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). In 2013, only 16 countries in our sample did not provide pharmaceutical process patents and just 24 countries did not provide pharmaceutical product patents[9].

[3] Many countries provide new drug developers with limited-duration property rights in pharmaceutical registration files, i.e., the data submitted by drug companies to regulatory authorities for the purpose of obtaining marketing approval for new drugs. The time-limited property rights to these data files vary across countries and are typically referred to as "data exclusivity.Ẅe do not include data exclusivity in the PP Index because it has an ambiguous effect on protection of pharmaceutical inventions, in some cases restricting generic entry and in other cases promoting it. For example, data exclusivity in the United States, as established in 1984 by the Hatch-Waxman Act, was designed to promote generic entry, as the Act's five-year period of data exclusivity expires well before the product's patent expires, thereby expediting entry by generic producers and decreasing the strength of pharmaceutical patents. See IFPMA (2000) and von Braun and Pugatch (2005).

[4] Ginarte and Park (1997) assigned equal weights (20 percent) to each of their five categories. We follow them in assigning a 20 percent weight to the PPIA Index, which uses variables from their "membership in international patent agreements" category. We assign a 40 percent weight to the PP Index, as it combines two Ginarte and Park categories ("extent of coverageänd "duration of protection") each weighted at 20 percent, and a 40 percent weight to the PPE Index, as it combines two Ginarte and Park categories ("enforcement mechanismsänd "provisions for loss of protection") each weighted at 20 percent.

[5] 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 they increase social welfare.

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

[7] 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.

[8] See Konan et al. (1995) and Blakeney (1996) regarding changes in ASEAN IPRs.

[9] 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.

3.1.2. New medical indication patents

Some countries issue patents covering a new medical indication of a known medical product[10]. Provision of a new medical indication patent is one variable in the PP Index. In the United States, for example, the April 2013 edition of *The Orange Book*[11] listed 664 new medical indication patents with marketing approval from the FDA.

Prior to the 1980s, European countries did not issue product patents for new medical indications (Ventose, 2009). 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"[12]. The European Patent Convention (EPC) adopted the Swiss type patent claim in 1984 (Article 54(5) EPC 2000)[13], 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 and methods of medical treatment.

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. Dosage and dosing 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, the blockbuster drug Lipitor registered six patents covering different dosage forms in 2013 despite the expiration of its product patent in November 2011 (U.S. Food and Drug Administration (USFDA), 2013).

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 their active ingredients, the patent owner may be able to indirectly extend the term of protection granted by the basic patent. In the United States, combination therapies must undergo the same FDA safety and efficacy testing as mono-drug therapies, thereby posing the same "cost-of-development" 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[14].

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 US 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 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 Biologics Price Competition and Innovation Act of 2009. 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[15].

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 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.

The Paris Convention was signed in 1884 by eleven members[16]. In 1960 just 41 of the 154 countries in our sample belonged, while by 2005, 136 countries in our sample were members, and by 2013, 174 countries[17]. The Convention's national treatment principle, mandating equal treatment of foreigners and nationals, and its restrictions on compulsory licensing are particularly important for the pharmaceutical industry. This is because most pharmaceutical R&D and development of new drugs are concentrated in just a few developed countries.

The Paris Convention requires each member to prevent the abuses of compulsory licensing[18]. The 1958 Lisbon Agreement revised the Paris Convention to restrict the issuance of compulsory licenses for non-working to a request filed after three or four years of failure to work or insufficient working of the patented invention; it must be refused if the patentee gives legitimate reasons to justify his inaction (Article 5.A.4). This provision is particularly important for protection of pharmaceutical inventions, 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 with 18 contracting states. By 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,

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

[11] The USFDA publishes *The Orange Book for the Approved Drug Products with Therapeutic Equivalence Evaluations* to inform market participants as to the number and term of all patents adhering to a particular pharmaceutical.

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

[13] In 2013 members of the European Patent Organization included all EU members as well as Albania, Croatia, Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey.

[14] Countries, e.g., India, which provide formulation patents on a case-by-case basis are coded as not providing a formulation patent.

[15] The United States has a *sui generis* IPR for pharmaceuticals, the efficacy supplement. A catch-all category, it provides protection to such items as changes in label, route of administration, marketing status, and patient population. Since no other country has enacted this type of IPR protection, we do not include it in the PIPP Index.

[16] Belgium, Brazil, France, Italy, Netherlands, Portugal, Spain, Switzerland, Tunisia, the United Kingdom, and Guatemala.

[17] Taiwan is not a party to the convention but recognizes priority claims from contracting parties.

[18] Compulsory licensing is a separate category in Ginarte and Park's Patent Index. Because limits on compulsory licensing are part of the amended Paris Convention, we do not include limits on compulsory licensing as a separate index variable to avoid double counting.

designating those countries in which the inventor wishes the application to have effect. Pharmaceutical companies file large number of PCT applications each year. Consider PCT applications filed in 2003. Merck was the first named applicant on 197 published PCT applications, followed by AstraZeneca (193), Novartis (187), Glaxo Group (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 (World Intellectual Property Organization (WIPO), 2004).

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 requires parties to comply with the Paris Convention (Article 2.1), to provide national treatment with respect to patents (Article 3.1), and to make patents available in all fields of technology, including pharmaceuticals (Article 27.1). It requires that the term of patent protection shall not end before a period of twenty years from the filing date (Article 33), mandates national enforcement of private patent rights (Part iii), and provides a robust dispute settlement process (Part v).

TRIPS also allows developing countries to delay implementation of certain provisions (Article 65 and 66). Developing countries 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 to 2016 for least-developed countries to provide pharmaceutical patents.

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 overlap with Ginarte and Park (1997); we add national exhaustion as a component of the PPE Index. Enforcement variables are preliminary injunctions, contributory infringement pleadings, burden-of-proof reversals, and national exhaustion; restrictions variables are working requirements 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. Under TRIPS Article 50.1, 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. Generally, patent infringement means an encroachment upon the domain belonging to a patent owner as described by the claims of the patent. Contributory infringement occurs when an essential element of a product, or method, is supplied to any person with the knowledge that it will be used in an infringing product or method. The concept of contributory infringement varies from country to country, and the law is not well developed in some countries. Neither TRIPS nor the Paris Convention provide much guidance regarding the nature or 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. 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 (TRIPS, Article 34). This procedure is applicable if the patent holder is unable through reasonable efforts to determine the process actually used (Straus, 2005). 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. A total of 92 of 154 countries had adopted it by 2005.

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 (Article 4) allows WTO members to decide whether the exhaustion principle should be applied within their national territory. "National" exhaustion only 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[19]. 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". 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 9 of 135 countries in our sample had a local working requirement, while in 2005, all but 13 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 by requiring judicial review of administrative decisions to revoke or forfeit patents. 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.

[19] Some WTO member countries in our sample provide for regional exhaustion. Because they allow some parallel imports, we score their national exhaustion variable as "zero".

3.2. Construction of the PIPP Index

The PIPP index is a composite of three sub-indexes: The Pharmaceutical Patent (PP) 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:

$$\text{PIPP Index} = \text{PP Index} \times \text{PPIA Index} \times \text{PPE Index}. \quad (1)$$

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 inventions. 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 inventions, i.e., when the PP and PPE Indexes register higher values. Third, measures available to enforce (or weaken) patent rights are more (or less) 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 PP and PPIA Indexes register higher values.

3.2.1. Construction of the PP Index

The PP index is specified as:

$$\text{PP Index} = \sum_{i=1}^{5} w_{PP\,i} \times patent_i \times \frac{duration_i}{std.term} \quad (2)$$

where $patent_i$ is a binary variable for the ith patent and w_{PP_i} is the weight assigned to $patent_i$. $Duration_i$ measures the term 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[20]. 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 pediatric 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 five types of pharmaceutical IPRS. For each type, a country scores "one" if its case or statutory law allowed this type of patent to be issued at any time during the calendar year and scores "zero" otherwise. See the Appendix for a complete listing of sources for each country. We follow Ginarte and Park in assigning equal weights to each patent category.

3.2.2. Construction of the PPIA Index

The PPIA Index incorporates country membership in the Paris Convention, the Patent Cooperation Treaty, and the World Trade Organization Agreement. 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:

$$\text{PPIA Index} = 1 + \sum_{i=1}^{3} w_{PPIA_i} \times agreement_i \quad (3)$$

where w_{PPIA_i} is the weight assigned to international agreement i.

3.2.3. Construction of the PPE Index

The PPE Index incorporates six variables ($enforce_i$) that either facilitate or restrict patent enforcement. For the four enforcement measures, we code each variable as "one" and "zero" otherwise. For the two restriction measures, we code each variable as "zero" and "one" otherwise. The PPE Index is specified as

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

where w_{PPE_i} is the weight assigned to the ith patent enforcement or restriction measure.

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:

$$\begin{aligned}\text{PIPP Index} = &\left[\sum_i w_{PP_i} \times p_i \times \frac{duration_i}{std.term}\right] \\ &\times \left[1 + w_{PPIA_i} \sum_{i=1}^{3} agreement_i\right] \\ &\times \left[1 + w_{PPE_i} \sum_{i=1}^{6} enforce_i\right] \end{aligned} \quad (5)$$

Solving for sub-index bounds that satisfy the first condition yields [0,1.71] for the PP 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 variable weights consistent with the upper bound of each index yields w_{PPIA_i} = 0.237, w_{PPE_i} = 0.118, and w_{PP_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 1).

We only include countries that were independent in 2000 and had a population of at least one million in 2005. We test the index's 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

[20] Ginarte and Park (1997) set the standard duration as 17 years from the date of the grant. 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.

Table 1
PIPP Index Scores, 1960–2005.

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
Afghanistan	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Algeria	Africa		0.00	0.00	0.00	0.00	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	1.19	1.72	3.45	3.45
Austria	OECD	0.00	0.00	0.00	0.00	0.00	0.00	2.40	2.79	2.79	2.79
Azerbaijan	O. Euro								0.69	1.01	1.01
Bangladesh	Asia				0.00	0.00	0.00	0.00	0.00	0.00	1.13
Barbados	S. America			0.00	0.00	0.00	0.00	0.00	0.00	0.00	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						0.00	0.00	0.00	1.95	2.17
Benin	Africa	0.00	0.38	0.47	0.47	1.72	1.72	2.05	2.05	2.38	2.38
Bhutan,	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.75	0.85
Bolivia	S. America	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.87	1.87
Bosnia and Her.	O. Europe								0.85	1.01	1.01
Botswana	S. America			0.00	0.00	0.00	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.48	1.72	1.72
Burkina Faso	Africa	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Cameroon	Africa		0.00	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	0.00	0.00	0.47	0.47	2.05	2.05	2.05	2.24	2.38	2.38
Chad	Africa	0.00	0.47	0.47	0.47	1.37	1.37	2.05	2.05	2.38	2.38
Chile	S. America	0.00	0.00	0.29	0.29	0.29	0.29	0.29	1.05	1.15	1.58
China	Asia	0.00	0.00	0.00	0.00	0.00	0.31	0.35	1.69	2.58	3.00
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	0.00	0.00	0.47	0.47	2.05	2.05	2.05	2.05	2.38	2.38
Costa Rica	S. America	0.00	0.00	0.23	0.23	0.23	0.23	0.23	0.29	1.96	2.17
Croatia	O. Europe								0.85	1.14	1.58
Cuba	S. America	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Cyprus	O. Europe	0.38	0.38	0.47	0.47	0.47	0.47	0.47	0.51	2.67	3.18
Czech Rep.	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	0.00	0.00	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	0.00	0.00	0.00	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								0.00	0.00	0.00
Estonia	O. Europe								1.01	1.58	2.32
Ethiopia	Africa	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.68	0.68	0.68
Finland	OECD	0.44	0.44	0.44	0.44	0.60	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	0.00	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
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	0.00	0.00	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	0.00	0.38	0.38	0.38	0.46	0.57	0.57	2.10	2.38	2.38
Guinea Bissau	Africa				0.38	0.46	0.46	0.57	0.64	2.38	2.38
Haiti	S. America	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.59	0.59
Honduras	S. America	0.34	0.34	0.34	0.34	0.34	0.34	0.34	0.50	1.69	1.69
Hungary	OECD	0.52	0.52	0.52	0.52	0.57	0.62	0.62	1.86	2.50	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.79	1.31	2.17
Iran	Middle East	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Iraq	Middle East	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Ireland	OECD	0.00	0.00	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	0.00	0.00	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	0.00	0.00	0.00	0.43	1.02	1.02	1.54	3.18	3.18	3.18
Jordan	Africa	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	1.02	1.72	2.08	2.08
Kuwait	Middle East	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Kyrgyzstan	Asia								1.01	1.17	1.17

Table 1 (*Continued*)

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
Laos	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Latvia	O. Europe								1.13	1.31	1.15
Lebanon	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Lesotho	Africa	0.00	0.00	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							0.00	1.01	1.10	1.45
Luxembourg	OECD	0.00	0.00	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	0.00	0.00	0.00	0.47	0.56	0.56	1.13	1.14	1.45	1.45
Malawi	Africa			0.42	0.42	0.50	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	0.00	0.38	0.38	0.38	0.46	2.05	2.05	2.24	2.38	2.38
Mauritania	Africa	0.00	0.00	0.47	0.47	0.57	2.05	2.05	2.24	2.38	2.38
Mauritius	Africa			0.30	0.30	0.37	0.37	0.37	0.44	0.44	2.05
Mexico	OECD	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Morocco	Africa	0.34	0.34	0.34	0.34	0.42	0.42	0.42	0.50	1.31	1.31
Mozambique	Africa					0.00	0.00	0.00	0.00	1.24	1.31
Myanmar	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Namibia,	Africa	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Nepal	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Netherlands	OECD	0.00	0.00	0.52	0.52	1.37	2.05	2.05	2.79	2.79	2.79
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	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
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				0.00	0.00	0.00	0.00	0.00	0.00	1.17
Paraguay	S. America	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.87	1.87
Peru	S. America	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.94	1.25	1.25
Philippines	Asia	0.33	0.34	0.40	0.40	0.40	0.40	0.40	1.13	1.37	1.58
Poland	OECD	0.39	0.39	0.39	0.39	0.52	0.52	0.52	1.60	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	0.00	0.00	0.63	0.63	0.76	0.76	0.76	1.19	2.13	2.13
Russia	O. Europe	0.00	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Senegal	Africa	0.00	0.00	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	0.00	0.29	0.29	0.29	0.29	0.29	0.29	0.29	0.76	0.76
Somaliland	Africa								0.00	0.00	0.00
South Africa	Africa		0.42	0.42	0.42	0.52	0.52	0.52	0.52	2.17	2.17
Spain	OECD	0.60	0.60	0.60	0.60	0.60	0.60	0.78	2.58	3.18	3.18
Sri Lanka	Asia	0.00	0.00	0.00	0.00	0.24	0.24	0.26	0.26	0.26	0.68
Sudan	Africa	0.00	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	2.60	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	0.50
Taiwan	Asia	0.00	0.00	0.00	0.00	0.00	0.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.87	1.87	1.87
Togo	Africa	0.00	0.29	0.35	0.35	2.05	2.05	2.05	2.24	2.38	2.38
Tri. and Tobago	S. America		0.30	0.30	0.30	0.30	0.30	0.30	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
UAE	Middle East				0.00	0.00	0.00	0.00	0.00	0.00	0.00
Uruguay	S. America	0.00	0.00	0.00	0.00	0.00	0.00	0.00	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	0.00	0.00	0.00	0.17	0.17	0.17	0.17	0.52	1.45	1.45
Vietnam	Asia	0.00	0.00	0.00	0.00	0.00	0.00	0.63	1.01	1.87	2.05
Yemen	Middle East							0.00	0.00	0.00	0.00
Zambia	Africa		0.54	0.57	0.57	0.57	0.57	1.15	1.37	1.37	1.58

Table 1 (*Continued*)

Country	Region	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
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
Maximum		1.91	1.91	1.91	1.91	2.27	3.41	3.67	4.48	4.51	4.51
Minimum		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Table 2
Sensitivity tests using different variable weights and sub-index aggregation methods.

	Spearman rank correlation coefficients (rho)									
Weighting method Aggregation method	1960	1965	1970	1975	1980	1985	1990	1995	2000	2005
1. Weights on component variables in PPE Index and PPIA Index are set to increase PPIA Index by 20% and PPE Index by 40% when all 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. Weight assigned to product patent is four times larger than weight assigned to other patent types in PP Index. *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 PP Index and PPE Index 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 assigned to five Ginarte–Park categories. *Additive aggregation*	0.79	0.77	0.85	0.86	0.90	0.91	0.95	0.92	0.93	0.92

to different weights, in part because it is a nonparametric measure of correlation (Ginarte and Park, 1997; de Haan, 2003; Schmid and Schmidt, 2007).

Our analysis proceeds by considering three different changes to the weights on 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 set $w_{PPIA_i} = 0.0737$ for each variable in the PPIA Index to ensure that when a country enters into all three specified agreements, the PIPP Index increases by 20 percent. Similarly, we set $w_{PPE_i} = 0.082$ for each variable in the PPE Index to ensure that when a country has provisions for all six enforcement measures, the PIPP Index increases by 40 percent. The 20 percent contribution of the PPIA sub-index and the 40 percent contribution of the PPE sub-index correspond to their weights in the Ginarte–Park Patent Index. We set the range of the PP Index to [0,2.744] to ensure that sub-index aggregation at the minimum and maximum bounds yields a range of [0,5]. Table 2, row 1, reports the Spearman rho between the PIPP Index and the reweighted PIPP Index with Ginarte–Park sub-index weights 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 assigns 50 percent of the total weight provided to pharmaceutical patents in the PP sub-index to the pharmaceutical product patent, as many academics and industry researchers believe that this patent is the foundation for protection of the most fundamental and valuable intellectual innovations in pharmaceuticals. New medical indications, formulation patents, process patents, and efficacy improvements again receive equal but much lower weights of 12.5 percent. Table 2, row 2, reports the Spearman rho for five-year intervals. The Spearman rho equals or exceeds 0.99 in each five-year interval[21].

Our third sensitivity test assigns weights to variables in the PP, PPIA, and PPE Indexes such that the upper bounds of the PP 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 weighting scheme for the sub-indexes at their maximum bounds. Table 2, row 3, shows that the Spearman rho equals or exceeds 0.98 in each five-year interval.

Our fourth sensitivity test takes variables from the PIPP Index and uses a methodology proposed by Ginarte and Park to construct an alternative PIPP-GP Index. It additively aggregates data from five categories: patent coverage, international agreements, enforcement, restrictions, and duration. Duration of patent protection is represented by, f, the actual protection term over the standard term, with $0 \leq f \leq 1$. Each variable within each category is weighted by $1/N$, with N the number of variables in each category. This yields a range of [0,1] for each category and a range [0,5] for the PIPP-GP Index. The PIPP-GP Index is:

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

[21] We also compare the PIPP Index with an earlier version of the index (Liu and La Croix, 2013). The Spearman rho exceeds 0.95 for all years.

Table 3
Comparisons between PIPP Index and alternative measures of protection.

	Spearman rank correlation coefficients (rho)									
	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

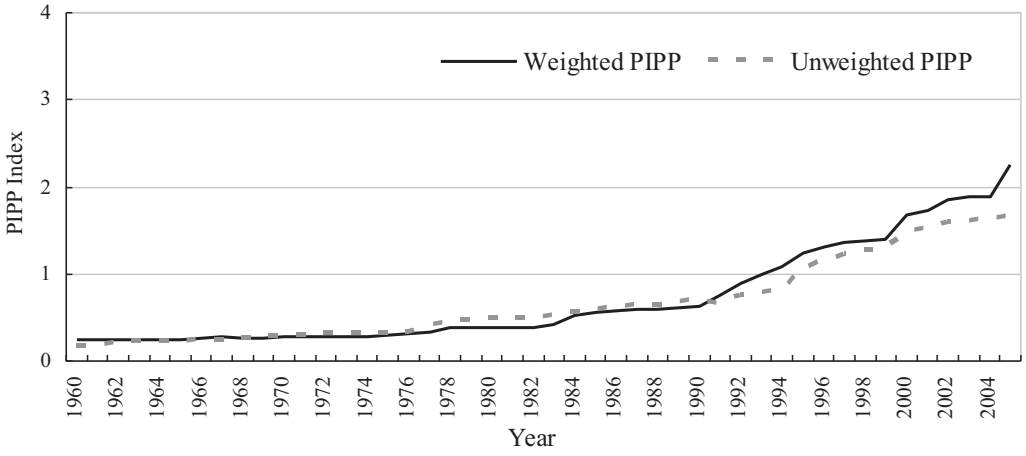

Fig. 1. Global PIPP Index, 1960–2005.

where $patent_i$ and $agreement_i$ correspond to the variables used in the earlier PIPP Index calculation (Eq. (5)) and the four variables in $enforcement_i$ and the two variables in $restrictions_i$ are the six variables used in $enforce_i$ in the earlier PIPP calculation (Eq. (5)). Table 2, row 4, reports the Spearman rank-order correlation coefficients between the PIPP Index and the reweighted PIPP-GP Index for five-year intervals. The Spearman rho registers 0.79 in 1960 and increases over time, reaching 0.92 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 two indexes share 114 countries. As shown in Table 3, 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, Spearman rhos fluctuate before increasing to 0.71 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 inventions in other fields provided little protection for pharmaceutical inventions. This relationship changed during the 1980s and 1990s, as countries with broad patent protection increased protection for pharmaceuticals.

We also checked the correlation between the PIPP Index and the pharmaceutical product patent and the pharmaceutical process patent. As shown in Table 3, 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 had increased to 0.83 (row 3). After 1995, most countries in our sample were WTO members and were required to provide both pharmaceutical product and process patents. As a result, the importance of the product and process patents in the PIPP Index's ordinal rankings of countries decreased. By 2005 the Spearman rho for the PIPP Index and process patent had fallen to 0.52 and for the PIPP Index and product patent to 0.62 (Table 3, rows 2-3).

6. The Global PIPP Index

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 second weights each country's annual PIPP Index by its share in global population. Fig. 1 displays the two indexes.

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 inventions 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 4.92 percent annually between 1982 and 2005 and the population-weighted Global PIPP Index growing 7.79 percent over the same period. 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 the world's two largest countries, China and India.

7. 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 from 1960 to 2005. Country ranking is robust to changes in weighting of

component variables. While most countries scored close to zero on the 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.

An initial application of our index investigates whether strengthening a country's pharmaceutical patent rights is associated with more pharmaceutical patenting activity by its residents and firms at the US Patent and Trademark Office (Liu and La Croix, 2014). For both developing and developed country samples, we find little evidence that a country's adoption of stronger pharmaceutical patent rights leads to more pharmaceutical patenting by its residents. While these findings are at odds with previous literature emphasizing the importance of patents to invention in the pharmaceutical industry, we note that they correspond closely to results from historical studies finding little linkage between stronger patent rights and inventions in other industries (Bessen and Meurer, 2008–2009).

Even if the link between pharmaceutical patent rights and invention is tenuous, pharmaceutical patent rights provide other important incentives for industry participants. For the late 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 more specialized in production and marketing of products. We note that small pharmaceutical firms focused on developing new drugs frequently sold their new drug or their entire firm to companies with established production and distribution networks. Pharmaceutical patent rights can also facilitate international trade, foreign direct investment, and technology licensing by industry firms in many situations. Yang and Maskus's (2009) general equilibrium model shows how both developed and developing countries can both gain from stronger patent rights when they facilitate technology licensing. In sum, the development of the PIPP Index will enable researchers from a wide variety of disciplines to conduct future empirical research on these issues, which are critically important to the global pharmaceutical industry and its customers.

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