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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.

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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 patented¹. 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.

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 inventions². 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.

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