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April 6, 2017

The Impact of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
on HIV/AIDS Mortalities

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An abstract of
a thesis submitted to the Faculty of Emory College of Arts and Sciences
of Emory University in partial fulfillment
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Bachelor of Arts with Honors

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Abstract

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This paper examines the impact of the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS" or "the Agreement" or "the Legislation") on the HIV/AIDS mortality rate of each member nation of the WTO based on country level analyses of the Joint United Nations Programme on HIV/AIDS (UNAIDS) data from 1990-2003. There is a statistically significant effect of the Agreement on the HIV/AIDS mortality rate based on the data provided by UNAIDS. This study finds that nations with poor legal regimes were most affected by the Agreement while developed nations were less affected. Nations with a strong legal infrastructure were able to cope with the requirements of this Agreement and as such their HIV mortality rate was unaffected. This study finds that after the introduction of antiretroviral treatments in 1996 an almost immediate decrease in HIV mortality rate occurred in developed nations as compared to a lagged effect in underdeveloped nations. Specifically the mortality rate in underdeveloped nations with poor patent protection continued to rise until 2003 with the initiation of the Presidents Emergency Plan for AIDS relief (PEPFAR). This statistical analyses holds true while controlling for a countries GDP per capita, unemployment rate, healthcare expenditures and life expectancy. The effect of this legislation does have larger impact on some of the member nations of the WTO relative to others.

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Acknowledgements

I would like to thank my advisor Dr. David Howard for his time and assistance along the way. Additionally I like to thank Dr. Maria Arbatskaya and Dr. Timothy Albrecht for their guidance and input. Also I would like to thank Dr. Robert O'Reilly for his assistance with data procurement and analysis.

Table of Contents

Table of Contents

I. Introduction	1
II. Literature Review	10
a. World Trends	15
III. Contributions	17
IV. Dataset and Equation Structure	18
a. Dependent Variable	18
b. Independent Variable.....	19
c. Control Variables.....	21
d. Equation Structure	24
V. Results	25
VI. Discussion and Limitations	27
VII. References	31
Tables	34
Summary Statistics	34
Table 1: Regression of <i>TRIPSeffect</i> on HIV/AIDS Mortalities, Year Included	35
Table 2: Regression of <i>TRIPSeffect</i> on HIV/AIDS Mortalities, Year Omitted	36
Table 3: Regression of <i>TRIPSeffect</i> on HIV/AIDS Mortalities, Year Included	37
Table 4: Regression of <i>Index of Economic Freedom</i> on HIV Mortality Rate	38

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I. INTRODUCTION

Instituted on January 1, 1995 the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) remains the most comprehensive and wide-ranging agreement involving intellectual property protection. Prior to 1995 patent protection varied from country to country, in most circumstances only developed nations would provide protection for new inventions. Typically patent length for a developed country lasted twenty years from the date of filing whereas most developing countries either did not issue patents or rather chose to only issue process patents whereby only the method of production was patented but not the product itself. Such patents would last for short periods of time, approximately 5 to 7 years (Elliott and Bonin, 2002). Estimates claim that at the time of implementation over 40 countries in the world did not grant patent protection for pharmaceutical products (WHO 2016).

Negotiated during the Uruguay Round of negotiations from 1986 to 1994, the TRIPS Agreement introduced intellectual property law into the international trading system by requiring each member of the WTO to implement the minimum uniform standards of intellectual property protection, including pharmaceutical patent protection. According to the WTO, "patents would provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions" (WTO 2016). This Agreement would effectively require all member nations to provide patent protection for pharmaceuticals filed after January 1, 1995.

Mainly lobbied by industrialized nations including the United States and the European Union, proponents of the Agreement argue that TRIPS would provide adequate standards of protection for intellectual property (IP) and would provide greater stability and predictability

within international economic relations (Subhan, 2006, 152). It was believed that different standards of IP protection would create unfair trading practices between developed and developing countries, and therefore this agreement would seek to remove such barriers to trade. According to the introduction of the TRIPS Agreement the set purpose is “to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade” (TRIPS Agreement, *supra* note 4, art. 30).

TRIPS along with two other Agreements, the GATT (the General Agreement on Trade and Tariffs and Trade) and the GATS (the General Agreement on Trade in Services) form the foundations of the WTO which remains to today the most powerful and influential regulator of international trade policy. As a result, compliance with all WTO regulations and trade agreements is a requirement for all member nations seeking to maintain and grow bilateral and multilateral free trade. In doing so, each individual country must ratify the WTO agreements within their own governments and change laws accordingly to maximize obedience to WTO standards. Failure to do by any member nation will result in severe discipline from the WTO’s dispute settlement process which has the power to remove an individual nation from international trading markets or to impose trade sanctions (Elliott and Bonin, 2002, 3).

The TRIPS Agreement, however, has been highly criticized by scholars and academics many of which argue by requiring all countries to implement a minimum standard for intellectual property rights, the effect of the Agreement would be detrimental to the health of individuals in poor nations (Ramon-Borrell, 2007, 505). It has been contended that strong protection of IP rights will prevent many of the diseased and sick to gain access to essential medications at an

affordable price. This is mainly the result of poorer nations no longer having the ability to manufacture or import generic forms of a patented drug. Thus the market exclusivity and the enactment of strict patent laws as provided by TRIPS seeks to slow the entry of much more affordable generic substitutes. Moreover, it is illegal for any pre-clinical trials or testing of generic drugs to take place prior to the expiration of the patent on a particular pharmaceutical. Not to mention that even if most countries had the ability to produce generic drugs, most undeveloped nations lack the healthcare infrastructure to manufacture these medications or the capital to pay for them (Abdelgafar, 2006, 50).

Furthermore, many developing nations suffer from a lack of legal means to rewrite legislation in their own parliaments to be in full compliance with TRIPS ultimately causing many to implement standards that developed nations adhere to, which in the majority of circumstances provides unnecessarily strong protection of intellectual property (Lanjouw, 2003, 92). Others have utilized the services of the World Intellectual Property Organization (WIPO), which unfortunately has often pushed underdeveloped nations to provide standards that are above the requirements needed to satisfy TRIPS (Finger, 2000, 430). There are two sides to the patent argument which has made a solution to these complex issues very challenging to obtain. The driving for and against argument are below:

Pro: Intellectual property laws foster innovation and provide incentives for pharmaceutical companies to invest large amounts of money and time into research and development (R&D) as well as the production of a medication (Anderson 2006).

Con: Intellectual property laws keeps drug prices high, as pharmaceutical manufacturers need to recoup R&D costs, and limits the availability of the drug in the marketplace, essentially causing medications to be less accessible by those who need them (Watal 2000).

The TRIPS Agreement, however, in an effort to quell a public health crises does allow for member nations to make use of two valuable mechanisms: compulsory licensing and parallel importing. Under Article 31 of the Agreement, member nations have the ability to issue compulsory licenses thus permitting either the government, a corporation or an individual to use or produce a drug without the rights or authorization from the patent holder (Subhan, 2006, 155). In essence, the Agreement allows for the rights of the patent holder to be circumvented at any time should a certain nation deem it necessary. As Elliott and Bonin describe “compulsory licenses are usually granted on grounds of general interest such as public health, economic development, national defense and the absence of working (i.e. when the holder is not “exploiting” its patent). The TRIPS Agreement does not limit the grounds on which governments or courts may issue compulsory licenses.” (2002, 5).

As Lanjouw importantly points out, “[compulsory licensing] allows for competition to lower prices and avoid delays due to protracted negotiations between the government and patentees over the level of controlled prices.” (2003, 114). Essentially as a result of this type of licensing generic drug companies can produce a drug and sell it at significantly lower prices due to the negligent costs of research and development (R&D). This method effectively reinstates power within governments seeking to quell major national emergencies and crises in their respective countries.

While it can be an effective tool at combating various strict guidelines of the Agreement, compulsory licensing is not without its limitations:

- *Reasonable effort is required to seek a voluntary license*, member nations must negotiate first with the patent holder in an effort to obtain temporary authorization for the creation of the pharmaceutical (TRIPS, Article 31, section(b))

- *Issuing a compulsory license would require significant legal framework*, as mentioned before many underdeveloped nations fail to have a sufficient legal infrastructure to enact compulsory licenses while maintaining compliance with TRIPS guidelines.
- *Adequate remuneration would still have to be paid to the patent holder*, essentially the patent holder must still be reimbursed in the form of a royalty if compulsory license is issued for the patented invention (TRIPS, Article 31, section (h))

Perhaps the greatest limitation of compulsory licensing lies within Article 31(f) of the Agreement, “*any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use*” (TRIPS, Article 31, section (f)). Thus more simply, member nations issuing compulsory licenses would not have the ability to export generic drugs to other nations, the issuing government could only supply the “domestic” market. This effectively creates a strong barrier blocking access to affordable medications. “Many developing countries don’t have the ability to produce their own generic drugs and would need to import them from other countries that do. But those countries that do have a generic drug industry are not permitted under TRIPS to issue a compulsory license authorizing someone to make a patent-protected drug primarily for export to other countries.” (Elliott and Bonin, 2002, 6).

The complications of domestic market supply, however, were resolved with the implementation of Paragraph 6 of the Doha Declaration, also known as the *Doha Assignment* ratified by the WTO on August 30, 2003. The Doha Assignment effectively excused all least developed countries from the requirement set forth by Article 31(f); therefore member nations whose manufacturing infrastructures is consistently lacking would now have the ability to import across borders generic drugs produced by other countries.

“The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph” (Paragraph 6, Doha Assignment, 2003).

Beyond compulsory licensing, another tool available to members of the WTO as provided in TRIPS includes the use of parallel importing. Based on the idea of “exhaustion” parallel imports, also known as grey-market imports, includes patented items shipped across borders. That is patented items originating from a particular nation brought into another nation where a patent already exists. Typically parallel importation takes advantage of the price differences for the same good available in different markets (t’Hoen, 2003, 43). Limitations to parallel importing are also clearly evident, some of which include: the lack of significant legal framework, investment in foreign markets rather than domestic, as well as the absence of differential pricing between markets.

As a result of the numerous limitations within the TRIPS Agreement as well as the many barriers evidently created my research would focus on the impact of the TRIPS Agreement and its effects on pharmaceutical patents of antiretroviral treatments for HIV/AIDS in developed and developing countries. My thesis would form around the following research question: How did the implementation of the TRIPS Agreement affect patient outcomes, measured by mortality rates of individuals due to HIV/AIDS in developed and developing nations? I specifically chose to only examine deaths as a result of HIV/AIDS as it would first of all allow me to narrow down the cause of death in my study but moreover HIV/AIDS is a terminal disease that has the ability to be cured with antiretroviral therapy drugs. Therefore HIV/AIDS would act as a strong

candidate to test my hypothesis regarding the impact of the TRIPS Agreement as I am able to compare firsthand the mortality rates of countries affected and those unaffected. As this agreement was instituted in 1995, the time period to be examined would be between 1990 and 2003, this span of thirteen (13) years would take into account the year's preceding and following the passing of the Agreement.

My initial hypothesis was as follows: From the years 1990 to 1996 both developed and underdeveloped countries will witness a constant rise in the number of HIV/AIDS mortalities resulting from both the lack an antiretroviral treatment as well as the absence of the TRIPS Agreement. With the introduction of antiretroviral therapy to the world market in 1996 as well as the implementation of TRIPS in 1995, developed nations will see a decrease in mortalities from 1996-2003 as they are not impacted by the TRIPS Agreement due to substantial intellectual property laws already in place. During the same period, 1996-2003, the death toll in undeveloped nations, many of them affected by TRIPS, will consistently rise until 2003 with the implementation of the Emergency Plan for AIDS Relief (PEPFAR) initiated by US President George W. Bush of that same year (Berger et al, 2011, 5). I excluded the PEPFAR period, 2004-Present, since this program provides generic ART's to underdeveloped nations at no cost. Graph 1 and 2 both depict the overall mortality trend as it relates to the USA, a developed nation, and South Africa, a developing nation.

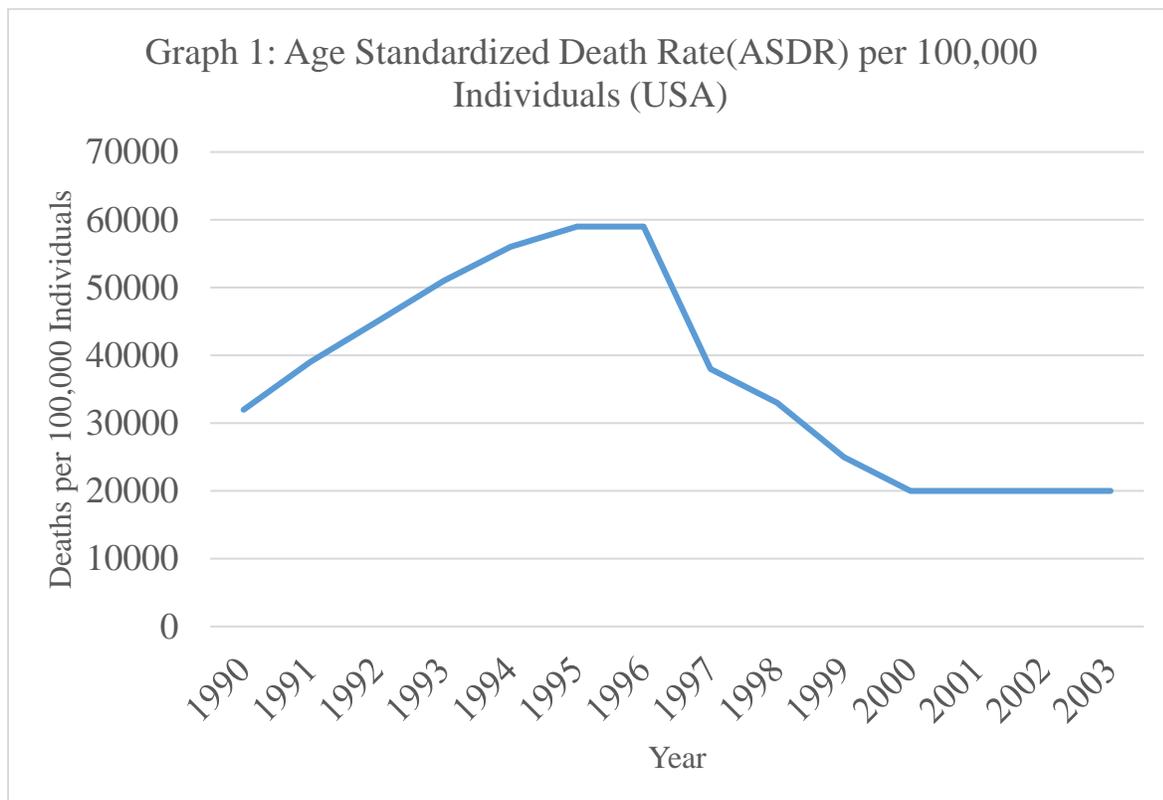
For reference purposes antiretroviral medications are not solely made up of one drug, in fact ART's are created by combining numerous different drugs and chemicals known as the "ART concoction", each of which has the ability to be patented. Therefore the process of creating generic versions of ART's becomes rather infeasible due to the intellectual property law

standards put in place by TRIPS and would therefore certainly face challenges within the stages of compulsory licensing and parallel importing.

According to the National Institutes of Health (NIH) the following antiretroviral medicines are required to treat HIV:

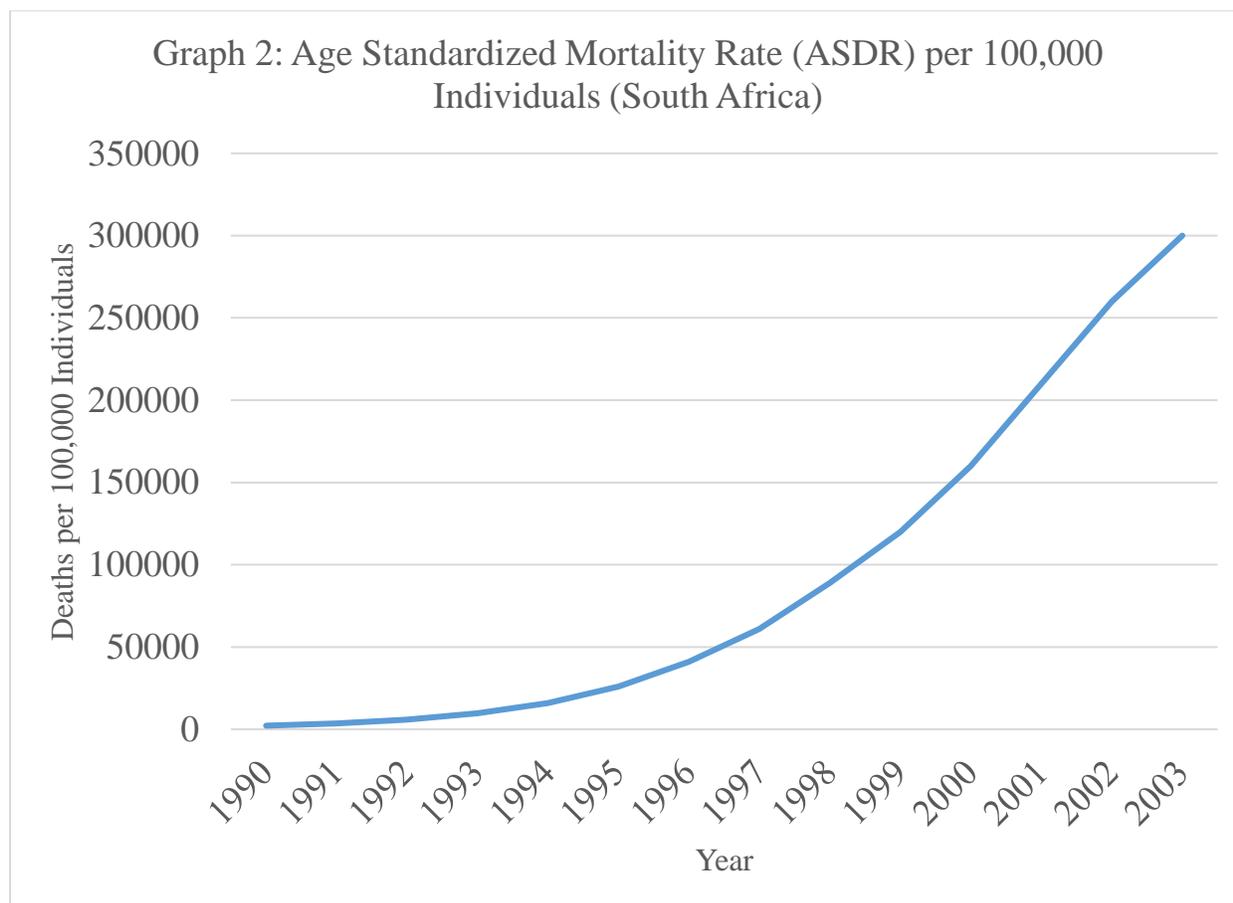
- Nucleoside/nucleotide reverse transcriptase inhibitors, such as abacavir
- Nonnucleoside reverse transcriptase inhibitors (NNRTIs), such as efavirenz
- Protease inhibitors (PIs), such as atazanavir, darunavir, and ritonavir
- Entry inhibitors, such as enfuvirtide and maraviroc
- Integrase inhibitors, such as dolutegravir and raltegravir

Graph 1: Overall HIV mortality trend in the United States



Source: UNAIDS data on HIV/AIDS Mortalities

Graph 2: Depiction of the HIV mortality trend in South Africa



Source: UNAIDS data on HIV/AIDS Mortalities

II. Literature Review

There exists substantial literature widely available to the public regarding the benefits and criticisms of the TRIPS Agreement. A number of scholarly articles have examined this topic and analyzed many of the central complications, and typically based on the findings many put forth recommendations for solutions to the present issues. Most of the studies discuss the impact of the Agreement upon access to HIV/AIDS pharmaceuticals and its effects on the prices of important

antiretroviral treatments, however, very few sources have researched whether or not there was a direct impact as seen by a change in the mortality rate.

Joan Ramon-Borrell (2007) has done extensive study in the field of pricing and patents. Using sales of AIDS drugs in 34 low-and-middle income countries between 1995 and 2000, Borrell found that patents do cause an increase in drug prices. These prices are correlated to the per capita income levels of the specific country. Borrell utilizes various data sets from the IMS Health database to run regressions of antiretroviral therapy drugs as compared to US price ratios. Much of her research shows that in the absence of generic drugs, drug prices happen to be significantly higher than the normal average. She provides 3 significant reasons as to the causes of changing pricing dynamics: (1) the introduction of cheaper generic drugs, (2) the decrease/increase in nominal prices in current US\$ for drugs already on the market and (3) the appreciation/depreciation between local and US currency. Perhaps most interestingly, she found that many drug manufacturing firms follow a “skimming strategy” whereby “drug firms introduce their products at a high price which later on declines” (Borrell, 2007, 506).

Her rationale for high prices of medications is directly in line with my hypothesis arguing that TRIPS mandate of patent protection will cause significantly higher prices. As she states in her work, “patents prevent competition between the innovator of the drug (and any of its licensees) and the imitators (unauthorized providers). Patents prevent competition between providers of products that contain the same therapeutically active substance and that only differ slightly in other characteristics. The lack of such close competitors is expected to shift prices upward” (Borrell, 2007, 506).

Richard Caves and Mark Hurwitz (1991) had conducted a study specifically in the USA to examine how the expiration of a patent would affect the price of the drug. Analyzing over 30

drugs that lost patent protection between the years 1976-87 using aggregate data on drug prices and costs from the Merck Drug Index, the U.S. Patent and Trademark Office and IMS America, their research concluded that the average generic to branded price ratio is 59%. That is with the entrance of one generic manufacturer, the price will of the generic will be 59% cheaper than branded drugs with an expired patent, but drops to 17% with 20 generic manufacturers. Caves and Hurwitz attribute to the fact that numerous generic competitors will actually cause the lead branded drug, which had lost patent protection, to increase in price.

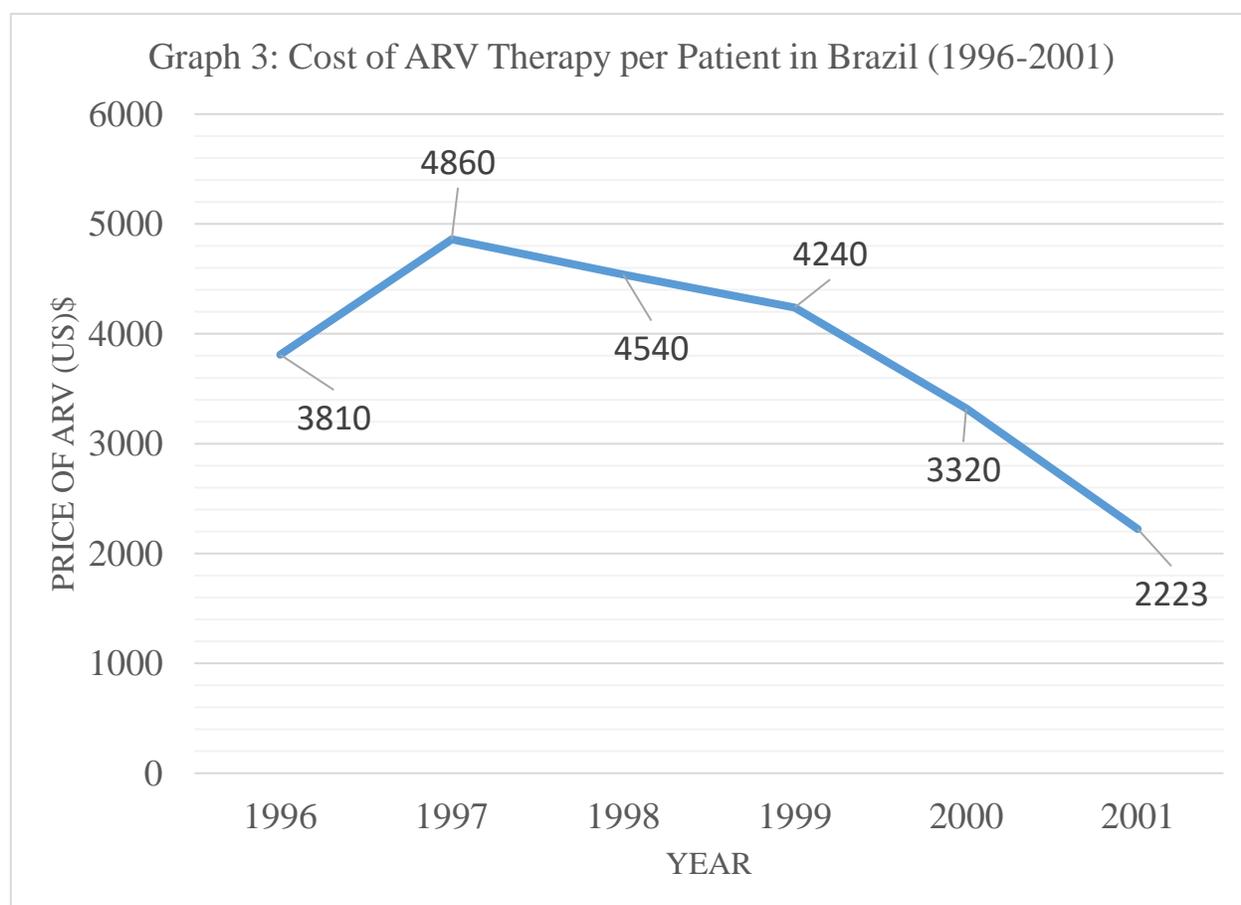
Jayashree Watal (2003) examined the impact of TRIPS on access to essential HIV/AIDS medications in developing countries during the years 1995-2003, using sales data from IMS Health. Watal collected 15 ARV's in 21 different countries to conduct her study and used a methodology of estimating the relationship between likely entry decision across the specific drug, country and year as well as the relationship to market coverage. Her findings were as follows:

- (1) On average patents increase availability of new drugs from 28% to 33%
- (2) But patents reduce sales by 59% once the drug is available in the market place
- (3) Therefore, the net effect of these two counterbalancing effects is that patents reduce sales by 34%

Perhaps most interestingly, however, Watal conducted research to determine what the effect would be if no patent protection existed: "switching all drugs under patent regime to a no patent regime in our sample countries would have only increased the percentage of AIDS patients with access to new drugs from 0.88% to 1.18% between 1995 and 1999" (Watal 2003).

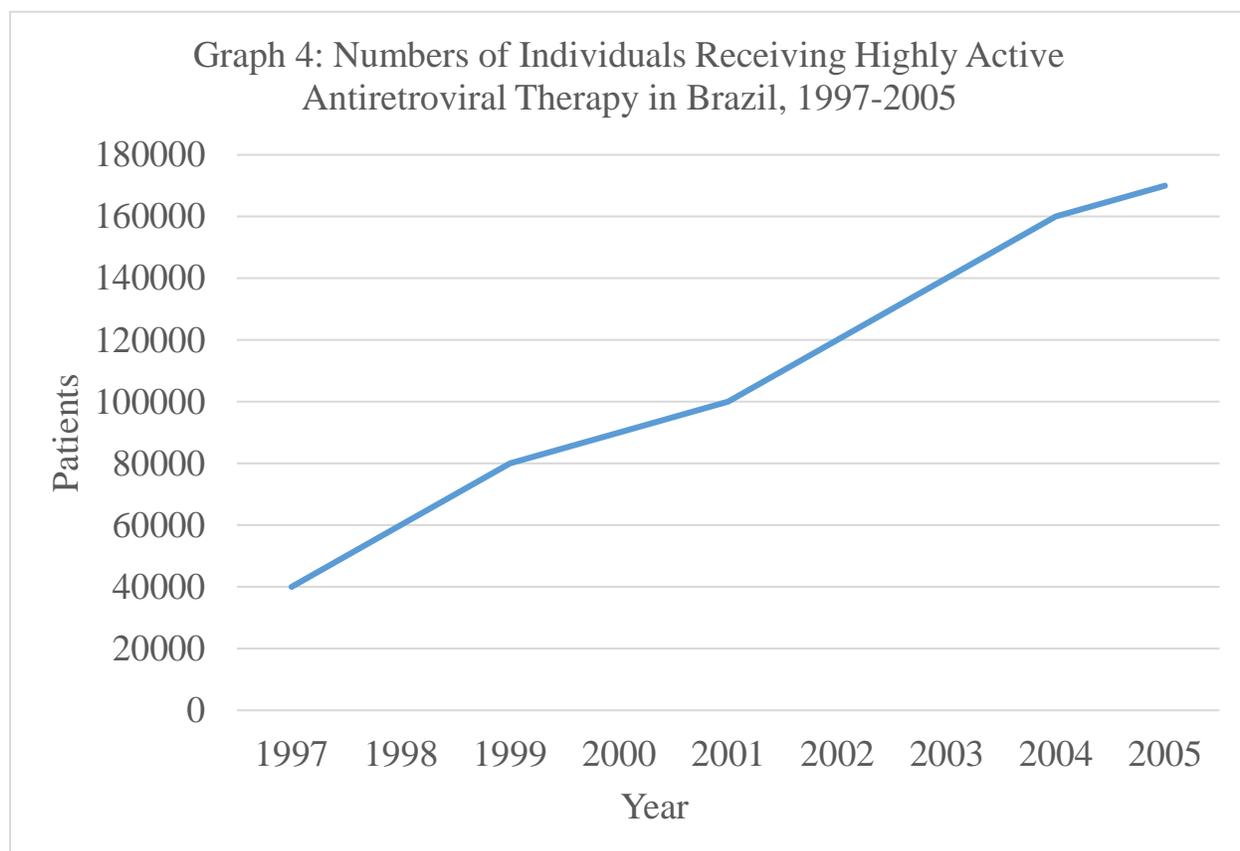
This begs the question of whether or not access was truly impacted since a significant change in availability is not directly evident.

A study conducted by Teixeira et al (2003) examined Brazil's approach to easy access of affordable essential medications. In the early 1990's Brazil implemented a universal access program to antiretroviral treatment. While Brazil claims the program is TRIPS compliant, it utilizes the threat of compulsory licenses to negotiate for lower prices of patented drugs. For drugs it cannot negotiate an acceptable low price, it produces locally and therefore is not subject to the costs of the patent holder. By doing so the average cost of ARV therapy has dropped continually from 1995-2001 as shown by the Graph 3 below.



Source: Ministry of Health, Brazil

These studies can be correlated with a continual increase in the number of individuals receiving ARV's over the same period, as shown in the Graph 4 below. It is clear based on the rational reasoning that as the price of the ARV's decrease more individuals will be able to afford them.



Source: Ministry of Health, Brazil

South Africa's legal struggles with the TRIPS are perhaps one of the most well-known examples of the Agreements shortfalls. In 1997 the U.S Trade Representative, at the request of 47 members of Congress as well as vigorous lobbying by PhRMA, famously filed a complaint against South Africa within the WTO's Dispute Settlement courts. The United States had argued that South Africa had enacted internal laws that favored compulsory licensing measures which contradicted standards of TRIPS.

We are writing to urge that the Administration respond to a law recently enacted by the Government of South Africa which effectively abrogates the intellectual property rights of foreign pharmaceutical companies operating in South Africa. These rights are guaranteed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which South Africa is a signatory (Letter to the US Trade Representative Ms. Charlene Barshefsky, February 2, 1998 retrieved from Fisher & Rigamonti, 2005, 35).

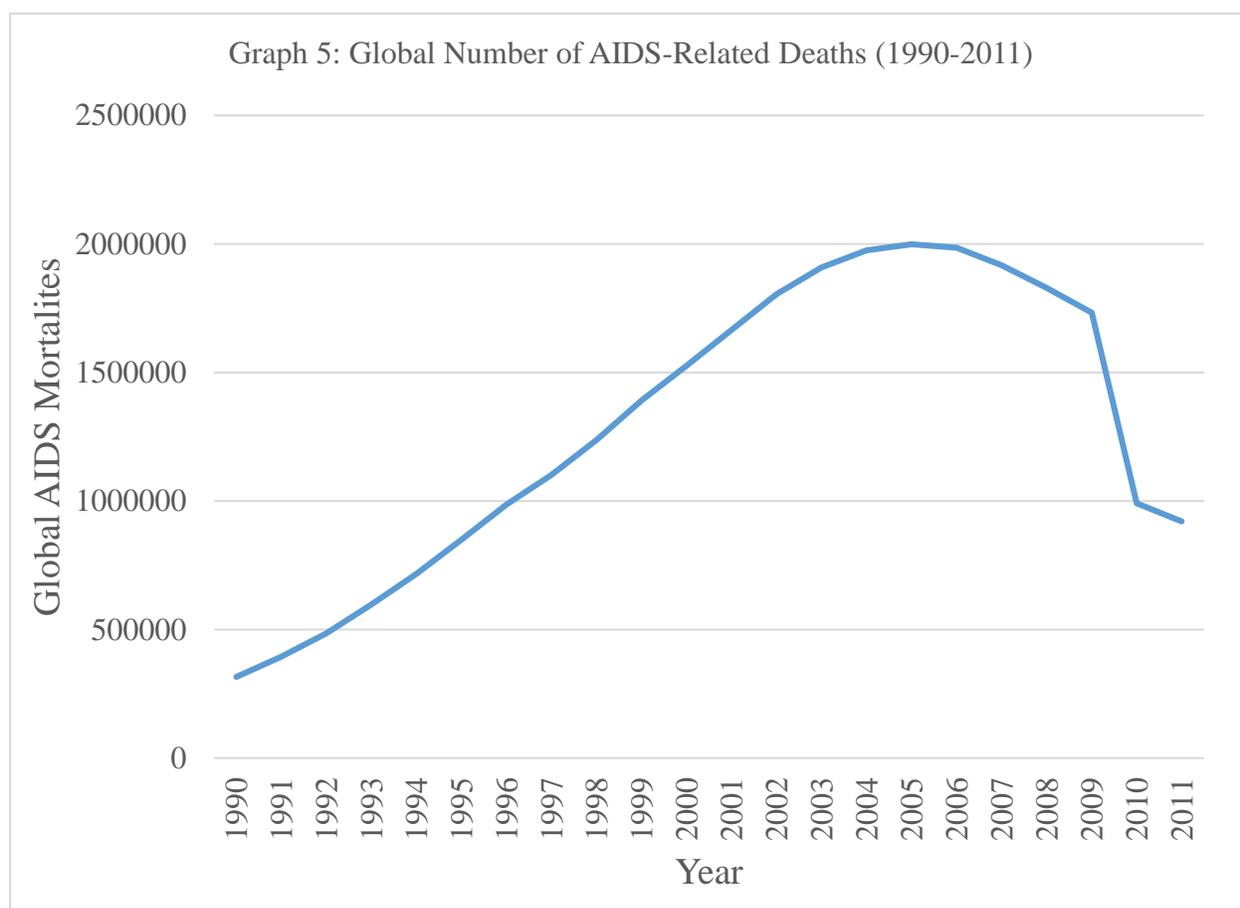
As a result the US had imposed trade sanctions upon South Africa, to only be removed should the South African parliament rewrite its laws. At this time South Africa was struggling from a major AIDS crisis with the death toll rising and pressure from the US made it very challenging to enact any sort of compulsory licensing for fear of retaliation. This was a major dilemma at the time considering antiretroviral therapy cost roughly \$1,000 per month while the average income per person was only \$2,600 per year (Fisher & Rigamonti, 2005, 3). While the US withdrew its complaint against South Africa in 1998 after worldwide condemnation, it became clear to some that TRIPS was not intended to be seen as a document that would allow for the promotion of public health, rather one that would serve the interest of pharmaceutical corporations.

a. World Trends

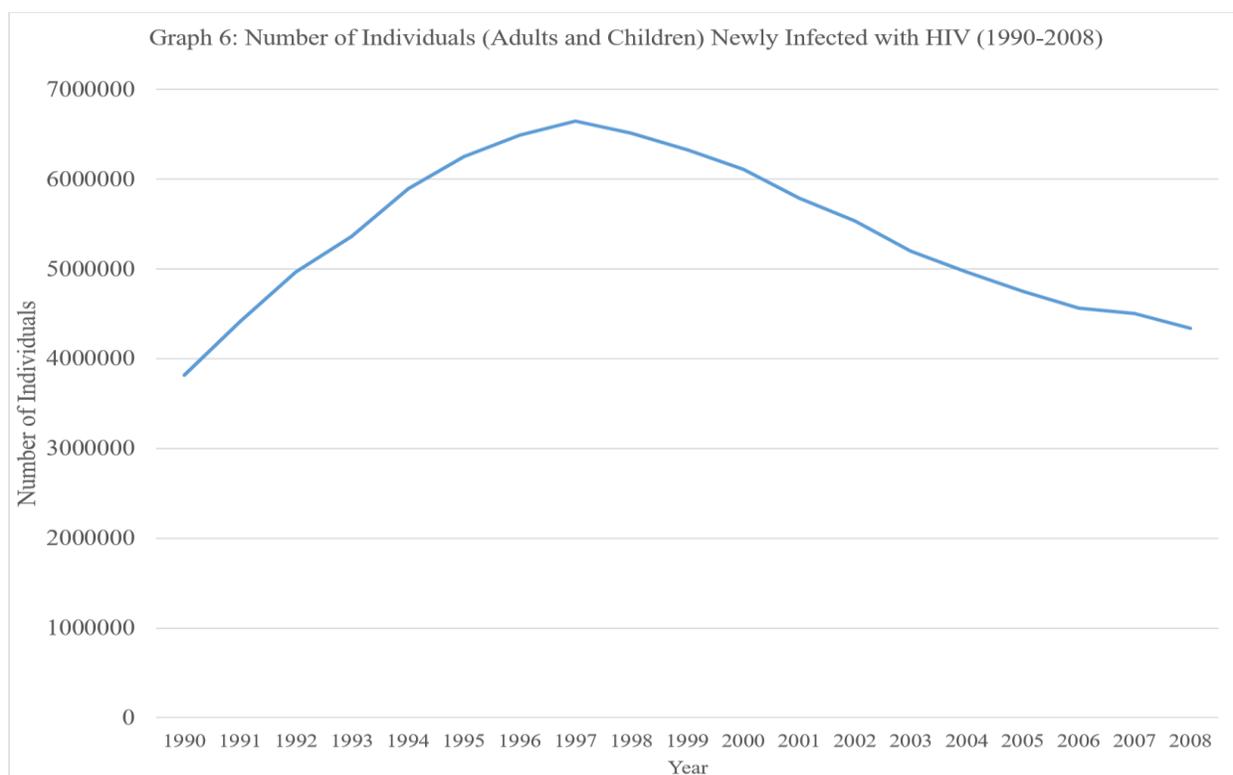
Generally speaking, global data shows a constant increase in mortalities due to HIV/AIDS from 1990-2004. The yearly death toll begins to decrease starting in 2005 and continuing into 2011. At the highest peak of the AIDS epidemic 2 million people died in the year 2005 as shown in Graph 5. New HIV infections globally plateaued in 1996 at 3.47 million individuals that year and has been on the constant decrease since then as shown in Graph 6.

These trends can be depicted in the graphic below depicting the global number of AIDS-related deaths.

The shift from a constant increase of both AIDS related deaths globally and new global HIV infections to a decrease in to a successive years can be directly related to the number of individuals receiving antiretroviral therapy (ART) across time. From this model it appears that as the number of individual's receiving ART's increases, total mortality as a result of AIDS decreases.



Source: UNAIDS



Source: World Development Indicators

One might note that new HIV infections globally actually begin decline in 1996, as shown by the graph immediately above, it is my belief that this is the result of individuals utilizing ART medications as a preventative measure. Various studies have tested and confirmed that taking ART's in advance may actually protect against later infections (Grant, 2010, 2588).

III. Contributions

This work presents two main contributions to the previous literature. First, while the prior literature makes strong mention as to how TRIPS had impacted pharmaceutical prices and accessibility of ARV's, my analysis is the first study to actually determine on a statistical level the effects of patent law. I use the implementation of the TRIPS Agreement as a platform to demonstrate universally how patent law may have had an impact on global mortality. Specifically, prior literature only made mention as to increase in HIV mortalities that may result,

but did however use observational data to determine the exact impact. This research uses aggregate data on HIV mortalities and legal structure quality to formulate a statistical argument that can be used to either justify or condemn the Agreement.

Secondly my research is a statistical analysis that depicts the HIV mortality rate declining in developed countries as a result of the introduction of ARV's as defined by the variable *PostTRIPS* to be explained later. In my study of previous literature, I have found that various works only alluded to the decreasing death rate following 2003, though however, do not make mention of the statistical impact ARV's had in developed nations that were able to afford them. I intend for my research to link to previous works conclusions of: 1) TRIPS on HIV mortalities in underdeveloped countries as well as 2) the impact of antiretroviral drugs in developed countries. To add to the previous points the table below is another clear example of how antiretroviral treatments do in fact have a major effect in the treatment of HIV as depicted through mortality.

IV. Dataset and Equation Structure

a. Dependent Variable(s)

The main outcome of interest for this study is the HIV/AIDS mortality rate, this is a cause-specific mortality rate measured by the following equation:

AIDS Mortality Rate

$$= \frac{\text{Deaths as a result of AIDS in a given year for a given country}}{\text{Size of the population of the country in which the deaths occurred for a given year}} \times 10^5$$

The rate was measured per 100,000 individuals

I obtained data regarding the number of HIV/AIDS mortalities from 1990-2003 using the data provided by the Joint United Nations Programme on HIV/AIDS (UNAIDS) Database. UNAIDS is one of the leading international organizations that track mortality rates due to HIV/AIDS over a period of time for all member nations of the WTO. UNAIDS compiles data by utilizing a combination of independent investigation by third party researchers as well as accumulating the data from the civil ministry of each respective country. According to UNAIDS one of the main methods of compiling data is through the Global Aids Response Progress Reports (GARPR) in which “data are compiled on antiretroviral therapy, HIV-related behaviours, policies, expenditure data, and other indicators measuring progress toward global commitments” (UNAIDS 2017). These data sets consist of panel data monitoring the number of deaths due to HIV/AIDS in a particular year and country. From here I will be able to graph and analyze the change in the mortality rate for a particular country and have the ability to narrow the search into my desired research period from 1990-2003.

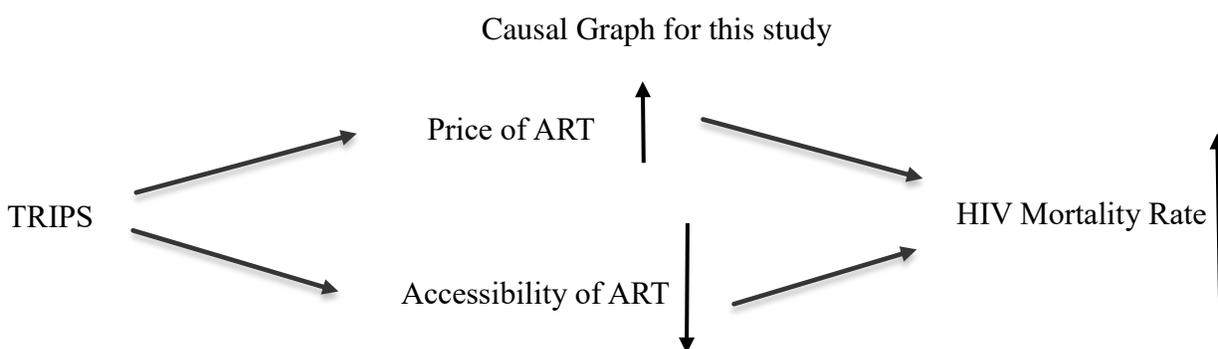
b. Independent Variable

The independent variable of this study will be defined as the presence of the *TRIPS impact* or as I define it *TRIPSeffect*. As I mentioned before in the introduction, the TRIPS Agreement applies to ALL member nations of the WTO, however it will ONLY impact countries that did not have intellectual property laws already established. By *TRIPSeffect* I am referring to the effect the Agreement has upon each member nation so to speak. For instance, if a nation has no intellectual property laws established prior to 1995 there will be an impact in that country with regards to patent rights for pharmaceutical medications.

If a country already has established intellectual property rights well beyond the requirements of TRIPS, the effect of the Agreement upon that respective nation will be

negligent. Based on the causal graph below entitled Model 1, my argument centers around the theory that the presence of the *TRIPSEffect* will cause prices of ARV's to remain steadily high while at the same time decreasing accessibility as a result of the market exclusivity and the absence of cheaper generics. By access I am referring to the availability of a drug in a certain

Model 1 that even if one did have the funds to pay for a particular medication, it could still not be obtained. Note that I do not imply that an increase in price decreases accessibility rather I am pointing out that both of those effects combined, an increase in price and decrease in accessibility, leads to a higher HIV mortality rate.



While data regarding the level of property rights protection is challenging to obtain, one can analyze the level of legal infrastructure associated with each patent regime. As a measure for my independent variable, the determination of the effect of TRIPS upon a particular nation's legal infrastructure, I will be utilizing data from a particular subset the *Index on Economic Freedom (IEF)* ranking property rights. More specifically it is a ranking assigned to each country based on the "degree of a country's legal protection of private property rights and degree of enforcement of those laws" (Index of Economic Freedom 2017). The *Index on Economic Freedom* is published annually by the Heritage Foundation and the Wall Street Journal. The *Index on Economic Freedom:Property Rights* is a ranking from 0 to 100 assigned to a country based on the ability of an individual to accrue private property that is fully secured and

protected by the laws of the state. Therefore the closer the value is to 100 the stronger the legal protection of property, both physical and intellectual, and the more robust patent protection regime and conversely the closer to 0, the weaker legal protection of property rights and patent protection regime. The data for the index can be found using the following link:

<http://www.heritage.org/index/explore>

c. Control Variables

While conducting this study is vital to control for several variables to allow the relationship between the other variables to be tested and better understood. In my literature review I have found that certain variables that need to be controlled for include: GDP per capita, the unemployment rate as a percent of the labor force, the development of healthcare infrastructure measured by healthcare expenditure as a percentage of GDP as well as life expectancy.

As defined by the World Bank:

- GDP per capita: GDP is the sum of gross value added by all resident producers in the economy plus any product taxes and minus any subsidies not included in the value of the products (“World Development Indicators, 2017”)
- Unemployment rate: Unemployment refers to the share of the labor force that is without work but available for and seeking employment (“World Development Indicators, 2017”)
- Healthcare expenditure: is a measure of the percentage of GDP spent on healthcare infrastructure such as hospitals, the provision of health services (preventive and curative), family planning activities, nutrition activities, and emergency aid designated for health (“World Development Indicators, 2017”)

- Life expectancy: Life expectancy at birth indicates the number of years a newborn infant would live if prevailing patterns of mortality at the time of its birth were to stay the same throughout its life (“World Development Indicators, 2017”)

Controlling for the GDP per capita in each country will allow for balanced income levels, essentially this variable is used for the determination of wealth in each nation. The unemployment rate is another factor that will also determine the wealth of a nation and the strength of an economy. Examining the healthcare infrastructure will assist in taking into account the ease at which one can access affordable healthcare. I believe controlling for this effect is significant as different healthcare systems can certainly play a factor in my research. For example, certain countries with a developed healthcare infrastructure will be able to mobilize its resources more effectively for its citizens. Data for all control variables (GDP per capita, unemployment rate, healthcare infrastructure, life expectancy) was gathered through the *World Bank Indicators Database* made available to me through the *Quality of Government (QOG)* Institute.

d. Regression Analysis

The objective of my study is to determine the association between TRIPS and HIV mortalities. My primary strategy is to examine HIV mortalities before and after the enactment of TRIPS. I ran a linear regression using OLS for the dependent variable, HIV mortality rate, based on the ranking of property right protection as gathered through the Index of Economic Freedom. I regress HIV mortality on the independent variable PostTRIPS to denote the years before and after the legislation was implemented. I then regress the HIV mortality rate upon the rest of my control variables as explained earlier. In running the regression I control for country and year fixed effects.

My preliminary regression is the following:

$$(1) \text{ HIV Mortality Rate}_{ct} = \beta_1 \text{Index of Economic Freedom} + \beta_2 \text{PostTRIPS} + \beta_4 \text{GDP per capita} + \beta_5 \text{Unemployment Rate} + \beta_6 \text{Healthcare Expenditure} + \beta_7 \text{Life Expectancy} + \alpha_c + \gamma_t + \varepsilon_{ct}$$

I have decided for purposes of simplicity to take the mean value of the *Index of Economic Freedom* for the desired years 1990-2003. By doing so I can negate the fluctuations in rankings over the years and create the binary variable *TRIPSeffect* which will be consistent for the years post legislation.

Therefore, I seek to estimate the following equation for country c in year t :

$$(2) \text{ HIV Mortality Rate}_{ct} = \beta_1 \text{TRIPSeffect}_{ct} + \beta_2 \text{PostTRIPS}_{ct} + \beta_3 \text{PoorLegal}_{ct} + \beta_4 \text{GDP Per Capita}_{ct} + \beta_5 \text{Unemployment Rate}_{ct} + \beta_6 \text{Healthcare Expenditure}_{ct} + \beta_7 \text{Life Expectancy}_{ct} + \varphi \text{Year} + \alpha_c + \gamma_t + \varepsilon_{ct}$$

HIV Mortality Rate is a continuous variable indicating the HIV Mortality Rate of country c at time t .

TRIPSeffect is a binary dummy variable equal to either 0 or 1 if the surveyed country was affected by the Agreement after its implementation. *TRIPSeffect* is the interaction term/variable between *PostTRIPS* and *PoorLegal*.

- From 1990 to 1995, all countries are given a value of 0
- From 1996-2010, if selected country had an *IEF* value greater than 70 (the 80th percentile), the country was designated as 0 for being unaffected by TRIPS
- From 1996-2010, if selected country had an *IEF* value less than or equal to 70 (the 80th percentile), the country was designated as 1 for being affected by TRIPS

PostTRIPS is a binary dummy variable equal to 0 if the country is surveyed in years 1990-1995. PostTRIPS is equal to 1 if the country is surveyed in years 1996-2003, and thus is an indicator for the time period post Legislation.

PoorLegal is a binary variable signaling if a country has a poor legal institutional rating.

- From 1990-2003, if selected country had an *average IEF* value greater than 70 (the 80th percentile), the country was designated as 0
- From 1990-2003, if selected country had an *average IEF* value less than or equal to 70 (the 80th percentile), the country was designated as 1

GDP per capita is a measure of the average per head GDP for a selected country c in a given year t .

Unemployment rate is a measure of the number of unemployed individuals in the labor force divided by the size of the labor force for a selected country c in a given year t .

Healthcare expenditure is a measure of the percentage of GDP spent on Healthcare infrastructure a selected country c in a given year t .

Life Expectancy is a measure of the average life expectancy for a selected country c in a given year t .

Where φ denotes the time trend for country c .

Both α_c and γ_t are country and year fixed effects, and ε_{ct} is the error term. Robust standard errors are adjusted for clustering of countries.

V. Results

Based on the results of my OLS regression (2) in Table 1, which included the examination of 137 nations, and looking purely at the effect of TRIPS on the HIV mortality rate in each member nation of the WTO, it appears that statistically TRIPS has a positive effect on the HIV mortality rate. That is to say that my results indicate that countries that have poor legal regimes (the countries that were assigned a one) do in fact see statistically 14.69 more deaths per 100,000 individuals as compared to countries assigned a zero. It is notable to point out the variable *PostTRIPS* in negative in the regression, indicating that in the years after the Legislation HIV mortality actually decreased. The time variable *Year* allows me to account for the overall rise in the mortality rate with time. As shown in the regression overall mortality does increase with time, with an additional 11.88 deaths per 100,000 individuals. Both control variables, life expectancy and GDP per capita, are negative. Populations with a higher life expectancy and a higher GDP per capita will see a lower HIV mortality rate. The unemployment rate, is consistent with typical predictions of increasing unemployment leading to an inability to afford patented medications, ultimately resulting in a higher mortality rate.

Now examining the second version of OLS regression (2) noted in Table 2 below, I removed the time variable *Year*, to allow the other explanatory variables to account for the change in mortality rates. Perhaps the greatest change is the shift in the *PostTRIPS* variable from significantly negative to now positive. I am assuming with the *Year* variable removed, *PostTRIPS* and *TRIPSeffect* now accounts for a greater percentage of the mortalities. Based on this method countries that do have poor legal regimes and patent protection will witness an additional 39.61 deaths per 100,000 individuals. This number is significantly higher than the previous number with the time variable included.

In the two previous regressions, I used a panel data fixed effects model which will typically reports smaller cluster-robust standard errors. Though the panel data fixed effects model is most likely best suited for this analysis, I have decided to conduct the regression using another fixed effects model will absorb the categorical variable, country, and include it in the regression as if it was specified by dummy variables. This regression was also modeled using OLS regression (2) and the results are shown in Table 3. It appears that the values of the estimators are almost identical to those on the original panel data fixed effects model regression. However, I want to point out some areas of significance. First, this regression reports smaller standard errors than the previous regression, an observation that may lead us to believe these estimates are more precise. Lastly, while not an interpretation of a casual factor, the R^2 value is significantly high in the model at .90. Meaning that 90% of the variation in the dependent variable, HIV mortality rate, is explained by the explanatory variable, *TRIPSeffect* as well as the other control variables.

Lastly in Table 4 the OLS regression estimators are based on econometric model (1). In this model as a substitute for *TRIPSeffect*, I decided to use the *Index of Economic Freedom* values as is. Therefore instead of using a binary variable to base a nation's legal regime, I simply used the ranking assigned. In this circumstance the results are as expected, the variable *Index of Economic Freedom* is negative, indicating that nations with higher standards of property protection will see on average lower mortality rates as compared to nations with lower values of property protection. The estimators point to the same conclusions as was specified by using regression (2), though perhaps the value of the estimator for the independent variable is not as large in magnitude as one may have been previously thought.

Based on these four regression outputs, it would be my recommendation to utilize the regression in the first table based on econometric model (2). These results measure the binary

effect of TRIPS, while taking into account the years before and after the implementation of the Agreement as well as the overall time trend. It is my belief that this regression is the strongest depiction of the HIV mortality rate as it relates to the legal regimes of both wealthy and impoverished nations. The results are clear and rather easily interpreted based on the simplicity of the regression model and the explanatory variables. With that being said I did, however, include the other three regressions as I thought they were also significant.

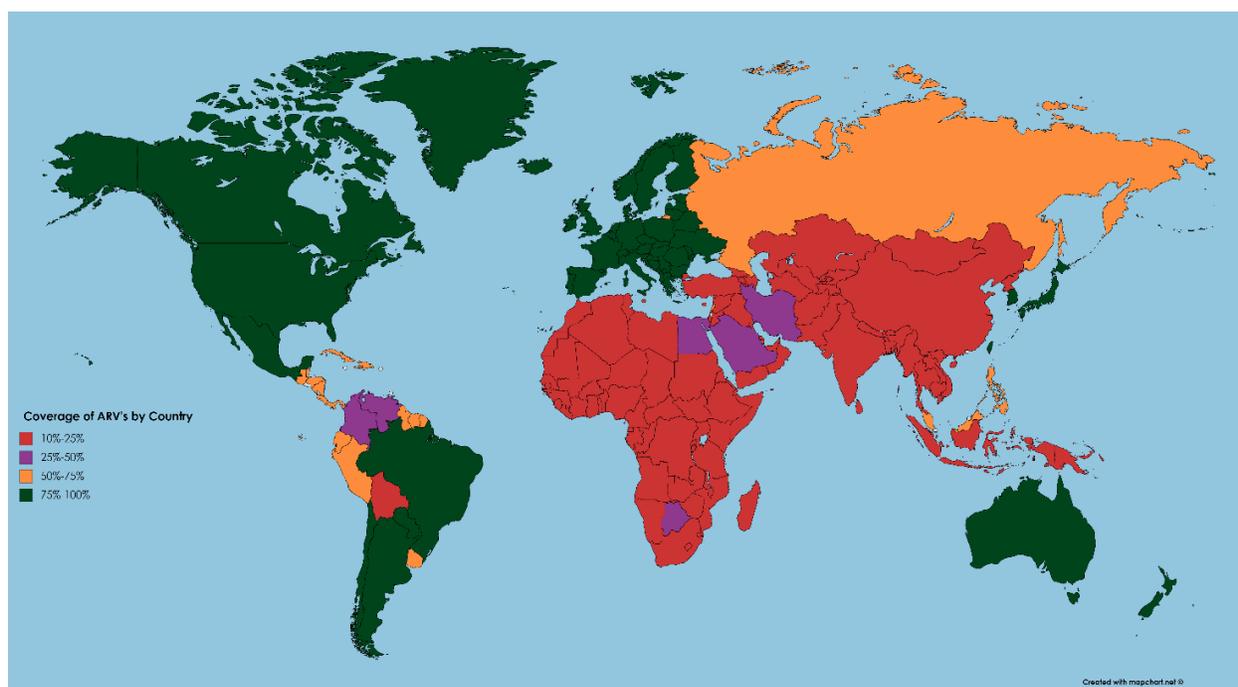
VI. Discussion and Limitations

The results of this analysis further supports my hypothesis that countries with poor legal regimes and a lack of patent rights were most affected by the Agreement. Based on my causal mechanism I had proposed that requiring all nations of the WTO to provide patent protection for pharmaceutical drugs would in fact increase the price and decrease the accessibility of medications leading to a higher mortality rate. This outcome is unanimous in all of my regressions, it is only the magnitude that varies. Considering this effect one might be able to judge TRIPS as a poor agreement for provoking a higher mortality rate, though we do not know the overall mortality rate if TRIPS had not been implemented. Simply speaking we cannot examine the mortality rate if this Agreement had never existed. Secondly, as pointed out previously in the introduction without such an Agreement incentives for new pharmaceutical medications would certainly be limited, thus also having a major effect on the mortality rate.

As expected with the time variable *Year* included to account for an overall time trend rise in mortalities, the variable *PostTRIPS* is negative. My explanation for the sign of this variable is based on the introduction of antiretroviral drugs to the marketplace in 1996 drastically transforming the ability to control the HIV mortality rate. It would make sense that in the years after ARV's enter the market developed nations would see a major decrease in their countries

mortality. Though while this is true for developed nations, the HIV mortality rate is still increasing as a whole signifying that the net-effect is still positive, statically $TRIPSEffect + PostTRIPs \neq 0$. More clearly, since the magnitude of the $TRIPSEffect$ is larger than of $PostTRIPs$ the HIV mortality rate is still increasing for countries that have a poor legal regime. Essentially the number of mortalities in the world is still rising even if the HIV death rate in developed countries is decreasing. Supporting the explanation of the variable $PostTRIPs$, even towards the end of the year 2003, based on Diagram 1 below countries with almost full coverage of ARV's are developed. Therefore it would follow the hypothesis of ARV treatments only being available to industrial nations between the years 1996-2003 while many developing and least developed nations were still left out.

Diagram 1: Coverage of Antiretroviral Treatment, 2003



Source: World Development Indicators

The values on the estimators of GDP per capita, life expectancy and unemployment were all to be expected. That is to say nations with a higher GDP per capita and life expectancy would witness a lower mortality rate. A larger GDP reflects the ability of a particular nations citizens to afford the costly treatments. It also reflects the larger amounts of public funds that can be placed into providing affordable medications, either by subsidizing the costs of the drugs or by investing in government funded research programs. Moreover, countries with a higher life expectancy were typically the ones least affected by the HIV disease. Longer life expectancies on average can signify a stronger resilience to terminal diseases in homogenous populations. It can also be tied in with healthcare infrastructure, meaning that a longer life expectancy can be related to strong national health systems.

Perhaps most surprising and unexpected was the fact that the variable for healthcare expenditure turned out to be positive. By this logic nations that have invested more of their GDP into healthcare would actually see a higher mortality rate contradicting rational reasoning. While this might be challenging to justify, my explanation would be one of reverse causality. Such that nations that are witnessing high mortality rates would invest large amounts of money into their healthcare infrastructure either by building more hospitals, treatment facilities or providing more awareness programs. Though it may not be that these investments were effective and therefore it is likely that the countries with continuous increases mortality rates would also witness larger amounts of funds being placed into healthcare systems.

a. Limitations

Perhaps one of the most significant limitations of the research is obtaining complete and accurate data. When true values cannot be generated or accurately calculated, they are often times estimated. For instance, this may be the case for certain World Development indicators,

when the data is not readily available for a particular country a combination of algorithms are used to predict what a certain value may be. Also with respect to the data regarding HIV mortality in member nations, the methods of procurement for this data may not be consistent. That is for example certain self-reporting nations may have an incentive to misrepresent or to distort the true and accurate numbers for political reasons. Along the same lines some data is not available either for various countries or for certain years. This makes empirical analyses very challenging as it decreases the number of observations in my sample. As similar with other research investigations the more observations available would decrease the amount of variability within the data and lead to stronger conclusions.

Additionally, another important limitation to be discussed is the lack or inability to control for other explanatory variables. It is certainly possible that other independent variables that exist, a few of which may have played a role in the HIV mortality rate, were not included and controlled for. Clearly there are many factors that can impact such a calculation, some of which are not universal to all nations or rather cannot be obtained through measurable means. Perhaps one of which might have been a variable denoting the size of the domestic pharmaceutical market, which may or may not have played a role in the ease of access to affordable medications. Or perhaps the number of people with insurance coverage in a particular nation, though this as well may certainly be hard to obtain and classify since insurance coverage and care is not consistent in each nation. Every nation designs their respective healthcare system differently, and some compared to others would be more willing to place an emphasis on the eradication of HIV.

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Summary Statistics

Summarization of the total HIV Mortality Rate

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	3,048	60.43147	143.6139	.0283634	1260.693

Summarization of the total HIV Mortality Rate if *Index of Economic Freedom* (IEF) is less than or equal to 70

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	2,355	69.40517	152.7124	.0283634	1260.693

Summarization of the total HIV Mortality Rate if *Index of Economic Freedom* (IEF) is greater than 70

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	693	29.93643	101.3804	.1171234	938.9993

Summarization of the total HIV Mortality Rate if the variable *TRIPSeffect* is equal to 1

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	1,651	84.26672	171.3718	.0283634	1260.693

Summarization of the total HIV Mortality Rate if the variable *TRIPSeffect* is equal to 0

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	1,262	32.14297	95.23629	.0304634	938.9993

Summarization of the total HIV Mortality Rate if *PostTRIPS* is equal to 1 (1996-2003) and *Index of Economic Freedom* is less than or equal to 70

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	1,044	82.20018	169.2887	.0283634	1260.693

Summarization of the total HIV Mortality Rate if *PostTRIPS* is equal to 1 (1996-2003) and *Index of Economic Freedom* is greater than 70

Variable	Obs	Mean	Std. Dev.	Min	Max
HIV_rate	261	37.36269	134.1578	.1174067	938.9993

Table 1)

Regression of *TRIPSeffect* on HIV Mortality Rate, Year included

	HIV Mortality Rate
PostTRIPS	-12.59 (11.57)
TRIPSeffect	14.69 (14.54)
Year	11.88*** (2.035)
Healthcare Expenditure	3.121 (2.179)
Life Expectancy	-25.36*** (6.937)
GDP per capita	-0.00348* (0.00167)
Unemployment Rate	0.911 (0.987)
Constant	-22002.0*** (3698.8)
R-squared	0.572
AIC	18951.8
BIC	18990.5
F	11.91
Observations	1852

Standard errors in parentheses

* p<0.05, ** p<0.01, *** p<0.001

Table 2)

Regression of *TRIPSeffect* on HIV Mortality Rate, Year omitted

	HIV Mortality Rate
PostTRIPS	32.58* (15.65)
TRIPSeffect	39.61* (15.73)
Healthcare Expenditure	9.113** (2.987)
Life Expectancy	-21.65** (6.801)
GDP per capita	0.00199 (0.00150)
Unemployment Rate	1.839 (1.158)
Constant	1339.3** (410.6)
R-squared	0.431
AIC	19476.8
BIC	19509.9
F	8.656
Observations	1852

Standard errors in parentheses

* p<0.05, ** p<0.01, *** p<0.001

Table 3)

Regression of *TRIPSeffect* on HIV Mortality Rate, Year included

	HIV Mortality Rate
PostTRIPS	-12.59* (5.807)
TRIPSeffect	14.69* (5.859)
Year	11.88*** (0.501)
Healthcare Expenditure	3.121* (1.456)
Life Expectancy	-25.36*** (0.617)
GDP per capita	-0.00348*** (0.000625)
Unemployment Rate	0.911 (0.602)
Constant	-22002.0*** (985.1)
R-squared	0.898
AIC	18953.8
BIC	18998.0
F	325.7
Observations	1852

Standard errors in parentheses

* p<0.05, ** p<0.01, *** p<0.001

Table 4)

Regression of *Index of Economic Freedom* on HIV Mortality Rate, Year included

HIV Mortality Rate

PostTRIPS	-3.918 (3.711)
Index of Economic Freedom	-0.365* (0.182)
Year	13.31*** (1.981)
Healthcare Expenditure	5.226* (2.624)
Life Expectancy	-32.14*** (5.309)
GDP per capita	-0.00494*** (0.00141)
Unemployment Rate	0.618 (1.174)
Constant	-24315.1*** (3660.4)
R-squared	0.643
AIC	13275.8
BIC	13312.2
F	15.47
Observations	1357

Standard errors in parentheses

* p<0.05, ** p<0.01, *** p<0.001