Collective licensing and asymmetric information: The double effect of the Medicine Patent Pool on generic drug markets

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Abstract

The paper studies the Medicine Patent Pool (MPP) as an effective coordinating mechanism to allow access to essential medicines. Focusing on one of the most important disease areas (HIV), we exploit heterogeneity in the timing of entry into the pool of active pharmaceutical ingredients across countries to estimate the effect of the pool on the market for essential drugs. We show that the pool works on two levels. First, it improves access to drugs by increasing competition by generics producers. Second and surprisingly, it further increases access by eliminating fundamental asymmetric information about the intellectual property rights status of drugs across geographical markets.

1 Introduction

The attribution of intellectual property rights (IPR) is a significant incentive for innovation. Patents can protect inventions from imitators, and expectation of temporary monopolistic rents underpins private investment in risky research and development (R&D) activities (Nordhaus, 1969). The pharmaceutical sector is well known for being one sector where patents are used most intensively (Pavitt, 1984; Grabowski, 2002; Cohen et al., 2000a) and where increasing patent protection promotes faster launch of new drugs (Cockburn et al., 2016; Lanjouw, 2005). The relevance of IPR in this sector is not only reflected in the high propensity to patent but also in the frequency of patent renewals (Liu, 2014; Schankerman, 1998).

A feature that makes pharmaceutical patents especially effective is their discreteness (Orsenigo et al., 2010). Contrary to sectors where several patents may be needed to cover a marketable product, pharmaceutical inventions have well-defined boundaries. This implies that patent thickets are rare relative to other technological domains (Shapiro, 2000). Thus, when a new active pharmaceutical ingredient (API) is discovered and patented, the inventing company (the originator) usually has very clear rights to exclusive production and sale of the associated drug. Among the few mechanisms that allow others than the originator to produce and sell the patented API is licensing, and in the absence of institutional mechanisms intervening on price, the licensing cost will reflect the high expected returns from monopoly power.

While patents might provide an incentive to innovate, concern has increased over the true novelty of some recent pharmaceutical patents and marketed drugs (Dra-

nove et al., 2014; Kyle, 2018) and the need to provide equitable access to treatments[1] (Lakdawalla, 2018; Morton and Kyle, 2011). To alleviate these concerns, and lower the costs and foster the diffusion of new treatments, policy makers have made efforts to facilitate market entry by generic drugs manufacturers after the expiry of a patent (see for instance the Hatch-Waxman Act in the United States). Indeed, several studies suggest that the introduction of generics has reduced prescriptions prices (Berndt and Aitken, 2011), and that this effect has been especially significant in more competitive markets (Reiffen and Ward, 2005; Tenn and Wendling, 2014). However, one of the most important constraints on drugs diffusion remains different economies' demand regimes: the highly uneven healthcare expenditure observed across countries can be a barrier to the adoption of essential medicines and keeps them well below the levels that would be required to achieve universal coverage. The strengthening of the patent regime through the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement has been associated to higher domestic pharmaceutical innovations only in the contexts of developed countries (Qian, 2007) and "global" diseases (Kyle and McGahan, 2012). The market for pharmaceutical products in the poorest countries remains very small with no provision for a substantial share of health needs.[2] In these markets, pharmaceutical companies often are not interested in pursuing aggressive IPR strategies and may decide to grant

[1]The statement by the World Health Organization that essential medicines should be available, of good quality, and accessible can be in conflict with the exclusivity rights granted by a patent. See: `https://www.who.int/medicines/areas/human_rights/en/` (accessed on the 10 January, 2020)

[2]In its 2001 report the Word Bank stated that Connecticut spends more on health than the 38 low-income sub-Saharan African countries combined (Kremer, 2002). Inspection of more recent figures from `https://www.cms.gov/` and `https://www.who.int/` (both accessed on July 2019) suggests that the situation has improved little over time.

voluntary licenses at low or null prices (Friedman et al., 2003).

In this paper, we analyze the Medicine Patent Pool (MPP) - an interesting solution to the problem of access to drugs in developing countries. The MPP provides a mechanism for originators to make licenses available to other manufacturers, thereby allowing generic drug producers to provide low-cost versions of patented medicines. As we explain in more detail later in the paper, this is an unusual application of the patent pool in sectors where it has already been used extensively (e.g. in information and communication technologies or ICT). Patent pools typically provide a "one-stop shop" solution which reduces the probability of royalty stacking and the search costs related to fragmented technology ownership (Mattioli and Merges, 2017; Merges, 1999; Shapiro, 2000).

Fragmented ownership often affects complex technologies where it is more difficult to identify *what* is the precise object of a patent, or to *which area* it might apply despite the availability of complete information on the relevant technical knowledge. Drugs are not complex technologies and in the vast majority of cases a single patent for a particular drug is perfectly sufficient to cover the relevant intellectual property (Cohen et al., 2000b). However, as we will see, what might be missing is fundamental information on the IPR status of a drug in different jurisdictions which could lead to significant welfare losses.

We begin our study by examining the patent pool literature before exploring the specific case of the pharmaceutical sector. We describe the institutional set-up of the MPP in one of the most critical disease areas (HIV). Our identification strategy exploits heterogeneity in the timing of entry of different APIs in the MPP across

countries, to estimate the effect of the pool on the market for essential medicines. We show that the MPP operates via two distinct mechanisms. Firstly, it improves access to essential drugs by increasing the size of generic drug markets. Secondly, it further increases access by eliminating fundamental asymmetric information on the IPR status of drugs across geographical markets. The magnitude of both effects is substantial.

2 Intellectual property rights and patent pools

A patent pool can be defined as an agreement among patent owners to license a subset of their IPR to one another or to third parties. It is an institutional arrangement with a relatively long history in the US economy where the first patent pool was introduced in 1856 in relation to the manufacture of sewing machines (Lampe and Moser, 2010). Since patent pools are collaborations among competitors, there is a risk that they could be used to reduce competition, generate higher prices, and induce lower consumer welfare (Mattioli and Merges, 2017; Shapiro, 2000; Merges, 1999; Gallini, 2014; Ishihara and Yanagawa, 2018). Moreover, patent pool participants might have fewer incentives to introduce technologies that are substitutes for those included in the pool. In addition, companies might reduce their investment in the generation of cumulative innovations, that is innovations stemming directly from prior knowledge whose incremental advantages build on the development of an existing technology (Gilbert, 2002; Mattioli and Merges, 2017; Lerner and Tirole,

2004).[3]

In a detailed study of the introduction of a patent pool in the sewing machine industry (1856-77), Lampe and Moser 2010 found that it not only led to reduced patenting activity and innovation (Lampe and Moser, 2010) but that it also affected the direction of technical change towards an inferior technology (Lampe and Moser, 2013b). A bigger study of 20 patent pools created between 1931 and 1938 under the New Deal across a variety of U.S. industries also found a negative relation between patent pools and R&D competition and innovation (Lampe and Moser, 2013a). The risk of monopoly power caused criticism of patent pools following World War II, and rendered them the target of antitrust concerns.

In the 1990s, the unfavorable postwar period approach developed into a more nuanced understanding of the conditions under which patent pools might be beneficial (Lerner and Tirole, 2004; Shapiro, 2000; Mattioli and Merges, 2017).[4] In some cases, patent pools were introduced into several markets where the aim was not to generate monopolistic rents but rather to solve fundamental coordination problems in the development of complex technologies which in the 1990s were causing an exponential increase in the number of patents and litigation cases in technologies characterized by fragmented IPR ownership. Fragmentation of ownership and complementary essential technologies can jeopardize the development of technological standards (Shapiro, 2000): the effectiveness of standards as welfare-improving mechanisms depends cru-

[3]The presence of grant-backs conditions - the obligation to pool all the subsequent patents developed by a pool member in a specific technological domain - exacerbates this problem.

[4]Shapiro (2000) provides an extensive account of the contents of three business review letters prepared by the Department of Justice in 1995 regarding the MPEG patent pool and two DVD patent pools.

cially on how easily implementers can access so-called standard essential patents (SEPs) (Lerner and Tirole, 2015). In famous cases such as CD, DVD, MPEG-2, and Wi-fi technologies, access to patents was made possible only by the introduction of patent pools (Flamm, 2012; Joshi and Nerkar, 2011).[5]

In the case of strong technological interdependencies, patent pools reduce transaction costs through the provision of "one-stop shop" solutions relative to the alternative scenario of a series of independent licensing deals (Merges, 1999).[6] In commenting on the ability of patent pools to enable high volumes of patent licensing, (Mattioli and Merges, 2017, page 288) go so far as to suggest that patent pools are the best possible form of licensing arrangement. Patent pools can be an effective way to address the so-called "complements problem" proposed by Cournot in a pioneering analysis (Shapiro, 2000; Lerner and Tirole, 2004). If two inputs are owned by two monopolists, the price of the final product will be higher than if there was a single input owner. Moreover, due to the monopolistic rents of input producers, the profits that accrue to the final product manufacturer (and consumer welfare) will be lower. In technology markets, a "complement problem" emerges if the monopolistic inputs are patented technologies, and patent pools are *the purest solution to avoid "royalty stacking"* (Shapiro, 2000, page 134). For this reason, the economic litera-

[5]It is interesting to notice that the introduction of patent pools in these product markets was not linked systematically to lower rates of innovation. Evidence of the effects of the pools on innovation in these technologies generally is mixed, and it has been argued that patent pools can differ widely in their organization and royalty-sharing rules such that certain pools can promote the entry of new members and competition and others not. These specificities are reflected in the different effects on innovation (Flamm, 2012; Joshi and Nerkar, 2011).

[6]A patent pool facilitates licensing to standard implementers. However, it does not directly solve the problem of internal royalty sharing, and the stipulation of sharing rules is fundamental to ensure participation in, and therefore success of the pool (Tesoriere, 2019; Layne-Farrar and Lerner, 2011).

ture stresses that patent pools should either include only complementary patents or should allow third-party licensing (Lerner and Tirole, 2004; Lerner et al., 2003).[7]

In this paper, we show that patent pools can reduce transaction costs in the case of both complex and discrete innovations. While the literature on standards-related patent pools focuses on the theoretical and empirical implications for complex technologies, the possible use of patent pools in cases where they do not solve the problem of technological complexity has been mostly overlooked. To our knowledge, the scholarship on this possibility is scant although patent pools can be instrumental for social welfare if there is ambiguity about the status of the IPRs. Since patents provide monopolistic power only for the countries where they are granted, information asymmetries can emerge about patent status relative to the geographical scope of the IPR. If this occurs, asymmetric information problems can lead to under-utilization of knowledge even though there may be no legal barriers restricting access to the technology in a specific market. Uncertainty about IPR scope can prevent the use of available technologies in countries with weak institutions and less mature patent systems.

[7]The concepts of complementary patents and complex technologies are strictly related. Patents are described as complementary if they are related to knowledge inputs which are strictly necessary to obtain a final, complex, innovation.

3 Access to drugs and the Medicine Patent Pool (MPP)

The introduction of the TRIPS agreement in 1994 required all member countries of the World Trade Organization (WTO) to introduce and enforce intellectual property protection. Before the TRIPS agreement, pharmaceutical industry patenting practices differed significantly between developed and developing countries. The latter, historically, were less inclined to patent medical innovations in order to favor the emergence of generic drugs markets (Sampat and Shadlen, 2015; Cockburn, 2009). Several scholars (Chaudhuri et al., 2006; Sonderholm, 2010; Kyle and McGahan, 2012) noted that the biggest concern related to the introduction of TRIPS was that it might cause a steep increase in the prices of essential medicines in the developing and least-developed countries[8].

However, the TRIPS agreement includes the possibility of applying some flexibility (Dusheiko and Gore, 2019; Burrone and Perry, 2014; Sagaon-Teyssier et al., 2016) to mitigate major drawbacks (Arora et al., 2008), and national governments in developing countries have tried to limit the use secondary patents which extend periods of exclusivity and delay competition from generics (Sampat and Shadlen, 2015). While donations and discounted prices are common examples of these flexibilities and can promote wider access to treatments, they have some significant limitations. For instance, donations can be problematic both because they are unsuitable for diseases that require continuous and long-lasting treatments (Guilloux and Moon,

[8]The WTO Doha Declaration approved in 2001, contributed to clarifying the ways in which the patent regime should be adjusted in the interests of public health.

2000) and because donated medicines may be redirected to richer countries against the original scope of this particular intervention (Friedman et al., 2003). Discounts also present problems because pharmaceutical companies generally fix lower prices for the same product sold in developing countries but these prices nevertheless are much higher than the price of generics (Moon et al., 2011).

After experimenting with various solutions for approximately a decade, in 2010, Unitaid sponsored the introduction of the new institutional arrangement of the MPP. James Love first proposed the idea of a patent pool for HIV drugs at the 2002 International AIDS Conference in Barcelona. He suggested a patent pool model similar to the one adopted in 1917 by the US Government to stimulate airplanes production. The 1917 model entailed compulsory licensing so that the owners of essential patents could not refuse to join the pool. However, the final version of the MPP was based on voluntary licensing, and the idea that patent holders would make licenses available, allowing other generic drug manufactures to use them to produce and sell low-cost versions of patented drugs in developing countries.[9]

In a least developed country context, when a new API is patented, the object and the owner of the IPR are quite clear; however, it can be difficult to identify institutional validity (WHO-MSF, 2003). In a 2003 report, Méedecins sans Frontiéres claimed that although medicines were not patented everywhere, *finding out whether a drug is patented in a particular country currently varies between being difficult and impossible* (Boulet et al., 2003, page 24). Because of this fundamental lack of information on the patent status of drugs, the perceived risk of patent infringement

[9]Ellen 't Hoen, the first MPP executive director, stated that the initiative had received large support from pharmaceutical companies and civil society (t Hoen, 2010).

can make drug procurement agencies reluctant to import the more affordable generic versions (Milani and Oh, 2011). Although several attempts have been made to simplify the determination of the patent status of medicines across borders (Milani and Oh, 2011; Attaran, 2004), the problem of incomplete knowledge persists (Beall and Attaran, 2016)[10].

The MPP performs the important function of collecting and organizing information on patent status in developing countries. Prior to its introduction, it was only the originators that had precise information on the patent status for their products in different countries. By collecting information from all originators, and compiling it and diffusing it as a public good, the MMP has dramatically reduced the asymmetry of information for generics producers and procurement agencies. The present paper addresses two questions. The first concerns the effectiveness of voluntary licensing for increasing drug access in less developed countries by stimulating competition in generics. By measuring market changes after MPP enforcement, we assess the benefits associated to regulated and widespread licensing. The second question concerns the effectiveness of the pool as an institutional arrangement which reduces efficiency losses due to asymmetric information about the geographical scope of patents. More specifically, we want to identify the additional effects of the pool on access to drugs even in those countries where there are no IPR barriers preventing use of third-party technological knowledge.

[10]It is worth pointing out that the introduction of TRIPS made the problem of ambiguous information even more relevant: although the TRIPS agreement aimed to harmonize patent regimes around the world, retrieving information about specific flexibilities that may be in force in a particular region can be much more demanding than identifying actual patent status.

4 Identification and estimation strategy

The MPP covers antiretroviral drugs (ARVs) used for the treatment of HIV, tuberculosis, and malaria. Among all relevant disease areas, data on HIV-related drugs present by far the most complete records. These drugs are an area of public policy intervention where high access costs are crucial and are even more important in developing countries as the number of people in need of HIV treatment increases, and new medicines able to overcome the problem of drug resistance become ever more expensive (Hoen et al., 2011).

The operation of the MPP is relatively simple. An API enters the pool when its originator signs a licensing contract. From that moment, generics manufacturers that join the MPP are allowed to produce and sell the generic version of the API within the countries included in the licensing agreement without risk of IPR infringement. To date, the pool numbers 20 commercial partners, 6 of which are originator companies and 14 generics manufacturers. Both originators and generics producers entered at different points in time following the MPPs establishment in 2010. Table 1 lists the APIs included in the pool for HIV treatment and indicates when their licenses were introduced. A licensing contracts territorial coverage can differ from product to product; therefore, each contract includes a list of those countries where the license is valid. Figure 1a depicts the 93 countries included in an MPP license for at least one API; figure 1b shows the heterogeneous distribution of licensing contracts across the countries belonging to the MPP. Figure 2 presents the share of countries included in a contract license for a specific API over time. These three figures taken together provide a clear picture of the high degree of heterogeneity in both the timing and

territorial distribution of MPP licenses. To isolate the effect of the MPP from the effects of other licensing arrangements, we focus our analysis on API and countries where a generic version was already available and commercialized before they joined the pool. It is only in these cases that the MPP can be considered the first mechanism to provide systematic voluntary licensing of an API in a particular country. It allows us to isolate the effects of the MPP from confounding factors (e.g. other forms of assistance such as drug donations and price discrimination).

Our empirical strategy exploits variations in the timing of entry to the MPP and territorial coverage to allow us to estimate the effect on access to HIV drugs. We exploit these sources of heterogeneity to observe the same API in countries with different licensing regimes, and assess the effect of joining the scheme. The MPP facilitates access to between 1 and 12 APIs over the period 2010-2017 for the countries included in figure 1b. We observe the sample before and after the MPP was introduced. Since the collective licensing agreement was established in 2010 but contracts for different APIs entered the pool at different points in time, we organize the data as a panel, and define a post-treatment dummy for each API-COUNTRY pair depending on the exact timing of entry to the pool.

First, we want to isolate the effect of joining the MPP on access to generic drugs. We begin by estimating,

$$\begin{aligned} Total\_Tnu_{act} =& \alpha + \beta Ever\_Lic_{ac} + \gamma Ever\_Lic_{ac} * Lic\_in\_Force_{act} + \\ &+ \delta Annual\_Cost_{act} + FE + \epsilon_{act} \end{aligned} \tag{1}$$

where $Total\_Tnu_{act}$ is the total number of units of a pill containing the API a

bought by procurement agencies for country c in year t. $Ever\_Lic_{ac}$ can be interpreted as a treatment dummy which takes the value 1 if the API a has ever been subject to an MPP license in country c. $Lic\_in\_Force_{act}$ is a dummy variable which takes the value 1 if the API a is licensed in country c at time t. $Annual\_Cost_{act}$ is the yearly expenditure incurred by procurement agencies to purchase a particular API for a specific country. This variable controls for the possibility that shifts are driven by changes in the agencies' budgets. Finally, FE are fixed effects, which are fundamental for our analytical purposes.

In order to verify that the identified effects, if any, are driven by a reallocation of the market shares between generic and originator companies as procurement agencies optimize their purchases under budget constraints (Beall and Attaran, 2016), we estimate:

$$\begin{aligned} Share\_Gen_{act} = &\alpha + \beta Ever\_Lic_{ac} + \gamma Ever\_Lic_{ac} * Lic\_in\_Force_{act} + \\ &+ FE + \epsilon_{act} \end{aligned} \tag{2}$$

where $Share\_Gen_{act}$ is the share of the total number of units sold by generic companies over the total for API a bought by procurement agencies for country c in year t.

In both equations, the coefficient of interest is the interaction term (γ) and its interpretation depends on the (FE) specification used.

The first specification is the "full fixed effect", set at the API-country pair level; the second specification includes API fixed effects; and the third includes country fixed effects.

Our second research question addresses whether collective licenses with clear statements about territorial coverage (i.e. MPP licenses) act as a signal which eliminates information asymmetries and solves a fundamental market coordination problem related to patents status. In equation 2 we add an interaction term for patent status for each API (i.e. presence or absence of an active patent), and estimate

$$\begin{aligned} Share\_Gen_{act} =& \alpha + \beta Ever\_Lic_{ac} + \gamma Ever\_Lic_{ac} * Lic\_in\_Force_{act} + \\ &+ \delta Ever\_Lic_{ac} * Lic\_in\_Force_{act} * Never\_Pat_{ac} + \\ &+ \chi Ever\_Lic_{ac} * Lic\_in\_Force_{act} * Ever\_Pat_{ac} + FE + \epsilon_{act} \end{aligned} \tag{3}$$

where the variables $Ever\_Pat_{ac}$ and $Never\_Pat_{ac}$ are two dummy variables indicating respectively whether or not an API has ever been patented in a certain country.

By comparing the magnitude of δ and χ, we can distinguish which mechanism is driving the change in the access to drugs after the introduction of the license. If $\delta > \chi$, increased access to generics is due to the licensing of a valid patent rather than to IPR uncertainty reduction. Conversely, if $\delta < \chi$ then increased access can be attributed to reduced IPR uncertainty.

5 Data and measures

In address our research questions, we build a novel dataset merging three data sources: the GPRM (Global Price Reporting Mechanism), the MPP website, and

the MedsPaL (Medicines Patents and Licenses database).

The GPRM database[11] records all transactions in HIV, tuberculosis, and malaria-related commodities made by national programs in low- and middle-income countries. For each transaction, it provides information on volume, price, destination country, and seller type (i.e. generic vs. originator firm). We use this information to construct our two dependent variables. The first ($Total\_Tnu_{act}$) is the total number of units of pills containing the API a bought by procurement agencies in country c in year t. The second ($Share\_Gen_{act}$) is the percentage of pills containing the API a over the total number sold by generic companies to procurement agencies in country c in year t.

From the MPP website[12] we retrieved information on API licenses in every country which we used to build our treatment and time dummy variables. The treatment dummy is $Ever\_Lic_{ac}$, and takes the value 1 if the API a has ever been subject to a license in country c. The time dummy is $Lic\_in\_force_{ac}$ and takes the value 1 for the years following the introduction of a license for API a in country c.

Finally, from the MedsPaL database[13] we retrieve information on patent status in low- and middle-income countries of selected HIV essential medicines. For all those cases where the API is associated to more than one patent (e.g. IPRs on different modes of drug delivery or different dosages), we apply the most stringent criterion: To consider the API as protected by IPR it is sufficient for there to be one granted patent for any product containing the focal API. On this basis, we build

[11] `http://www.who.int/hiv/amds/gprm/en/` accessed on February 2018
[12] `https://medicinespatentpool.org/` accessed on March 2018.
[13] `http://www.medspal.org/` accessed on March 2018

the two variables used to estimate equation 3. First, the variable $Never\_Pat_{ac}$ takes the value 1 if API a was never granted patent protection in country c; second, the variable $Ever\_Pat_{ac}$ takes the value 1 if API a was granted patent protection in country c.

The final dataset includes 3,862 observations and 616 unique COUNTRY-API pairs observed between 2005 and 2017[14]. The maximum number of countries where one of the unique APIs is distributed is equal to 96.

6 Results

Licensing and generics competition

Table 2 presents the estimation results for equation 1. The dependent variable is the total number of pills of a specific API bought yearly by procurement agencies and delivered in a specific country. Column 1 reports the results for the baseline model which does not include fixed effects. The coefficient of interest is the interaction term (*Ever_Lic*Lic_in_Force*) which measures the difference in the total number of units between API-country combinations with and without a license, keeping agencies annual expenditure (*Annual_Cost*) fixed. The model in column 1 does not consider any specific characteristics of the identifier pair. The magnitude of the impact is positive and significant. After introducing the licensing agreement into the pool, the total number of pills increases by about 2.5 million units. This result is robust to model specifications which include fixed effects. Column 2 presents the results

[14]Note that the panel is unbalanced since not all the APIs entered the GPRM dataset at the same moment in time.

obtained when including the "full fixed effect" which controls for all time invariant characteristics of API-country pairs. The interaction coefficient γ can be interpreted in the same way as in a difference-in-differences framework as the treatment effect (i.e. the API-country pair subject to a license) in the after-shock (e.g. post-MPP entry) period. The results show that after licensing an API in a specific country, 2.9 million more units of pills containing that specific API are procured for that country. Model 3 includes only the API fixed effect. In this case, the coefficient of the interaction indicates the difference between the total number of units of *the same* API bought for a country with and without a license. In other words, we consider observations related to an API in a country without a license as suitable to control for the case of the same API covered by a license in another country. This fixed effect specification confirms our previous findings on the magnitude and significance of the effects. Countries with a license for a specific API receive about 2.9 million more units of pills than countries without the license. Finally, table 2 column 4 presents the results for the estimations that include only country fixed effects. Here the interaction coefficient indicates the average observed difference between APIs with and without a license within the same country. Also, in this case we observe that the total number of pills is comparatively higher if the API is subject to a license but the magnitude of the effect is smaller.

Since all model specifications suggest that the absolute number of pills sold to procurement agencies increases with the introduction of a license, we investigate whether it is a shift towards generics producers which is driving this result. We estimate equation 2 and report the result in table 3. The results are robust across

the entire set of specifications (i.e. without the full fixed effect and with all three fixed effects). Indeed, API licensing in a country increases the share of the total number of units of pills bought from a generic company in the total number. The magnitude of the coefficient indicates an increase of between 19.4% and 20.4%. The results in equations 2 and 3 indicate that the absolute increase in the total number of units is due to a reallocation of the market shares of the originator and generic drug companies. We can conclude, therefore, that licensing through the MPP stimulates generics competition, thus improving technology access.

6.1 Licensing and asymmetric information

In this section we present some novel results on the effect of collective licenses as solutions to the IPR status information problem. Table 4 presents the combined patent and license status distribution in our sample of 616 uniquely identified API-COUNTRY pairs. In 251 cases, there is a patent for a specific API in a specific country. Of these, in 93 cases (15.1% of the total) there has never been a MPP license, while in 158 cases (25.6% of the total) a valid patent is not preventing competition from generics since a license on the protected API exists. However, in the majority of cases (365) there are no patents associated to a specific API in a specific country. In 133 cases (21.6% of the total) no MPP license has ever been introduced, and in 232 cases (37.7% of the total) there is a license but no patent. This case of no patent is highly counter-intuitive because the rationale for licensing is permission to use the technological knowledge protected by formal IPR. Table 4 shows that licenses exist in cases where there is no formal requirement for them, i.e. in cases

where the API is not protected by a patent. Intuitively we would expect the introduction of a license not to play a significant role in these 232 curious cases in our sample. A positive and significant effect would suggest the possibility of incomplete or ambiguous information on the patent status of the drugs sold in developing countries playing a role. Table 5 presents the results from the estimation of equation 3 which includes two dummy variables and the interaction term to indicate whether an API has ever been patented in a given country or not (*Ever_Pat* and *Never_Pat*). The coefficient of the term *Ever_Lic*Lic_in_Force *Ever_Pat* captures the reaction of the generics market share to the licensing of a patented product. Analogously, the coefficient of the term *Ever_Lic*Lic_in_Force *Never_Pat* captures the reaction of the generics market share to the licensing of a non-patented product. Both coefficients are positive and significant, confirming our conjecture about the additional effect of MPP licenses as a solution to an informational coordination problem. In particular, the coefficient of the 'with patent' scenario is always higher than the *Never_Pat*=1 scenario regardless of the specific estimation. However, although significant and positive, the effect of uncertainty reduction activated by the pool is weaker than the effect of increased access to the generic version of patented drugs.

7 Robustness checks

7.1 Split sample analysis

To further validate the finding that collective licensing with an explicit statement of territorial coverage has an effect even in cases where no patents are in force on a

specific product, we perform a split sample analysis as described in equations 4 and 5.

$$\begin{aligned} Share\_Gen_{act} =& \alpha + \beta Ever\_Lic_{ac} + \gamma Ever\_Lic_{ac} * Lic\_in\_Force_{act} + \\ &+ FE + \epsilon_{act} \qquad if \quad Never\_Pat = 0 \end{aligned} \tag{4}$$

$$\begin{aligned} Share\_Gen_{act} =& \alpha + \beta Ever\_Lic_{ac} + \delta Ever\_Lic_{ac} * Lic\_in\_Force_{act} + \\ &+ FE + \epsilon_{act} \qquad if \quad Never\_Pat = 1 \end{aligned} \tag{5}$$

Equation 4 estimates the impact on generics competition of API license in cases where a patent exists (i.e. $Never\_Pat$=0). Equation 5 estimates the impact on generics competition of an API license for those cases where a patent does not exist (i.e. $Never\_Pat$=1). The coefficient of c captures the MPP effect that applies even in scenarios where legally a license is not required. A positive and significant coefficient suggests that collective licensing reduces informational not legal issues related to the IPR status of the relevant API. Table 6 presents the results of the estimates of equations 4 and 5. Columns 1 to 3 present the result for if there is at least one patent protecting the API. In this case, the 93 observations with a patent on the API but which do not have a license related to a specific country act as a control group for the 158 observations where a valid patent is accessible via the MPP license. Columns 4 to 6 present the effect of the MPP in the more puzzling scenario where the licensed product is not protected by a patent. The 133 observations not subject to either a patent or a license act as the control group for the 232 "only license" cases. The δ coefficient in equation 5 is positive and significant, confirming our intuition and previous findings.

7.2 Ginarte-Park index and Patent Vintage

We run some further robustness checks to confirm that our results are not driven by other factors affecting the strength of any patent rights at both the country and product levels.

The strength of the different countries patent systems might contribute to determining the effectiveness of the relevant licensing agreements because it might affect the extent to which patents can be enforced and patent infringers prosecuted. We test this alternative explanation explicitly by including in equation 3 the Ginarte Park index (*G_P Index*) updated to 2005, as a control variable, (Park, 2008). This proxies for the strength of national patent protection and it is a composite index that includes several patent law characteristics such as extent of coverage and duration of protection. Since *G_P Index* is time-invariant, we can only estimate the model with API fixed effects. The coefficient of the interaction term *Ever_Lic * Lic_in_Force* reported in table 7 column 1[15] has similar sign, significance, and magnitude to the coefficient in table 5. The variable *G_P Index* has a negative and significant coefficient, in line with our expectations.

IPR strength might be influenced also by the age of the original API patent. It is plausible to suppose that older APIs are associated to lower originator interest in patent enforcement, and that originators might try to replace APIs whose patents have expired with newer and more profitable ones. To test this possibility in equation 3 we add as a control patent expiry date to proxy for the inverse of patent vintage

[15]Note that the number of observations in column 1 is lower than the number in table 5; this is because for 34 countries the variable *G_P Index* is not available.

(*Expiration_date*). We retrieved this information from Juneja et al. (2017, p.4 - table 2). Since this variable is API-specific, we can include a country fixed effect. Similar to the results reported in column 1, the coefficient of the interaction term *Ever_Lic * Lic_in_Force* reported in table 7 column 2 is in line with the results in table 5. This is further confirmation that our results are robust: in line with our expectation, the coefficient of the added control variable (*Expiration_date*) is negative and statistically significant.

8 Conclusions

There is some consensus in the literature (Guilloux and Moon, 2000; Friedman et al., 2003; Moon et al., 2011) that licensing - either voluntary or compulsory - is the most effective way to improve access to drugs. Not only does licensing increase technology diffusion, it also acts as an incentive for R&D investments. The MPP was the first attempt to provide a systematic and organized voluntary licensing tool for developing countries. We examined how the market for HIV drugs responded to introduction of the MPP scheme. We quantified the potential benefits of adoption of collective licensing on access to more affordable drugs for developing countries, and demonstrated the mechanisms at play. First, we provided evidence of an expected increase in the share of generics obtained as a result of easier access to the technology via the MPP; second - and this is a novel result - we showed that voluntary licensing promotes access to essential drugs by reducing information asymmetries related to patent status across countries between originators and generics manufacturers.

Where such information asymmetry exists, this is likely responsible for underutilization of viable resources (i.e. production of generic drugs) due to the threat of patent infringement. To our knowledge, the present study is the first to explore the hypothesis that collective licensing schemes can act as information signals that resolve the problem of asymmetric information by eliminating uncertainty about IPR status. The economic literature so far has generally considered that patent pools reduce transaction costs related to accessing patented technologies, and that no further explanation is required, as noted by Mattioli and Merges (2017). Moreover, the focus is on how patent pools increase transparency by determining ownership in relation to complex technologies, while overlooking search costs related to discrete technologies. Transaction costs can stem from different sources of uncertainty and different kinds of information asymmetries. To improve both theorizing about IPR transactions and policy design, it is essential to disentangle the different aspects of this issue. This study makes a significant contribution in this direction. Our results indicate that following the introduction of the MPP there was a marked increase in the share of generic drugs traded in the market. This suggests that prior to the MPP, the canonical flexibilities considered by the TRIPS agreement were not sufficiently strong to encourage diffusion of generic versions of essential drugs for the treatment of HIV. The introduction of new licensing contracts through the MPP, caused a strong and positive reaction in the market.

We demonstrated also that collective licensing through the pool has considerable advantages in the context of non-complex technologies and institutional environments that involve unclear IPR status across countries. We found that in more than half

of the cases we observed, countries where no relevant patents were filed or granted on a specific API were included in the licensing contracts.

Our findings suggest that the effect on the share of generics transactions is significant and positive even in these cases, and we argue that this is due to collective licensing representing the solution to the problem of asymmetric information about patent status in developing countries. Overall, our results suggest that organized forms of collective licensing such as the MPP can be crucial for ameliorating accessibility conditions in the drugs markets in developing countries. Their potential should be investigated in more detail, and arguably their application should be extended.

9 List of tables

Table 1: List of API and Timing of MMP Licence

API	Year of Entry in MMP
Emtricitabine	2011
Dolutegravir	2014
Ritonavir	2015
Darunavir	2010
Abacavir+Lamivudine	2013
Lopinavir+Ritonavir	2015
Atazanavir+Ritonavir	2013
Tenofovir+Emtricitabine	2014
Abacavir+Lamivudine+Zidovudine	2013
Abacavir	2013
Atazanavir	2013
Tenofovir	2011
Tenofovir+Lamivudine	2011

Table 2: Effect of the pool on the total number of units (*Total_TNU*)

	NO FE	FULL FE	API FE	COUNTRY FE
	(1)	(2)	(3)	(4)
Ever_Lic	1439935.5**		1322158.9**	-15740.6
	(445342.5)		(468067.7)	(512948.7)
*Ever_Lic*Lic_in_Force*	2519753.5***	2990422.1***	2995410.3***	2429993.4***
	(449407.7)	(474713.2)	(494764.9)	(431497.0)
Annual_Cost	417.2***	-47.84	439.1***	235.9***
	(25.63)	(31.21)	(25.73)	(27.56)
Constant	-2972.0	1787848.5***	-305724.3	-628686.7
	(332000.8)	(229043.7)	(616865.4)	(2711791.8)
Api Fixed Effects	No	Yes	Yes	No
Country Fixed Effect	No	Yes	No	Yes
Full Fixed Effect	No	Yes	No	No
Num of Observations	3862	3862	3862	3862

Note: Estimations are performed using Ordinary Least Square models with different specifications of fixed effects. Column 1 does not include fixed effects. Column 2 includes fixed effects on the API-COUNTRY identifier. Column 3 only includes fixed effects at the level of API and Column 4 only considers fixed effects at the level of countries. Dependent variable: *Total_TNU*. Standard errors reported in parentheses. Legend: * p<0.05, ** p<0.01, *** p<0.001

Table 3: Effect of the pool on the share of generics (*Share_Gen*)

	NO FE	FULL FE	API FE	COUNTRY FE
	(1)	(2)	(3)	(4)
Ever_Lic	0.171***		-0.0252	0.177***
	(0.0306)		(0.0245)	(0.0347)
*Ever_Lic*Lic_in_Force*	0.204***	0.194***	0.200***	0.202***
	(0.0147)	(0.0153)	(0.0147)	(0.0147)
Constant	0.462***	0.562***	0.779***	0.540**
	(0.0239)	(0.00696)	(0.0339)	(0.189)
Api Fixed Effects	No	Yes	Yes	No
Country Fixed Effect	No	Yes	No	Yes
Full Fixed Effect	No	Yes	No	No
Num of Observations	3862	3862	3862	3862

Note: Estimations are performed using Ordinary Least Square models with different specifications of fixed effects. Refer to the note of Table 2 for further explanation. Dependent variable: *Share˙gen*. Standard errors are reported in parentheses.
Legend: * p<0.05, ** p<0.01, *** p<0.001

Table 4: Cross-tabulation of *Ever_Lic* and *Never_Pat*

		Ever_Lic				
		0		1		Total
Never_Pat	0	93	15.1%	158	25.6%	251
	1	133	21.6%	232	37.7%	365
	Total	226		390		616

Table 5: Effect of the pool with and without patents in force

	FULL FE	API FE	COUNTRY FE
	(1)	(2)	(3)
*Ever_Lic*Lic_in_Force* Never_Pat*	0.124***	0.134***	0.167***
	(0.0217)	(0.0205)	(0.0205)
*Ever_Lic*Lic_in_Force* Ever_Pat*		0.208***	0.388***
		(0.0337)	(0.0398)
Constant	0.646***	0.856***	0.526**
	(0.00753)	(0.0423)	(0.181)
Api Fixed Effects	Yes	Yes	No
Country Fixed Effect	Yes	No	Yes
Full Fixed Effect	Yes	No	No
Num of Observations	3862	3862	3862

Note: Estimations are performed using Ordinary Least Square models with different specifications of fixed effects. refer to the note of Table 2 for further explanation. Dependent variable: *Share˙gen*. Standard errors are reported in parentheses
Legend: * p<0.05, ** p<0.01, *** p<0.001

Table 6: Split sample analysis

	With Patent *Never_Pat=0*			Without Patent *Never_Pat=1*		
	FULL FE	API FE	COUNTRY FE	FULL FE	API FE	COUNTRY FE
	(1)	(2)	(3)	(4)	(5)	(6)
Ever_Lic		-0.0230	0.137**		-0.0586	0.221***
		(0.0425)	(0.0517)		(0.0310)	(0.0478)
*Ever_Lic*Lic_in_Force*	0.262***	0.264***	0.248***	0.124***	0.141***	0.162***
	(0.0218)	(0.0212)	(0.0211)	(0.0214)	(0.0205)	(0.0205)
Constant	0.583***	0.756***	0.615	0.554***	0.888***	0.524**
	(0.00982)	(0.0448)	(0.408)	(0.00983)	(0.0976)	(0.192)
Api Fixed Effects	Yes	Yes	No	Yes	Yes	No
Country Fixed Effect	Yes	No	Yes	Yes	No	Yes
Full Fixed Effect	Yes	No	No	Yes	No	No
Num of Observations	1731	1731	1731	2131	2131	2131

Note: Estimations are performed using Ordinary Least Square models with different specifications of fixed effects. See legend in Table 2 for further explanation. Dependent variable: *Share_gen*
Standard errors are reported in parenthesis.
Legend: * p<0.05, ** p<0.01, *** p<0.001

Table 7: Robustness Checks on strenght of the patent right

	Ginarte	Patent Vintage
	API FE	COUNTRY FE
	(1)	(2)
Ever_Lic	-0.0318	0.0895*
	(0.0281)	(2.54)
*Ever_Lic*Lic_in_Force*	0.188***	0.189***
	(0.0163)	(12.84)
G_P Index	-0.0960***	
	(0.0185)	
Expiration_date		-0.0297***
		(-7.28)
Constant	1.065***	60.69***
	(0.0695)	(7.34)
Api Fixed Effects	Yes	No
Country Fixed Effect	No	Yes
Full Fixed Effect	No	No
Num of Observations	2774	3862

Note: All the models are estimated using (OLS). As the Ginarte index is invariant within countries Column 1 only includes fixed effects at the API level. As Patent Vintage is invariant within APIs Column 2 only includes fixed effects at the country level. Observations in Column 1 are fewer as the Ginarte index is not available for all countries. Dependent variable: *Share_gen*
Standard errors are reported in parentheses
Legend: * p<0.05, ** p<0.01, *** p<0.001

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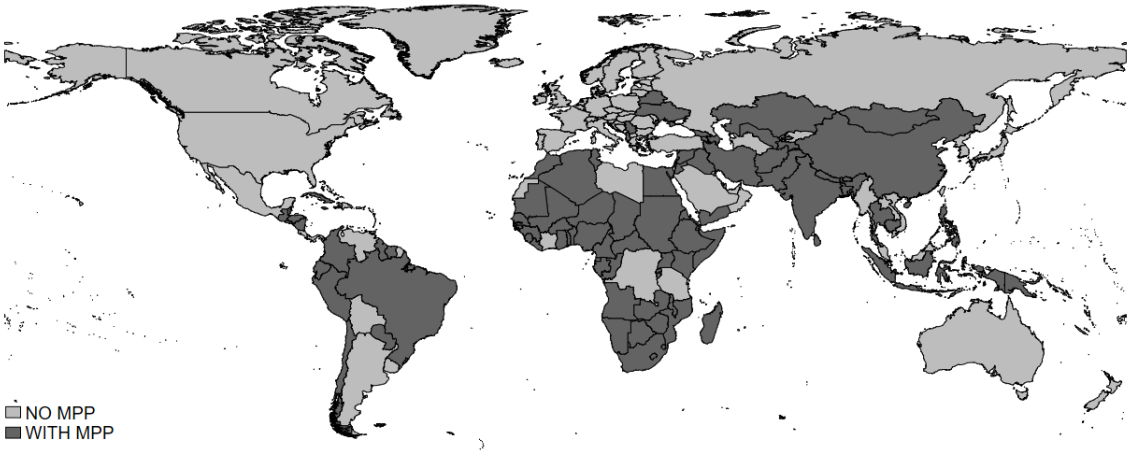
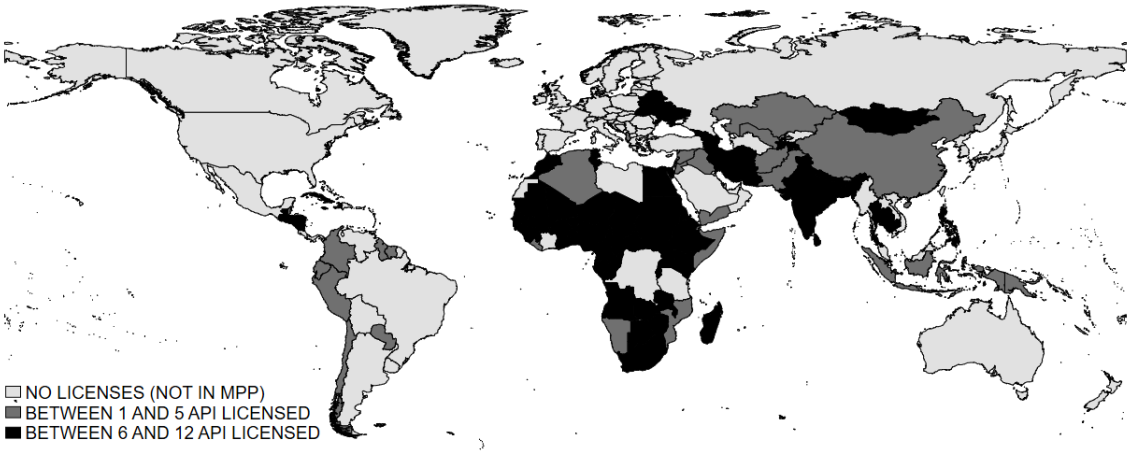


(a) Countries included in the MPP at least for one API in black



(b) Number of APIs licensed to each country included in the MPP. Darker color indicates a larger number of licensed APIs in the country.

Figure 1: Territorial coverage of MPP

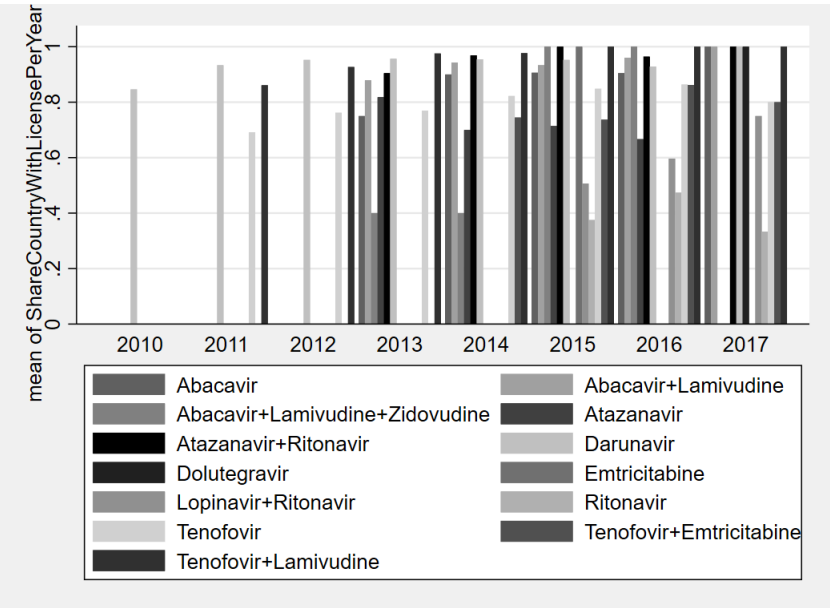


Figure 2: Share of countries involved in license contract for specific Api at different years.

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A Appendix

Table A.1: List of countries included in the MPP

Country	
Albania	Philippines
Angola	RussianFederation
Armenia	Senegal
Azerbaijan	SouthAfrica
Bangladesh	SriLanka
Belarus	Sudan
Benin	Swaziland
Botswana	Tajikistan
Brazil	Thailand
BurkinaFaso	Togo
Cameroon	Tunisia
CentralAfricanRepublic	Uganda
Chad	Ukraine
China	Uzbekistan
Colombia	Zambia
Congo	Zimbabwe
Cuba	SyrianArabRepublic
Ecuador	Burundi
Egypt	Cambodia
ElSalvador	Chile
EquatorialGuinea	Eritrea
Gabon	Ethiopia
Gambia	Iran(IslamicRepublicof)
Georgia	Namibia
Ghana	Paraguay
Guatemala	Suriname
Guinea	Haiti
Guinea-Bissau	Iraq
Honduras	Liberia
India	Madagascar
Indonesia	Myanmar
Jamaica	Nepal
Kazakhstan	Rwanda
Kenya	SierraLeone
Lebanon	Mongolia
Lesotho	Mozambique
Libya	Afghanistan
Malawi	Algeria
Mali	Belize
Mauritania	Bhutan
Mauritius	Djibouti
Morocco	Guyana
Nicaragua	Jordan
Niger	Maldives
Nigeria	PapuaNewGuinea
Pakistan	SaoTomeandPrincipe
Peru	Serbia
Somalia	Seychelles
SouthSudan	Yemen

Table A.2: Dolutegravir and Tenofovir territorial heterogeneous coverage

Egypt	Sri Lanka
Kosovo	Pakistan
Tunisia	Sudan
Micronesia	Chad
Korea Dem. Republic	Papua New Guinea
West Bank and Gaza	India
Morocco	Indonesia
Belarus	Somalia
Malaysia	Mongolia
Dominica	Senegal
Fiji	Rwanda
Palau	Cameroon
Barbados	Angola
Belize	Cote dIvoire
Jamaica	Vietnam
Grenada	Solomon Islands
Anguilla	Moldova
Saint Kitts and Nevis	Bangladesh
Turks and Caicos Islands	Malawi
Thailand	Burundi
British Virgin Islands	Tanzania
Aruba	Zambia
Tonga	Botswana
Maldives	Mozambique
Timor-Leste	Republic of the Congo
Saint Lucia	Georgia
Nauru	Ethiopia
Ecuador	Vanuatu
Kazakhstan	Equatorial Guinea
Cuba	Yemen
Dominican Republic	Samoa
Bahamas	Cape Verde
Montserrat	South Sudan
Saint Vincent & the Grenadines	Niger
Suriname	Mauritius
Antigua and Barbuda	Central African Republic
Seychelles	Tajikistan
El Salvador	Nicaragua
Togo	Ghana
Guatemala	Mauritania
Eritrea	Sierra Leone
Gambia	Philippines
Syrian Arab Republic	Sao Tome and Principe
Gabon	Guinea
Afghanistan	Kenya
Turkmenistan	Kiribati
Burkina Faso	Laos
Djibouti	Nigeria
Nepal	Haiti
Democratic Republic of the Congo	Uzbekistan
Comoros	Madagascar
Honduras	Guinea-Bissau
Ukraine	Liberia
Uganda	Namibia
Cambodia	Mali
Bolivia	Swaziland
Zimbabwe	South Africa
Bhutan	Lesotho
Armenia	Kyrgyzstan
Myanmar	Tuvalu
Guyana	Benin

Legend:

Countries included only in Dolutegravir License

Countries included only in Tenofovir License

Countries included in both licenses