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An Assessment Of The Trips Agreement And Its Implication On Access To Medicine In Africa: A Focus On Covid-19 Pandemic

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ABSTRACT
The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was one of the foundational agreements at the establishment of the World Trade Organisation (WTO). By getting member nations to agree to a single set of rules governing the protection of intellectual property, the WTO was able to create a bedrock for rules-based international trade. However, it was quickly realized that while TRIPS served the interests of the developed nations and their well-established industrial bases, it was a millstone around the necks of developing nations, and nowhere was this more glaringly apparent than in the field of pharmaceuticals. The objective of this research was to examine in detail, the TRIPS agreement and its implication on access to medicine in Africa, with COVID 19 in focus. It reviewed the effects of the agreement on Africa and recommended greater implementation of public health concerns into the existing legal framework. This article discovered that the agreement restricted the ability of developing countries and African countries in particular to access vaccines and therapeutics for the treatment of COVID 19 pandemic. The article found out that in addition to high cost of production and specialized facilities required for the production of the COVID 19 vaccines which were domiciled in developed countries, the agreement made it difficult for developing countries to manufacture generic drugs. We recommended that tests and therapeutics for production of medications be included in the waiver for patent protections. We also recommended that, Africa has a critical role to play in solving its problems by ensuring that no agreement for trade negotiations is reached if its implementation will prevent them from making use of the flexibilities allowed in the TRIPS agreement. In addition, a human rights based approach to incorporate right to health into its national laws should be adopted by African countries to enhance access to medicines in Africa.

Keywords: Assessment, Trips, Agreement, Medicine, Implication, Covid-19, Pandemic

INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international legal agreement between all the member nations of the World Trade Organisation which sets minimum standards for regulation of many forms of intellectual property [1]. The negotiations on trade-related aspects of intellectual property rights began at the Uruguay Round of General Agreement on Tariffs and Trade (GATT) talks in 1986 and with intense lobbying by the United States, European Union, Japan and other developed nations, the TRIPS agreement as the most comprehensive multilateral agreement on intellectual property was concluded [2]. The Agreement came into force to be administered as part of the WTO Agreement on January 1, 1995 [3]. It provides enforcement procedures, dispute resolution procedures and remedies for member nations. The TRIPS agreement requires member countries to make available copyright rights, protecting the rights of authors and copyright holders and other related rights such as patents for any inventions, in all fields of technology whether (products or processes) without discrimination subject to the normal tests of novelty.

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations [4]".4 [Emphasis added]

Any country that intends benefitting from the numerous international market trading opportunities provided by WTO and admitted as a member into the WTO, must enact the intellectual property laws stipulated by TRIPS. These important requirements for the protection of intellectual property rights include the following:

1. Copyright must be granted automatically, and not based on any "formality", such as registrations, as specified in the Berne Convention [5];
2. Copyright must extend at least 50 years, unless based on the life of the author [6];

3. Computer programmes must be regarded as "literary works" under copyright law and receive the same terms and protection;
4. Patents must be granted for "inventions" in all "fields of technology" provided they meet all other patentability requirements (although exceptions for certain public interests are allowed [7] and must be enforceable for at least 20 years [8];
5. Exceptions to exclusive rights must be limited, provided that a normal exploitation of the work [9] and normal exploitation of the patent [10] is not in conflict;
6. Legitimate rights to third parties have to be taken into account by patent rights [11];
7. No unreasonable prejudice to the legitimate interests of the right holders of the computer programmes and patent is allowed;
8. In each member state, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPS signatories under the principle of National Treatment (with certain limited exceptions) [12]. Trips also has a Most Favoured Nation Clause.

Historical Evolution of Trips Agreement

In September 1986, at Punta del Este, Uruguay, trade ministers from the world's trading nations through a Ministerial Declaration launched the Eight GATT round (Uruguay Round) to address problems which the General Agreement on Tariffs and Trade (GATT) could not manage. The problems identified included structural deficiencies and spill over impacts of certain countries' policies on world trade. All the original GATT articles were put up for review and negotiating talks were to extend trading systems into other new areas of intellectual property, trade in services and reform trade in agriculture and textiles.

The negotiations should have ended in December 1990, however, the EU and the US did not reach a consensus on the reformation of agricultural trade hence, the talks were extended. In November 1992, the EU and US in a deal known as "the Blair House Accord" settled most of their differences and ministers from most of the 123 participating governments at a meeting in Marrakesh, Morocco signed the deal on 15 April, 1994 [13].

The World Trade Organisation (the only international organization dealing with the global rules of trade between nations) was established by this agreement and it came into force on January 1, 1995, to succeed the GATT system. Currently, the WTO has 164 member states representing over 98% of global trade and global GDP [14]. The agreement is regarded as the most scholarly institutional reform of the world trading system since the establishment of GATT [15]. The GATT still subsists as the WTO's umbrella treaty for trade in goods though updated as a result of the Uruguay Round negotiations. It is not solely the legally binding agreement included in the final act; about 60 annexes, decisions, agreements and understandings was adopted into six main parts:

1. Services (General Agreement on Trade in Services (GATS);
2. Goods;
3. Dispute settlement (DSU);
4. An umbrella agreement (the agreement establishing the WTO); Goods and investment (the Multilateral Agreements on Trade Related Investment Measures (TRIMS);
5. Reviews of governments' trade policies (TPRM);
6. Intellectual property (Agreement on Trade-Related Aspects of Intellectual Property Rights) [16].

This paper focused on the Agreement on Trade-Related Aspects of Property Rights on: COVID-19 is the focus of this paper.

Key Terms

1. Intellectual Property:

Intellectual property are the intangible creations of the human intellect such as inventions, literary and artistic works, designs and symbols, names and images used in commerce [17]. Intellectual property are of various types and are more recognised by some countries than others. The most common types are trademarks, trade secrets, copyrights and patents.

2. Intellectual Property Rights:

Intellectual property rights are the legal, institutional and exclusive rights given to the inventor or creator to protect creations of his mind. These rights divided into two main parts:

i) Copyrights and Rights Related To Copyrights

They are the rights that relate to expression of ideas in the material form of literary and artistic works (such as music, books, sculptures, paintings, artistic, cinematography work, audio tapes and computer software. They are usually protected for a minimum period of 50 years after the death of the author. The main reason for the protection of copyrights and related rights is to reward and encourage creative work.

ii) Industrial Property

It is divided into two major areas:

a) Protection of distinctive signs in particular; trademarks (which is a sign, or combination of signs that distinguish goods or services of one business from another);
b) Geographical indications (is a sign which identifies a good as originating in a particular place with particular characteristics, quality and reputation of the good attributable to the geographical origin).

Protection of industrial property aims at protecting the customers by preventing the unauthorised use of such signs that can be misleading customers, misleading practices thereby ensuring fair competition [18] .As long as the sign is distinctive, the protection may last indefinitely. Other forms of industrial property protected to stimulate design, innovation and the creation of technology include industrial designs, trade secrets and inventions (which are protected by patents). A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing. The protection is usually given for a finite term (typically 20 years in the case of patents).

3. Treaty

A treaty is a written, legally binding agreement between two or more countries and international organisations which is to be governed by international law. A treaty may be used in various terminologies such as protocol, convention, international agreement, exchange of letters, pact however, they are all subject to the same rules of international law [19]. In Nigeria,

"No treaty between the Federation and any other country shall have the force of law except to the extent to which any such treaty has been enacted into law by the National Assembly [20]"

Administrative Framework of the TRIPS Agreement

The World Trade Organisation is the institution charged with the responsibility of controlling trade among nations with the aim of bringing greater certainty, predictability to international markets and enhancement of economic welfare in general [21]. The WTO is saddled with multiple roles which is encapsulated in the six key objectives: (1) to set and enforce rules for international trade, (2) to provide a forum for negotiating and monitoring further trade liberalization, (3) to resolve trade disputes, (4) to increase the transparency of decision-making processes, (5) to cooperate with other major international economic institutions involved in global economic management, and (6) to help developing countries benefit fully from the global trading system.

Features of the TRIPS Agreement

Globalisation of Intellectual Property Rights

The TRIPS agreement is one of the most controversial issues in both academics and political arena. Public opinion and civil activists have denounced the agreement as a colonialist act which imposes the Intellectual Property Rights' system of the West to the rest of the world [22].

The main features of the Trips agreement are:

1. **Standards:** The TRIPS agreement stipulates the minimum standards of protection to be provided by each member of the WTO in respect of each of the main areas of intellectual property covered by the agreement. The main elements of protection are defined and they are namely: the subject-matter to be protected, the rights to be conferred, permissible exceptions to those rights and the minimum duration of protection. These standards are set by the TRIPS agreement with certain requirements first that the core obligations of the Paris Convention for the Protection of Industrial Property (Paris Convention), the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) and the main conventions of WIPO in their most recent versions are complied with. All the core provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS agreement between TRIPS member countries with the exception of the provisions of the Berne Convention on moral rights.
   The provisions which relate to the Paris Convention and the Berne Convention are found in Articles 2.1 and 9.1 of the TRIPS agreement. Secondly, the TRIPS agreement includes additional duties on matters where the pre-existing conventions are seen as being inadequate or silent. The TRIPS agreement is sometimes referred to as Paris-plus and Berne agreement.
2. **Enforcement:** domestic procedures and remedies for the enforcement of intellectual property are dealt with by the second main set of provisions. General principles applicable to all Intellectual Property Rights enforcement procedures are provided by the agreement. It contains provisions on provisional measures, civil and administrative procedures and remedies and special requirements related to border measures and criminal procedures which specify in certain details, the procedures and remedies that must be present before enforcement of rights by right holders can be effective.
3. **Dispute Settlement:** the agreement makes disputes between WTO Members about the respect of the TRIPS obligations subject to the WTO's dispute settlement procedures.

The TRIPS agreement also makes provision for certain basic principles, such as national and most-favoured-nation treatment, in addition to some general rules to ensure that procedural difficulties in acquiring or maintaining IPR's do not nullify the substantive benefits which should flow from the agreement. The agreement provides for equal application of obligations to all member countries,

however, the developing countries will have a longer period to phase them in. In situations where a developing country does not presently provide product patent protection in the area of pharmaceuticals, special transition arrangements become operative.

The TRIPS agreement permits members to determine the appropriate method of implementing the provisions of the agreement within their own legal practice and system. It also allows members provide more extensive protection of intellectual property since the TRIPS agreement is a minimum standards agreement.

The TRIPS Agreement And Access To Medicine

The globalisation of intellectual property rights under TRIPS soon began creating problems in the sphere of public health, particularly issues surrounding the use of the Agreement's compulsory licensing procedures. Article 31 of the TRIPS Agreement permits a government to compulsorily licence and use any patent without the consent of the patent owner. However, any goods produced under this compulsory licence can only be used domestically. Additionally, only countries possessing manufacturing capacity can make use of compulsory licensing under TRIPS. This meant that countries producing medications under compulsory licence could not export such medications to other countries in need.

With the rising concerns on the TRIPS agreement as a barrier on the poor (developing and least-developed) countries accessing affordable medicine, attempts to settle this concern and clarify the scope of the TRIPS led to the Doha Ministerial Declaration on Public Health in 2001. Paragraph 6 of the declaration stated: "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002 [23]".

In 2003, a Decision on patents and public health was reached by the WTO, specifically permitting a country lacking domestic manufacturing capacity to import medications under compulsory licensing from another country which could manufacture them. At the time of this decision, the focus of the WTO members was primarily on Anti-Retroviral medications (ARVs) needed for the treatment of HIV/AIDS, and the only country to take advantage of the public health exemption was Rwanda, for the purpose of acquiring ARVs from a Canadian manufacturer. The decision was made a permanent amendment to the TRIPS Agreement in 2017 [24]

The conflict between the need to protect IP and promote innovation, and the public health needs of developing countries flared up again only 3 years after the TRIPS Agreement was amended, and this time, it came in the form of a global pandemic.

The Trips Agreement And Access To Covid-19 Vaccines In Africa

COVID-19 is a highly transmittable viral infection caused by zoonotic novel coronavirus named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which first appeared in Wuhan, China, in December 2019. The World Health Organization (WHO) on March 11, 2020, declared the coronavirus (COVID-19) outbreak a global pandemic [25]. The disease spread across the globe quickly and was confirmed to have spread to Africa on 14 February 2020, with the first confirmed case announced in Egypt. The first confirmed case in sub-Saharan Africa was announced in Nigeria at the end of February 2020 [26]. In 2022, at the time of this manuscript preparation, there have been 534,711,462 reported cases and the virus has caused 6,304,632 deaths [27]. It is estimated however, that the actual number of deaths may be far higher than reported.

In order to contain the spread of the virus, governments around the world instituted strict lockdowns and social distancing protocols, resulting in huge economic losses. The price of Brent Crude went negative as oil producers began paying customers to take product off their hands. At the time the outbreak commenced, there were no effective treatments or vaccines for COVID-19, and it was postulated the development of an effective vaccine would take 18 – 24 months. This hypothetical timeline was based on the existing process for development of new medicines, taking into account the costs of clinical trials and the peer review of results.

However, due to the aforementioned economic losses occasioned by the global lockdowns, the governments of developed nations such as the USA, UK, Canada and the EU placed orders for vaccine doses long before the pharmaceutical companies involved had even demonstrated any viable candidate vaccines [28]. These pre-orders helped fund the clinical trials and other aspects of vaccine production, and greatly sped up the vaccine development process. On December 11, 2020, the Pfizer-BioNTech COVID-19 vaccine was the first to receive emergency use authorisation from the Food and Drug Administration [29] well ahead of the initially postulated 18 – 24-month timeline. With the TRIPS agreement curtailing the rights of countries to manufacture generic drugs and rely on brand name productions, it is easy to see how the ability of governments in Africa to contain and control the

pandemic could be constrained by an insistence on the strict protection of IP related to COVID vaccines.

It is worthy of note that the inequality in access to the Covid-19 vaccines by developing nations threatened to prolong the pandemic and delay global economic recovery. The developed countries acquired large piles of the covid-19 vaccines for their citizens while the developing nations like Africa could not access these vaccines as they do not have the funds to pay for these vaccines that are being developed. This necessitated new collaborative efforts and global initiatives such as the ACT Accelerator and its COVAX initiative alongside with the Global Alliance for Vaccines and Immunisation (GAVI) and Bill Gates foundation in bridging the gaps by ensuring equitable and rapid access to covid-19 vaccines for all countries. With the reluctance by some Americans to be vaccinated, stocks of the vaccines were donated to COVAX for shipment to developing countries. The initiative proposed to deliver at least 1.3 billion donor-funded doses of approved vaccines to the 92 low and middle income countries by the end of 2021. These efforts were underfunded hence, the competition for limited vaccine supply against bilateral agreements negotiated by developed countries [30].

In Africa, the unaffordability of medicines and vaccines to address deadly diseases such as covid-19, has raised serious concerns as to the fundamental right to health as defined by Article 12 of the United Nations International Covenant on economic, social and cultural rights which provides that right to health can only be attained if good and quality healthcare services are available, accessible and affordable.

A question that comes to mind is: Does TRIPS impede Africa's ability to access covid-19 vaccines?
For the developing and least developed nations, TRIPS has been identified as one of the barriers to vaccine affordability. TRIPS provided many IPs related to vaccines with most of the countries engaged in research and development of COVID vaccines coming from the developed world.

Article 33 of TRIPS mandates patent protection for pharmaceutical products for up to 20 years and any violation, results in trade sanctions [31]. With the patent on pharmaceutical processes/products and the monopolies over vaccine production, maximum profit is ensured by the developed countries with the imposition of outrageous prices by these multinational pharmaceutical companies while the developing countries struggle tooth and nail to afford them. One of the arguments against TRIPS is that the western IP rights are being forced on developing countries where their need for access to the IP outstrips their interest in protecting private company's investments in the IP. If IP rights are being enforced strictly, it will be difficult for industries in the developing countries to develop as they will be bound by restrictions on copying the processes of the developed nations as it is.

Another argument made against the patent protection of covid-19 vaccines is that a lot of the research which went into vaccine development was publicly funded. For instance, the National Institutes of Health (NIH), a public health agency in the United States of America, made its research on the use of messenger RNA (mRNA) freely available to pharmaceutical companies, which helped speed up their vaccine research. The Pfizer-BioNtech Vaccine is an mRNA vaccine and is partly based on this publicly-funded research. So, what is the rationale behind charging exorbitant amounts for research that was publicly funded?

Upon this backdrop gave rise to moral, social, political discussions and pressure on developed nations to waive patent protections for COVID vaccines for production by Africans, India and anywhere else where production facility can be set up. The importance of waiving patent protections and eradicating the pandemic globally cannot be over emphasised. The US president, Joe Biden at the height of COVID awareness commented that "COVID cannot be stopped in your own country until it is stopped everywhere else". The argument is that vaccines should be made as available as possible in order to stop sick people from travelling over to the US or other country. A working paper by WTO staff highlighted that the evidence-based debate on the scope and effect of the Trips policy options is a task more important today than ever [32].

Guimon *et al*. [33] also stated that "the covid-19 pandemic will not recede until its vaccine is seen as a global good". Furthermore, the UNAIDS Executive Director, Winnie Byanyima, in an open letter to the global pharmaceutical industry leaders called on the global pharmaceutical industry "to unlock the secrets to their COVID-19 vaccine technologies" to produce cheap and accessible "peoples vaccine" and not a "profit vaccine [34]

Impact Of Covid On The Trips Agreement

The pandemic has caused nations to contemplate measures to override intellectual property rights and patents in order to facilitate the production and distribution of vaccines, medicines, diagnostics and medical devices. Discussions have emanated as to whether the COVID-19 pandemic may be categorised as "emergency in international relations" and whether Article 73 of the TRIPS agreement may be invoked as a legal basis to override IPRs otherwise required to be made available or enforced.
Article 73(b) of the TRIPS agreement provides as follows:

(Security Exceptions)

Nothing in this Agreement shall be construed
"to prevent a member from taking any action which it considers necessary for the protection of its essential security interests".
Article 73(b)(iii) states "taken in time of war or other emergency in international relations".
The Security Exceptions provided for in Article 73 which is similar to the Security Exceptions provided for in article XXI of the General Agreement on Tariffs and Trade (GATT) of 1994 poses a question as to whether COVID-19 constitutes an "emergency in international relations", within the meaning of Article 73(b)(iii).

An objective evidence in the positive is in the statement of the WHO Director General who declared the COVID-19 outbreak, a Public Health Emergency of International Concern (PHEIC) [35] on 30 January, 2020 by stating, inter alia, "Our greatest concern is the potential for the virus to spread to countries (outside China) with weaker health systems and which are ill-equipped to deal with it". Public Health Emergency of International Concern basically involves pathogens and virus being transmitted across borders and diverse geographies. In addressing the pandemic, a major issue is the allocation of vaccines and medical devices across nations especially to the developing and least developed countries since the developed countries are able to subsidise and/or to pay for the vaccines [36]. The allocation of scarce resources across the globe makes it an issue of "international relations". This is evidenced with the establishment of viable mechanisms such as the COVAX initiative, GAVI, Bill Gates Foundation by the international community, with the aim of ensuring equitable access to vaccines.

Asides the aforementioned instances, the slow international trade and economic activities occasioned by the pandemic affecting the world and particularly the most economically vulnerable establishes an emergency in international relations. In addition, the UN Secretary-General while addressing the Security Council on April 9, 2020 observed that the pandemic is responsible for the escalations of threats of terrorist activities and hostilities which is also an emergency in international relations [37]. The impact of COVID on TRIPS is that the perception of TRIPS being vital to the protection of intellectual property rights to the world has been weakened. This is because the doctrine of necessity/need has been demonstrated to the effect that TRIPS can actually be set aside if there is an impediment on access to life saving medication.

Article 73 however may be invoked to override IP protections because specific provisions in the TRIPS agreement addressing emergencies do not preclude members from invoking Article 73, the pandemic constitutes an emergency in international relations within the meaning of Article 73(b)(iii) and this provision allows governments to take necessary actions to protect their essential security interests [38].

Covid-19 Patent Waiver
Discussions on patent waivers to remove monopolies on COVID-19 medical tools to help increase peoples' access to needed treatments, vaccines and tests have been ongoing. According to Dr Christos Christou, Médecins Sans Frontières (MSF) International President, "the waiver proposal offers all governments opportunities to take action for better collaboration in development, production and supply of COVID medical tools without being restricted by private industry's interests and actions, and crucially would give governments all available tools to ensure global access [39]".
"Countries must stop obstructing and show the leadership required to deliver on the 'global solidarity' they have so often declared during this pandemic", "It is time to champion access to medical tools for everyone, wherever they live, said Dr Christou.

In October 2020, India and South Africa had submitted the first proposal, suggesting a waiver for all WTO members on the implementation of certain provisions of the TRIPs Agreement in relation to the prevention, containment or treatment of COVID. The temporary waiver would apply to certain IP on COVID-19 medical tools and technologies until herd immunity is reached. On the 3rd of May 2022, a revised proposal was submitted by 62 co-sponsors, including India, South Africa, and Indonesia with around 100 countries supporting the proposal overall. India has engaged countries like Australia, Switzerland, and Japan on a regular basis to allay their concerns on a proposal for temporary waiver of certain provisions of the WTO agreement on intellectual property rights to deal with the coronavirus pandemic [40]

On June 17, 2022, the WTO announced that members had reached an agreement on a partial waiver of patents for COVID-19 vaccines only. The deal, which excluded tests and therapeutics, was slammed by activists for not going far enough, and for going too far by the pharmaceutical industry [41].

India, which had pushed for patent waivers, expressed disappointment that the agreement had taken so long to arrive, that the vaccine patent waivers were all but useless due to a global oversupply of vaccines, as manufacturers had produced 13 billion doses. In fact, the only nation which seemed pleased with the outcome was South Africa, which quickly put 3 manufacturers to work on producing the Pfizer/BioNtech mRNA vaccine.

CONCLUSION

The failure of the WTO to include tests and therapeutics in the waiver must be seen as a disappointment. With the pandemic entering its third year and the prospect of vaccine-resistant variants emerging in the wild, the limited production of accurate, rapid tests constitutes an ongoing public health risk. Testing and therapeutics are key tools in the arsenal of governments facing such risks, and failing to waive patent protections for their production places health officials at a distinct disadvantage, and will surely prolong the pandemic. At a time when the focus of the world has shifted to the Russian invasion of Ukraine and fears of an impending global recession, it is advised that against the case by case, nation by nation application for compulsory licensing provided in paragraph 6 of the TRIPS agreement, the World bank reviews such application to be more flexible because of the difficulty in predicting market prospects that generic companies need to invest in the development of a product as the case of COVID-19.

A strong political will by nations along with human rights based approach to incorporate the TRIPS flexibilities such as right to health into their national laws can enhance access to medicines and vaccines in Africa. It is advised that Africa develops a strong pharmaceutical manufacturing capacity to provide covid-19 vaccines and medications to the continent. This will facilitate the production of generic drugs in the continent in addition to making the compulsory licenses easier and more attractive. Also, the establishment of an African Free Trade Zone and local manufacturing of pharmaceutical products will make drugs cheaper in the continent since trade barriers or excise duties will not be applicable in the zone. Where this approach is employed, government will be held accountable for the provision of healthcare and its breach. In order to address the current pandemic, it is recommended that intellectual property should be waived on COVID 19 as the global pandemic affects everyone and as such we all need access. Countries should be granted the exclusive rights to produce the medication and vaccine to COVID 19 as "No one is safe until everyone is safe" [42]

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