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

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Motivation

Limited availability of life-saving drugs is common in low-income countries

Example: HIV drug Etravirine approved by FDA in 2008 but not available in 75% of low-income countries in East Europe in 2015

Literature has shown key role of national income, patent systems or price regulation which affect profitability of branded pharmaceutical and generic firms (Cockburn, Lanjouw and Schankerman, 2016)

Many policy proposals address this issue, this paper examines one of them: *patent pools*

Patent pools

Patent pool: voluntary arrangement where patentees authorize the pool to license specific patents, typically as a bundle, to third parties

Expected to facilitate commercialization and follow-on innovation by lowering the transaction costs of licensing (bilateral negotiation with specialist). Widely used in electronics and telecommunications where the focus is licensing of complementary innovations

More recently proposed for biomedical innovation (SARS vaccines, neglected tropical diseases,..) with a focus on promoting wider *geographic diffusion* and transparent licensing terms. Expected to be particularly beneficial for poor countries

Take action now

Solidarity Call to Action

Endorsements of the Solidarity Call to Action

Commitments to share knowledge, intellectual property and data

The COVID-19 Technology Access Pool (C-TAP) will compile, in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data. The Pool will draw on relevant data from existing mechanisms, such as the Medicines Patent Pool and the UN Technology Bank-hosted Technology Access Partnership. Shared knowledge, intellectual property and data will leverage our collective efforts to advance science, technology development and broad sharing

A challenge in the innovation literature

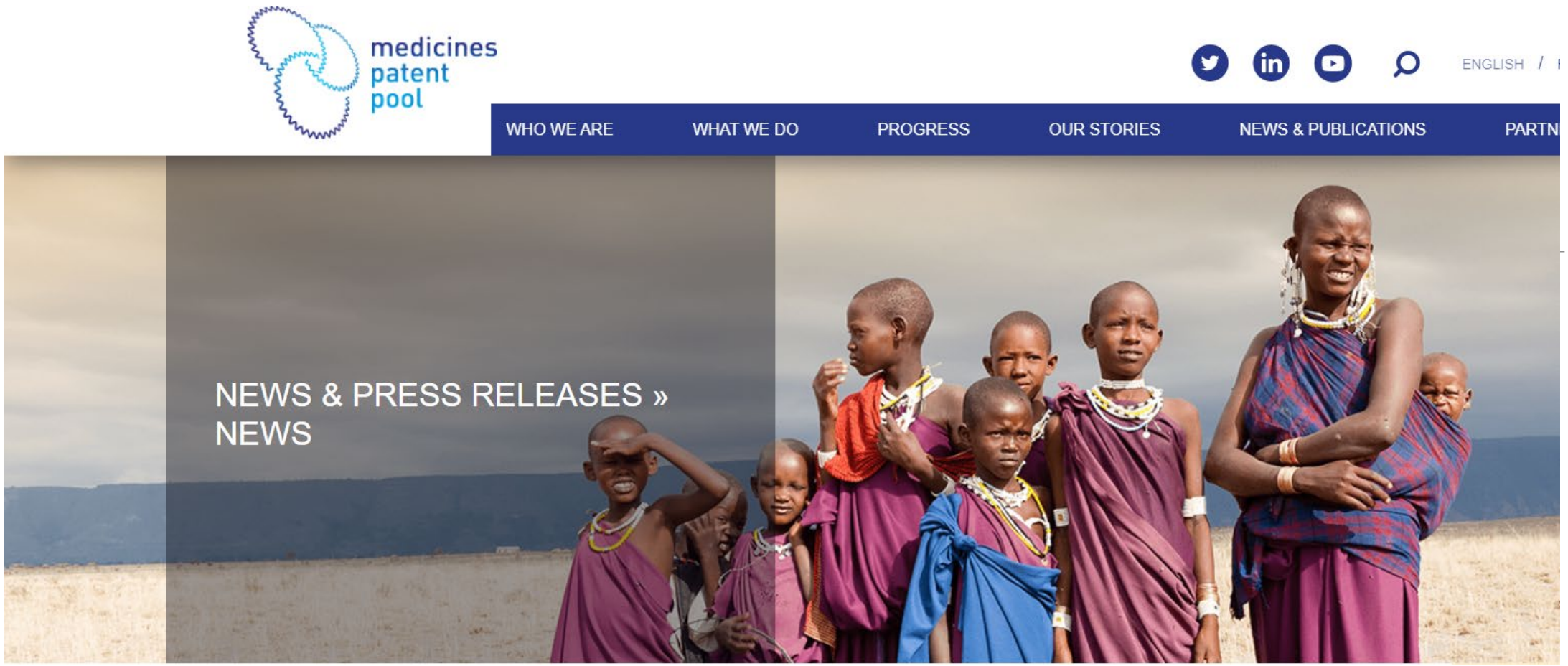
Very challenging to study empirically whether patent pools do, in practice, promote patent licensing and product launches:

- licensing information is often confidential

- finding a control group is difficult as inclusion in pool is non-random

This is why most of the academic work on patent pool has been theoretical, or looked at other empirical outcomes (e.g., R&D activity in the technology area)

In this paper we exploit a rich dataset on licensing from the **Medicines Patent Pool** (MPP) that allows us to conduct an empirical analysis of licensing and product launches



At the Medicines Patent Pool, we aim to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries through an innovative approach to voluntary licensing and patent pooling. So wherever people live, they have rapid access to effective treatments.

https://medicinespatentpool.org/who-we-are/about-us/

The medicines patent pool

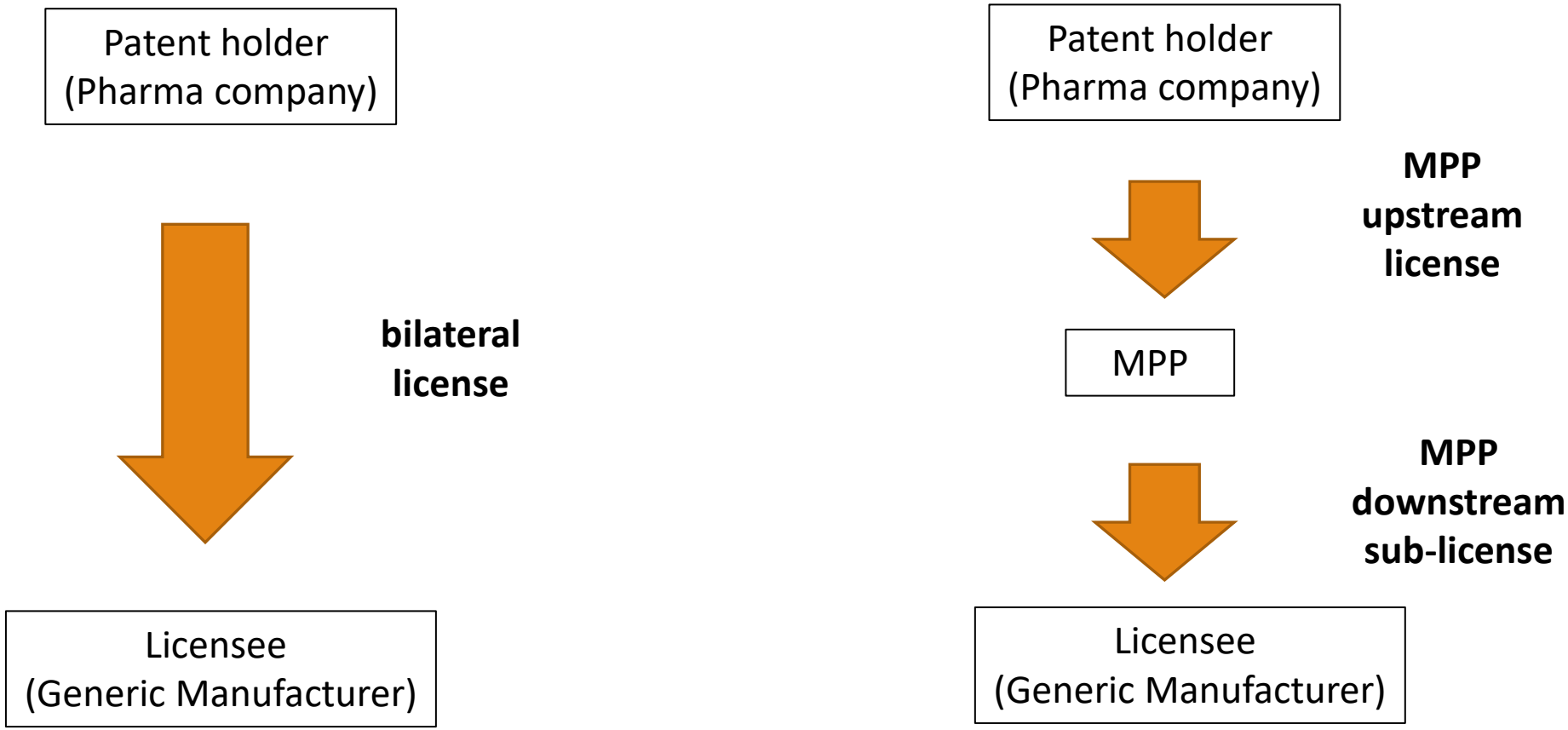
Established in 2010 by UNITAID for HIV drugs in LMICs. In 2015 expanded to Hep C and TB.

MPP negotiates upstream license with drug firms. Aim at large public health impact and broad geographical coverage.

MPP offers generic producers (downstream) standardized sublicences. MPP also ensures that sub-licensees obtain regulatory approval and follow strict quality assurance requirements

Most MPP licenses have either zero, or very low, royalty rates.

Licensing deals



Model compares pool vs bilateral licensing

Basic Tradeoff: lower transaction cost per-patent vs licensing full bundle

- In general, patent pool can increase or reduce total amount of licensing, due to the tradeoff.
- If pool and bilateral licensing *co-exist*, the pool does not reduce licensing (the case of MPP)
- Correlation between licensing and commercialization is weaker with pool, since the firm is constrained to license patents for unprofitable markets.

Data

Product-country-year panel dataset covering the period 2005-2018

Products: MedsPal (MPP) + medicines in 2017 WHO essential medicine list for HIV, TB and Hep C in the 2010 MPP priority list. 216 products defined by a molecule-strength combination (e.g. Abacavir 300mg)

Countries: 177 LMICs as per World Bank

Patents: MedsPal + additional sources

Licensing data

MPP upstream licenses (MPP/Pharma) and **sublicenses** (MPP/generics) are in MPP web-site. MPP shared with us all the historical contracts, so we can track how each upstream deal has evolved over time

Bilateral (non-MPP): MedsPal (public sources + non-confidential direct communications to the MPP)

MPP tracked bilateral licensing also for non-MPP products!

Deals = total number of licensing deals (bilateral or MPP sublicense) in the product-country-year

Access = 1 if at least one licensing deal (bilateral or MPP sublicense) in the product-country-year

Summary Statistics

	obs.	mean	min	max
Access	80,103	**0.18**	0	**1**
Deals	14,453	**4.59**	1	**20**
MPP sublicenses	14,453	**1.41**	0	**17**
Bilateral deals	14,453	**3.18**	0	**13**

Econometric model

Difference-in-differences estimation:

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

Dep Var Y = licensing measure in product, p, country, c, and year t

MPP =1 for product-countries included in upstream license between MPP and drug firm in year t

X = time-varying country controls. δ and f are year and product-country fixed effects

Robust standard errors clustered at the product and country level

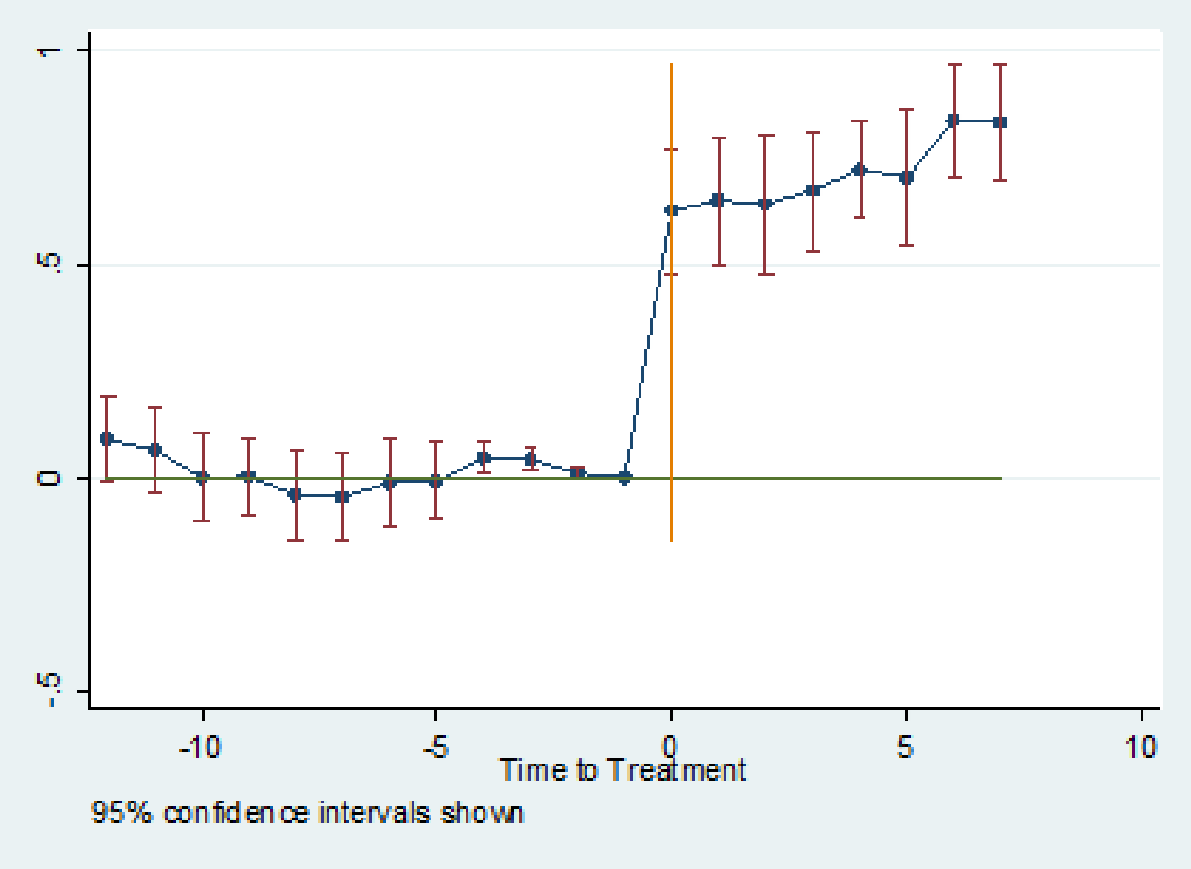
Baseline Regression

	(1)	(2)
Dep. Var.	***access***	***deals***
MPP	0.663***	4.610***
	(0.010)	(0.113)
Year effects	YES	YES
Product-country effects	YES	YES
Observations	80103	80103

Probability of access increases by 500% relative to Access for non-MPP products-countries

Number of deals increase of 10 times

Timing of the effect



Growth in licensing follows MPP entry quickly and increases

Similar timing observed using *Deals*

Endogeneity of MPP medicines

Products are not randomly allocated to MPP. Included products may differ substantially from randomly chosen drug. Unobserved factors correlated with inclusion in the MPP and subsequent diffusion may create bias

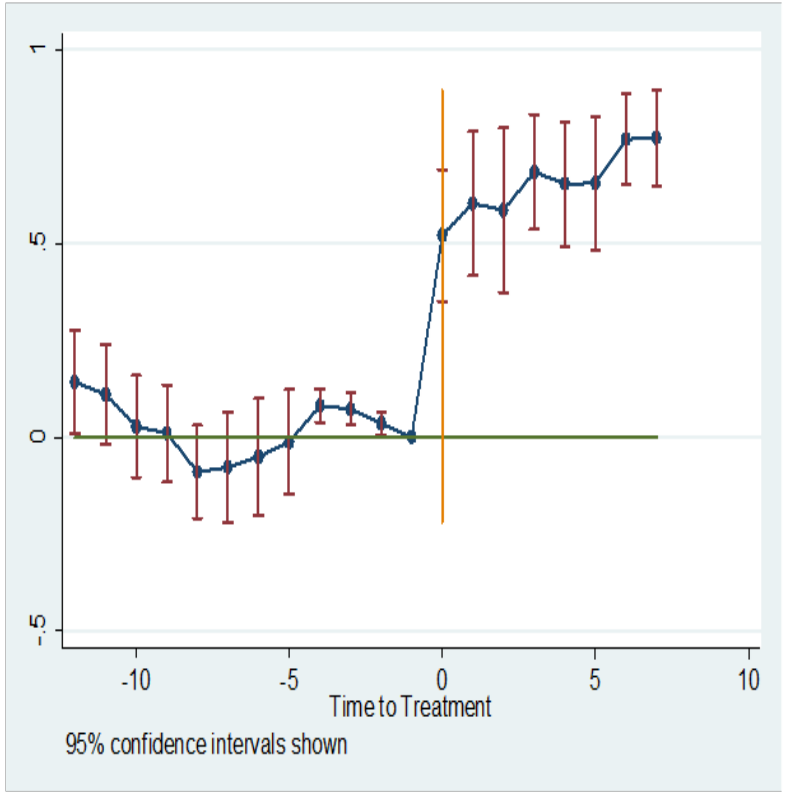
Example: MPP interested in the most effective drugs, which also have greater demand of licensing across countries

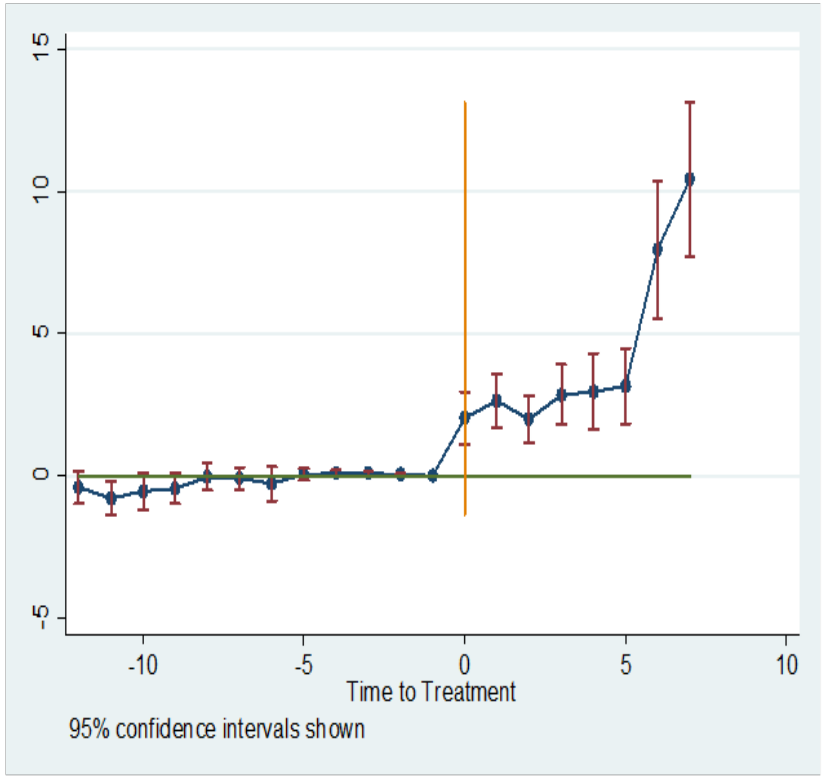
We address this issue focusing on the MPP 2010 priority list of medicines. Products that MPP would have liked to be included in the pool in 2010. Negotiation with patentee began **for all these products** (83) but only 38.5% eventually make it to the MPP

Key underlying assumption is that drugs in the 2010 priority list would have trended identically in the absence of MPP inclusion. Analogous to Greenstone et al. (2010)

MPP 2010 priority list

	(1)	(2)
Dep. Var.	access	deals
MPP	0.603***	3.083***
	(0.055)	(0.617)
Sample	2010 priority list	2010 priority list
Observations	40536	40536





Endogeneity of MPP countries

Baseline regression includes product-country fixed effects.

Concern: unobserved factors that make market more attractive will make bilateral licensing more likely and inclusion in MPP less likely (thus *under-estimates* MPP effect)

Address this with a **fuzzy RDD design**: use World Bank income classification for Lower vs Upper middle income as an instrumental variable for MPP inclusion.

Result: MPP effect rises by 60% when we instrument; but not statistically different from baseline OLS estimates.

Heterogenous effects

Two reasons for bilateral license: royalties and corporate social responsibility (CSR)

Both channels require large HIV population. However, for a given level of HIV population:

- If royalty incentive dominant, bilateral licensing should be higher when income is higher so *MPP effect should be smaller when income is higher.*
- If CSR motive dominates, bilateral licensing should be lower when income is higher, so *MPP effect should be larger when income is higher.*

Result: We find that the royalty incentive dominates in bilateral deals in LMICs.

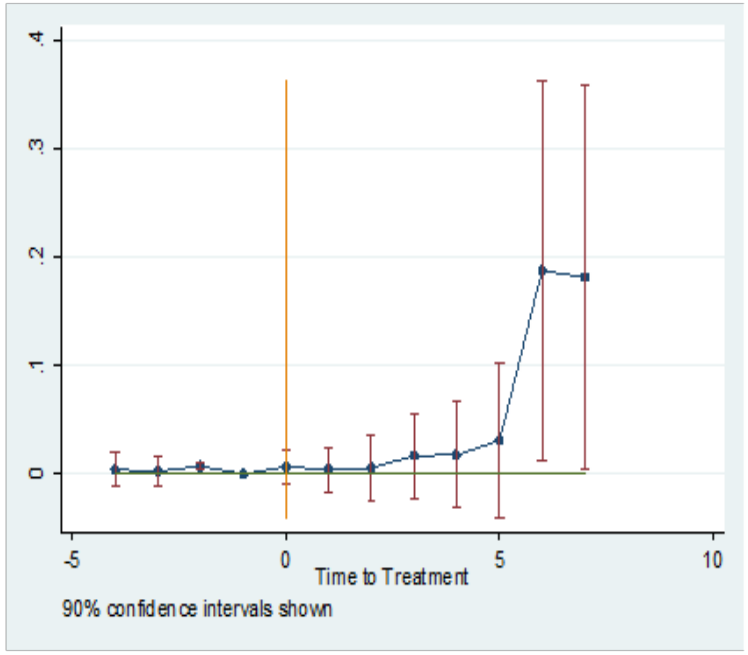
Drug launches and sales

Complement data on licensing with launch, sales and volume data purchased from IQVIA

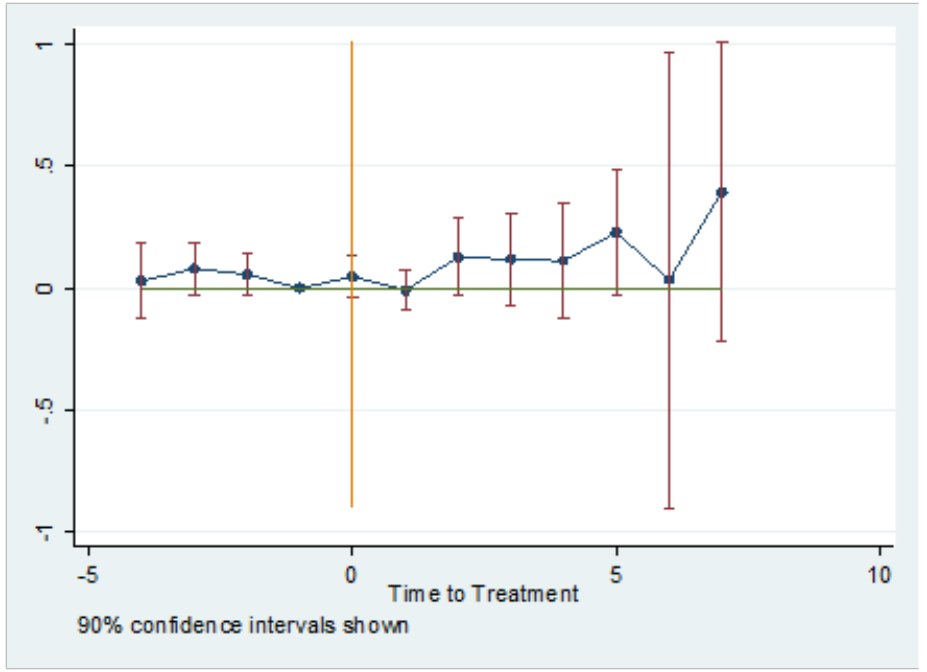
IQVIA data do not cover our full sample:

- **32 countries** of the 129 countries in our sample, mostly middle-income countries
- ~ **80 percent of the products** in our sample

MPP and entry



MPP and sales revenue



Implied magnitude of MPP effect on entry (40%) much smaller than the one on licensing (500%).
Consistent with theory + data limitation (no Low Income countries + delayed effect)

Welfare: Back of the envelope

Null effect on revenue + positive effect on quantities implies that demand is unit elastic. Consistent with Kremer and Snyder (2015, 2018) and Dubois et al. (2020)

Functional form is $p = A/q$ where *A* = revenue. Total welfare is $W = Alog(q)$.

We do back of the envelope computation of ΔW from MPP drugs using info on revenues in MPP countries (~A) and Δq from our regression

Welfare gain ~27 mill USD for 2010-18. This is extreme lower bound: (ii) many MPP countries not in our sample; most MPP products are entered pool <5 years

Total MPP operating costs for the period 2010-2015 ~23 million (Juneja et al., 2017) suggesting positive welfare effect

Conclusions

- Inclusion in MPP sharply increases probability of licensing
- Heterogeneous impacts: MPP effect is *smaller* in countries with large HIV exposure and higher income
- MPP increases launches and volumes but by much less than for licensing

Thus, focusing only on licensing may overstate the impact of pools on actual diffusion.

Results suggest patent pools can be useful for diffusion of biomed innovation to LMICs.

Thank you!