TRIPS-Plus Provisions and the Access to HIV Treatments in Developing Countries

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In recent years, a maximalist trend regarding intellectual property (IP) rights has been observed among high-income countries while negotiating bilateral, regional and multilateral trade agreements. In fact, the provisions regarding intellectual property included in recent trade agreements, known as TRIPS-Plus, have a tendency to either far exceed the minimum global standard on IP set by the 1995 Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) or to eliminate the flexibilities that this multilateral agreement assured to its members for the purpose of promoting universal access to medicines (Chen *et al.,* 2013).

Since its establishment a considerable body of literature has been published on the impact of the TRIPS agreement on public health, however, far too little attention has been paid to the fact that TRIPS-Plus provisions have a much more negative impact on the affordability of treatments for spreadable diseases such as the human immunodeficiency virus (HIV) that affects the lives of 37.9 million people (Unaids.org, 2019).

Furthermore, a point that is worth stressing is that this exacerbating effect is disproportionally felt by the poorest communities living in developing countries that are more vulnerable to HIV spreading. In fact, “the vast majority of people living with HIV are located in low- and middle-income countries, with an estimated 68% in living in sub-Saharan Africa”. (Carlson, 2019).

Hence, the intent of this essay is to provide evidences that disclose that the inclusion of TRIPS-Plus provisions in recent trade agreements is a strategic move carried out by high-income countries to limit the generic competition in the pharmaceutical industry that represents for the global South because it further limits the possibilities of developing countries to obtain affordable medicines needed to face the epidemic of HIV.

Therefore, in the first part, this essay will address the minimum global standard of intellectual property protection set by the 1995 TRIPS agreement with regards to patent regulations as well as theoretical arguments supporting the inclusion in recent trade agreements of stronger provisions on intellectual property. Subsequently, this essay will challenge these arguments by presenting evidence suggesting that TRIPS-Plus provisions are largely justified by profit-driven motives and that they pose a serious threat to public health in developing countries because they reduce access to essential treatments for HIV by delaying the entry of cheaper generics in domestic markets and causing significant price increases in medicines. This essay will conclude that the theoretical justifications in support of TRIPS-Plus provisions can be partially considered reasonable, however, once they are applied to the reality of international trade, they tend to disclose their shortcomings. Hence, the inclusion of TRIPS-Plus provisions in recent trade negotiations serves primarily as a strategic tool in the hands of developed countries for avoiding competition with cheaper generic drugs produced in developing countries, however, this comes at the expense of developing countries’ ability to access affordable antiretroviral regimens for HIV treatments.

TRIPS Agreement and IP Regulations

The multilateral agreement on Trade-related Aspects on Intellectual Property (TRIPS) represents the most comprehensive, yet highly controversial, international agreement regarding intellectual property (IP). The agreement

was established in 1994 as part of the seismic change in international trade caused by the 1994 Marrakesh Agreement Establishing the World Trade Organization.

The TRIPS agreement covers vast areas of intellectual property including provisions that concern "copyright, trademarks, geographical indications, industrial designs, patents, the layout-designs of integrated circuits and undisclosed information including trade secrets" (World Trade Organisation, 2020). In particular, this essay will focus on the branch of intellectual property that deals with patent regulations.

The agreement sets a minimum global standard for patent regulation that needs to be observed by member states. In fact, the agreement only states that patents should be granted for new, inventive and useful process and products, leaving to members the prerogative to decide whether a new formulation of a drug or a new combination of existing molecules deserves a new patent (Médecins Sans Frontières Access Campaign, 2020).

A particularly controversial set of provisions included in the agreement concerns the possible, yet limited, exemptions to the provisions of the agreement, the so-called TRIPS flexibilities. Among TRIPS flexibilities, compulsory licensing and parallel imports represent by far the most debated forms of exceptions to the TRIPS agreement. The term "compulsory licensing" indicates a government decision to allow a firm to produce the patented drug without the consent of the right holder, while "parallel imports" indicate products marketed by the patent owner in a country and imported into another country without the approval of the right owner. These flexibilities are allowed under the TRIPS agreement in order to attempt to balance the intent of promoting access to existing drugs and promoting research and development into new medicines, however, they have to be interpreted in light of the protection of the rights of the patent holder (World Health Organization, 2020).

Hence, it is significant to highlight that the agreement adopted a narrow understanding of this possibility as well as a significant vagueness in its wording causing ambiguity regarding the impact on public health of the terms of the agreement. Therefore, many low- and middle-income member states raised awareness on the possible negative impact of these patent regulations on public health.

Doha Declaration

In 2001, WTO Members adopted a Ministerial Declaration at the WTO Ministerial Conference in Doha to address the impact of the agreement on the affordability of medicines for populations living in underdeveloped countries in their attempts to control spreadable diseases such as HIV, tuberculosis, malaria and other sexually transmitted diseases. While acknowledging the role of IP rights as an incentive for the creation of new drugs, the Declaration recognizes concerns about its effects on the affordability of medicines. The Doha Declaration affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" (World Health Organization, 2020). WTO members stressed the importance of interpreting the TRIPS Agreement with the intent of promoting access to medicines and the creation of new ones. As a result, Article 5 of the Doha Declaration confirms that WTO Member States have the right to use measures such as compulsory licences or parallel importation to promote access to affordable medicines and their freedom to determine the grounds for granting compulsory licensing in case of national emergencies such as the HIV epidemic (World Trade Organisation, 2001).

An Opposing Tendency in IP Regulation

It has recently been observed a tendency in international trade that concerns IP regulations, especially dealing with patent law. In fact, it can be noted that developed countries, among others the United States, Japan and the EU, are currently pressuring developing countries for the implementation of a stronger IP regulation that either limits the use of flexibilities allowed under the TRIPS agreement or far exceeds the minimum global standard for IP protection set by the agreement.

For example, according to Jing Chen *et al.* (2013), China has been placed on the U.S. Trade Representative's Office (USTR) priority watch list, a report that identifies countries with an IP regulation that not satisfies the minimum standard set by the TRIPS agreement. According to the report, there is a necessity to make amend the domestic IP

regulation to address a variety of IP issues including barriers towards pharmaceutical innovation. The US has issued a complaint to the WTO Dispute Settlement Mechanism (DSM) over China's IP regulations, therefore, pressuring the country to straighten its IP regulation by implementing TRIPS-Plus provisions in its domestic law. Along with China, other countries such as Indonesia, India, Russia, Ukraine and Venezuela are also been pressured to adopt similar provisions.

Arguments for Stronger IP Regulations

A question that, therefore, is worth raising regards the justifications that have been raised by developed countries for the support of the implementation of maximalist intellectual property provisions. Generally speaking, the rationale in support of a stricter intellectual property protection gravitates around four core assumptions that can be summarised by these essential words: incentives, compensation, piracy and natural right.

In fact, the rationale behind stronger IP provisions is based on the assumption that IP rights motivated the dissemination of innovation through research and development. Advocates of stronger IP provisions highlight the high costs of developing new drugs and the need for substantial compensation for providing lifesaving drugs that without patent protection they may be freely counterfeited and plagiarized at the expense of the inventor (CNIPA, 2019). On the other hand, the assumption that intellectual property is a natural right that has to be treated and enforced just like other forms of humane property can be traced back to John Locke and his Natural Law theory.

According to Robert P. Merges (2011), Locke's theory can be used as an ethical justification for enhancing IP provisions. The author suggests that "appropriation is a movement" that brings unowned things lying in an impersonal world to the space of humanity in which these things acquire a purpose. This movement occurs once physical or intellectual labour is applied to the "found" environment. Therefore, according to this theory, IP provisions represent necessary legal protections towards creative works carried out by humanity for humanity's sake. Furthermore, it can be argued that a stricter IP regulation can be preferred because the globalised world carries a threat towards individual ownership, especially with reference to intangible and incorporeal assets such as the kind protected by intellectual property provisions.

However, if TRIPS-Plus provisions are truly necessary, beneficial and ethical why do they represent a so controversial concept once they are applied to the reality of international trade, especially with reference to its effect on the affordability of medicines for populations living in developing countries in their efforts to control spreadable diseases such as HIV, tuberculosis and malaria?

90-90-90 Targets and TRIPS-Plus Provisions

In 2014, the Joint United Nations Programme on AIDS (UNAIDS) launched the ambitious 90–90–90 targets aiming at the elimination of spreadable diseases such as HIV, viral hepatitis and sexually transmitted infections by 2030. In order to do so, UNAIDS set the global target of diagnosing 90% of all people living with HIV, provide antiretroviral therapy for 90% of all HIV-positive persons and ensure that, by 2020, 90% of people living with HIV and receiving ART treatment have suppressed viral loads (World Health Organisation, 2019, p.8).

In order to reach this fundamental goal, there is a necessity to guarantee that affordable and sustained treatments are in reach of people living in low-income countries, however, TRIPS-Plus provisions seem to go against this necessity by raising the price of medicines and causing HIV treatments to be available discontinuously.

As a matter of fact, these provisions, limiting the possibility of using the flexibilities allowed under the TRIPS agreement, tend to maximise the profit of wealthier countries over developing countries' public health by limiting the competition between generic drugs and patented ones.

Researches (Ramani, 2015) have shown that the threat of compulsory licences represents an important tool in the hands of developing economies because it can increase the bargaining power of governments in price negotiations. In 2001, brand name antiretroviral (ARV) drugs cost over $10,000 per person per year, which made them

unaffordable for people living in developing countries. Subsequently, Cipla, an Indian pharmaceutical company, began to reproduce the same treatment for a dollar a day and since then, the cost of ARVs has fallen to 10% of their original price due to the same competition between generic drugs and brand name ones that TRIPS-Plus provisions tend to limit.

Another form of IP provision that is worth addressing is data exclusivity because it can have an extremely negative impact over the generic competition by delaying the entrance of generic drugs into national and international markets. Data exclusivity prohibits generic competitors to use clinical test data that have been submitted by original pharmaceutical companies, therefore impacting generic companies, usually located in developing countries, that are unlikely to have the necessary funds and capabilities to reproduce the time-consuming clinical trials needed, for example, by the Food and Drug Administration (FDA) to prove the safety and efficacy of a certain drug.

Case Study: Vietnam

In order to address how these provisions have a tangible impact on developing countries, this paper will now present the case of Vietnam. The country, with a GDP per capita of only US$8.07 thousand in 2019 (International Monetary Fund, 2019), is arguably highly vulnerable to provisions that tend to limit the affordability of medicines for treating HIV. Especially, if we take into consideration that in 2018, 230 000 people were HIV-positive and of all adults aged 15 years and over living with HIV only 65% were on treatment (UNAIDS.org, 2018). A situation that is not likely to improve and reach the 90-90-90 target set by UNAIDS, since in 2019 the European Union and Vietnam signed a Free Trade Agreement that includes TRIPS-Plus provisions.

As a matter of fact, article 12.40 paragraph 3 states that:

“a Party may make available an extension, not exceeding five years, of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the marketing authorisation procedure” (European Commission, 2018, p.38).

This article, granting the possibility to extend the duration of the exclusive right of a patent owner over his invention beyond the twenty years set in the TRIPS agreement, has a significant impact towards Vietnam’s ability to access affordable medicines because patent protection implies that a creation cannot be commercially made, imported, or sold by others without the patent owner’s consent.

Furthermore, the Free Trade agreement signed, includes another provision that is worth highlighting because it significantly limits the production of generic, and therefore more affordable, drugs. Article 12.40 paragraph 2 declares that:

“no other applicant for marketing approval may, without permission of the person that submitted the data, rely on that data in support of an application for marketing approval during a reasonable period, which shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product” (European Commission, 2018, p.39).

Case Study: Jordan vs Egypt

There are a number of studies that have identified data exclusivity as one of the elements in free trade agreements that affects the price of medicines available in the market by limiting the possibility of international competition in this particular field. According to Oxfam (2007), before 2000 Jordan mainly relied on generic medicines, however, the US–Jordan Free Trade Agreement, signed in 2001, “led to a 20% increase in medicine prices, and delayed generic entry for 79% of newly launched medicines” (Malpani, 2007, p.2). Moreover, compared to Egypt, which adopted no TRIPS-Plus policies, medicine prices were two to ten times higher and “additional expenditures for medicines with no generic competitors were estimated to be between $6.3 and $22.04 million” (Malpani, 2007, p.2).

Therefore, these provisions shaping the commercialisation of knowledge, they can be considered as signals of a

motive lurking behind intellectual property regulations that cannot be considered as ethical but rather pure utilitarianism.

Discussion

The developing world, non-governmental institutions and strands of the civil society are currently manifesting their dissatisfaction with the "unfair" current IP regime. According to the protesters, high-income countries, such as the United States, Japan and the EU, tend to favour stricter forms of IP regulations designed and implemented not to maximise innovation or research, "but to maximise the profits of big pharmaceutical companies able to sway trade negotiations" (Stigliz, 2017).

They argue that the claim that IP rights provide incentives for the creation and dissemination of innovation through research and development is factually incorrect. Governments and philanthropy, not pharmaceutical companies, are driving innovation and funding research and development. In fact, governments and non-profit organizations in the US fund over 40 percent of research and development costs. Pharmaceutical companies then commodify that intellectual work under patent protection for 20 years or longer. This system causes U.S. taxpayers to pay higher prices for patented medicines because the level of prices includes the government-collected taxes to fund research plus the amount of money that pharmaceutical companies claim as a reward for the cost of producing the drug. Subsequently, instead of devolving these funds to develop a cure to mortal diseases such as HIV, profits are poured into marketing, lobbying and stock buybacks at the expense of those patients to which affordable medicines are denied and that have to face much higher healthcare costs overall (Treatment Action Group, 2018).

On the other hand, it needs to be highlighted that the claim that TRIPS-Plus provisions represent necessary legal protections towards creative works in order to prevent medicines to be freely counterfeited and plagiarized can be considered partially reasonable in the sense that without a rigorous method of control over highly impacting drugs such as the ones used for the treatment of HIV, versions of patented drugs could be freely produced and sold with the intent to deceptively present its authenticity or effectiveness at the serious detriment of the user.

The Indian Example

Large developing countries, among others are currently promoting this counterattack and are the first liners of this protest. India, for example, produces 80% of the HIV generic drugs that the organisation Médecins Sans Frontières (MSF) uses to treat over 200,000 people living in developing countries. India freely produced these medicines until 2005, when it was obligated to start granting patent protections according to the TRIPS agreement (Médecins Sans Frontières Access Campaign, 2017). However, the country decided to amend its domestic patent law including safeguards, such as strict standards on what deserves a patent trying to strike a fairer balance between acknowledging IP protection and protecting the right to affordable medicines. The multinational pharmaceutical industry, backing the US, the European Union and other countries, is currently pressuring India to strengthen its IP regulation in order to guarantee more monopoly power to pharmaceutical companies producing branded drugs at the expense of public health safeguards. This phenomenon poses a potential threat not only in relation to the affordability of drugs in India, but also worldwide. In fact, if the Indian Government would decide to give up this challenge, this could be disastrous for millions of people living in developing countries around the world and for international organisations like MSF, who rely on Indian generic medicine to guarantee sustained and affordable treatments across the globe (Médecins Sans Frontières Access Campaign, 2017).

Hence, if the theoretical case for a stricter IP legislation is partially sound, in reality, this regime has erected barriers to the use and circulation of knowledge, causing the gap between the private and public returns of innovation to widen (Stigliz, 2017). Developed economies have lobbied and shaped a regime within the WTO that clearly focuses solely on profits, posing a threat to developing economies in their intent to face serious health emergencies.

The IP regime, established in 1994, was not sustainable because it has maximised profits for a few at the expense of the development and welfare of many. Nonetheless, in 2020, the situation is even worse with an intellectual property that, limiting the use of TRIPS flexibilities or enhancing the provisions included in the original agreement, eliminates

the possibilities for affordable and sustained treatments to HIV to be in reach of people living in low-income countries.

Conclusions

This paper has investigated the extent to which the inclusion of TRIPS-Plus provisions in trade agreements affect the possibility for developing countries to access affordable HIV treatments. Returning to this question it is now possible to state that the inclusion of these provisions is a strategic move carried out by high-income countries to limit the generic competition in the pharmaceutical industry and represents a serious threat for developing countries because it further limits their possibilities to obtain affordable medicines needed to face the epidemic of HIV. In this essay, both supporting and opposing arguments to TRIPS-Plus provisions have been presented and, taken together, the results suggest that the theoretical case for a stricter IP legislation can be considered reasonable only in relation to piracy and counterfeit medications. In fact, the cases of India, Vietnam and Jordan presented in the essay provide sound arguments disclosing the negative externalities of TRIPS-Plus provisions and the exacerbating effect that they impose on developing countries. The analysis has some limitations, nonetheless, this work could represent a useful aid for decision-makers in developing countries in their efforts to resist the pressure coming from the multinational pharmaceutical industry, the US, the European Union and other countries, to strengthen their IP regulations at the expense of their citizens.

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