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The Effect of Intellectual Property Rights on Domestic Innovation in the Pharmaceutical Sector

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Summary. — There is little empirical evidence concerning the effect of Intellectual Property Rights (IPR) protecting pharmaceutical products and processes on pharmaceutical domestic innovation. Indeed, existing literature does not provide a punctual estimate of this effect for developing countries. This paper fills this gap, by exploiting a self-constructed dataset which provides, for a 22-year period, information concerning IPR reforms involving pharmaceuticals for 74 developed and developing countries. The identification strategy exploits the different timing across these countries of two sets of IPR reforms. Domestic innovation is measured as citation-weighted domestic patent applications filed at the European Patent Office (EPO): the highly skewed distribution of the dependent variable, and the high number of zero observations, are taken into account using count data models. In particular, a Zero Inflated Negative Binomial model is adopted, to overcome previous literature assumption that all innovations are patented in the main markets of reference, and to take into consideration the choice not to patent at the EPO. Results show that innovation is sensitive to IPR protection, but not to its degree. Moreover, the effect is not long lasting. My study also finds that developing countries profit significantly less than developed ones from the protection, benefiting from an effect that is roughly half of that for developed countries. Consequent policy implications are examined, and include the conclusions that a “one size fits all” approach can be inappropriate, and that gradual reforms should be preferred to rare reforms that greatly alter the level of IPR protection.
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Key words — intellectual property rights, developing countries, pharmaceutical sector, innovation, patents, TRIPS

1. INTRODUCTION

Over the last 30 years, an increasing number of countries at various stages of development have introduced or extended their national level of Intellectual Property Rights (IPR) protection. This trend saw the establishment of the Agreement on Trade-Related aspects of Intellectual Property rights (TRIPS) in 1995 when, with different transitional periods depending on their level of development, all WTO members were required to set down and implement minimum regulation standards for all industries. The agreement caused an intense debate concerning whether IPR legislation, granting exclusive rights to inventors to enable them to recoup the costs of R&D investments, could stimulate enough innovation to justify the social welfare costs associated with monopoly pricing. The debate was particularly lively regarding the pharmaceutical sector. Developing countries were worried about higher drug prices associated with pharmaceutical patents, whereas developed countries pointed out the beneficial effects of such protection, claiming that the agreement would stimulate domestic innovation, research for tropical diseases, and technology transfer (Lanjouw, 1998).¹

This analysis focuses on an aspect of this debate, and in particular on whether pharmaceutical patent protection stimulates pharmaceutical domestic innovation in developed and developing countries. It is conducted on a panel of 74 countries: for these countries, reforms modifying patent protection are observed over the period 1977–98. The different timing of reforms across countries is exploited to identify the causal effect of protection, as in a Difference-in-Differences identification strategy.

Most empirical contributions study the impact of IPR by considering all industries together. As a consequence, their findings cannot be easily translated into policy recommendations. Indeed, as pointed out by Lo (2011), the effect of IPR

may vary strongly across industries, depending on their peculiarities. For example, in countries where patents may be granted, the pharmaceutical sector relies heavily on them to protect innovation. Instead, the employment of trade secret protection or lead time advantages is limited (Nagaoka, Motohashi, & Goto, 2010). The high uncertainty and the high R&D costs characterizing this sector may explain the strong recourse to patents. Indeed, as few as one or two out of 10,000 tested compounds end up as a marketable drug (Sloan & Hsieh, 2007; European Commission, 2009; Scherer, 2010), and the average cost for the discovery of a new molecule is estimated to be between 500 and 900 million US\$ (DiMasi, Hansen, & Grabowski, 2003; Paul *et al.*, 2010).² The R&D on sales ratio, equal to 18% (European Commission, 2009), is around seven times higher than in other manufacturing industries (Scherer, 2010). Moreover, while producers of branded drugs have to incur high R%D (and clinical trials) costs, and bear a high uncertainty, producers of generics only incur the expenses for demonstrating the equivalence of their product with an already approved one. Thus, to recover from the high R&D costs, producers of branded drugs resort to patents to appropriate the benefits of new innovations.

Although the pharmaceutical sector is characterized by the aforementioned peculiarities, few contributions focus on it. Most of them analyze the reactions to specific changes in

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patent protection of a single country, raising doubts on the generalization of their findings (Branstetter, Fisman, & Foley, 2006). To the best of my knowledge, only two studies use panel data to estimate the effect of patent protection on pharmaceutical domestic innovation, and they yield contrasting results. In their working paper, Liu and La Croix (2014) find that patent protection has no effect, whereas Qian (2007) shows that patent protection alone does not stimulate domestic innovation, although the interaction of protection with the country's GDP per capita has a statistically significant impact. Differently from Qian (2007) contribution, this paper provides punctual estimates of the effect of patent protection for both developed and developing countries. In particular, my examination brings some evidence in favor of a positive effect of protection in both sets of countries although, for developing countries, this is roughly half in comparison with developed ones.

This contribution also provides novelties with respect to previous literature along three technical directions. First of all, instead of using a quinquennial index of IPR protection (as in Liu & La Croix, 2014), or to consider different policy interventions in this field (as in Qian, 2007), the effects of two sets of IPR reforms are evaluated. The first set concerns reforms granting a level of patent protection comparable to the one established by the TRIPS Agreement, while the second one includes reforms granting a lower level of protection.

The second novelty concerns the use of applications filed at the European Patent Office (EPO)³ to measure innovation. Patents of more than local relevance are assumed to be registered in the main markets of reference (Qian, 2007) but, although both the US and Europe represent the largest markets for pharmaceuticals, previous empirical literature has considered only patents filed at the United States Patent and Trademark Office (USPTO). This paper marks a departure, by considering patents filed at the EPO. These present a lower number of self-citations, since 95% of references to previous patents are added by the examiner instead of by the applicant (OECD, 2009): this makes EPO citations a more precise measure in retrieving patents' innovative value than USPTO citations.

The third novelty relates to the models used to perform the analysis. To account for the highly skewed distribution of patent applications, count data models are adopted. Besides an unconditional Negative Binomial (NB), an unconditional Zero Inflated Negative Binomial (ZINB) model is carried out. This model explains the high quantity of zeros characterizing the flow of yearly national applications by taking into account the two processes that can determine them: nature (the lack of innovative capabilities) and choice (the decision not to patent in Europe). Thus, differently from the NB model, it does not require the assumption that all innovations of more than local relevance are patented in the US and Europe.

Results show a high, positive and significant effect of TRIPS compliant protection on domestic innovation. However, this effect is not long lasting, disappearing after six years. Also offering lower forms of patent protection has a positive effect, which is not statistically different from the one computed for TRIPS compliant protection: this suggests that domestic innovation is sensitive to IPR protection, but not to its degree. Importantly, my findings point out that developing countries profit significantly less than developed ones from all forms of protection. Results for the ZINB model also confirm previous literature assumption that all innovations of more than local relevance are patented in the main markets of reference, even when local protection is offered. Placebo estimations support the causal interpretation of the results.

2. LITERATURE REVIEW

(a) *Theoretical literature*

The role of patent protection and the optimal structure of patent system, in terms of patent length and breadth,⁴ have been extensively studied since the end of the '60s (Nordhaus, 1967; Scherer, 1972; Nordhaus, 1972). When inventions are independent, the optimal patent structure has to address the trade-off between the dynamic benefits associated with more innovation, and the static costs caused by monopoly prices. In this context, a strengthening of protection is found to promote innovations (Arrow, 1962; Bessen & Maskin, 2009; Hall & Harhoff, 2012; Jaffe, 2000). Instead, when new discoveries are based on their predecessor, the optimal patent structure has to take into account also (positive and negative) innovation externalities. Indeed, while knowledge inbuilt in an early patent stimulates further inventions, subsequent activity may be affected by the concern with regard to infringing previous patents. Moreover, R&D incentives for basic research may be reduced because new inventions make previous ones obsolete. In this context, optimal patent structure involves no protection (Scotchmer, 1996), or protection limited to larger innovations (O'Donoghue, 1998) for second-generation products, or longer protection for early inventions (Green & Scotchmer, 1995; Chang, 1995).⁵

(b) *Empirical literature*⁶

Several contributions have exploited the recent IPR reforms undertaken in different countries to analyze their effect on domestic innovation. Many of these contributions resort to patents, assigned to the inventors' countries of residence, as a proxy for domestic innovation. In particular, patents filed in a foreign office are used when the goal is to estimate the effect of a reform on the propensity to innovate (exceptions are represented by Sakakibara & Branstetter, 2001; Hall & Ziedonis, 2001; Yang, 2008). Indeed, changes in regulation in the country where the patent is filed affect also the propensity to patent (Lo, 2011).

Studies evaluating reactions to changes in the IPR regime of a single country highlight a consequent boost of innovation: see, among others, Kortum and Lerner (1999) and Lo (2011), who study the impact of two similar reforms taking place during the '80s in the US and Taiwan, respectively. However, doubts can arise concerning the generalization of these results (Branstetter *et al.*, 2006). Moreover, as pointed out by Jaffe (2000), the analysis based on a single country makes it extremely difficult to identify the causal effect of IPR strengthening because of its interaction with many other variables. Cross-country studies overcome these difficulties. Nevertheless, they face another obstacle: the comparison of IPR regimes across countries. Given the strong heterogeneity in patent protection, many papers resort to the use of patent rights indexes, such as the one created by Ginarte and Park (1997), which takes into account: extent of coverage, membership in international patent agreements, restrictions on patent rights, enforcement mechanisms, and duration of protection.⁷

The main drawback of these indexes is that they are not constructed on yearly basis, but usually they are calculated over a five-year period. An alternative to the use of an IPR index is represented by the identification of homogeneous reforms. Branstetter *et al.* (2006), for example, analyze the impact of a set of interventions extending patent rights along at least four of the following five aspects: range of patentable goods,

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