

Patent Law and Pharmaceuticals: Effect of the TRIPs Agreement on AIDS Related Deaths

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Introduction

In 1995, the World Trade Organization adopted an agreement that set minimum standards regarding patent laws in signatory countries. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) required countries recognize patents from other countries and adopt a patent term of 20 years. All 164 members of the World Trade Organization (WTO) are required to sign TRIPS, ensuring nearly every nation on the planet would adopt patent enforcement mechanisms. (World Trade Organization, 2017) Hence, TRIPS could lead to a decrease in the quantity supplied of patented products including life-saving pharmaceuticals, such as those used in combatting the global HIV/AIDS crisis. This prompts the question of whether TRIPS has triggered an increase in the number of HIV/AIDS related deaths, especially in the poorest countries, which had the weakest patent protections prior to TRIPS.

A notable feature of TRIPS was the gradual adoption using a three-tiered country designation. These categories are: Least developed countries (LDCs), developing countries (DCs), and developed countries. LDCs must meet objective standards set by the U.N. to receive that designation. DCs can self-designate as a DC, though other member states of the WTO can challenge that designation. Other countries are referred to as developed countries. A more gradual adoption was allowed for LDCs and DCs.

Simultaneously to the introduction of TRIPS, infections and deaths related to HIV/AIDS were growing globally and the disease became a global priority. A notable feature of HIV/AIDS is that it can be managed through pharmaceuticals, extending the lifetime and quality of life of an individual indefinitely. Given the effectiveness and usage of pharmaceuticals on HIV/AIDS, policy related to pharmaceuticals would likely influence individuals dealing with this disease, particularly, affecting the number of people who die due to this disease.

By looking at the relationship between the HIV/AIDS crisis and TRIPS adoption this paper aims to explore the relationship between patents and a quantifiable measure which should be affected.

Background and Theory

Patents serve to protect intellectual property. They allow an inventor to disclose the design of an invention in return for time-limited exclusive rights to said item or process. Patents must have a term of 20 years to be TRIPS compliant. Hall and Harhoff (2012) discuss the rationales behind implementing a patent system.

Patents can spur the development of new inventions. Disclosing an invention allows others to observe its invention and to license the use of said invention if an agreement is made with a patent holder. This encourages the spread of knowledge. Additionally, disclosure could allow others to innovate further on the item which was publicly disclosed. Others could find novel uses for inventions that have been publicly disclosed.

Patents encourage higher investment in innovation. Patents allow the monopolization of an item for 20 years, which can lead to profits which could be used to recoup investment costs. This increases the incentive to innovate, leading to inventions which would not have otherwise been pursued. This is particularly relevant to pharmaceuticals, as the price of research is extremely high. Having a patent may also increase availability and marketing for patented products because of the artificial monopoly.

Patents may also have negative effects. The standard model of a monopoly suggests that the price and quantity that will occur are not efficient. Besides the abstract deadweight loss, this can be thought about in more concrete terms. A lower than optimal availability of life-saving drugs could lead to deaths. Gold et al (2009) find that patents do increase the cost of pharmaceuticals in high, middle, and low-income countries.

The benefits of increased knowledge may be offset by the long length of time that patents last for. This could also hamper any innovation that builds upon inventions that have been patented, as many new inventions contain hundreds of parts which each may be patented. This makes innovation build upon prior work extremely difficult.

Very simple inventions – inventions as simple as 1-click checkout (Dewitt, 2017) – may be patented, which could reduce the usage of certain inventions well below the optimal level. Hall and Harhoff (2012) suggest that ‘firms and individuals that are endowed with such a rather complex legal instrument will learn to use it strategically in ways that may not serve the intent of the legislation that created the instrument.’ Between patenting trivial ideas and taking advantage of regulatory framework, inefficiencies may arise. Overall, results appear to be very mixed.

TRIPS essentially creates a global framework for patents. We would expect to observe some results related to some or all the theories above as well. Kyle and McGahan (2009) find that the TRIPS agreement and patents led to more innovation in developed countries, but not in the poorest countries. They also found that most corporations ended up focusing on research for wealthier countries since the highest profits could be found here.

Data & Empirical Model

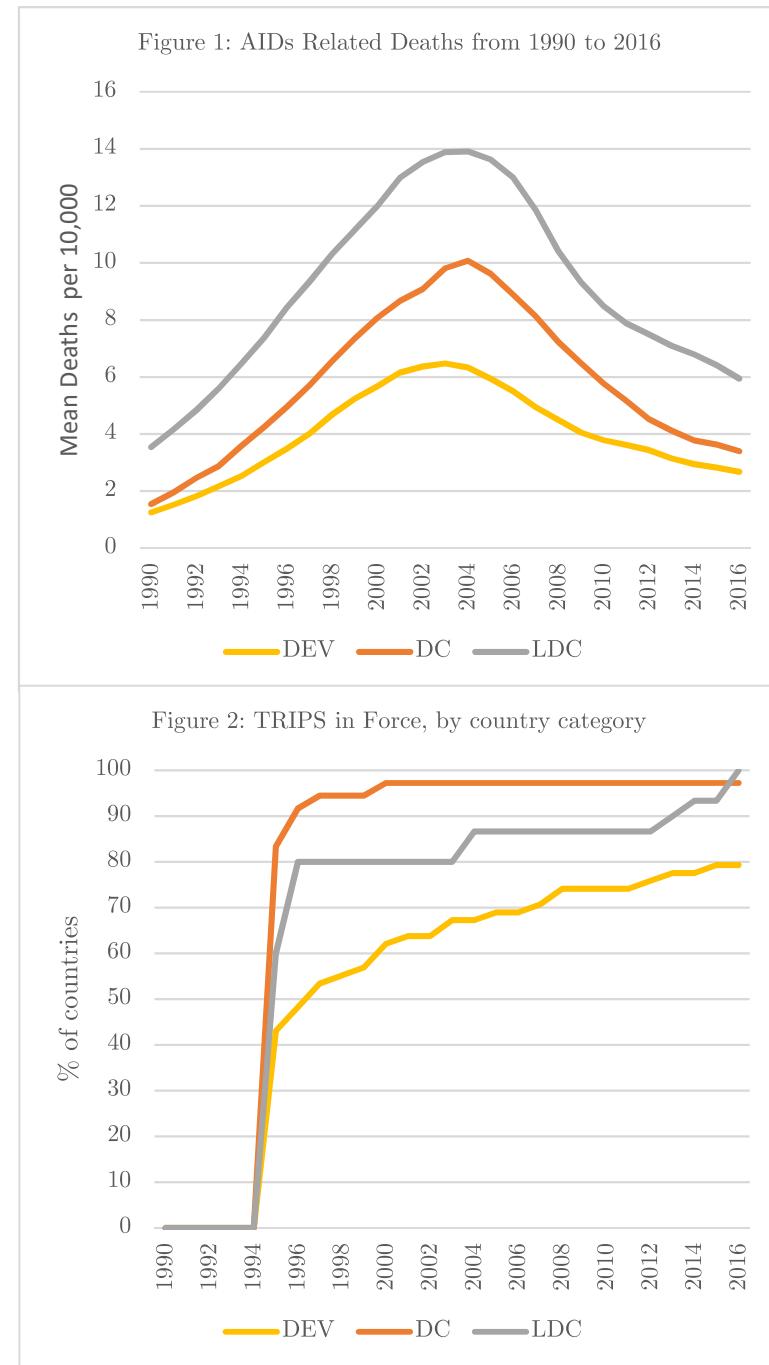
Data was collected from several sources. As a proxy for patent strength in a country, the date that TRIPS came into force for a given country was taken from the World Intellectual Property Organization. The number of AIDS related deaths by country by year was taken from UNAIDS AIDSInfo. In several instances, a range containing upper and lower bounds was given for deaths, as well as an estimate. In these instances, the estimate was used. Any country without data on deaths or population in a single year was dropped from this analysis. This leaves us with 3348 observations from 124 countries across the years 1995 to 2016, inclusive. Country classifications were taken from two sources. LDCs were taken from the WTO. DCs were taken from Deere (2009).

Figure 1 was constructed by averaging deaths per 10000 by country category by year. Figure 2 represents the percentage of countries by category which had implemented TRIPS in a given year. Figure 3 presents mean deaths per 10000 by country category by years before/after TRIPS. A vertical line marks the graph in the year that TRIPS was implemented.

Table 1 presents the mean and standard deviations for deaths_per_10000. Figure 1 presents the mean deaths_per_10000 across all years as well. This table and figure tell a relatively straightforward story: HIV/AIDs had the largest impact in LDCs, and a smaller impact on developed countries. Additionally, the HIV/AIDs crisis slowly got worse before getting better. This trend holds both of all data and when the data is divided by country category.

Figure 2 presents the changes in adoption of TRIPS over time. Initially, TRIPS was in force in 73 countries in 1995. This is 58% of the countries within the data set. By the end of 2016, 111 countries within the data set had TRIPS in force. This is 89% of the countries within the data set. Adoption by DCs was done by 2000, while developed and LDCs adopted more gradually over time following the high number of initial adopters in these categories. This is displayed in figure 2.

By comparing figure 1 to figure 2, we would might expect to see some evidence of TRIPS influencing HIV/AIDs related deaths. A cursory glance indicates that this isn't the case. It is possible that the HIV/AIDs crisis is severe enough that any change due to implementation of TRIPS is small relative to the changes due to the spread of the disease and efforts by nations



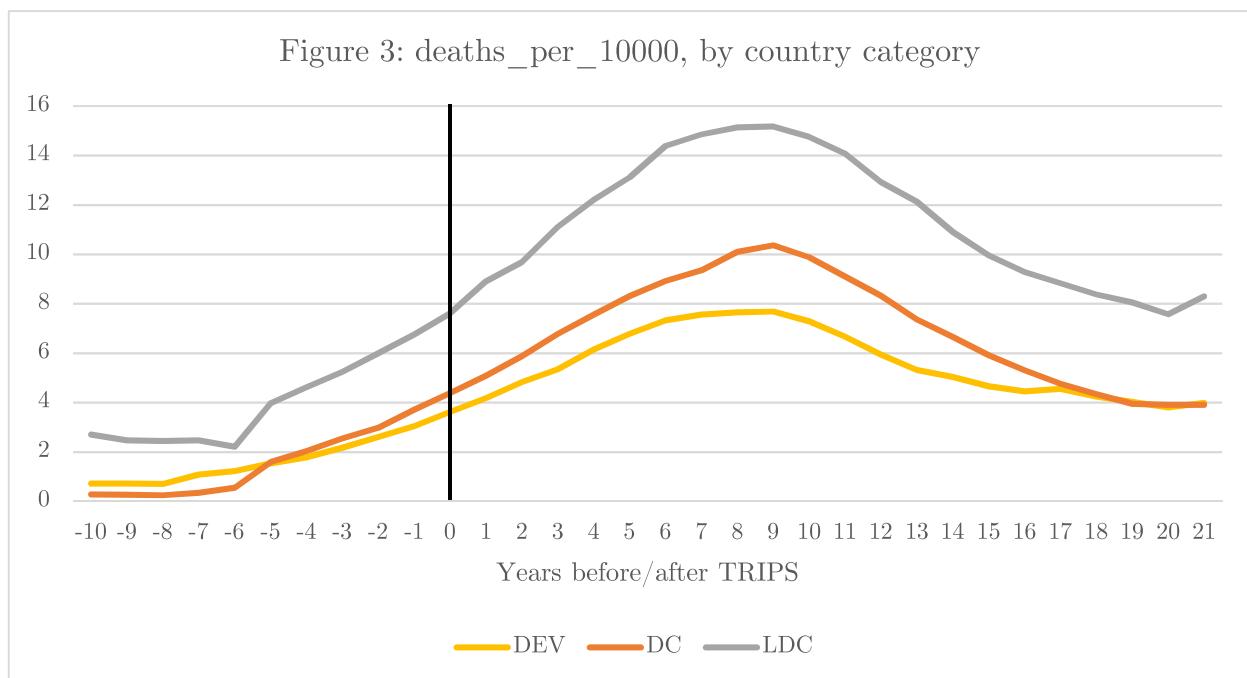
and international bodies to combat the disease. This would indicate that there may be other omitted variable affecting the spread of HIV/AIDs.

Table 1

		All Countries	LDCs	DCs	Developed Countries
	1995-2016	5.773 (12.239)	9.109 (13.740)	5.841 (12.551)	4.005 (10.777)
deaths_per_10000	1995	4.248 (9.300)	7.376 (12.369)	4.245 (9.869)	3.010 (6.509)
	2005	8.869 (17.350)	13.632 (18.756)	9.622 (18.216)	5.937 (15.678)
	2015	3.926 (6.662)	6.413 (9.292)	3.632 (5.686)	2.821 (5.237)
Total Number of Countries		124	30	36	58

Note: Means and standard deviations presented. Standard deviations are in parentheses.

To look more closely at the effect of TRIPS on HIV/AIDs related deaths, figure 3 presents the mean deaths_per_10000 using the time before/after TRIPS was implemented instead of year. One might expect to see a sharp increase immediately or shortly after TRIPS implementation and a steeper slope following the implementation. This is not immediately clear from the graph, likely due to similar reasons mentioned earlier occurring frequently after the implementation of TRIPS. A regression may be more effective at picking up any potential effects of TRIPS.



Econometric Model

A panel regression was performed. The specification is as follows:

$$D_{cy} = \alpha + \beta_1 T_{cy} + \beta_2 DC_c + \beta_3 DC_c * T_{cy} + \beta_4 LDC_c + \beta_5 LDC_c * T_{cy} + \delta_y + \delta_c + \epsilon_{cy}$$

D_{cy} is deaths_per_10000 in country c in year y . Population by country was taken from The World Bank and was combined with HIV/AIDS related deaths per country. T_{cy} is a dummy variable which is 1 if country c has joined the TRIPS agreement in year y and is also referred to as TRIPS_in_force. LDC_c is a dummy variable which is 1 if country c is a LDC, and DC_c is a dummy variable which is 1 if country c is a DC. Interaction terms using T_{cy} and both LDC_c and DC_c were also used. δ_y and δ_c represent year and country fixed effects, respectively. Country fixed effects allow for country specific effects to be considered, such as a high initial prevalence of HIV/AIDS in a country. Year fixed effects will consider global factors of the disease, such as efforts by international bodies to combat the disease. The results of this regression are presented in table 2.

	deaths_per_10000		
TRIPS_in_force	2.117*** [.486]	4.961*** [.594]	4.014*** [.677]
DC		.669 [.501]	.004 [.977]
DCxTRIPS_in_force			1.140 [1.140]
LDC		4.404*** [.517]	2.079** [.873]
LDCxTRIPS_in_force			3.582*** [1.084]
Country Fixed Effects	Yes	No	No
Year Fixed Effects	Yes	Yes	Yes

*** - significant at the 1% level ** - significant at the 5% level * - significant at the 10% level

Standard errors are contained in brackets. Data is from 124 countries from 1990 to 2016, inclusive, resulting in 3224 observations.

Under all specifications used with this model, TRIPS_in_force has very significant positive coefficients. In the model using interaction terms, countries which had TRIPS in force experienced 4.014 more deaths per 10000 than a country that didn't, a result which is significant at the 1% level. Given that the mean number of deaths per 10000 is 2.565 across all observations when TRIPS was not in force, TRIPS is expected to increase HIV/AIDS related deaths by 156%. This result is in line with the theoretical impact as well: granting a monopoly for a lifesaving drug would reduce the quantity of life-saving medication sold, and increase deaths.

Another key result revolves around the interaction terms LDCxTRIPS_in_force. The coefficient means that LDCs experience an additional 3.582 deaths per 10000 when TRIPS as compared to a developed country or DC. This result is significant at the 1% level. This means that an LDC which has implemented TRIPS experiences 7.596 more HIV/AIDs related deaths relative to a country which has not implemented TRIPS. The equations needed to derive this result follow below.

$$\begin{aligned} E(D|TRIPS_in_force = 1, LDC = 1) &= \alpha + \beta_1 + \beta_4 + \beta_5 \\ E(D|TRIPS_in_force = 0, LDC = 1) &= \alpha + \beta_4 \\ \hline E(\Delta D|\Delta TRIPS_in_force, LDC = 1) &= \beta_1 + \beta_5 \end{aligned}$$

In least developed countries, where the average number of HIV/AIDs related deaths per 10000 is 4.276 in years in which TRIPS was not implemented, we would expect to see a 177% increase in HIV/AIDs related deaths due to TRIPS implementation. Theory supports this outcome: Most developed countries already had strong patent systems in place prior to TRIPS, while many LDCs did not. This would mean that TRIPS would disproportionately affect LDCs. Switching between using country fixed effects and dummy variables for LDCs and DCs changes the coefficients, but doesn't change the sign or the significance.

The HIV/AIDs crisis and patent laws are both complex items that have many factors affecting them. This leads to a possibility of omitted variables. One omitted variable is the issuance of compulsory licenses. TRIPS contained a provision allowing the licensing of drugs for crises. This was provided to potentially offset the negative effects of patents. A regression using a dummy variable for compulsory licenses was also performed. Instances of compulsory licensing were taken from Beall and Kuhn (2012). A dummy variable was created, called compulsory_license. This variable is 1 in a country and year when a compulsory license was issued for HIV/AIDs related drugs. The results of that regression are presented in table 3. Note that this data only reflects instances of compulsory licensing prior to 2011.

In theory, it would be expected that compulsory licenses would reduce HIV/AIDs related deaths by making pharmaceuticals more available. Additionally, it would also be expected to decrease the value of TRIPS_in_force, since the most severe instances of HIV/AIDs outbreaks would be addressed by a compulsory license. Only one regression found a significant coefficient for compulsory licenses. While this mechanism may work in theory to reduce the negative effect of increased patent protection, the results of the regression do not support that. Additionally, there were only 19 instances where compulsory licenses were issued in 1990-2010, indicating that the tool is rarely used.

Table 3

	deaths_per_10000		
TRIPS_in_force	2.171781*** [.5344734]	5.74884*** [.7229842]	4.663023*** [.8358431]
Compulsory License	2.024914 [1.546565]	4.889376 [2.990102]	4.969208* [2.99637]
DC		.5423498 [.6224861]	.1274091 [1.081929]
DCxTRIPS_in_force			.942453 [1.32513]
LDC		4.661789*** [.6357835]	2.315978** [.9823342]
LDCxTRIPS_in_force			4.024603*** [1.288404]
Country Fixed Effects	Yes	No	No
Year Fixed Effects	Yes	Yes	Yes

***- significant at the 1% level ** - significant at the 5% level * - significant at the 10% level

Standard errors are contained in brackets. Data is from 124 countries from 1990 to 2010, inclusive, resulting in 2480 observations.

Robustness Test

One might observe that HIV/AIDs was increasing over the years, particularly in 1995 when many countries signed onto TRIPS. This increase may be correlated with TRIPS_in_force, even though it was already occurring prior to TRIPS. Running the same regression with all years prior to 2005 removed from the sample results in coefficients of similar values and significance to earlier regressions, indicating that this upward trend from 1990 to 2004 wasn't being captured by the TRIPS_in_force variable in prior regressions. The results are presented in table 4.

Table 4

	deaths_per_10000		
TRIPS_in_force	2.581*** [.987]	3.324*** [.811]	2.399*** [.901]
DC		1.196* [.687]	1.406 [.692]
DCxTRIPS_in_force	See note		
LDC		4.596*** [.711]	.4799274 [1.900]
LDCxTRIPS_in_force			4.767** [2.041]
Country Fixed Effects	Yes	No	No
Year Fixed Effects	Yes	Yes	Yes

***- significant at the 1% level ** - significant at the 5% level * - significant at the 10% level

Standard errors are contained in brackets. Data is from 124 countries from 2005 to 2016, inclusive, resulting in 1488 observations.

Note: Since all DCs except one implemented TRIPS prior to 2005, this variable would capture nearly the same information as DC. As such, it has been left out of the regression.

Further Work

One key way to improve the results of this paper would be to find the exact dates TRIPS related laws went into effect in a country. Currently, the date that a country joined TRIPS is included in this paper – but the exact dates that these reforms were implemented would paint a more accurate picture. This task would be difficult, as it would involve acquiring and reading through patent laws – historical and modern – for most of the globe.

An alternative mechanism which could provide even more accurate regressions would be acquiring the length of the term of a pharmaceutical patent by country by year. This would involve a similar process to the above, but would require even more details from said pharmaceutical patents broken out by year.

There is evidence there may be omitted variables. Other variables should be found and incorporated into this study. These additional variables may include price controls and other mechanisms which countries can use under TRIPS to reduce the price of pharmaceuticals, such as compulsory licensing. Epidemiology papers on the spread of HIV/AIDs would be a good location to begin searching for more explanatory variables.

Similar research on other diseases could be done to verify these effects. Research could also be done in a different area of the economy to get further insight into the effects of the TRIPS agreement on the more general economy.

Conclusion

The results of regressions used within this paper suggest TRIPS introduction is correlated to deaths due to HIV/AIDs. This lines up with the theory regarding patents and more broadly monopolies. The granting of monopolistic rights for a patent would reduce the quantity sold of an item, and if that item is a lifesaving item, it may increase deaths. Additionally, TRIPS seems to have disproportionately affected LDCs, which is a similar conclusion that Gold et al found in their work as well.

While the results of this paper seem to paint a negative portrait of patents, more research into the area would be needed to be more conclusive. Instead of using TRIPS as a proxy for patent strength, finding individual, country level patent information would provide a stronger explanatory variable. Additionally, the HIV/AIDs crisis is very complex, and omitted variables are something that should be further addressed.

References

- Beall, Reed, and Randall Kuhn. "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis." PLOS Medicine. January 10, 2012. Accessed November 13, 2017.
<http://journals.plos.org/plosmedicine/article?id=10.1371%2Fjournal.pmed.1001154>.
- WIPO. Accessed November 13, 2017. <http://www.wipo.int/portal/en/>.
- "AIDSinfo." AIDSinfo | UNAIDS. Accessed November 13, 2017. <http://aidsinfo.unaids.org/>.
- Deere, Carolyn. "The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries." Oxford Scholarship Online. May 2009. Accessed November 13, 2017.
- Dewitt, Julia. "Amazon's 1-Click Patent Is About To Expire. What's The Big Deal?" NPR. September 06, 2017. Accessed November 13, 2017.
<https://www.npr.org/2017/09/06/548819270/amazon-s-1-click-patent-is-about-to-expire-what-s-the-big-deal>.
- Gold, E. Richard, Warren Kaplan, James Orbinski, Sarah Harland-Logan, and Sevil N-Marandi. "Are Patents Impeding Medical Care and Innovation?" January 2009. Accessed November 13, 2017. <http://apps.who.int/medicinedocs/documents/s17581en/s17581en.pdf>.
- Hall, Bronwyn H., and Dietmar Harhoff. "Recent Research on the Economics of Patents." January 2012. Accessed November 13, 2017. <http://www.nber.org/papers/w17773.pdf>.
- Kyle, Margaret, and Anita McGahan. "Investments in Pharmaceuticals Before and After TRIPS." October 2009. Accessed November 13, 2017. <http://www.nber.org/papers/w15468.pdf>.

"Population, total." Accessed November 13, 2017.
<https://data.worldbank.org/indicator/SP.POP.TOTL>.

"Understanding the WTO - least-developed countries." Accessed November 13, 2017.
https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm.

"World Trade Organization." Members and Observers. Accessed November 13, 2017.
https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.