Licensing Life-Saving Drugs for Developing Countries: Evidence from the Medicines Patent Pool

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August 22, 2022

[1]We are grateful to the Editor and two referees for their detailed and constructive suggestions. We thank Esteban Burrone and Amina Maillard for providing access to licensing data and discussions about the Medicine Patent Pool. We also thank Eric Bartelsman, Iain Cockburn, Saul Lach, William Matcham, Tim Simcoe and seminar participants at Boston University IP Day conference, Tinbergen Institute in Amsterdam, OECD IPSDM conference in Warsaw, University of Toronto, University of Utah, Charles River Associates and University of Cambridge for helpful comments. Harveen Sidhu provided excellent research assistance. Alberto Galasso is grateful for financial support from the Social Sciences and Humanities Research Council of Canada. Mark Schankerman gratefully acknowledges financial support from a STICERD Research Grant at the London School of Economics.

Abstract

We study the effects of the Medicines Patent Pool – an institution that pools patents across geographical markets – on the licensing and adoption of life-saving drugs in low- and middle-income countries. We show that there is an immediate and large increase in licensing when a patent is included in the MPP. There is also evidence that the pool increases actual entry and volume of sales, but these impacts are much smaller than on licensing, which is due to the geographic bundling of licenses. The paper highlights the potential of pools in promoting diffusion of biomedical innovation in developing countries.

Keywords: patents, licensing, patent pool, pharmaceuticals, HIV, public health, developing countries

JEL Codes: I18, O31, O34

1 Introduction

In 2008 the U.S. Food and Drug Administration approved the use of Etravirine, an HIV antiretroviral drug designed for patients with established resistance to other drugs. Yet, by 2015, Etravirine was available only in about 25 percent of the lower and upper middle-income countries in Central and Eastern Europe. This is not atypical, other important HIV antiretrovirals and drug cocktails have limited availability in these countries (Gokengin et al., 2018). Nor are such delays limited to HIV drugs. Cockburn, Lanjouw and Schankerman (2016) show that global drug diffusion is very slow, especially in countries with relatively low income.

Promoting rapid and affordable access to essential drugs is a key health policy objective. One proposed approach is to use patent pools, which are voluntary arrangements where patentees authorize the pool to license specific patents, typically as a bundle, to third parties. Historically, patent pools have been widely used in conjunction with technology standards – e.g., in the electronic and information technology sectors – where the focus is on licensing complementary innovations. Such pools are designed to facilitate commercialization of standard-compliant products and follow-on innovation by lowering the transaction costs of licensing and coordinating the use of complementary innovations (Merges 2001). More recently, a different type of patent pool has been proposed in the biomedical field, which focuses on promoting wider geographic diffusion of specific innovations rather than aggregating technologically-related innovations. Examples include vaccines for the SARS epidemic, neglected tropical diseases and diagnostic testing (Van Zimmeren et al., 2011), and the COVID-19 patent pool recently proposed by the WHO.

Advocates of geographic patent pools argue that they can be particularly beneficial for promoting the diffusion of essential pharmaceutical products in small, low- and middle-income countries, where market entry may be at best marginally profitable. A specialized, centralized licensing platform may reduce the transaction costs of writing, monitoring and enforcing patent

contracts between drug companies and generic manufacturers, and thereby facilitate product launches in poor countries. However, skeptics claim that these pools are essentially public relations exercises, and that there is no evidence of real impact on access to medicines (Kennedy, 2015). They also argue that pharmaceutical companies can unilaterally facilitate diffusion in low-income countries by not filing, or committing not to enforce, patents in those markets. Other critics point out that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement allows countries to facilitate access by generic manufacturers through flexible provisions, such as compulsory licensing. These different views in the policy debate highlight the need for empirical research.

There is limited evidence on whether patent pools do, in practice, promote licensing and product launches because data on licensing contracts is typically confidential and difficult to obtain. In this paper, we exploit a rich dataset on licensing from the Medicines Patent Pool (MPP) that allows us to conduct such empirical analysis. Established by the United Nations in 2010, the MPP is a voluntary licensing institution with a mandate to promote access to affordable and quality-assured treatments for HIV, tuberculosis and hepatitis-C in low- and middle-income countries. The MPP negotiates inclusion of patents in the pool with patent-holding pharmaceutical companies, and then licenses the patent rights to interested generic drug companies. MPP licenses are non-exclusive, with low or zero royalty rates, and wide geographical scope.

We study how the MPP affects the licensing, launch and sale of drugs in low- and middle-income countries. We begin with a short theoretical discussion of the differences between bilateral licensing by the patentee and a pool with geographical bundling. With a specialized patent pool as intermediary, the licensee is likely to face lower transaction costs but, at the same time, is constrained to license in all the countries designated by the pool. Such mandatory bundling reduces the correlation between licensing and drug launch because the pool is likely

to include geographic markets where the licensee has no interest in launching. As we show later, this means that empirical studies of patent pools that focus only on licensing outcomes are likely to overestimate the effect on actual new product launches and welfare.

Our empirical analysis is based on panel data covering 173 pharmaceutical products and 129 countries over the period 2005-2018. The product set encompasses medicines for HIV, tuberculosis and hepatitis-C recognized as essential by the WHO. The sample covers countries classified by the World Bank as low- or middle-income and for which patent protection was in place for at least one of the sample drugs. We obtain licensing information for each product-country from the MPP. Crucially, the licensing information includes both MPP licenses and non-MPP bilateral licenses between the upstream patentee and generic firms, and covers both the medicines in the pool and other products in our sample. Moreover, licensing data are available from 2005, five years before the formation of the pool.

Our baseline empirical specification uses difference-in-differences and examines changes in patent licensing when product-country combination are included in the MPP relative to those not included. The main endogeneity concern relates to the selection of products that enter into the MPP through upstream negotiations between the patent holder and the MPP. There may be unobservable factors that are both correlated with the inclusion of a medicine in the MPP and that affect diffusion of the product across countries. For example, the MPP may be interested in the most effective drugs which, in turn, would also be more attractive to generic licensees. To address this selection problem, we exploit the list of medicines that the MPP aimed to license when the pool was formed in 2010. This so-called 'priority list' includes about 80 products. Fewer than half of these medicines eventually made it into the pool, but the MPP started a negotiation with the relevant patentees for all of them. This information allows us to estimate the effect of being included in the MPP by using as the control group those drugs for which bargaining with the pool started but failed. This identification strategy

is closely related to the approach in Greenstone et al. (2010), who study the effect of large plant openings in a county using as a counterfactual counties that were considered by the plant managers but not chosen. We show that the estimates of the impact of the MPP using this approach are quantitatively similar to our baseline estimates.

There are three main empirical findings. First, the likelihood of observing at least one patent licensing deal covering a product-country combination increases substantially – by more than five-fold – once the associated patent is included in the MPP. This finding is robust to a wide variety of alternative specifications and controls. Second, the effect is heterogeneous: the increase in licensing due to the MPP is smaller in middle-income countries with high HIV incidence. These are more attractive markets for pharmaceutical companies, and bilateral deals are more likely to have been in place before the MPP. Finally, using additional data on product launches and sales for a subset of countries, we show that being included in the MPP also affects product market outcomes, not just licensing. The MPP is associated with higher entry rates (launches) of licensees, and this translates to higher quantities of products and lower prices.

The estimated impact of the MPP on market outcomes is much smaller than its effect on licensing. This is due to the geographic bundling of the MPP license contracts, as highlighted in our theoretical framework. This point is noteworthy because most studies of pools focus on how they affect licensing. But when licensing is bundled, this will overstate the impact on what ultimately matters, which is commercialization and product entry. Our estimates imply that, in our sample (which does not include sub-Saharan Africa), the probability of observing a licensing deal for product-countries in the MPP is more than seven times larger than those not in the MPP, but the probability of observing an actual launch by a licensee increases by a more modest, but still substantial, 40 percent.

The paper is organized as follows. Section 2 discusses the related literature and Section 3 provides institutional details on the MPP. Section 4 presents a simple conceptual framework. In

Section 5 we describe the data and the empirical specification. Section 6 presents the baseline estimates of the effect of the MPP on patent licensing. Section 7 examines the heterogeneity of the effect across countries. In Section 8 we investigate the impact of the MPP on drug launches and sales. We conclude with a brief summary of the findings and their implications.

2 Related Literature

Our paper is related to three strands in the literature on innovation. The first is the empirical literature on the diffusion of new drugs in developing countries. Cockburn, Lanjouw and Schankerman (2016) show that income levels, and patent and price regulation regimes, strongly affect how quickly new drugs are launched in a wide range of countries. Kyle (2006, 2007) examines the role of firm characteristics and price controls on pharmaceutical product launches in European countries. Duggan, Garthwaite, and Goyal (2016), Delgado, Kyle, and McGahan (2013) and Dubois, Lefouili and Straub (2021) study how patent protection and centralized procurement affect drug sales and prices. Our paper complements this line of research by examining how a geographic patent pool can speed up the diffusion of essential drugs in low- and middle-income countries.

The second strand is the empirical literature on bargaining frictions in the market for technology (Furman and Stern, 2011; Williams, 2013; Galasso and Schankerman, 2015, Sampat and Williams, 2019). Furman and Stern (2011) show that the establishment of a public clearinghouse for biological resources (the U.S. Biological Research Center) promotes cumulative innovation. Williams (2013) shows that (contract-based) intellectual property protection on genes retards cumulative innovation, while Galasso and Schankerman (2015) find that patent rights slow down cumulative innovation, albeit with very heterogeneous effects across technology areas. Our paper complements these studies by showing how a patent pool can reduce transaction costs and thereby promote licensing and technology diffusion. Our empirical ap-

proach is different, however, in that we rely on rich patent licensing data (both for patents included in the pool and related patents not included in the pool), as well as information on failed negotiations for inclusion in the pool, in order to identify causal effects.

Third, our paper relates to the literature on standards-based technology patent pools. The theoretical work studies incentives to form patent pools and the effect of such pools on innovation incentives (Lerner and Tirole, 2004; Quint, 2014; Reisinger and Tarantino, 2019). The empirical work is limited, and focuses on two aspects: the factors that affect the participation decision, including the licensing and governance rules (Lerner, Strojwas and Tirole 2007; Layne-Farrar and Lerner, 2011), and the impact of pools on innovation outcomes (Lampe and Moser, 2013; 2019).

Finally, there are two recent studies on the MPP. Wang (2020) examines the impact of the MPP on pharmaceutical research expenditure, clinical trials and sales of generic drugs. Martinelli et al (2020) study the effect of MPP inclusion on the volume of drugs bought by procurement agencies and on the reallocation of market shares between originators and generics. Our paper complements these studies by focusing on the direct impact of patent pooling on licensing and its interaction with market outcomes. We also develop new identification strategies to address endogeneity of MPP patents ad countries, which may also prove useful for future studies using MPP data.

3 The Medicines Patent Pool

The Medicines Patent Pool (MPP) is a voluntary licensing and patent pooling mechanism, established in 2010, with a mandate to accelerate access to affordable, appropriate and quality-assured HIV treatments in developing countries. The global health organization UNITAID provided most of the financial support to the establishment of the MPP. In 2015, the mandate of the MPP was expanded to include hepatitis C and tuberculosis (Medicines Patent Pool,

2018).

The MPP negotiates patent licensing agreements with patent-holding pharmaceutical companies. The medicines to be licensed are identified through in a priority list of drugs both approved and at the pipeline stage. The priority list is defined after consultations with the World Health Organization and experts from the government and the civil society. The choice of drugs takes into account medical needs and patent status in low- and middle-income countries (LMICs). Once a drug enters the MPP priority list, the MPP approaches relevant patent holders to negotiate for inclusion of the drug in the pool. In negotiating a license deal, the MPP focuses on the public health impact, and aims to obtain broad geographical coverage and freedom to develop pediatric formulations and fixed-dose combinations that meet the needs of resource-limited settings. MPP licenses are typically royalty-free (more than 60 percent of licenses). In about 30 percent of the licenses royalties are paid to the patentee (typically 5% of net sales of finished products). In the remaining cases, royalties are collected by the MPP and channeled back to community-based HIV organizations in the country paying the royalty.[1]

Once a license deal with a patent holder is in place ('upstream license'), the MPP issues an expression of interest inviting generic producers to apply for sub-licenses. In striking sub-licenses, the goal of the MPP is to ensure that licensees have the capacity, willingness and commitment to obtain appropriate regulatory approval, follow strict quality assurance requirements, develop the formulations and make them available in the licensed territory. MPP sub-licenses are non-exclusive and wide in geographical scope, including up to 131 low- and middle-income countries. Licenses often allow generic manufacturers to sell outside the licensed territory if they are not infringing on a patent.

[1]There is no within-firm variation in royalties in our sample. In particular, the 5% royalties involve all the HIV products licensed from Gilead, and the royalty channeled back locally is related to the only HIV drug licensed from Bristol-Myers Squibb. This prevents us from identifying the effect of royalties as it would be collinear with the firm effect.

4 Theoretical discussion

When the market for a pharmaceutical product is small – in terms of number of potential users and per capita income – the costs of negotiating, drafting and enforcing a patent licensing contract may exceed the profits that can be extracted. In such cases, a drug company may still be interested in licensing its patents as an investment in corporate social responsibility (CSR) and virtue-signaling, which generates indirect market value (Hong and Liskovich, 2015). A geographic patent pool can increase the private return to CSR investments by absorbing the costs of negotiating and monitoring licenses with generic manufacturers. Moreover, the information about the involvement of the patentee in poor countries may be disseminated more effectively by the pool.

When drug patents are included in a pool, downstream generic manufacturers negotiate with the pool for a bundled license that provides the right to sell the product in multiple countries. This can affect licensing outcomes and product launch decisions. In Appendix A1 we develop a simple model illustrating the different implications of bilateral and pool licensing. The model is based on two key assumptions. First, we assume that pool licenses involve a fixed bundle of countries, whereas bilateral deals allow patentee and licensee to include in the contract the desired target countries. Second, we assume that the cost to the licensee of negotiating, drafting and implementing a license contract might be lower when done through the pool as compared to a bilateral deal. The costs required for a bilateral license increase with the number of countries included, as the license become more complex with the involvement of patents in different jurisdictions and country-specific contractual provisions. Negotiating a license with the pool is less expensive than obtaining the full bundle of countries with a bilateral negotiation. In the context of the MPP, this difference is likely to be particularly large because most aspects of the MPP license contracts are standardized and do not require negotiations. In other contexts, where pool licenses are more tailored toward the specific licensees, the difference

in transaction costs between bilateral and pool license may be much smaller.

We use this simple model to compare the conditions required to have licensing and commercialization across countries with and without pool. There are two basic predictions. First, a geographic patent pool has an ambiguous effect on the total amount of licensing relative to bilateral contracting. When the profits from commercialization in each of the countries licensed in the pool bundle are large relative to the transaction costs, creating a patent pool has no effect on licensing as all patents would be licensed with or without a pool. When the profits that can be obtained across countries are asymmetric, the presence of a pool may increase or decrease the number of patents licensed. This is because with a bilateral deal the licensing firm chooses to license only patents associated with countries for which commercialization profits exceed licensing transaction costs. With the pool the licensee has to license the full bundle of countries and this is profitable only if the corresponding transaction costs are not too large.

To see how this can lead to less licensing, consider a pool bundling N countries and a firm able to extract positive commercialization profits only in one of those countries. The bilateral deal would focus only on the profitable country. Assume that the commercialization profits made in this country are marginal, and barely exceeds the transaction costs required to strike the bilateral deal. In this case there may be no license if the firm is constrained to obtain the full bundle of countries from the pool, as the small commercialization profits (the same as in the bilateral deal) may be lower than the transaction costs associated with a contract covering the N patents for the N jurisdictions. Conversely, a pool may increase the total number of patents licensed when the transaction costs required to access the bundle of countries are small and close to (or lower than) those for the one-country bilateral license. This is likely to be the case in the context of the MPP, because most aspects of the bundled contracts are standardized and do not require negotiations.

The second implication of our model is that, in a patent pool with bundled licenses,

the correlation between patent licensing and drug launch may be low. With costly bilateral licensing, the generic firm is expected to launch the product in any country for which it has a license. With a pool, the firm is constrained to license a bundle of countries, in some of which a launch may not be profitable. This observation highlights an important distinction between patent pools that license complementary technological components and pools like the MPP which bundle different geographical markets for a given technology. In the first case, one would expect that most, if not all, the licensed patents would be used by the licensee to ensure compliance with the technology standard. This does not apply in pools which serve as clearinghouses for international market access. As a consequence, empirical studies that rely on licensing data alone may over-estimate the effect of a pool on actual commercialization.[2]

Appendix A1 discusses the model in greater detail, and shows that the empirical predictions are robust to a variety of generalizations. These include allowing for the coexistence of MPP and bilateral licensing, differences in royalties between MPP and bilateral deals, and the presence of multiple licensees.

5 Data and econometric specification

5.1 Data construction

The analysis starts with a balanced, product-country-year panel data set covering the period 2005-2018. The products in our sample were retrieved from three different sources. First, we download the products listed in MedsPal, a data portal managed by the MPP providing information on key drugs for HIV, hepatitis C, tuberculosis and a few other diseases prominent in low- and middle-income countries. Second, we added to this list all the medicines in the 2017

[2]This also applies to studies in the public health literature (e.g., Juneja et al., 2017) that have tried to estimate the impact of the MPP assuming that its commercial impact takes place in all countries covered by its licenses. In practice, even a technology patent pool may contain patents that are not, strictly speaking, essential for the implementation of a standard. To this extent, some of the patents may not be implemented by all licensees (Lemley and Simcoe, 2018).

WHO Essential Medicine List for HIV, tuberculosis, and hepatitis C that were not included in MedsPal. This list is a guide for national institutions in identifying products that need to be available in a functioning health system, and is based on disease prevalence, public health relevance, clinical efficacy and cost-effectiveness. Finally, we include products related to compounds in the 2010 MPP priority list, if these were not included in MedsPal or the Essential Medicine List.

The data set covers 216 products. Each product is defined by a molecule-strength combination (e.g. Abacavir 300mg or Etravirine 100mg). About half (52 percent) of the products are in the 2017 WHO Essential Medicine List. The 2010 MPP priority list includes 83 products. The countries in our sample are the 177 countries listed by MedsPal in July 2019, which includes all countries classified as low- or middle-income by the World Bank and some countries that, in recent years, graduated to high-income status. We collected information on the patents protecting products in each country. For 63 percent of the products in our sample, this information is provided by the MedsPal dataset. For the remaining 37 percent (80 products), the information was retrieved manually from a variety of sources (including the DrugBank data base, the WIPO Pat-INFORMED data, and Google Patents). Using this information, we identify product-country-years for which there is at least one non-expired patent protecting the product in the country in the focal year.

Our main source of data for patent license agreements is the MPP. In this paper, for clarity, we refer to licensing deals between the MPP and pharmaceutical firms as "upstream licenses", and licensing deals between the MPP and downstream generic manufacturers as "sublicenses". Finally, we refer to the non-MPP deals between a pharmaceutical company and a generic producer as "bilateral licenses".

The MPP website provides access to the full text of their upstream licensing deals. In some cases, these agreements were renegotiated over time to include additional countries or drug

formulations. The MPP shared with us all the historical contracts, allowing us to track how each upstream licensing deal evolved over time. The pool's website also provides information on sub-license agreements between the pool and generic manufacturers for all the drugs in the pool. The MPP also discloses, through its MedsPal database, information on bilateral licensing deals related to non-MPP drugs. This information is retrieved both from public sources (such as licensors' websites or official press releases) and from non-confidential direct communications to the MPP from the licensors. The information on bilateral licences deals available on the MedsPal portal only covers deals signed after 2010, but the MPP also collected information on bilateral deals signed between 2001 and 2010 and shared it with us for this project.

The final data set is an unbalanced panel with 80,103 observations encompassing 129 countries and 173 products.[3] Focusing on product-country-years observations in which patent protection is in place allows us to examine the effect of inclusion of a patent in the Medicines Patent Pool on the likelihood that the patent is licensed in the country. If anything, restricting to this sample leads to an under-estimation of the effect of the pool if licensees also sell in countries where patent protection is not in place.[4]

5.2 Descriptive statistics

Our empirical analysis focuses on two outcome variables. The first is *Deals*, which is defined as the total number of licensing deals (either bilateral or MPP sublicense) which are in force in the product-country-year observation. The second is a dummy variable, *Access*, which is equal to

[3] We drop products that are listed in MedsPal with patents expired before 2005, those with patents filed after 2018, and products that are not in MedsPal and for which patent information could not be retrieved from other data sets. We drop countries for which our data show no patent filed for all of the products during the entire sample period. These include conflict-affected poor countries (such as Afghanistan and South Sudan) and a number of very small countries (such as the Cook Islands, Tonga and Mirconesia).

[4] Typically, MPP license deals allow licensees to sell outside the licensed territory as long as they are not infringing on any granted patents. Our discussions with MPP executives suggest that this provision is not present in many bilateral (non-MPP) deals which may include stricter restrictions on sales.

one if at least one of these licensing deals is in force in the product-country-year observation.[5]

Panel A of Table 1 provides summary statistics for some of the key variables in our data set. The dummy *Access* equals one for about 18 percent of the product-country-year observations in our sample. Conditional on having at least one license in place, the average number of *Deals* is 4.6. Of these deals, 1.4 are MPP sublicenses and 3.2 are bilateral deals. By the end of 2018, about 27 percent (47/173) of the products in our sample are included in the MPP.

Appendix A2 provides additional descriptive analysis comparing the geographical scope of MPP licenses with non-MPP bilateral agreements that are related to the same set of products. Summarizing briefly here, the average number of countries covered by MPP licenses is 24 (median is 9), whereas the mean for bilateral license is 15 (median is 2). This ranking holds more generally – the distribution of geographical scope in the MPP licenses stochastically dominates the one for bilateral deals. Moreover, this comparison actually under-estimates the extra geographic coverage – what we call 'geographic additionality' – provided by MPP licenses.[6] Examining the identity of the countries covered, we found that, on average, MPP licenses include 9.9 countries in excess of the bilateral deals covering the same product; the median number is 3 countries. Finally, we show that the MPP additionality is much larger in the

[5] While the number of MPP sublicenses is accurately reported, for some of the bilateral deals we do not know the exact number of licensees involved (but we do know the products involved and the geographic coverage of the deal). This required us to perform two types of imputations in our data. First, we set the number of deals as equal to one in cases where no information on the number of licensees is reported in our data. Second, in some of these cases licensing deals are expanded geographically and we assume that that the revised agreement involves all the original licensees. In Appendix A3 we show that adding a dummy for these adjustments or dropping these subsamples has no impact on our findings.

[6] To illustrate, consider a product for which the MPP license covers 24 countries, and the bilateral license covers 15 countries. The difference in the number of countries covered captures the additionality only if all the countries included in the bilateral agreement are also included in the MPP license. If the MPP license includes only a subset of those covered by the bilateral deal, a simple count of countries will under-estimate the MPP additionality. In the extreme case where there is no overlap between the countries in the MPP and bilateral licenses, the MPP additionality is 24 countries, which is much larger than the simple comparison of the number of countries covered, which is 9 in this example.

lower middle-income countries, as compared to low-income or upper middle-income countries, and this is even more pronounced when countries are weighted by population.

Panel B of Table 1 provides preliminary evidence of the effect of a country-product dyad entering the pool. The first row shows the baseline probability of at least one MPP license (*Access*) and the average number of deals for country-product combinations that are not included in the MPP during our entire sample period. The second row presents the same information for country-products that enter the pool, for the sample years before their inclusion in the MPP. The last row provides similar statistics for country-products in the pool during the sample period in which they are included in the MPP.

The results are striking. Access rates are respectively 0.13, 0.09 and 0.87, implying that the probability of striking at least one license deal related to the product-country is nearly 10 times larger once the product-country is included in the MPP. Similarly, the average number of deals are 0.48, 0.45 and 5.45. These are very large effects, but they may confound the causal effect of pool inclusion with unobserved heterogeneity driven by country and product characteristics. The econometric analysis below attempts to control for these dimensions of heterogeneity. Moreover, as emphasized earlier, given the bundled licensing by the MPP, patent license deals capture "potential generic entrants" for the product/country rather than actual entry. In Section 8 we examine this distinction in detail, using drug launches and sales data purchased from a private vendor.

5.3 Empirical model and identification

Our empirical strategy relies on a difference-in-differences specification:

$$Y_{p,c,t} = \alpha + \beta MPP_{p,c,t} + \gamma X_{c,t} + \delta_t + f_{p,c} + \varepsilon_{p,c,t} \tag{1}$$

where the dependent variable, $Y_{p,c,t}$, captures licensing activities in product, p, country, c, and year t. The unit of observation is a product-country-year. The treatment variable, $MPP_{p,c,t}$

is equal to one for product-country dyads that are included in an upstream license between the MPP and a pharmaceutical firm in year t. The term $X_{c,t}$ captures a series of time-varying country controls. The terms δ_t and $f_{p,c}$ are year and product-country fixed effects. The coefficient β is the difference-in-differences estimator identifying the effect of entering the pool on licensing relative to product-countries that are not in the MPP. The baseline regressions are estimated by OLS, with standard errors clustered at the product and country level.

One potential concern with our empirical approach is that products are not likely to be randomly allocated to the patent pool. There may be unobservable factors that are correlated both with the likelihood that the product enters the MPP and the underlying demand for licenses for that product. The direction of the induced bias is ambiguous, however, and would depend on how the MPP decides which products to target. For example, the MPP may decide not to target the most effective drugs with large demand, as it may anticipate that there would be licenses for these products even without their intervention. This would induce a negative bias in the OLS regression of licensing against MPP inclusion. At the same time, the MPP may not consider drugs with niche markets and small demand, as it might expect no licensing interest even if the drugs were included in the MPP. This would induce a positive bias in our estimates.

Our identification strategy to address this issue is to use the drugs for which negotiations with the MPP failed as a counterfactual for what would have happened to the drug that entered the pool in the absence of pool inclusion. To conduct such analysis, we exploit the MPP 2010 priority list. This list of medicines was compiled when the pool was established, after consultations with the WHO, national governments and other experts. It comprises medicines that the MPP wanted to be included in the pool in 2010. For all these drugs, MPP entered a negotiation with the pharmaceutical company owning the patent. The 2010 priority list encompasses 83 of our sample products, but only 38.5 percent of them eventually made it into

the MPP. Under the assumption that success/failure in the negotiation for these drugs was quasi-random – i.e. not related to unobservable drivers of future licensing – focusing on this priority list would alleviate concerns related to selection into the MPP.[7] The key identification assumption for this analysis is that drugs in the 2010 priority list would have trended identically in the absence of MPP inclusion, conditional on the other control variables. This identification strategy is similar to the one employed by Greenstone et al. (2010), who estimate the effect of large plant openings in a county using counties that were considered by the plant managers, but not chosen, as a counterfactual. It also resembles the approach in Seru (2014) who exploits failed mergers to generate exogenous variation in acquisition outcomes of target firms.

We complement the standard difference-in-differences estimation (1) with the more flexible dynamic specification:

$$Y_{p,c,t} = \alpha + \sum_{t} \beta_{t-\tau} MPP_{p,c,t-\tau} + \gamma X_{c,t} + \delta_t + f_{p,c} + \varepsilon_{p,c,t} \tag{2}$$

where τ is the year in which the product-country is included in the MPP. The dummies $MPP_{p,c,t-\tau} = 1$ at $t - \tau$ years from inclusion and zero otherwise. Notice that $t - \tau$ includes leads and lags. In this extended model the coefficients $\beta_{t-\tau}$ capture the differences between the treatment and control product-countries for each year before and after inclusion in the MPP. Following convention, we take as the baseline effect the year before inclusion, (i.e. we normalize by setting $\beta_{-1} = 0$).

[7] Using failed negotiations over drugs in the priority list should also take care of another possible concern. Specifically, a licensee might decide to delay a bilateral negotiation over a product-country once it learns that the MPP is negotiating with a pharmaceutical company. Since this information is available at the same time for both treatment and control group, such strategic delay should not cause any bias.

6 Empirical Results

6.1 Baseline specification

Table 2 provides the baseline results. In column 1, the dependent variable is *Access*, an indicator equal to one if at least one licensing deal is in place for product p and country c in year t. The estimated β is positive and statistically significant: the likelihood of at least one deal for the product-country increases by 66 percentage points after the product-country combination enters the MPP. Since the mean value of *Access* for non-MPP products-countries is 0.13, this corresponds to a 5-fold increase in the likelihood of observing at least one licensing deal. In column 2 the dependent variable is the total number of licensing deals. The estimated MPP treatment effect is an increase of 4.6 deals, and it is strongly significant. Compared to the mean number of deals for product-countries that never enter the MPP, this represents a 10-fold increase.

Columns 3 and 4 estimate the model on the sample of products on the MPP priority list of 2010. This approach uses the drugs for which negotiations failed as a counterfactual for what would have happened to the drug that entered the pool in the absence of pool inclusion. The MPP treatment effect on *Access* and the number of deals are similar to those in our baseline regressions, indicating that product-level selection into the MPP does not seem to be a source of bias.

Using the MPP priority list sample, we also estimate the dynamic specification described in equation (2). Panel A in Figure 1 plots the estimated coefficients and their 95-percent confidence intervals, using *Access* as the dependent variable. The results confirm that inclusion in the MPP is associated with a large increase in the likelihood of licensing. The coefficients estimated for the period before inclusion are very small in magnitude and mostly statistically insignificant, broadly supporting the common-trends assumption required for identification in diff-in-diff models. There is clear evidence of a sharp, large and immediate increase in patent

licensing after MPP inclusion, and the estimated increase in licensing is statistically significant. This pattern confirms that MPP patented products are quickly involved in licensing deals after introduction in the pool.

Panel B in Figure 1 plots the estimates for the specification using the number of *Deals* as the dependent variable. Here too we see a substantial and immediate increase in licensing deals after inclusion in the MPP, and the graph suggests that the effect is not driven by pre-existing trends. Figure A2 in the Appendix provides several robustness checks for this visual analysis of the dynamic effects of MPP inclusion.

As an alternative approach to address unobserved heterogeneity, in columns 5 and 6 we estimated a model including a full set of country-year and product-year effects in the full sample. These controls capture time-varying factors related to the economy of each country or the international market success of each product. In this more demanding specification, the size of the MPP coefficients falls by about 15-20 percent relative to the estimates in columns 1 and 2, but the MPP effect remains statistically significant and economically large.

6.2 Robustness

We perform a variety of robustness checks on our main findings. These include further analysis of the priority list sample, using alternative econometric specifications and dependent variables, and conducting the estimation at the molecule, rather than the product, level of analysis, The details of these (and other) empirical tests are presented in the online Appendix A3. In this sub-section we briefly summarize two main robustness checks related to the staggered treatment rollout and the endogeneity of the countries included in the MPP licenses.

Decomposition of the treatment effect using the imputation estimator. Our empirical setting differs from the standard difference-in-differences setup because units in the panel are treated (included in the MPP) at different points in time. Recent studies in the

econometrics literature have shown that identification problems can arise when treatment roll-out is staggered (see Baker et al., 2021 for a survey). The resulting biases are more severe when the estimation relies heavily on a comparison of units that are treated over a period of time and 'reference' units which are treated earlier in the sample, relative to completely untreated units in the control sample. In our setting, the size of the treatment group is small relative to the control group, so most of the comparison is likely to be between drugs included in the MPP and the control drugs, rather than between those included in the MPP earlier rather than later, so the bias may be limited.

We address this concern in two ways. First, we decompose our two-way fixed effects estimator, following the procedure developed by Goodman-Bacon (2021). The decomposition confirms that the timing variation accounts for less than four percent of the estimated effect, and that essentially all the identifying variation comes from comparisons to product-country pairs that are not included in the MPP during our sample period. Second, we re-estimate our baseline model using the "imputation estimator" developed by Borusyak, Jaravel, and Spiess (2021) which is robust to treatment effect heterogeneity in panels with staggered rollout. This estimator computes unit and period fixed effects using only untreated observations, and then generates imputed, untreated potential outcomes to estimate treatment effect for treated observations. As it turns out, the estimated coefficients (reported in Appendix Table A1) are essentially identical to our baseline coefficients.

Endogeneity of country coverage Our baseline regression includes product-country fixed effects which account for unobserved, time-invariant characteristics that may be correlated with both upstream and downstream licensing. However, there could be time-varying country characteristics that affect both the inclusion of countries in MPP licenses and bilateral licensing. For example, government policies that make the market more attractive to a patent-holding drug company may make bilateral licensing more likely and thus make it less likely that the

country will be covered by the upstream license with the MPP. To address this potential endogeneity of country coverage, we exploit the annual World Bank classification of countries by income level. When negotiating the geographical scope of a deal, the MPP focuses primarily on low and lower middle-income countries, though occasionally upper middle-income countries may be covered.[8]

In Appendix A3, we first confirm that the likelihood of being included in the MPP is much higher for lower middle-income, as compared to upper middle-income, countries. Based on this, we exploit a fuzzy regression discontinuity design to estimate the treatment effect, using a dummy for whether the country is below the upper middle-income threshold at the time of negotiations as the instrument for inclusion in the pool. The key identifying assumption requires that the World Bank classification, for countries near the threshold, does not affect licensing negotiations directly - i.e., through channels other than the MPP – which seems reasonable in this context. Because this RDD analysis uses only observations in the neighborhood of the income threshold, it relies on a much smaller sample. The first stage regression confirms a strong negative correlation between the upper middle-income status of the country and inclusion in the MPP. The estimated treatment effect of the MPP, using IV estimation, is slightly larger than the OLS estimate, but the difference is not statistically significant (see Appendix A3 for details). This analysis suggests that endogenous country coverage does not seem to bias our results.

7 Heterogeneus treatment effects

In this section we examine whether the impact of the MPP varies across countries. In the online Appendix A4 we discuss additional evidence of heterogeneous effects across patentees

[8] This is both because drug companies see greater potential for bilateral deals for the upper middle-income group (e.g. Brazil or China) and because the MPP itself has less interest in such countries (Branigan, 2018). We confirmed this directly with MPP executives, who reported that companies often use the upper middle-income thresholds as a key criterion for agreeing whether to include a country into the upstream license.

and products.

From a theoretical perspective, we expect the MPP to have a smaller impact on licensing in geographical markets where patent owners have enough incentives to license their patents bilaterally. These incentives can come from two different sources: sufficient market size that makes royalties large enough to enter, or markets with characteristics that generate indirect market value through corporate social responsibility (CSR) and virtue-signaling (Hong and Liskovich, 2015). To be at play, both the royalty channel and the CSR-signaling channel require a large population affected by the virus, as countries with limited demand for HIV medicines are unlikely to generate substantial revenue or halo effects. For a given level of HIV population, higher per capita income should strengthen the royalty motive, but weaken the CSR motive, for bilateral deals.

Therefore, in order to assess the strength on these two mechanisms, we compare the MPP treatment effect in low-income versus high-income countries where both have a large viraemic (HIV) population. If bilateral deals are driven by CSR motives, the treatment effect of the MPP on licensing should be *smaller in the low-income* countries, whereas it should be *smaller in middle-income* countries if bilateral deals are driven by direct financial returns.

We begin by examining whether the MPP treatment effect on *Access* varies across countries with different levels of HIV population. For this we only include in this sample products related to HIV. Using the full sample, column 1 in Table 3 distinguishes countries in the top 10 percent in terms of population living with HIV (retrieved from the World Bank data portal) versus the rest. The estimated MPP treatment effect is about 5.6 percentage points smaller for the countries with the largest viraemic population, but the coefficient is not statistically significant.[9]

[9]We confirm this finding in a more flexible specification that includes dummies for various deciles of the distribution of viraemic population. We again find a negative interaction between MPP and the level of HIV population, with effects larger in the higher deciles, but these estimates are not statistically significant in most specifications.

To distinguish between the royalty and CSR motives, column 2 splits the countries in the top decile of population with HIV into two groups: low-income and middle-income countries, using the World Bank classification. The results indicate that the impact of the MPP is 21 percent smaller in countries where there is both a sizable viraemic population (potential market) *and* sufficient ability to pay (effective market). In these cases, the market is profitable enough to induce bilateral deals, and thus reduces the impact of the MPP on the probability that at least one license is observed. In column 3 we restrict the sample to the priority list drugs, and the results are even stronger – the MPP impact is now 30 percent smaller in markets with large HIV population, middle-income countries. Interestingly, in all these regressions the estimated coefficient on the interaction of the MPP dummy with a large HIV population is essentially zero and highly insignificant. This suggests that halo effects are not large enough to incentivize bilateral deals in the poorest countries.

Finally, in column 4 we enlarge the sample to include products related to tuberculosis (TB) and hepatitis C (HepC). We construct a measure of each country's population that is affected by TB and HepC and, as before, we separate countries for which the viraemic for the disease targeted by the product is above the 90th percentile of the sample.[10] Adding these additional products does not change the conclusion from our baseline with only HIV products. The impact of the MPP on *Access* is again lower in countries where disease prevalence and income level are large enough to stimulate bilateral licensing.

Our analysis focused on *Access* rather than the number of deals as the dependent variable. Coefficients on the interaction of MPP and country characteristics tend to be small and statistically insignificant when we use *Deals* as dependent variable. The main reason is that

[10] We use data on the incidence of TB per 100,000 people and country population provided by the World Bank. The World Bank data portal does not provide data on HepC. To construct a measure for HepC, we use the estimates in Blach et al. (2017) for the prevalence of viraemic HepC at the end of 2015 across 100 countries. Notice that these measures are not available for all our sample countries, so the sample size is smaller than our baseline analysis.

MPP downstream deals give licensees access to a bundle of countries. Therefore, any additional MPP licensee increases the number of deals in every MPP country covered by the license by one, independently of country characteristics. Provided there is only limited substitution with bilateral deals, the effect of the MPP on the total number of licensing deals will be more similar across heterogeneous countries.[11]

These results show that the MPP is more important in promoting greater access to poor countries and in middle income countries with lower exposure to HIV. In this respect, the patent pool represents a gateway to needed drugs for countries that are not big enough to be an attractive market for bilateral deals.

8 Impact on market outcomes

Thus far we focused on the impact of the MPP on downstream licensing deals. However, these contracts give licensees the right to practice the patented product, but they may not necessarily translate into actual launch and sales. In short, patent license deals measure potential entry of the generic firms rather than actual entry. This distinction is important in our setting where MPP license contracts include large bundles of countries, as licensees are likely to only be interested in a subset of the countries.

To examine this issue requires data on actual entry by generic firms and their sales across the countries in our sample. We purchased a dataset with this information from a private vendor, IQVIA, a leading provider of data on international sales of pharmaceutical products. The IQVIA data provide detailed information on the launch of new products across countries, sales revenues (in US dollars) and volume (effective number of tablets) for the period of our

[11] To gain the intuition for this general feature of geographic pools, consider the following illustrative example. A drug is available for license in two countries: Albania and South Africa. Assume that in the absence of MPP there are no licensees in Albania and 4 licensees in South Africa. Assume that both countries are included in the MPP license for the drug and that 3 sub-licensees sign up. The number of deals increases by 3 in both countries, but the dummy Access changes from 0 to 1 in Albania and is not affected in South Africa.

study. Despite this level of detail, the IQVIA data do not cover our full sample. The sales data are only available for 32 countries out of the 129 countries in our sample, mostly middle-income countries outside Sub-Saharan Africa (such as Egypt, Pakistan, Peru and Vietnam), and about 80 percent of the products in our sample.[12] Matching this information with our licensing data set, we obtain an unbalanced panel with 24,663 product-country-year observations.[13]

8.1 Impact on entry, volume and sales

We estimate how inclusion in the MPP of a country-product affects three market outcomes: product launch (entry), quantity sold, and sales revenue. To do this, we estimate the dynamic diff-in-diff specification described in equation (2).

Panel A in Figure 2 plots the estimated coefficients and their 90-percent confidence intervals, where the dependent variable is a dummy equal to one if at least one licensee has launched the product in the country in the focal year. Panels B and C do the same, using the logarithm of sales revenue and volume of product sold, respectively.[14] We use the full sample of products in these regressions, but the results are very similar when we restrict the sample to those on the MPP priority list, as we report in Appendix Figure A4. Even with the full IQVIA sample of products, the limited number of launches observed (most products entered the MPP

[12] This is an important difference with recent studies examining the effects of the MPP (Martinelli et al., 2020; Wang, 2020). They focus on transactions that rely on resources from international organizations, such as the Global Fund, which predominantly operate in Sub-Saharan Africa. The IQVIA data includes local sales financed by these organizations as well as other local sales to local governments and private entities.

[13] Because many Sub-Saharan and poor countries that are often included in MPP agreements are not present in the IQVIA data, the dummy MPP is equal to one for only 3.6 percent of the sample (compared to 7 percent in the licensing sample). For about 75 percent of the sample, we observe no firm active in the product-country, i.e. no firm has launched the product in the country by that year. On average, at least one licensee launches a product in about 7 percent of the observations. Despite the smaller sample, the relationship between licensing and inclusion in the MPP replicates well in the IQVIA sample. The coefficient in the regression of Access on the MPP dummy is 0.691 (p-value<.01), and for the number of deals the coefficient 4.241 (p-value<.01). These are similar to the baseline estimates in column 1 and 2 in Table 2.

[14] Volume is constructed at the product level adjusting the IQVIA data on packs sold for the number of vials or tablets in each pack.

late in the sample period), makes it hard to estimate any impacts precisely. Moreover, we use conservative standard errors (clustered by product and country), which further contributes to large confidence intervals. Nonetheless, we think the results are a useful first step.

Panel A strongly suggests that inclusion in the MPP increases the likelihood that at least one licensee launches the product in the country, but this entry takes place with about a five year lag. There is no evidence of any pre-MPP effects, consistent with the parallel trends assumption. The observed entry delay is consistent with information reported on the MPP web-site and publications on the time needed for licensees to sell once a patent deal is in place. Launch requires obtaining WHO prequalification of the generic version of the drug, and setting up manufacturing and distribution facilities in the country.

Panel B shows that there is no statistically significant effect of being included in the MPP on *sales revenue*. There is also no evidence of any pre-trend effects. However, as Panel C shows, there is evidence that the MPP is associated with a steady increase in the *quantity sold* after a short lag, rising by about 60 percent by the fifth year. Some of this increase in the early years may be due to volume associated with firms who entered before the product was included in the MPP. We cannot distinguish the source of the increase in volume.[15]. Together, the null effect on sales and the positive effect on volume suggest that the underlying demand for life saving drugs has roughly a unit elasticity. This is consistent with the estimates for HIV drugs in Kremer and Snyder (2015, 2018) and Dubois et al. (2021), who study the impact of drug procurement systems on prices in low- and middle-income countries.[16]

In summary, the evidence indicates that entry into the patent pool promotes product

[15] With the available data, we cannot identify the effect of the MPP on the number of entrants for a given product-country. For about 70 percent of product-country-years in which entry occurs, there is only one active firm. A more thorough analysis of this issue will require richer data on market outcomes.

[16] The range of demand elasticity estimates in Dubois et al. (2021) vary between -0.73 and -0.97. Their analysis uses a wider set of molecules than the one in our data (including, but not limited to, HIV and tuberculosis) but only seven countries.

launches and adoption of essential medicines. The limitations of the IQVIA data do not allow us to pin down the effects with precision. Nonetheless, the results point to a potential gain in consumer welfare from the MPP, though the required product launches appear to take several years to materialize.

8.2 Discussion and potential welfare effects

We have shown that entry into the MPP sharply increases the likelihood of observing at least one licensee for the product-country. Our simple model explains this as being driven by a reduction in transaction costs. An alternative explanation, however, is that the patent pool may offer more favorable licensing terms than bilateral licenses. We do not have information on the terms and conditions of the bilateral deals in our sample to test this hypothesis directly. However, there are several reasons why we expect the differences in licensing terms not to be substantial. First, media statements by pharmaceutical companies after the implementation of bilateral agreements indicate that royalties are often low or zero.[17] Second, many of the bilateral deals in our sample focus on Sub-Saharan Africa or other low-income countries, which have limited potential to generate royalty income in any case. Finally, there is some anecdotal evidence that the MPP designed some of its downstream licenses using drug companies' bilateral contracts as templates.[18] In view of these considerations, our findings about the impact of the MPP appear more consistent with the transaction cost interpretation.

Our analysis also shows that the likelihood of a product launch in the country increases after entry into the MPP. However, the size of this effect on launch is much smaller, and more delayed, than the impact on licensing, which is consistent with the theoretical discussion in

[17] For example, the 2011 license between Bristol Myers Squibb and Matrix Laboratories for stavudine and didanosine in Sub-Saharan Africa is royalty free. The same is true for a number of Boehringer-Ingelheim's licenses of nevirapine in low-income countries.

[18] This led some advocacy groups, such as the Initiative for Medicines, Access, and Knowledge (I-MAK), to voice concerns after the 2011 MPP-Gilead agreement because it appeared too similar to existing Gilead's licenses. Source: www.i-mak.org/2011/10/11/implications-of-the-patent-pool-licenses-with-gilead-part-ii/

Section 4. To get a better sense of the relative size of the effects on licensing and launch, our baseline regression (column 1, Table 2) – evaluated at the means of covariates and the estimated fixed effects – implies that the probability of observing at least one license is 0.11 for product-countries that are not in the MPP, and 0.84 for those in the MPP. Using estimates from an unreported regression of launches on *Access,* we find that having one licensing deal translates into an actual launch with probability 0.62 for product-countries that are not in the pool and 0.12 for those covered by the MPP. Together, these estimates imply that, in country-products not covered by the pool, the probability of observing one launch is about 0.07 (= 0.11 x 0.62), but it is 0.10 (= 0.84 x 0.12) for product countries included in the MPP. In short, inclusion in the MPP increases the probability of licensing by 73 percentage points (from 0.11 to 0.84), but it increases the probability of observing an actual launch by only 3 percentage points (from 0.07 to 0.10). This finding has an important implication for empirical research on patent pools with bundled licensing, as it shows that focusing on licensing can be very misleading as to the impact of the pool on actual entry and diffusion.

An important caveat is that more than half of the MPP product-countries in our sample were included in the pool in the past five years. Product launches take several years, as commercialization requires setting up manufacturing and distribution facilities as well as obtaining WHO prequalification of the generic version of the drug. Thus, censoring may lead us to underestimate the impact of the MPP on launches in the baseline specification where we use a linear probability model. To address this issue, in Appendix A5 we analyze the link between MPP inclusion and product launches using hazard models. As predicted, we find larger effects in these specifications which allow for censoring. This provides further support for our conclusion that the MPP increases the likelihood of actual launches, not just licensing.

Finally, while bearing in mind the serious data limitations for our analysis of market outcomes, we provide a 'back of the envelope' calculation of the welfare gains from the MPP.

As explained earlier, our findings on sales and volume imply an underlying (roughly) unit elastic demand. This takes the form $p = A/q$, where A is the total sales revenue obtained in the market. When at least one unit of product is consumed, the corresponding total welfare is $W = A\log(q)$, which implies that an increase in quantity by z percent translates to a welfare gain of $Az/100$. To make this computation, we need to know the sales generated by a drug after it enters the pool and use our parameter estimates of the MPP impact on volume to compute the welfare generated by each drug licensed by the MPP. This computation is likely to be a substantial underestimate, since many of the countries in the MPP are not in the IQVIA sales data, and many of the MPP licenses are in our data for a very short timespan. Doing this computation on the available data, we estimate a welfare gain of roughly 27 million USD for the period 2010-18. By comparison, the total operating costs of the MPP for the period 2010-2015 was 22.9 million USD (Junejia et al., 2017). Even this lower-bound estimate suggests that the welfare gains from the MPP exceed the cost of the institution. However, a more complete welfare analysis requires richer data in terms of launched products and a longer time series on market outcomes.[19]

9 Concluding remarks

In this paper we examine how the Medicines Patent Pool affects licensing and launch of HIV and other essential drugs in low- and middle-income countries. There are three key empirical findings. First, inclusion in the pool is associated with a large increase in the probability of licensing. Second, this effect is heterogeneous - it is smaller in middle-income countries with large exposure to HIV (where bilateral deals are more likely). Finally, there is some evidence

[19] To perform this computation we identified the product-countries in which MPP licenses were in place for more than 5 years and for which positive sales were recorded by IQVIA. We used the average revenue generated in the sample years following the fourth after MPP inclusion as a proxy for the demand scale parameter, A. The increase in quantity is obtained by exponentiating the coefficient estimated for the 5th year after MPP inclusion in the regressions underlying Panel C in Figure 2 (61 percent), and we assume this increase in volume lasts until the patent expires in the focal country.

that the MPP increases not only licensing, but also the likelihood of launch and the quantity of these drugs sold in the market. However, the effects on launch and market outcomes are much smaller than on licensing, as a consequence of the geographical bundling of license contracts by the patent pool. This finding highlights that, in order to study the impact of such patent pools on technology diffusion, it is important to go beyond their impact on licensing which, by itself, is likely to overstate their impact. More broadly, our paper suggests the potential of pools to promote the diffusion of essential vaccines and other types of innovation in developing countries.

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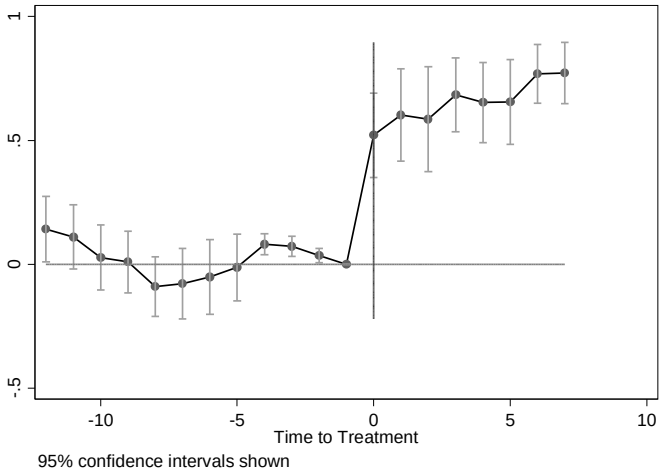
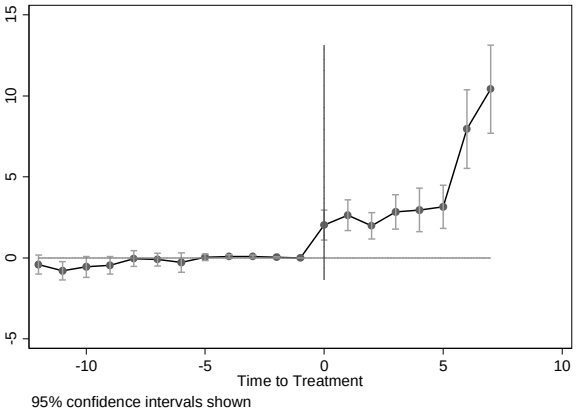
Figure 1: Dynamic Effects of MPP inclusion

Panel A – *Access* as dependent variable



NOTE: This figure plots the estimates of a regression in which the effect of the MPP is separately estimated for each year before and after inclusion. The figures plot the coefficients (and 95% confidence intervals) with the year before inclusion normalized to zero. Standard errors are clustered at the product and country level. The dependent variable *Access* is equal to 1 if the total number of licensing deals for the country product in year t is positive. The sample only includes products in the 2010 MPP priority list.

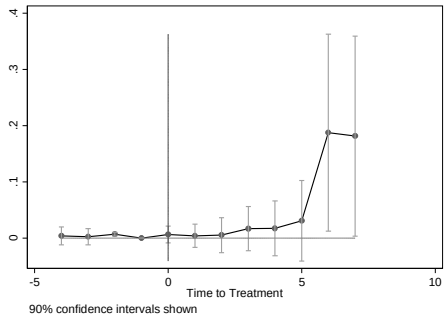
Panel B– *Deals* as dependent variable



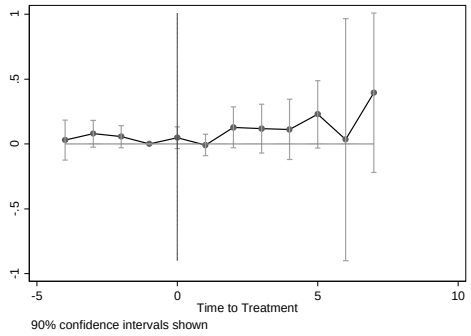
NOTE: This figure plots the estimates of a regression in which the effect of the MPP is separately estimated for each year before and after inclusion. The figures plot the coefficients (and 95% confidence intervals) with the year before inclusion normalized to zero. Standard errors are clustered at the product and country level. The dependent variable is equal to the total number of licensing deals for the country product in year t. The sample only includes products in the 2010 MPP priority list.

Figure 2: MPP and market outcomes

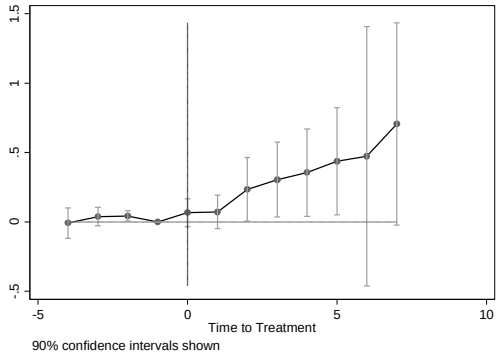
Panel A – Launch by one generic as dependent variable



Panel B – Log(Sales) as dependent variable



Panel C – Log(Volume) as dependent variable



NOTE: This figure plots the estimates of a regression in which the effect of the MPP is separately estimated for each year before and after inclusion. The figures plot the coefficients (and 90% confidence intervals) with the year before inclusion normalized to zero. Standard errors are clustered at the product and country level. The sample is the full IQVIA dataset. The dependent variable Launch by one generic is equal to 1 if at least one licensee has commercialized the drug in the country in year t. Sales are in US dollars and volume is in tablets.

Table 1 - Panel A: Summary Statistics

	obs.	mean	sd	min	max
Access	80,103	0.180	0.385	0	1
Deals	14,453	4.589	4.365	1	20
MPP sublicenses	14,453	1.408	2.801	0	17
Bilateral deals	14,453	3.181	3.609	0	13

Panel B: Mean comparisons for MPP inclusion

	obs.	Access	Deals
Product-countries never in MPP	65,886	0.133 (0.339)	0.481 (1.842)
MPP product-countries before entry	8,588	0.092 (0.290)	0.454 (1.857)
MPP product-countries after entry	5,629	0.870 (0.335)	5.454 (5.021)

NOTES: Unit of observation is product-country-year. In panel A the statistics for Deals, MPP sublicenses and Bilateral deals are restricted to the sample in which Access=1. In panel B standard deviations are in parentheses.

Table 2: MPP, access and licensing deals

	(1)	(2)	(3)	(4)	(5)	(6)
Dep. Var.	Access	Deals	Access	Deals	Access	Deals
MPP	0.663***	4.610***	0.603***	3.083***	0.588***	3.730***
	(0.054)	(0.779)	(0.062)	(0.615)	(0.052)	(0.526)
Sample	Full	Full	2010 priority list	2010 priority list	Full	Full
Year effects	YES	YES	YES	YES	YES	YES
Product-country effects	YES	YES	YES	YES	YES	YES
Product-year effects	NO	NO	NO	NO	YES	YES
Country-year effects	NO	NO	NO	NO	YES	YES
Observations	80101	80101	40534	40534	80052	80052

NOTES: standard errors clustered at the product and country level in parentheses. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$. Deals= total number of licensing deals for the country product in year t (includes MPP and non-MPP deals). Access=1 if Deals>0. MPP =1 if the product-country is included in an upstream MPP license. Columns 3 and 4 only include products in the 2010 priority list.

Table 3: Heterogeneous effects

	(1)	(2)	(3)	(4)
Dep. Var.	Access	Access	Access	Access
MPP	0.646***	0.646***	0.591***	0.650***
	(0.058)	(0.058)	(0.064)	(0.053)
MPP x High disease prevalence	-0.056	0.004	-0.018	0.027
	(0.039)	(0.033)	(0.047)	(0.028)
MPP x High disease prevalence x Middle income		-0.139***	-0.176***	-0.103**
		(0.041)	(0.037)	(0.048)
Year effects	YES	YES	YES	YES
Product-country effects	YES	YES	YES	YES
Sample	HIV products	HIV products	2010 Priority List	All Products
Observations	51613	51613	33444	72524

NOTES: robust standard errors clustered at the product and country level in parentheses. * p < 0.10, ** p < 0.05, *** p < 0.01. Access=1 if Deals>0. MPP =1 if the product-country is included in an upstream MPP license. High disease prevalence = countries in the top decile for number of people with disease related to the product in the year. Middle income=1 for countries classified by the World Bank as middle income. Models include direct effects for High disease burden and Middle income.

ONLINE APPENDIX – NOT FOR PUBLICATION for "Licensing Life-Saving Drugs for Developing Countries: Evidence from the Medicines Patent Pool"

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Appendix A1: Theoretical Model

A patentee owns two patents related to a pharmaceutical product, one covering country A and another for country B. A potential licensee is considering whether to license the patents and commercialize/launch the product. We denote the present value of the profits generated during patent protection in market j by R_j with $j \in \{A, B\}$. A launch in country j involves a sunk cost C_j, which includes the cost of securing regulatory approval in the target country and investment in distribution channels and marketing. If the patents are not included in a pool, the patentee and licensee bargain over a bilateral license that grants permission to launch in the countries. The cost of striking a license deal for one country is c, and $c + \Delta$ for two countries with $\Delta > 0$ and $c + \Delta \leq 2c$. If the patents are included in a pool, the licensee can only license the bundle (both countries) at a cost $\underline{c} \leq c + \Delta$.

The most natural interpretation of the parameters c, Δ and $\underline{c}$ is as transaction costs. These costs encompass the expenses that a licensee sustains to negotiate, draft and review a patent license contract. We assume that it costs more to negotiate a bilateral patent license contract for two countries than for only one country, i.e. $\Delta > 0$, as it involves patents in different jurisdictions and country-specific contractual provisions. The innocuous assumption that $\Delta \leq c$ accommodates economies of scale in bargaining. The assumption that $\underline{c} \leq c + \Delta$ implies that negotiating a two-country license with the pool is less expensive than the corresponding bilateral negotiation. In the context of the MPP, we expect $\underline{c}$ to be low relative to $c+\Delta$ because most aspects of the MPP license contracts are standardized and do not require negotiations. In other contexts, where pool licenses are more tailored toward the specific licensees, the difference between $\underline{c}$ and $c + \Delta$ may be much smaller.

The timing of the game is as follows. In period 0 the licensee decides whether to license the patents. In period 1 the licensee decides whether to pay the cost C_j and enter in each of the countries for which a patent license is in place. Consider first the case where patents are licensed bilaterally. At time 1 the licensee launches in country j only if $\Pi_j = R_j - C_j \geq 0$. At time 0 the licensee will obtain a license for both countries only if the following two conditions are met:

$$\begin{aligned} \Pi_A + \Pi_B - c - \Delta &\geq 0 \\ \Pi_A + \Pi_B - c - \Delta &\geq \max_j \Pi_j - c. \end{aligned}$$

These conditions require that the expected profits of joint licensing are positive and greater

than the profits from licensing in only one country. If these conditions are not satisfied, the licensee will license only one patent and license in the country with the highest Π_j as long as $\max_j \Pi_j - c > 0$. There will be no license and launch in any country if $\max_j \Pi_j - c < 0$.

Now consider a patent pool with bundled licensing for both countries at cost $\underline{c}$. At stage 1, commercialization in country j will take place only if $\Pi_j \geq 0$. Licensing and commercialization in both countries is optimal if the following conditions are satisfied:

$$\begin{aligned} \Pi_A + \Pi_B - \underline{c} &\geq 0 \\ \Pi_A + \Pi_B - \underline{c} &\geq \max_j \Pi_j - \underline{c}. \end{aligned}$$

These conditions are the same as the bilateral licensing case, except that the licensing cost is now $\underline{c}$ rather than c or $c + \Delta$.

Discussion and extensions

A comparison of the conditions required to have licensing and commercialization in both countries with and without pool yields two basic empirical predictions. First, a geographic patent pool has an ambiguous effect on the total amount of licensing relative to bilateral contracting. When both Π_A and Π_B are large relative to $c + \Delta$, creating a patent pool has no effect on licensing as both patents would be licensed with or without a pool. When the profits that can be obtained in the two countries are asymmetric, the presence of a pool may increase or decrease the number of patents licensed. To see this, consider the case where $\Pi_A < 0$ and $\Pi_B > c$. In the case of a bilateral deal, the firm will only choose to license patent B. With a patent pool, the firm enters a license for both countries if $\Pi_B > \underline{c}$ and for no country if $\Pi_B \leq \underline{c}$. We expect $\underline{c}$ to be relatively close to c for the MPP, and thus that the MPP should increase licensing.

The second implication of our model is that, in a patent pool with bundled licensing, the correlation between patent licensing and drug launch may be low. With costly bilateral licensing, the generic firm is expected to launch the product in any country for which it has a license. With a pool, the firm is constrained to license a bundle of countries, in some of which launch may not be profitable. This observation highlights an important distinction between patent pools that license complementary technological components and pools like the MPP which bundle different geographical markets for a given technology. In the first case, one would expect that most, if not all, the licensed patents would be used by the licensee to ensure compliance with the technology standard. This does not apply in pools which serve as

clearinghouses for international market access. As a consequence, empirical studies that rely on licensing data alone may over-estimate the effect of a pool on actual commercialisation.

Having examined the main implications of our analytical framework, we now discuss some of the key assumptions of the model and the robustness of the empirical predictions to a variety of alternative specifications and generalizations.

Coexistence of MPP and bilateral licensing. The baseline model compares the licensing through a pool versus direct bilateral licensing. In practice, the MPP does not restrict the ability of participating drug companies to engage also in bilateral licensing. When $\underline{c}$ is low, as in our empirical context, the coexistence of the pool and bilateral licensing would not change the prediction that a patent is more likely to be licensed when it is included in the pool. This is because the presence of a low-cost geographically-bundled license is likely to increase the incentives of the downstream firm to license the patent. However, in a more general setting, the formation of a geographic pool may reduce overall licensing activity. This can occur when negotiations are costly ($\underline{c}$ is close to $c + \Delta$) and when the pool does not permit independent licensing by patentees. Thus, the impact of a geographic pool depends on the particular costs involved and the restrictions it may impose on participating patentees. This is consistent with Lerner and Tirole (2004) who show that rules allowing independent licensing affects the participation of firms and the welfare impact of technology patent pools.

Royalties and differential licensing profits. For simplicity, our model assumed royalty free licensing contracts. This is a feature of the majority of MPP licenses and the evidence we discuss in the paper suggests that this is also common in bilateral deals for low and lower middle income countries. The absence of licensing payments is consistent with theoretical frameworks where the licensee has full bargaining power, or where the patentee extracts benefits from CSR and virtue-signaling. One can relax this assumption and include royalties or other licensing payments by interpreting Π_j as net of these expenditures. When licensing terms differ between bilateral and pool licenses, we can denote the downstream commercialization profits (net of royalties) as Π_j^L and Π_j^P respectively, with $j \in \{A, B\}$. In the MPP case one would expect $\Pi_j^L < \Pi_j^P$, which is consistent with the idea that the pool charges lower royalties relative to the licensee or that the pool provides licensees some additional support to commercialization through other channels.[1]

[1] In more general settings one can also have $\Pi_j^L > \Pi_j^P$. This can emerge when bilateral licensing involves transfer of knowledge not codified in patent documents, or it includes some form of commercialization support by the patentee.

It is straightforward to show that the pool has a theoretically ambiguous effect on licensing and that there is a stronger correlation between licensing and commercialization when the deal is bilateral in this extended setting, as in the baseline model. A key difference, though, is that now there are two effects at play. First, as in our baseline model, geographic bundling may affect licensing because transaction costs become equal to $\underline{c}$ rather than c or $c+\Delta$. Second, the licensee's incentives may also change because commercialization profits are now different between pool and bilateral licensing, i.e. $\Pi_j^L \neq \Pi_j^P$.

As we previously discussed, the standardized nature of MPP licenses suggests that $\underline{c}$ is very close to c in our empirical setting, and thus we should expect the MPP to increase the likelihood of licensing. If MPP royalties are also substantially lower than those charged in bilateral licenses, the resulting larger commercialization profits would also induce greater licensing incentives. This is analogous to the pool serving as a cap on royalties, as discussed by Rey and Tirole (2019) in the context of regulatory price caps. In the paper we provide additional discussion of this issue and show that the limited information available on the terms and conditions of the bilateral deals in our sample suggests that the differences between MPP and bilateral licensing terms do not appear substantial.

Multiple licensees. Our baseline model assumes that there is only one downstream licensee. In the presence of multiple licensees, outcomes from bilateral and pool licensing may differ if the pool does not allow exclusive contracts. This is the case in our empirical setting, where the MPP only offers non-exclusive licenses.

Consider an extension of our model in which there are two identical downstream licensees, and both bilateral and pool licenses are royalty free. If markets A and B are large enough to generate profits for two firms, one would expect licensing and entry by both downstream firms in the context of a patent pool. In the case of bilateral licensing, depending on the assumptions about the bargaining protocol between the upstream patentee and the downstream licensees, we may obtain an equilibrium with exclusive licensing, where entry in each market is restricted to only one firm. In this case, we would observe similar outcomes between pool and bilateral licensing at the extensive margin (the presence of at least one licensee), but different outcomes at the intensive margin (the number of licensees). This difference may impact sales and welfare, an issue that we discuss and examine empirically in the paper.

When the downstream markets cannot generate enough profits to accommodate two firms, a non-exclusive geographic patent pool may create a potential coordination problem. To

see this, consider the case in which markets A and B are natural monopolies. With bilateral licenses, the patentee may restrict entry in each country to only one licensee, but this cannot be done when access to both countries is offered through a bundled license by a pool. In this case downstream firms may be reluctant to license from the pool and launch due to the risk of uncoordinated, excessive entry.

To formalize this point, let us indicate with $\Pi_j(1)$ the profits that an exclusive licensee can extract from launching the drug in market j, and with $\Pi_j(2)$ the profits when two firms launch the product, with $j \in \{A, B\}$. We consider the case of symmetric natural monopolies in which $\Pi_A(2) = \Pi_B(2) = \Pi(2) < 0$ and $\Pi_A(1) = \Pi_B(1) = \Pi(1) > 0$ and assume that licenses are royalty free as in our baseline model. In the bilateral license case, the patentee offers an exclusive license to only one of the downstream licensees in each market, and thus avoids coordination failure.

Consider now the case of a patent pool which only offers non-exclusive licenses to the full bundle. We are going to solve the model by backward induction. First, we examine the launch choices of downstream firms who have obtained a patent license. We then study the decision to enter a licensing deal.

When a firm has obtained a bundled license from the pool, the transaction cost $\underline{c}$ is sunk. If a firm is the only one to have signed a pool license, its profits are maximized launching in both countries and obtaining $2\Pi(1)$. When two firms have a pool license, the profits from launching are summarized by the matrix below, where A (B) indicates the decision to launch only in country A (B) and AB captures the decision to launch in both markets. We indicate with 0 the strategy of not entering any market. The first payoff in each cell captures the commercialization profits of the raw player and the second payoff captures the commercialization profits of the column player. These profits do not include the sunk transaction costs.

	A	B	AB	0
A	$\Pi(2), \Pi(2)$	$\Pi(1), \Pi(1)$	$\Pi(2), \Pi(2) + \Pi(1)$	$\Pi(1), 0$
B	$\Pi(1), \Pi(1)$	$\Pi(2), \Pi(2)$	$\Pi(2), \Pi(1) + \Pi(2)$	$\Pi(1), 0$
AB	$\Pi(2) + \Pi(1), \Pi(2)$	$\Pi(1) + \Pi(2), \Pi(2)$	$2\Pi(2), 2\Pi(2)$	$2\Pi(1), 0$
0	$0, \Pi(1)$	$0, \Pi(1)$	$0, 2\Pi(1)$	$0, 0$

Entry game with two licensees

There are four asymmetric pure strategy Nash equilibria in which only one of the two licensees enters each market. The literature on economic coordination suggests that these

asymmetric equilibria are unconvincing in a symmetric setting like ours. For example, Crawford and Haller (1990) argue that it is inappropriate to focus on asymmetric pure-strategy equilibria because it is not clear how players find one of those equilibria. Therefore, we follow Bolton and Farrell (1990) and focus on the symmetric mixed strategy equilibrium in which each player enters only market A with probability p, only market B with probability g, both A and B with probability z, and enters no market with probability $1-p-g-z$. The equilibrium is obtained solving for the probabilities which equate the payoffs across the four entry modes. This leads to

$$\begin{aligned} p &= g = \frac{\Pi(1)}{\Pi(1)-\Pi(2)} - z \\ 1-p-g-z &= z - \frac{\Pi(1)+\Pi(2)}{\Pi(1)-\Pi(2)} \end{aligned}$$

which characterize the set of symmetric mixed strategy Nash equilibria of the entry game. There is not a unique equilibrium as there are multiple mixtures of entry combinations that generate the same payoffs. Nonetheless, in all the equilibrium strategies the expected payoff of the player is zero, as the mixed strategy renders players indifferent across the entry options which include the zero-profit no-entry action.

Having solved the entry game which emerges when players obtain a bundled license, we can now consider the licensing stage in which each player decides whether to obtain a license from the pool or not. If a player decides not to obtain a pool license its payoff is zero. The payoff obtained if the firm signs a pool license but the other firm does not is $2\Pi(1) - \underline{c}$, as the licensee is a monopolist in both markets. When both firms enter a bundled license, the expected payoff is $-\underline{c}$ because in this case the firms play one of the mixed strategies equilibria of the game described in the matrix above, which leads to zero expected product market profits. This implies that the licensing game can be summarized by the following table

	license	not-license
license	$-\underline{c}, -\underline{c}$	$2\Pi(1) - \underline{c}, 0$
not-license	$0, 2\Pi(1) - \underline{c}$	$0, 0$

Licensing game with two firms

It is easy to see that this licensing game has a unique mixed strategy Nash equilibrium in which each firm obtains a pool license with probability $e^* = (2\Pi(1) - \underline{c})/2\Pi(1)$. Because $e^* < 1$ for any $\underline{c} > 0$, in equilibrium there is a positive probability that neither firm takes a license.

This does not occur in the bilateral license case in which the upstream patentee can use exclusive deals to coordinate the outcomes toward the asymmetric (pure strategy) Nash equilibrium in which there is only one firm operating in each country. In principle, a patent pool can mitigate the coordination failure by providing information to the players that may prevent excessive entry. It is interesting to note, based on conversation with MPP executives, that the MPP collects data on where licensees are planning to launch (for example on where they file for commercialization to local regulatory authorities) and provide it to other companies in an anonymized manner.

Appendix A2: Geographical scope of MPP contracts

To provide additional information on the geographical scope of the MPP agreements, we exploit information on the countries reached by the 47 products in our sample which are licensed by the MPP. The average MPP license covers 24 of our sample countries, with a median of 9 and standard deviation equal to 25.98. To provide a better sense of the size of the coverage, we also considered the non-MPP bilateral licenses that are related to the same set of products. The average geographical scope of bilateral licenses is 15 sample countries, with a median of 2 and standard deviation equal to 23.69.

In panel A of Appendix Figure A1 we plot the cumulative distribution of geographical scope for the two group of licenses. The graph shows quite sharply that the MPP distribution stochastically dominates the distribution for bilateral contracts. While Figure A1 illustrates that the scope of MPP contracts tends to be greater than the one of the bilateral deals, one point needs to be made. Comparing the number of countries covered in MPP licenses and the number of countries in bilateral deals may actually under-estimate the extra-geographic coverage provided by MPP deals relative to the bilateral deals. To see this, consider a product for which the MPP license covers 24 countries and the bilateral license covers 15 countries. The difference in geographical coverage (9 countries) captures the extra-coverage of the MPP countries only in the case in which all the countries included in the bilateral license are also included in the MPP licenses. In the case in which the MPP license does not include all the country of the bilateral deal, the extra-coverage provided by the MPP is actually larger than 9 countries. In the extreme case in which there is no overlap between the countries in the MPP license and those in the bilateral deal, the extra-coverage provided by the MPP is 25 countries, which is much larger than the one suggested from a simple comparison of the

number of countries covered.

To consider this issue, we computed the extra-geographical coverage for MPP licenses relative to bilateral deals, examining the specific countries covered. On average, MPP licenses include 9.9 countries in excess of the bilateral deals covering the same product. The median is 3 countries and the standard deviation is 16.8. The variation is substantial with almost 20 percent of the deals not providing extra-geographical coverage over the corresponding bilateral deals. About 25 percent of the MPP deals cover more than 10 countries relative to the corresponding bilateral license.

We conclude the analysis unbundling the extra-coverage between low-income, lower middle income and upper middle-income countries. Panel B of Figure A1 shows that the extra geographical coverage provided by the MPP appears concentrated on the lower middle-income countries. The average MPP deals includes 5 lower middle-income countries that are not present in the corresponding bilateral deal, but only about 2 low-income and upper middle-income countries. We also weight each country by its population in 2010. The difference is even more striking in this case, as the extra lower-middle income countries reach on average more than 600 million people, whereas the extra low-income and upper middle-income countries appear much smaller in size.

Appendix A3: Robustness of the baseline findings

In this section we describe a series of robustness checks on our main finding of positive effect of MPP inclusion on licensing.

Additional analysis of the MPP priority list

In Table 2 we have shown that our findings are robust to using the drugs for which negotiations failed as a counterfactual for what would have happened to the drug that entered the pool in the absence of pool inclusion. Specifically, we exploited the MPP 2010 priority list. Under the assumption that success/failure in the negotiation for these drugs was quasi-random – i.e. not related to unobservable drivers of future licensing – focusing on this priority list would alleviate concerns related to selection into the MPP.

One concern with this analysis is that there could be confounding, time-varying unobservables that are correlated both with success of the negotiations and with the number of downstream licensing deals executed. For example, during the negotiations new information

about the potential market may be revealed that changes the interest of the pool in the medicine as well as subsequent bilateral deals. Discussions with MPP executives identified one such case, Etravirine whose product-country observations account for roughly 6 percent of our sample. During the negotiation new market information was revealed that the medicine would only have a niche market, and led the MPP to drop its negotiation with the patentee. This would induce an upward bias in the estimated MPP effect. In columns 1 and 2 of Table A1 we drop this drug from our priority list sample and re-estimate the baseline model. The point estimates are indeed smaller, but the magnitude of the change is small. In panel C of Figure A2 we show that the dynamic effects of the MPP are also similar excluding this drug from the sample.

An additional concern is that positive shocks to the product's profitability may lead patentees to keep the market for themselves and not license the product neither through the MPP or bilateral deals. This would lead us to over-estimate the effect of MPP, as negotiations that break down will be associated to products with less bilateral deals. Our baseline estimates are robust to controlling for commercialization activity by the original patentee, suggesting that this mechanism is not generating bias in our estimates.

We also examined differences in sales for the treated and control groups medicines in the priority list. Because of the limited number of countries in the IQVIA data, the analysis relies on a much smaller sample than the analysis of licensing. Specifically, focusing on the medicines in the priority list means restricting the licensing analysis to a sample of 40,536 observations and the sales analysis to a sample of only 12,239 (which is about half of the observations used in our analysis of market outcomes). Despite the data limitations, the results support the parallel trends assumption– the treatment and control groups are similar in terms of sales before inclusion in the MPP. A simple comparison of means shows that, in the period before 2010, sales were slightly higher for product-countries that are never included in the MPP but the difference is not statistically significant (p-value=0.35). We also confirm this result with event study regressions similar to those performed in the licensing analysis. where we observe no pre-trend difference between treatment and control groups before MPP inclusion (see Figure A4).

Alternative econometric specifications and dependent variables

Appendix Table A1 shows that the relationship between MPP and deals is robust to using alternative econometric specifications. In columns 5 and 6 we re-estimate the baseline model

using Poisson and Negative Binomial specifications, and confirm the strong and statistically significant positive correlation. The estimated coefficient in the Poisson model implies that product-country pairs in the MPP experience 370 percent more deals than their non-MPP counterparts.[2]

The dependent variables used in our baseline analysis are stock variables based on the number of licensing deals that are in place in a specific product-country-year. A cumulative measure is preferable in our setting since licensing deals are long lasting, and the total number of generic firms with a license agreement in place captures more directly the potential supply and competition in the country. In unreported regressions we redid the analysis with flow versions of the dependent variables, and the results are in line with the baseline specification – the flow of licensing deals sharply increases after a product-country enters the MPP.

Extension of existing MPP licenses

Part of the effect we estimate in Table 2 is mechanically due to extension of existing upstream deals to new countries. When the MPP and upstream drug company agree to revise an existing license to include additional countries, the existing sub-licensees automatically gain immediate access to the newly listed countries. To remove this effect, Appendix Table A2 re-estimates columns 1 and 2 of Table 2 using only the countries listed in the first upstream deal between the MPP and the upstream drug company and dropping the product-country combinations that enter the MPP through a revision of an existing deal. The coefficients in these regressions are only slightly lower than those estimated in Table 2, indicating that the treatment effect is not driven by a broadening of the existing sub-licenses.

Because of missing information in our data, some of the number of bilateral deals in our sample had to be imputed. Column 3 of Appendix Table A2 takes this into account by adding a dummy for observations in which the number of deals was not precisely measured and by dropping these observations from the sample. Overall this has no impact on our estimates, indicating measurement error associated with these imputed deals is not a problem.

[2] We also confirmed the result using the logarithm of the number of deals (plus one) as dependent variable. The results are also robust to two alternative corrections of the dependent variable with values of zero in the log specification – specifically, we add 0.01 instead of 1 to the zero value, and include a dummy control for observations with zero deals. We also re-estimated the specification with *Access* as dependent variable using a proportional hazard survival model with an exponential distribution. We find that the effect of the MPP is a very large increase in the hazard of *Access,* confirming our finding with the OLS specification.

Molecule level analysis

Finally, our analysis defined products by a molecule-strength combination, even though pharmaceutical patents often cover an entire molecule. There are two reasons why this is the more appropriate level of analysis in our setting, rather than the molecule level. First, many of the licenses in our data only cover a subset of the products related to a molecule. This is particularly the case for licenses that focus on pediatric or adult formulations. For example, the MPP licenses on the pediatric formulations of abacavir includes the 60mg but not the 300mg version of the product. Second, several products in our sample are combinations of multiple compounds and are protected both by molecule patents and patents on combination therapies and layered tablets. Nonetheless, in order to confirm that our results are not driven by the disaggregated nature of the data, we re-estimate our baseline regressions using data at the molecule-country level. The results, reported in columns 5 and 6 of Appendix Table A2 are very similar to those of our baseline model.[3]

Fuzzy regression discontinuity design

To address endogeneity of MPP countries we exploit the fact that the MPP targets countries in the low- or lower middle-income bracket. This allows us to implement a fuzzy regression discontinuity design. This approach provides a more convincing counter-factual for countries included in the MPP, but it has the disadvantage it relies on local cross-sectional variation and thus is based on a much smaller sample.

Discussions with MPP executives indicate that the pool considers a variety of factors when negotiating the geographical scope of a deal. One prominent element is the income level of the country and special attention is given to the income groupings provided by the World Bank. Each year the World Bank classifies countries into income categories distinguishing between low-income, lower middle-income, upper middle-income and high-income.[4] The mission of the

[3] In these regressions we re-define the MPP dummy as equal to one if at least one product related to the molecule-country is included in an MPP license, and measure Deals as the maximum number of licensees across the products related to a molecule-country. In Appendix Table A2 we drop product combinations, and cluster standard errors at the molecule-country level. Results are similar when we treat each combination as if it was a separate molecule or when we cluster the standard errors at the molecule level.

[4] This classification exploits thresholds of gross national income (GNI) per-capita calculated using the World Bank Atlas method. For example, in 2018 low-income economies were defined as those with a GNI per capita of $1,025 or less; lower middle-income economies are those with a GNI per capita between $1,026 and $3,995; upper middle-income economies are those with a GNI per capita between $3,996 and $12,375; high-income economies are those with a GNI per capita of $12,376 or more.

MPP, as stated on their web-page, is to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries.

High-income countries are typically excluded from MPP deals. The distinction between lower and upper middle-income plays an important role. The typical upstream MPP license includes a large number of lower middle-income countries but only a handful, if any, of upper middle-income countries. This is both because drug companies see greater potential for bilateral deals for the upper middle-income group (e.g. Brazil or China) and because the MPP itself has less interest in such countries (Branigan, 2018). We confirmed this directly with MPP executives, who reported that companies often use the upper middle-income thresholds as a key criterion for agreeing whether to include a country into the upstream license.

Panel A of Figure A3 illustrates how the World Bank classification status affects the likelihood of entering the MPP. To construct this figure, we focus on drugs that enter the MPP during our sample period and identify countries that were within \$2,205 below and \$3,195 above the upper middle-income threshold in the year in which the drug joined the pool. The difference in the likelihood of inclusion in the pool is striking and significant at the 0.01 level. About 67 percent of the product-country dyads related to lower middle-income countries are included in the pool, whereas only 35 percent of those in upper middle-income bracket enter the MPP.

This evidence motivates a fuzzy regression discontinuity design where we use a dummy for whether the country is below or above the upper middle-income threshold as an instrument for inclusion in the MPP. The IV estimator captures the local average treatment effect for the sub-set of countries for which inclusion in the MPP is affected by the instrument, under the exclusion restriction that the World Bank classification does not affect licensing negotiations directly -i.e., through channels other than the MPP.

To implement the fuzzy RD design, we re-shape our dataset as a cross-section and estimate the following specification:

$$Y_{p,c} = \alpha + \beta MPP_{p,c} + Entry\_year_p + z_{p,c} + \varepsilon_{p,c} \tag{1}$$

The unit of observation is a product-country. The dependent variable is the total number of licensing deals in a time widow after the inclusion in the pool. The term $Entry\_year_p$ captures any macroeconomic effect in the year the product enters the pool. The term $z_{p,c}$ captures the running variable in our specifications. This variable is defined as the difference between the GNI per-capita and the threshold used by the World Bank to classify countries as upper middle-

income in the year of the negotiation. We allow the marginal effect of the running variable to differ for GNI levels below above the thresholds. We use a first order polynomial. Results are robust to using higher order polynomials, but Gelman and Imbens (2019) warn against using higher order polynomials when higher order coefficients are not significant.

We instrument MPP with the World Bank status of the country at the time of inclusion of the product in the MPP. The sample only includes products that enter the MPP by 2018. A cross-sectional dataset is required because the IV does not vary over time for a product-country. The focus on products that enter the MPP is required because the instrument is not defined for products that are not included in the MPP.[5] We estimate equation (1) on the sub-sample of product-countries for which countries had GNI per-capita within a small window around the World Bank upper middle-income threshold at the time of inclusion of the product in the MPP.

More precisely, in our setting the probability of inclusion in the MPP changes once the GNI per-capita of the country, $z_{p,c}$, crosses the World Bank upper middle-income threshold, z_0:

$$\lim_{\delta \to 0} \Pr(MPP = 1 | z_{p,c} = z_0 + \delta) \neq \lim_{\delta \to 0} \Pr(MPP = 1 | z_{p,c} = z_0 - \delta),$$

and it is consistent with the assumption that the potential MPP status is monotonic in X in some small neighborhood around x_0. This allows us to interpret the ratio of the change in the regression of the outcome on the World Bank status to the change in the regression of the MPP indicator on the World Bank status as an average causal effect of the MPP. Formally, the estimand is

$$\frac{\lim_{\delta \to 0} E(Y | z_{p,c} = z_0 + \delta) - \lim_{\delta \to 0} E(Y | z_{p,c} = z_0 - \delta)}{\lim_{\delta \to 0} E(MPP | z_{p,c} = z_0 + \delta) - \lim_{\delta \to 0} E(MPP | z_{p,c} = z_0 - \delta)}.$$

This is just the Wald estimator of the treatment effect with instrumental variables (Lee and Lemieux, 2010). Panel B of Figure A3 provides a graphical representation of the discontinuity when the running variable crosses zero using a linear fit. The plot uses bins constructed with the integrated mean-squared error of the local means estimator, which trades off local fit with variability within bins. The figure confirms the idea that the likelihood of inclusion in the MPP is lower for countries classified by the World Bank as upper-middle income relative to those classified as lower-middle income. More importantly, there appears to be a discontinuity in the

[5] We also restrict attention to the first negotiated deal, dropping country-product dyads that are included in the sample after a re-negotiated deal. Results are similar if we include these dyads.

estimated line once the running variable crosses the zero threshold, which supports the idea of using a RDD analysis.

To estimate the fuzzy RDD model, we need to specify the sample window around the threshold. Our main sub-sample consists of the sample with a GNI per-capita between $2,205 below and $3,195 above the World Bank threshold (which consists of 50 percent of the product-country dyads involving middle-income countries on each side of the upper middle-income threshold). This includes 602 observations.

Column 1 in Appendix Table A3 provides the OLS estimate of (1) in this sub-sample. Despite the much smaller sample size, the point estimates confirm the findings in the baseline specification – the MPP is associated with an increase of 5.3 licensing deals in the 3-year window that follows inclusion in the pool.

Turning to the IV estimation, in column 2 we report the first stage regression which confirms a strong negative correlation between the upper middle-income status of the country and inclusion in the MPP. Column 3 presents the parameter estimates using the World bank threshold as the instrument for MPP inclusion. The point estimate of the coefficient on MPP is about 60% larger than the OLS estimate, but the difference is not statistically significant.

One might be concerned that upper middle-income status may affect licensing negotiations through channels other than the MPP (violating the exclusion restriction). The main candidate is financing by the Global Fund (GF) a large international organization which supports programs targeted at AIDS, tuberculosis and malaria. Eligibility to receive GF financing is driven by a variety of factors, including World Bank income status. While all low- and lower middle-income countries are eligible, not all upper middle-income countries are eligible. To check whether our estimated MPP effect is affected by changes in GF financing eligibility, we collect information provided in the GF web-site and re-estimate the IV specification where we include a control for the eligibility of the country for GF financing around the time the drug entered the MPP. The coefficient on the (instrumented) MPP variable is essentially identical to the one in column 3, lending credence to the exclusion restriction.

Appendix A4: Other dimensions of heterogeneity

We also explored two additional sources of heterogeneity. First, we examine whether the effect may be driven by the products of a handful of large pharmaceutical firms by re-estimating the baseline where we drop (one at a time) each of the three largest pharmaceutical companies in

our sample (accounting for 52 percent of the sample) – Gilead, ViiV and Janssen. Unreported results shows that our findings are robust to dropping each of these players. The largest change occurs when we drop Gilead, where the estimated coefficient is about 20 percent lower than the one in the full sample, but still large and statistically significant.[6]

Second, we examined whether the effect of the MPP on licensing is stronger for products relying on a combination of compounds ("drug cocktails") relative to single compound products. About 40 percent of the products in our sample involve combinations of multiple compounds. If the compounds are owned by different patentees, bilateral bargaining failure is more likely in those cases, so being covered in the pool would have a larger impact. The estimated impact of the MPP on *Access* is 7.3% larger for combination products, and 15.4% larger when we use *Deals* as the dependent variable and the differences are statistically significant.[7] This points to some bargaining failure but the difference is modest. The explanation for this result is that many combinations in our sample involve compounds licensed by the *same* company (e.g., many cocktails mix subsets of tenofovir, emtricitabine, cobicistat, and elvitegravir, all licensed by Gilead). Other combinations are a mix between a patented compound and older compounds no longer subject to patent protection (such as abacavir/lamivudine or dolutegravir/lamivudine). These features make negotiations over combinations quite similar to those related to one compound products.

Appendix A5: Additional Robustness of the Market Outcomes Analysis

More than half of the MPP product-countries in our sample were included in the pool in the last five years of our sample. We showed that the increase in licensing after entering the MPP is fast, most of it occurring within a year or two. However, censoring is more likely to be serious for launches. The MPP website and publications indicate that the time required

[6] Our results are also robust to a specification which includes firm-year effects, which capture time-varying, firm-level unobservables. We also examined how upstream drug firms react to inclusion of their patents in the MPP in terms of their bilateral licensing activity. The bilateral deals of Gilead appear to react positively to MPP inclusion. For all other firms, the effect of MPP on bilateral deals is small, negative and, in most specifications, statistically insignificant. This suggests that the pool had a differential effect on the licensing strategies of upstream drug companies. A detailed examination of this issue is outside the scope of the paper but a potentially fruitful direction for future research.

[7] Using *Access* as the dependent variable, the split-sample estimates (standard errors) are 0.688 (0.012) for combinations and 0.641 (0.016) for single compound products. For *Deals,* the coefficients are 4.938 (0.152) and 4.280 (0.161).

for licensees to launch the product and start sales, after a patent deal is in place, may be substantial, as commercialization requires setting up manufacturing and distribution facilities as well as obtaining WHO prequalification of the generic version of the drug. An example is the drug Dolutegravir (DGT) which entered the pool in April 2014 and is highlighted by the MPP as one of the medicines with relatively fast penetration in developing countries. A number of licensees signed up a downstream agreement shortly after MPP inclusion – e.g., Cipla in June 2014 and Mylan in July 2014. MPP documents report that these two companies applied for prequalification of generic DTG in November 2016 and that no shipment to developing countries took place before the spring of 2017.

Ideally, one would want a longer time window for a full examination of launches, but that is not available. To address this issue, in Appendix Table A4 we estimate a proportional hazard model with an exponential distribution for the probability of "launch" (at least one launch) for the product-country dyad, either through a bilateral license or the MPP. We get broadly similar results using the more flexible Weibull distribution. We estimate a variety of specifications: including only the dummy for inclusion in the MPP, using product and country fixed effects, and product fixed effects plus the time-varying demographic controls (GDP per capita and population). In all cases standard errors are clustered at the product-country dyad level.

The estimates show that entry into the MPP raises the hazard rate of launch by about 40% with only the MPP dummy, 62% with product and country fixed effects, and as much as 188% with product fixed effects and country demographics. With the linear specification, we found that the MPP increased the probability of launch by about 42%. These results confirm the idea that MPP substantially increases the likelihood of actual launches, not just licensing, and that this result is even larger when we adjust for censoring.

IQVIA also provided us with partial data on product launches for seven additional countries, all former members of the Commonwealth of Independent States (CIS): Armenia, Azerbaijan, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, and Uzbekistan. For these countries we do not have information on volume or sales. Moreover, information on launches is aggregated at the molecule level (i.e., not by dosage) and it is available only for a subset of molecules accounting for about 55 percent of the products in our sample. We re-estimated Figures 2 at the more aggregate molecule level, including these countries but restricted to the subset of available compounds. The unreported results are broadly consistent with the findings in the

paper.

References

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[2] Crawford, Vincent, and Haller, Hans (1990) "Learning How to Cooperate," *Econometrica* 58: 571-595

[3] Gelman, Andrew, and Guido Imbens (2019) "Why high-order polynomials should not be used in regression discontinuity designs." *Journal of Business & Economic Statistics* 37: 447-456

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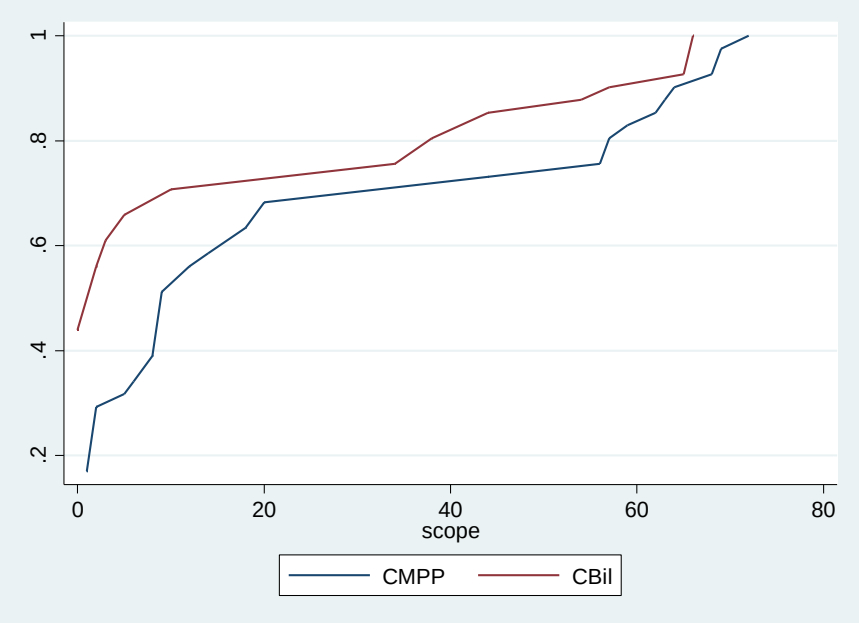
[5] Lerner, Josh and Jean Tirole (2004) "Efficient patent pools," *American Economic Review* 94: 691-711

[6] Rey, Patrick, and Jean Tirole (2019) "Price caps as welfare-enhancing coopetition" *Journal of Political Economy,* 127: 3018-3069.

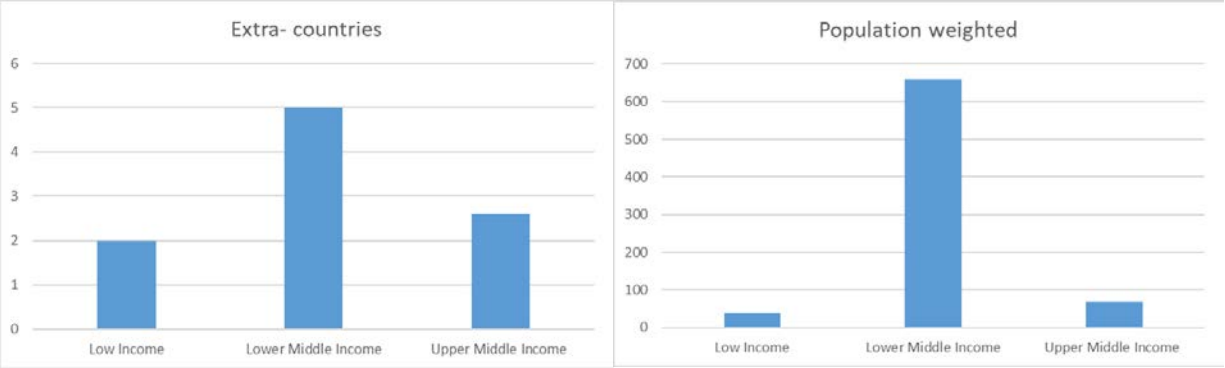
Appendix Figure A1: Geographical scope

Panel A- Cumulative distribution of the geographical scope of the contracts



NOTE: The figure plots the cumulative distribution of the number of sample countries covered by MPP licenses (CMPP) and bilateral licenses (CBil). The sample encompasses the 47 products included in the MPP during our sample period.

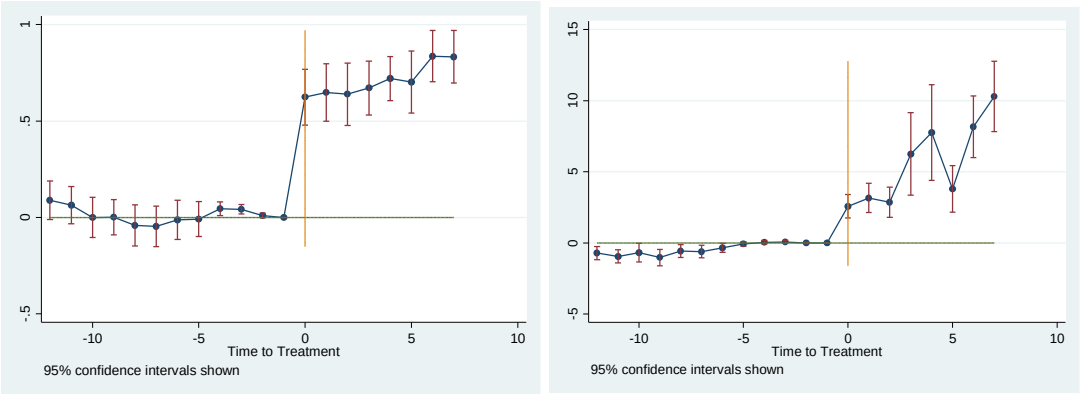
Panel B- Extra countries



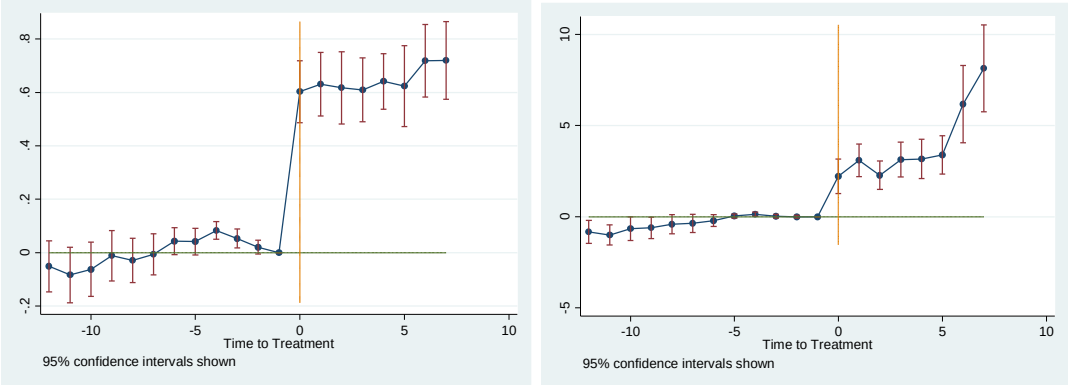
NOTE: The histograms capture the average number of sample countries covered by MPP licenses which are not present in the corresponding bilateral licenses. Population weighted figures are in millions.

Appendix Figure A2: Dynamic effects of the MPP on Access and Deals

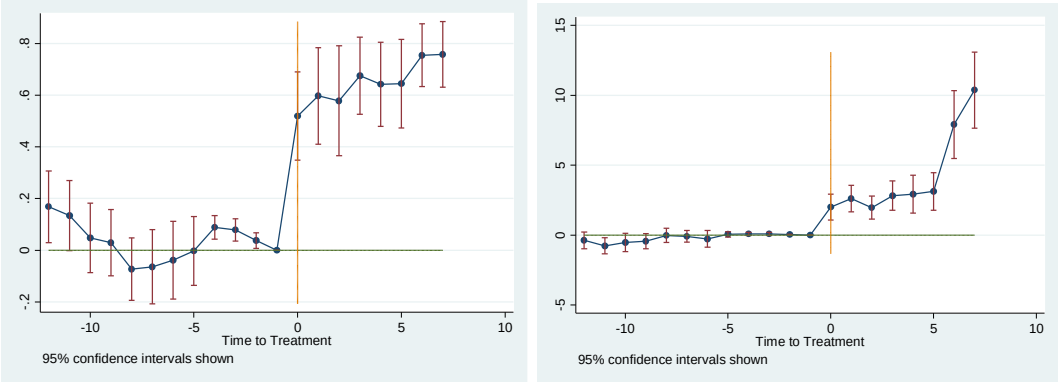
Panel A- Full sample



Panel B– Full sample with product-year and country-year effects



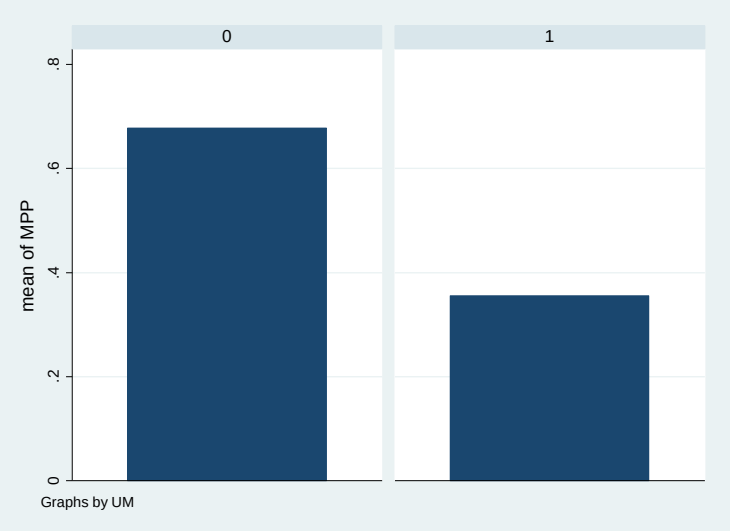
PANEL C – Priority list sample dropping Etravirine



NOTE: The figures show the estimates of regressions in which the effect of the MPP is separately estimated for each year before and after inclusion. The figures plot the coefficients (and 95% confidence intervals) with the year before inclusion normalized to zero. Standard errors are clustered at the product and country level. The dependent variable is Access for the graphs on the left and it is Deals for those on the right.

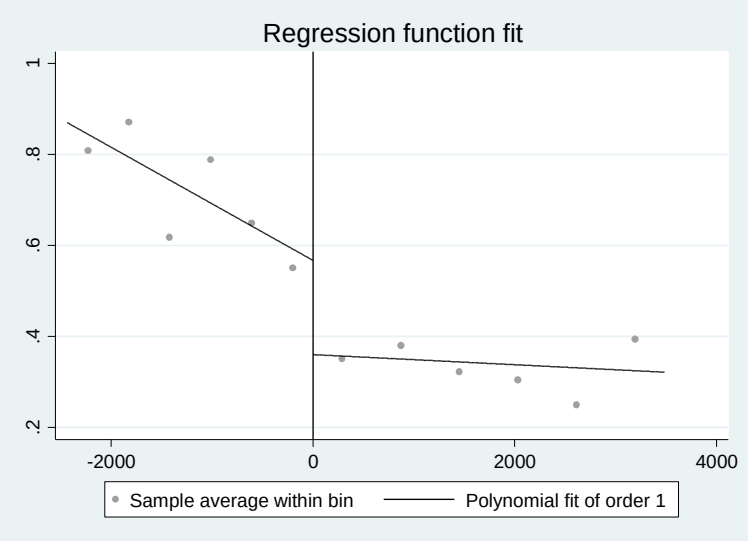
Appendix Figure A3: World Bank Status and MPP inclusion

Panel A - Lower-middle income vs. upper-middle income countries



NOTES: The sample includes product-country observations for countries that were within $2,205 below and $3,195 above the upper middle-income threshold in the year in which the drug joined the pool. The first bar captures mean MPP inclusion for lower-middle income countries and the second bar for upper middle-income countries.

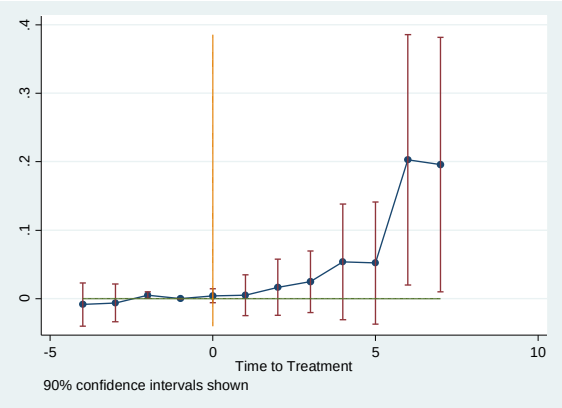
Panel B - Discontinuity at the upper-middle income threshold



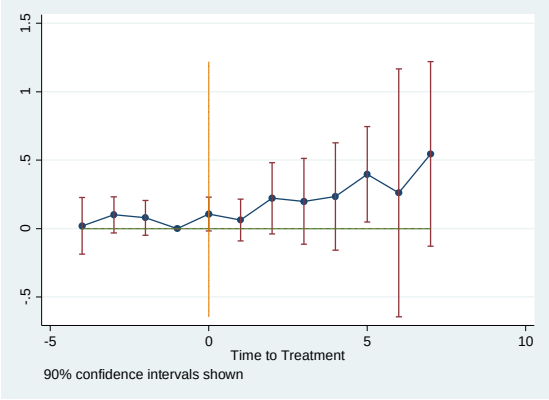
NOTES: RDD plot with running variable equal to the difference between the country GNI per-capita and the threshold used by the World Bank to classify countries as upper middle-income in the year of the negotiation. Bins constructed with the integrated mean-squared error of the local means estimator.

Appendix Figure A4: MPP and market outcomes in the priority list

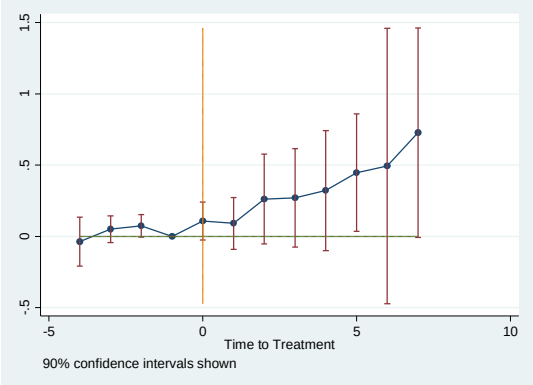
Panel A- Launch by licensee as dependent variable



PANEL B– Log(Sales) as dependent variable



PANEL C – Log(Volume) as dependent variable



NOTE: The figure replicates the estimates in Figure 2 of the paper using only the drugs in IQVIA which are also in the 2010 MPP priority list.

Table A1: Robustness to alternative econometric models

	(1)	(2)	(3)	(4)	(5)	(6)
Dep. Var.	Access	Deals	Access	Deals	Deals	Deals
MPP	0.589***	3.046***	0.666***	4.657***	1.552***	1.920***
	(0.064)	(0.614)	(0.009)	(0.065)	(0.122)	(0.035)
Sample	Priority list without Etravirine	Priority list without Etravirine	Full	Full	Full	Full
Estimation	OLS	OLS	Imputation estimator	Imputation estimator	Poisson	Neg. Bin.
Observations	38134	38134	80103	80103	29183	29183

NOTES: * p < 0.10, ** p < 0.05, *** p < 0.01. Deals= total number of licensing deals for the country product in year t (includes MPP and non-MPP deals). Access=1 if deals>0. MPP =1 if the product-country is included in an upstream MPP license. Standard errors clustered at the product and country level in columns 1 and 2. Robust standard errors in columns 3-6. Estimates in columns 3 and 4 follow the approach developed in Borusyak, Jaravel, and Spiess (2021). Product-country and year effects included in all specifications.

Table A2: Deals extension, imputation and molecule level analysis

	(1)	(2)	(3)	(4)	(5)	(6)
Dep. Var.	Access	Deals	Deals	Deals	Access	Deals
MPP	0.653***	4.508***	4.615***	4.916***	0.677***	4.529***
	(0.011)	(0.117)	(0.113)	(0.116)	(0.021)	(0.223)
Imputed deals			-0.131**			
			(0.064)			
Notes	drop deal extensions	drop deal extensions	full sample	drop imputed deals	molecule-country aggregation	molecule-country aggregation
Observations	77817	77817	80103	77867	18639	18639

NOTES: * p < 0.10, ** p < 0.05, *** p < 0.01. Deals= total number of licensing deals for the country product in year t (includes MPP and non-MPP deals). Access=1 if Deals>0. MPP =1 if the product-country is included in an upstream MPP license. Imputed deals=1 if information on bilateral deals is incomplete. Columns 1 and 2 drop product countries that enter MPP through revisions of existing deals. Standard errors clustered at the product and country level in parenthesis. In columns 5 and 6 the data are aggregated at the molecule-country level with standard errors clustered at the same level. Product combinations dropped from the sample in columns 5 and 6.

Table A3: World Bank status and MPP effect

	(1)	(2)	(3)
Dep. Var.	Deals 3 yrs	MPP	Deals 3 yrs
MPP	5.294*** (0.335)		8.676*** (2.964)
Upper Middle-Income		-0.202*** (0.074)	
Sample	25 percentiles above/below upper middle-income threshold	25 percentiles above/below upper middle-income threshold	25 percentiles above/below upper middle-income threshold
Estimation	OLS	OLS - 1st stage	IV
First stage F-stat			7.65
Observations	602	602	602

NOTES: * p < 0.10, ** p < 0.05, *** p < 0.01. Deals 3 years= total number of licensing deals for the country product in the three years following MPP inclusion. Upper Middle-Income= 1 if country classified as upper middle-income by the World Bank. MPP =1 if the product-country is included in an upstream MPP license. Columns 3 instruments MPP with the dummy Upper Middle-Income. The sample is a cross-section and only includes medicines that enter the MPP. Robust standard errors in parentheses. Regressions control for running variable and the year of inclusion in the MPP

Table A4: Proportional Hazard Model for Launch

	(1)	(2)	(3)
Dep. Var.	one licensee	one licensee	one licensee
MPP	1.395	1.618**	2.882***
	(0.306)	(0.335)	(0.777)
Country effects	NO	YES	NO
Product-effects	NO	YES	YES
Country controls	NO	NO	YES
Observations	21798	21798	21798

NOTES: Relative Hazard Rates. Robust standard errors clustered at the product-country level in parentheses. * p < 0.10, ** p < 0.05, *** p < 0.01. One licensee =1 if at least one licensee has launched. Country time-varying demographics are log(GNI per capita) and log (Population).