INTELLECTUAL PROPERTY RIGHTS PROTECTION AND HEALTH: THE CASE OF TUBERCULOSIS[1]

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1. Introduction

Tuberculosis (TB, hereafter) is a high-impact communicable disease. It is present in all countries and affects all age groups. Despite being curable and preventable, in 2019, TB generated globally 10 million infections and 1.4 million deaths, ranking among the top 10 causes of death in low-income countries (WHO, 2020). Reducing the burden of the TB epidemic is a health target of the United Nations Sustainable Development Goals (SDG).[2]

TB is caused by a bacterium (Mycobacterium tuberculosis) that spreads through the air from one sick person to another. Most often, it affects the lungs, but it can also affect other body parts. Approximately a quarter of the world's population has latent TB. Despite being infected, people with latent TB do not necessarily develop the disease and, because they do not suffer an active illness, they cannot transmit TB to others. A relatively small proportion (5-10%) of those with latent TB will eventually fall ill and require care. People with compromised immunity (e.g., HIV) or those suffering from undernutrition, poverty, smoking, and diabetes are at greater risk of both being infected and becoming ill (WHO, 2020). Most TB patients can be treated with a 6-month antimicrobial drugs regimen. However, the treatment can be longer (9-20 months) for patients who have developed a multidrug-resistance TB, which is a major concern at the country and global level. The success rate of the treatment varies by country and heavily depends on countries' capacity to early diagnose and detect drug resistance, propose shorter treatment regimens, and support patients to increase adherence.

The scientific debate has shed light on the need to increase the research and development effort on TB. Rapid tests for diagnosing the infection and the disease and detecting drug resistance, safer and more effective treatment strategies, and a vaccine, are necessary for a rapid decline in TB mortality and to end the TB epidemic

[1] The article is the result of the joint work of the three authors.

[2] Specifically, the SDG target 3.3 aims at ending the TB epidemic by 2030. The strategy implies reaching an 80% reduction in the TB incidence rate (new and relapse cases per 100 000 population per year) by 2030, and a 90% reduction in the annual number of TB deaths by 2030, compared with 2015.

(Reid *et al.*, 2019). Furthermore, recent data show that, despite the presence of new and safer drugs, many people still do not have access to them because of barriers resulting from patent-backed monopolies and high prices (Makoni, 2021).

Over the past 30 years, almost all national economies have adopted some level of intellectual property rights (IPR) protection. Becoming a member of the World Trade Organization (WTO), established to facilitate trade among countries, is conditional to signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which extends IPR protection to knowledge-intensive products, such as pharmaceuticals, computers, and telecommunication. When joining the WTO, developing and least-developed countries (LDCS) were obliged to strengthen their IPR legislation.

The discussion on IPR protection in the pharmaceutical industry, characterized by a complex system of regulations including patents, clinical testing, and market exclusivity, is particularly controversial (Boldrin and Levine, 2013). IPR protection can have both positive and negative effects on economic efficiency. On the one hand, obtaining monopoly power as a reward for innovation enhances the firms' incentive to innovate. On the other hand, research and development efforts might be refrained by the penalties and legal actions, such as those set by the TRIPS, that necessarily exist to deter patent infringement. IPR protection might also reduce domestic innovation in developing countries that typically innovate through imitation. Moreover, in the pharmaceutical sector, stricter protection legislation could threaten public health by making low-cost generic drugs less available to citizens.

Most of the economic literature has focused on the impact of IPR protection on innovation and economic outcomes. Many studies document that stricter IPR enforcement decreases domestic innovation in developing countries, while it can stimulate research and development in developed and richer countries (Kyle and McGahan, 2012; Delgado *et al.*, 2013; Gamba, 2017). Less is known, however, about the effects of stricter IPR on pharmaceuticals in the health domain.

In this work we try to fill this gap by studying the potential effect of implementing the TRIPS on the dynamics of the global burden of TB. Because TRIPS compliance is motivated by the commercial benefits of joining the WTO, the agreement's implementation can be used as a natural experiment to understand whether and to what extent IPR protection in the pharmaceutical sector influences health outcomes. For this reason, we exploit country variation in the time of compliance to estimate the impact of IPR on TB burden. We use data provided by the World Health Organization (WHO), the WTO, and the World Bank, for 184 countries in the years 1990-2017 in a Difference-in-Differences research design. We estimate a 2-way staggered Fixed-Effect (FE) regression model for TB mortality rate, controlling for socio-economic and health risk factors, and provide a full dynamic specification of the effect.

We find that TRIPS compliance has a negative effect on TB mortality rate in high-income countries, and a positive effect in low-income countries. While the effect is persistent in all countries, it starts in the year after the introduction of TRIPS in high-income countries and in the sixth year after treatment in the low-income ones. We find no significant effect in middle-income countries.

2. Data and summary statistics

Our analysis exploits data from different sources. The outcome variable is the TB death rate, provided by WHO. It measures the number of deaths over 100,000 people due to TB, excluding HIV, for the period 1990-2017 in 184 countries. We use an indicator for *education* (the mean years of schooling within a country) provided by the United Nations Development Program, and the *GDP per capita* provided by the World Bank (WB), as socio-economic controls.[3] We also use the indicator of life expectancy at birth provided by the United Nations Department of Economic and Social Affairs. It reflects the population general health status in each country by considering the mortality pattern that prevails across all age groups.

Moreover, to take into account country differences in the incidence of TB, we expand our dataset with two variables that should act as proxies of poor living conditions and living out of urban areas, which are important risk factors for TB (WHO, 2020). Specifically, we use *drinking water services*, which measures the percentage of population with access to an improved drinking water, and *sanitation*, which is calculated as the percentage of population using at least basic sanitation facilities (ventilated improved pit latrines, compositing toilets, or pit latrines with slabs). Poor sanitation also contributes to malnutrition, which is another important TB risk factor. These variables are provided by WHO and, contrary to more specific indicators of poverty and inadequate living, are available for all countries included in the analysis for almost all years.

Our policy indicator is the dummy variable TRIPS, that takes value 1 since the year of the agreement's adoption. To build this indicator, we use the information on TRIPS compliance by country provided in Kyle and McGahan (2012). We also use the WTO website to update information on the most recent adoptions by those least developed countries which have benefitted of extended transition periods to apply provisions of the TRIPS.

In Table 1 we present descriptive statistics for our unbalanced sample of countries. Drinking water services and sanitation conditions are not homogenous

[3] Mean years of schooling is defined by UNDP as the average number of years of education received by people ages 25 and older, converted from education attainment levels using official durations of each level.

among countries, as shown by the between-country variation. However, for these variables, as well as for GDP and education, the within-country variation suggests low variability over time.

Table 1 – *Descriptive statistics.*

	Mean	*Std. Dev.*	*Min*	*Max*
TB death rate	19.21	30.03 (26.25; 13.91)	0	278
GDP per capita	12.12	17.52 (16.68; 3.10)	0.19	111.97
Mean years of schooling	7.45	3.19 (3.19; 0.92)	0.4	14.1
Life expectancy	68.51	9.66 (9.10; 2.95)	26.2	84.3
Drinking-water services	83.55	18.82 (18.43; 5.07)	19	100
Sanitation	69.77	31.00 (30.79; 6.13)	3.4	100

Notes. The sample size is 4,405. GDP per capita is constant in 2010 US$ and is expressed in thousands of dollars. Between and within Std. Dev. are reported in brackets.

Table 2 reports the descriptive statistics for unbalanced sub-samples of countries. Countries have been stratified in high-, middle-, and low-income economies (Kyle and McGahan, 2012). As expected, the TB death rate decreases with income level and low-income countries are those that suffer the most the burden of TB. Life expectancy at birth is particularly low, on average, in low-income countries, where living conditions, lifestyles, education levels, and access to healthcare are below the standards of wealthier nations, thus reflecting a lower general health status of the population.

Table 2 – *Descriptive statistics by income level.*

	High-income countries (N=1307)				Middle-income countries (N=2325)				Low-income countries (N=773)			
	Mean	*Std. Dev*	*Min*	*Max*	*Mean*	*Std. Dev*	*Min*	*Max*	*Mean*	*Std. Dev*	*Min*	*Max*
TB death rate	2.1	3.3	0	23.0	19.3	25.5	0	180.0	47.8	43.1	3.5	278.0
GDP per capita	33.0	19.8	5.3	111.9	4.2	2.9	0.4	15.9	0.6	0.3	0.2	1.5
Mean years of schooling	10.3	1.9	5.3	14.1	7.1	2.5	0.4	12.9	3.6	1.9	0.7	11.0
Life expectancy	77.0	4.4	53.3	84.3	68.0	7.2	42.5	79.9	55.6	7.4	26.2	72.1
Drinking-water	98.0	5.5	51.0	100	83.9	14.7	30.3	100	56.6	15.5	19.0	97.0
Sanitation	96.8	6.1	54.8	100	68.8	25.4	7.0	100	26.9	19.9	3.4	97.0

3. Empirical Strategy

The existing literature assumes the timing and strength of IPR protection to be exogenously determined (Branstetter *et al.*, 2006; Moser, 2005; Lerner, 2002). According to Kyle and Meghan (2012), in the case of the TRIPS implementation, developing and least developed countries were resistant to adopting or strengthening IPR protection, and did so mainly because they expected large benefits from WTO membership. For all these reasons, IPR reforms are often used as natural experiments to understand how IPR protection influences economic activities.

To assess the causal impact of TRIPS compliance on TB mortality, we set up a quasi-experimental research design and estimate a staggered 2-way FE (country and year) Difference-in-Differences model (DD henceforth), where we center the time of the policy switch to zero to have all the countries facing the same initial treatment time. We first estimate the following baseline 2-way fixed effect DD model:

$$y_{it} = \beta D_{it} + \theta X'_{it} + \alpha_i + \delta_t + \alpha_i \cdot t + \varepsilon_{it}$$

where y_{it} is the TB deaths rate in country *i* in year *t*, D_{it} is the absorbing treatment status (1 in any year after the reform for the treated country i, 0 otherwise), X'_{it} is the matrix of controls, α_i is the country fixed effects, δ_t the year fixed effects and $\alpha_i \cdot t$ is the country-specific linear trend.

We further extend the classical specification of the DD with a dynamic analysis that relies on "event study" estimates. More precisely, given the availability of data and the observed time windows around the staggered adoption of the policy (1990 – 2017), we standardized the time dimension as $m = 27$ periods before and n$= +24$ periods after the TRIPS adoption. We then have a certain time $(-27, \ldots, 0, \ldots, +24)$, where 0 is the year of policy switch, that allows us to capture either the immediate effect of the policy, and any additional effects that occur *n* periods after adoption. We combine the years in 5-years intervals (1-5, 6-10, etc.) instead of using a one-year increment, because we expect the policy to affect health gradually. We set the baseline period as one year before, as common in practice. The ending point is fixed at 21plus year, both in the before and after periods. We disentangle the full dynamic response of the TB mortality rate to the institutional change and estimate the following DD regression augmented with leads and lags:

$$y_{it} = \sum_{l \neq -1} \beta_l D_{it}^l + \theta X'_{it} + \alpha_i + \delta_t + \varepsilon_{it}$$

where, ceteris paribus, D_{it}^{l} are interactions of the binary indicator of treatment TRIPS, here D_{it} , (1 in any year after the reform for the treated country *i*, 0 otherwise) with group-year dummies *l* (observed time window: 27 years before Trips, 0, 24 years after TRIPS, grouped in 5-years intervals).

Table 3 - *Estimated impact of TRIPS compliance on TB mortality rates*

Deaths due to tuberculosis among HIV-negative people (per 100 000 population)	(1) All	(2) High-income countries	(3) Middle-income countries	(4) Low-income countries
Pre-TRIPS mean	27.95	3.81	22.38	49.35
TRIPS X POST	1.81**	-1.16***	-1.33	10.1***
	(0.844)	(0.12)	(0.83)	(3.70)
Controls				
GDP per capita (constant 2010 US$)	-0.02	-0.05***	-0.64*	-24.62***
	(0.04)	(0.01)	(0.35)	(8.98)
Mean years of schooling	-0.94***	-0.09*	-0.68	-12.63***
	(0.35)	(0.05)	(0.48)	(4.11)
Life expectancy	-0.09	-1.88***	-0.49	0.84**
	(0.22)	(0.16)	(0.32)	(0.36)
Drinking-water services	-0.02	0.04	0.37***	-0.51*
	(0.12)	(0.03)	(0.10)	(0.27)
Sanitation	0.28**	0.05	-0.12*	1.01***
	(0.12)	(0.05)	(0.07)	(0.38)
Constant	13.67	142.4***	38.42*	62.12*
	(17.72)	(13.29)	(22.62)	(34.64)
Country fixed-effects	Yes	Yes	Yes	Yes
Year fixed effects	Yes	Yes	Yes	Yes
Country-specific linear trend	Yes	Yes	Yes	Yes
Observations	4,405	1,307	2,325	773
R-squared	0.93	0.97	0.94	0.89

Notes: All models include country, year fixed effects and a country-specific linear trend. Robust standard errors in parentheses, *** p<0.01, ** p<0.05, * p<0.1

4. Results

Table 3 presents the estimated impact of the TRIPS compliance on TB mortality rates, using the full sample and the samples stratified by income level. TRIPS compliance has a negative effect (an average of – 1.16 over 100,000 people in the whole post-treatment period) on TB mortality rate in high-income countries, and a positive effect (an average of about 10.1 over 100,000 people) in low-income countries.

Table 4 - *Event study*

	(1)	(2)	(4)	(3)
Deaths due to tuberculosis among HIV-negative people (per 100 000 population)	All	High-income countries	Middle-income countries	Low-income countries
Mean mortality rate at $t = -1$	16.84	2.73	22.08	32.36
21-27 years before TRIPS	-1.57	-0.93	8.38	-19.33*
	(5.96)	(1.35)	(7.73)	(10.30)
15-20 years before TRIPS	7.31*	2.06	15.68***	0.83
	(4.21)	(1.38)	(3.84)	(8.58)
10-15 years before TRIPS	3.524	2.651***	5.163**	7.46
	(2.87)	(0.918)	(2.569)	(6.891)
5-10 years before TRIPS	-4.24**	1.94***	-0.11	-3.18
	(1.89)	(0.46)	(2.17)	(6.35)
2-5 years before TRIPS	-1.68	0.23	-0.38	-1.69
	(1.78)	(0.29)	(1.87)	(6.41)
1-5 years after TRIPS	3.88**	-2.08***	-0.57	9.83
	(1.73)	(0.43)	(1.85)	(6.72)
6-10 years after TRIPS	9.51***	-3.35***	0.37	32.52***
	(1.85)	(0.68)	(1.93)	(8.36)
11-15 years after TRIPS	12.90***	-3.92***	0.61	37.84***
	(2.00)	(0.95)	(2.09)	(10.32)
16-20 years after TRIPS	15.83***	-4.19***	-0.75	35.09***
	(2.22)	(1.24)	(2.29)	(10.64)
21-24 years after TRIPS	19.96***	-4.51***	-2.80	Not estimable
	(2.55)	(1.54)	(2.64)	
GDP per capita	0.25***	-0.01	1.08***	-28.93***
	(0.05)	(0.01)	(0.26)	(8.84)
Mean years of schooling	0.60*	-0.09	-0.31	-2.92
	(0.34)	(0.06)	(0.45)	(2.45)
Life expectancy	-0.15	-1.02***	-0.79***	1.56***
	(0.19)	(0.08)	(0.22)	(0.38)
Drinking-water services	-0.09	0.12***	0.18*	-0.15
	(0.11)	(0.03)	(0.01)	(0.21)
Sanitation	-0.19***	-0.04	-0.35***	0.14
	(0.06)	(0.04)	(0.06)	(0.25)
Constant	37.38**	76.30***	79.11***	-6.372
	(17.81)	(6.706)	(17.66)	(32.91)
Observations	4,405	1,307	2,325	773
R-squared	0.83	0.93	0.88	0.72

Notes. All models include country and year fixed effects. Robust standard errors in parentheses, *** p<0.01, ** p<0.05, * p<0.1

Table 4 shows the results of the "event study" as described in Section 3. The 5-10 and 10-15 years before TRIPS dummies are statistically significant for high-income countries, while for middle-income countries the statistically significant leads refer to 10-15 and 15-20 years before TRIPS, suggesting that the parallel trends assumption does not seem to hold. Therefore, we can provide a causal interpretation only to the results for low-income countries, while for high and middle-income countries we must be cautious and provide only a descriptive interpretation. In low-income countries the TRIPS compliance has a positive and statistically significant effects on mortality rates. However, such effects seem to occur only after 6 years from the introduction of the TRIPS, and to persist over time. The magnitude of such effect is not negligible, because 6 years after the TRIPS there seems to be an increase in mortality rates of about 32.5 over 100,000 individuals, and it becomes about 38 over 100,000 after 10 years. Considering that in low-income countries the mean mortality rate at $t = -1$ is about 32 deaths over 100,000 individuals, the increase in the mortality rate corresponds to about 100% after 6 years, and 117 % after 10 years.

As a robustness check, we have estimated an alternative specification that, instead of using GDP, education, and life expectancy at birth as separate indicators, includes a summary indicator directly. Specifically, we have used the Human Development Index (HDI), which assesses countries development achievements with respect to three fundamental dimensions (standard of living, education, and health). Overall, results are robust to the change in the specification.[4]

5. Conclusions

In our study we investigate the potential effect of implementing the TRIPS on the dynamics of the global burden of Tuberculosis. We use data for 184 countries in the years 1990-2017 and estimate the causal effect of the TRIPS on TB mortality rates using a Difference-in-Differences design in which the treatment occurs at different timing for different countries, using 2-way FE estimator. The TRIPS compliance appears to cause an increase in TB mortality rates in low-income countries, although such effect is not immediate but appears to take at least 6 years to occur.

Our study suffers from a few limitations. The specification of our regression model is very parsimonious. We face an issue of data availability, because we deal with a long panel (28 years) for a very large number of countries (184). Moreover, because TB incidence rates are made available by WHO only for a limited time span (2000-2019), which covers only a short pre-policy period, we preferred to focus on TB mortality rates which have a broader coverage.

[4] Tables of results are available on request.

Our DD analysis relies on the assumption that the treatment effect is homogeneous across countries and over time. However, a recent influential piece of the literature has questioned the use of the 2-way FE estimator because it might produce biased estimates of the dynamic of the treatment effect. In fact, when the treatment hits groups of units (cohorts) at different points in time, parallel trends are not sufficient for identification, and leads and lags indicators may be contaminated by cohort specific average treatment effects from other periods (see, e.g., Sun and Abraham, 2020; de Chaisemartin and d'Haultfoeuille, 2020; Callaway and Sant'Anna, 2021; Goodman-Bacon, 2021). Hence, potential pitfalls may arise that weaken the reliability of our dynamic estimates and leave room for the application of more recent and sophisticated methods robust to treatment effect heterogeneity in future research.

In our paper we have not investigated the "transmission mechanisms" linking the TRIPS Agreement to health outcomes. Previous literature has investigated the effects of IPR protection on R&D investment in pharmaceuticals, approximating the latter, as an example, by number of clinical trials (Kyle and McGahan 2012). Patent protection appears to be associated with greater R&D investment in diseases that affect high-income countries, and the treatments developed as a result may benefit people in poorer countries as well. Therefore, in the future we could test the hypothesis that "efforts in R&D" is the factor linking the TRIPS Agreement to health outcomes.

Our findings are relevant for policy makers that aim to overcome the trade-off between IPR protection and health, which is particularly relevant in low-income countries. Rapid and affordable access to essential drugs could be guaranteed by the use of "patent pools".[5] The latter aggregate patent rights of multiple patent holders and make pooled patents available to member and non-member licensees. Usually, the pool allocates a portion of the licensing fees it collects to each member in proportion to each patent's value (WIPO 2014). An example of an effective patent pool is the Medicines Patent Pool (MPP), established by *Unitaid* in 2010. MPP operates as a non-profit voluntary licensing mechanism through partnerships with originator pharmaceutical companies and generic manufacturers. MPP negotiates licences with patent holders and licenses those patents to multiple manufacturers, who develop the licensed medicine. It might also facilitate the development of new regimens by licensing drugs that are still under development.[6] The treatments are

[5] "Patent pools are voluntary arrangements where patentees authorize the pool to license specific patents, typically as a bundle, to third parties" (Galasso and Schankerman, 2021).

[6] With regard to TB "in early 2017, MPP signed its first agreement with the Johns Hopkins University. This agreement was to facilitate the clinical development of *sutezolid*, a promising investigational treatment for tuberculosis. It was followed by a second agreement with Pfizer in October 2019 to access

then made available in a given set of developing countries. Preliminary empirical evidence suggests that the MPP increases the likelihood of launch of essential drugs, their quantities sold and reduces their prices (Galasso and Schankerman, 2021).

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Pfizer's preclinical, phase I and phase IIa clinical study data and results on *sutezolid*" (MPP website, www.medicinespatentpool.org)

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SUMMARY

Intellectual Property Rights Protection and Health: the Case of Tuberculosis

Tuberculosis (TB) is a high-impact communicable disease, spread globally, representing one of the top 10 causes of death in low-income countries. Since 1995, less developed and developing countries, where the burden of TB is very high, have been obliged to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to become members of the WTO. The TRIPS extends the Intellectual Property Rights (IPR) protection to knowledge-intensive products, such as pharmaceuticals, with potential effects on drug innovation and public health. Empirical evidence on the latter effect is scarce. In this work, we exploit country differences in the timing of TRIPS compliance to study whether and to what extent IPR protection might affect health outcomes. We use thirty years of data on TB mortality rates, socio-economic and health risk factors for 184 countries to estimate a 2-way staggered FE regression model and provide a full dynamic specification of the effect of the policy. We find that the TRIPS led to higher mortality rates in low-income countries, while high-income countries had beneficial effects on reducing TB mortality.

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