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Evaluating the Efficacy of Article 31bis of TRIPS Agreement in Facilitating Access to COVID-19 Vaccines

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Abstract
Sudden out breaking of Pandemic Covid-19 alarmed the world and provided an opportunity to re-prioritize the things. It became top of the priority to save life rather to save money. If your life is in danger you will never think about other things like accumulation of wealth and other luxuries except how to save your life. Pandemic brought the world united in awaiting and accessing vaccination. Difficulty raises more for those who have not enough wealth to purchase those drugs to save their lives. In other words, they would die due to their poverty. 'Doha Declaration on the TRIPS Agreement and Public Health' was intended to cater this problem therefore it provided a solution in the form of 'Export Compulsory Licensing' for essential drugs more than two decades ago but still only one successful venture has been carried out under this scheme. This research intends to explore the possible reasons of its failure and how it can be benefited more in future. Furthermore, this article will also provide some ways out for Pakistan to access easy and affordable medicines keeping itself compliant to international intellectual property laws and obligations.

Keywords: Export Compulsory Licensing, Covid-19, Doha Public Health Declaration, TRIPS etc.

Introduction

It is both desirable and difficult to achieve equilibrium between pharmaceutical patents and access to medications but The COVID-19 pandemic has brought to light a difficult balancing act between preventing drug shortages and using patent rights to encourage the development of new drugs. Legislators worldwide battled throughout the 20th century to strike a balance between guaranteeing that citizens had cheap access to life-improving therapies and encouraging the creation of new medical technologies through the patent system (Christopher, n.d. 2020). A wide range of varied solutions were produced as a result of their efforts, reflecting the underlying variability in social, political, and economic reality. Jurisdictions with unfettered pharmaceutical patentability and privatized healthcare systems are at one extreme, while those with universal public healthcare and a total ban on medical patents are at the other. A full galaxy of intermediate positions existed in between, usually combining limited pharmaceutical patent protection with partially financed healthcare.

In this situation, compulsory licensing is old and common recourse. Compulsory

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licenses (CLs), which have a long history, are fundamentally the same in all jurisdictions: they are a type of authorization that a government gives to a public or private organization to use a patent's subject matter without the patent holder's consent. A significant exception to the patent's exclusive nature is provided by CLs. They lessen the patent holder's powers otherwise total authority over the invention vests into his inventor (Cynthia Ho, 2009). Countries used CLs in various ways as they attempted to strike a balance between pharmaceutical patents and access to medications. Some only used them as a remedy to punish patentees who artificially limited supply or demanded exorbitant rates. Other regions took things a step farther. With the stated goal of increasing access to medications and promoting domestic biochemical production capabilities, they implemented special regimes that made it easier to issue CLs for medical patents.

Severe shortages was resulted from the COVID-19 pandemic's spike in demand for medications and vaccines. Pharmaceutical firms were not required to grant third parties licenses to their technology in order to boost supply, even in the midst of the crisis (Kumar, 2022). Compulsory licensing under TRIPS Article 31can be useful in certain circumstances, but it doesn't force businesses to share the know-how required to make complex medications (Joshua, M. n.d., 2020). The method known as ‘compulsory licensing,’ which is allowed by the “Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)”, allows nations to enter into agreements with outside manufacturers to produce patented goods in exchange for the government paying the patent holder (World Trade Organization, 2018). The patent law (of the Pakistan also grants similar rights under section 59 with the title of “Powers of Controller in granting Compulsory Licensing” of “Patent Ordinance 2000”. Countries looking to supply medications to their citizens in times of public health crisis may find that compulsory licensing is a helpful instrument. Admittedly, it is not a perfect solution: sophisticated medications, like mRNA vaccines, might be too difficult or time wasting for others to replicate without the patent holders "know-how," and shortages in raw materials and production capacity could also make medicine supply more problematic (Review & Kumar, 2022). Compulsory licensing, however, can improve access and enhance supply for at least some medications. A number of wealthy nations have changed their stances on the usage of compulsory licensing in the case of scarcity as a result of the pandemic. Canada, Israel, and several other governments enacted pandemic-specific legislation that gave national health ministries the power to grant compulsory licenses, as did some European Union member states (Times of Israel, 2021). Israel amended the provisions of its “Patent Law 1967”, section 104 and 105 wherein its designated minister was empowered to allow the use of patented medicines in case of state needs. In consequent to this it issued a compulsory license in March 2020 against a patented medicine (lopinavir/ritonavir) to produce its generic version because it was claimed that patentee could not supply its required quantity (admin, 2020). Similarly Canadian Parliament passed a legislation on March, 2020 “Covid-19 Emergency response Act” which amended their Patent Act to make the process easy for issuing compulsory license. This legislation allowed Canadian Government to grant compulsory license for any patent to respond health emergency. Russia In November 2019, Russia also introduced a bill for the amendment of its relevant Articles 1360 and 1362 of

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Civil Code which allowed Russian Government to grant compulsory licensing without court permission to protect their citizens in health emergency like Covid-19.

Importantly, as the 20th century came to an end, the decisions nations made about how to balance access to medications and medical patents changed from being a domestic issue to becoming a source of international conflict. Developed countries, which issued extensive patents for pharmaceutical breakthroughs, bemoaned international drug piracy and free riding and asked for the adoption of protection levels that were comparable to their own on a global scale. These demands were challenged by developing countries. They said that it was completely within their sovereign authority to deny medical patents or to generously subject them to CLs. They insisted that protecting their residents' access to medications came before preserving the profits of international pharmaceutical firms.

The creation of the “World Trade Organization” and the accompanying TRIPS ended this deadlock (WTO, 2019). Developing nations agreed that all WTO Members (Members) would be required to implement the TRIPS minimum requirements for intellectual property (IP) into their national laws in exchange for tariff free access to the agricultural and commodities markets of industrialized nations. Importantly, all technological inventions, including pharmaceutical items and procedures, must be protected by patents under this convention. TRIPS softens this bright line rule by allowing Members to use flexibilities to limit patentees' rights, such as the ability to issue CLs (Nicol & Owo. Eye, 2013).
Some analysts even went so far as to refer to the TRIPS regime for medical discoveries and CLs as structural violence (Srividhya Ragavan & Vanni, 2021). The Global North was charged with imposing its legal system on the Global South, creating a neo-colonial framework for international trade law that would force economically dependent but formally sovereign developing nations to acknowledge and uphold the property rights of industrialized nations (Ezzine & Andreas, 2009). The worlds impoverished would be condemned to suffer from treatable diseases under this new legal system since they could not afford medications. When a serious flaw in this paradigm surfaced during the global HIV/AIDS crisis, these voices became more prominent, with devastating results.

Before TRIPS, poor nations would purchase copyrighted medications that were either inaccessible or prohibitively expensive from countries where they were widely and inexpensively available, either because they were patented or not. By requiring pharmaceutical patents across the WTO and prohibiting the export of goods made under CLs, TRIPS suddenly closed these opportunities (M Correa, 2017). The only way for Members to enhance the supply or decrease the price of a patented drug under this treaty was to provide a domestic producer a CL directing them to supply the necessary medicament. However, it would be pointless to issue such a CL if no local producer had the requisite facility and expertise.

Members acknowledged this problem at the 2001 WTO Doha Ministerial

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Conference and decided that an expeditious solution was required. The result of two years of arduous discussions was Article 31bis (WTO, 2016). Through an exception to Article 31, this clause creates a procedure that allows a Member with limited pharmaceutical manufacturing capacity to import patented medications from a generics drug manufacturer operating under an export compulsory license ("ECL") granted by another Member. Lawmakers, non-governmental organizations (NGOs), and commentators hailed this treaty modification at the time of its passage as a much-needed update to the TRIPS mandatory licensing structure. There were great expectations that ECLs would emerge into effective instruments for developing nations in their efforts to provide their citizens with sufficient access to medications. Furthermore, this innovative legal tool's collaborative nature was commended for creating a cooperative avenue for the Global South to get access to the expertise and technology developments of the Global North. Unfortunately, because only one ECL has been given and effectively carried out in the last 20 years in which Rwanda (import country) sought production of a generic version of a patented medicine antiretroviral drugs for HIV/AIDS treatment from a Canadian company Apotex Inc. The whole venture went successfully and the required quantity of drugs was also achieved but the procedure and complexities involved make the parities tired and even the said company denounced this exercise in future until it is made easy and simple (American Society of International law, 2007). The hopes and optimisms associated initially diminished subsequently because after that we found no other case of ECL (Ezzine & Andreas, 2009).
This article examines the current condition of Article 31bis's inactivity, suggests ways to make it reality, and examines how successful it was in cooping the SARS-CoV-237 (Covid-19) epidemic. Additionally, this article also suggests some practical measures which Pakistan can also take like India toward accessing cheap and affordable medicines for its citizens.

Possible Reasons for Least use of Article 31bis System

As already mentioned, only one time in history export compulsory licensing system under article 31bis of TRIPS was used in 2007 by Rwanda as an importing country involving Canada as an exporting country. Initially, people associate high hopes with this system as a viable source of accessing cheap and affordable medicines. The basic system under article 31 of TRIPS was amended after a very long debate and demands, starting from 2003 by waiving article 31(f) to finally in 2017 when it was officially incorporated, by developing countries because the basic compulsory licensing system does not provide help those countries who have not their own manufacturing capacity and facility. An alternative was provided to those countries (least developing countries) to involve the country for the production of drugs who have good manufacturing capacity as an exporting countries.

Various debates have been held on different occasions in WTO TRIPS Council amongst its members for exploring reasons and their possible solutions. In such sessions various aspects like implementations barriers, developed vs. developing countries perspectives and complexity in procedural aspects were discussed in length. This debate gain momentum during the out-breaking of COVID-19 when especially developing countries (100 countries) sought waiver of some

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intellectual property rights during pandemic. In a joint study on access to medical technologies and innovation, the WHO, WTO, and WIPO also openly admitted the Article 31bis System's inactivity (WHO, 2020). In addition, a variety of explanations have been developed by scholars, activists, and non-governmental organizations to explain why ECLs have not been successful. When taken as a whole, it was discovered that these sources have distinguished four major categories of problems: economic difficulties, procedural complications, obtrusions brought about by domestic laws and free trade agreements, and corporate and governmental meddling. Now, let us examine each one separately as under:

Governmental and Corporate Sector's Pressure

Considering the controversial history of compulsory licensing, some have argued that least developing members (LDCs) avoid using the "Article 31bis System" due to fear of retaliation from pharmaceutical corporations and developed members. Scholars and non-governmental organizations have long criticized the way the US government has historically used Section 301 of the US Tariff Act of 1974 as a weapon to pressure and punish states that they believe do not sufficiently protect US intellectual property rights. There can also be cited some examples in which developing members have granted compulsory licenses in the recent past and were sanctioned. For instance, Thailand granted compulsory licenses for a number of patented pharmaceutical drugs used to treat some major diseases like cancer, heart problems and HIV/AIDS etc. between 2006 and 2008. A royalty was also set at 0.5% to 2% of the entire sale price served as payment without consulting the patent holders. Since all citizens of Thailand are entitled to free healthcare at the point of access, the government estimated that these actions would result in a huge reduction in the cost of these medications. The impacted pharmaceutical companies and a few developed members reacted aggressively (Edward J Kelly., 2020). In 2007, the United States placed Thailand on its Special 301 "Priority Watch List," (Nation, 2025) citing "the lack of transparency and due process exhibited in Thailand represents a serious concern, even though the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules." Thai exports were unable to enter the US market duty-free due to sanctions imposed by the US. The response from the European Union was not totally consistent. The "European Commission" asked to the Thai government regarding the legality of its compulsory licensing practices, despite the European Parliament passing a resolution endorsing developing Members ensuring that the use of TRIPS flexibilities to protect the right of their citizens of cheap and affordable medicines.

Similarly, an Indian company that was exporting the disputed medication into Thailand was also threatened by Sanofi (which had patent) for legal action against it. Even more concerning is the fact that Abbott, the company that holds the patent for lopinavir/ritonavir, pulled a number of new medications off the Thai market that were intended to treat blood clots, kidney illnesses, arthritis, high blood pressure, viral infections, and inflammation (MSF, 2007). Despite the eventual reversal of this vengeful action, Thai patients endured needless suffering at the hands of a private foreign actors. For the period of the dispute, they were denied access to necessary therapies, some of which had no other option.

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Coercive measures, such as punitive trade policies and pharmaceutical product withdrawals in response to compulsory licensing, are examples of governmental and private retaliatory measures that violate the TRIPS flexibilities, Articles 7 and 8 of TRIPS, the Doha Declaration, and even the "WTO Dispute Settlement Body". More on, it is also violation of "Article 31bis (4)" which says that a legitimate issued compulsory license cannot be challenged. Apart from it is against the principle of state sovereignty.
The aforementioned measures, however, appear to have been less stringent in recent years than in the past because, in nearly every instance of developing members issuing compulsory licenses for pharmaceutical products in the late 1990s and early 2000s, patent holders fiercely opposed the move, political pressure was applied, and national governments, often led by the United States, imposed trade sanctions.

TRIPS-PLUS Measures by States to Fail Article 31bis System
Sometimes states act beyond from TRIPS standards in the form of mutual agreements. Members may engage into bilateral, regional, or multilateral free trade agreements (FTAs) that impose IP protection criteria that are stronger than those set forth by TRIPS (often known as "TRIPS-Plus"), including limitations on ECLs and data exclusivity provisions in such agreements. It is worth to mention that WTO legal regime does not prohibit such measures. Members also have the freedom to pass domestic patent laws that restrict ECLs in some way. The argument put forth by commentators is that the Article 31bis System is being undermined by an increasing number of domestic legislation and TRIPS-Plus free trade agreements. For example, signatory states to the US-Jordan, US-Singapore, and US-Australia free trade agreements commit to only issuing compulsory licenses for domestic use and when acting as an exporting state in order to address a limited set of issues, such as patent holders' anti-competitive behavior, public non-commercial use, and extremely urgent situations. Furthermore, the free trade agreements between the United States and Singapore and Australia prohibit patent holders from being compelled to assist compulsory licensees by disclosing "undisclosed information or technical know-how" "(United States – Singapore Free Trade Agreement, 2003)". It is generally accepted that such actions are harmful to the "Article 31bis system". In these situations, the issuance of ECLs is either directly or indirectly prohibited under national laws and international free trade agreements. If this approach were taken by the large majority of members with established pharmaceutical firms, the "Article 31bis System" might be considered dead letter.

Procedural Complexities
It is widely believed that the export compulsory licensing is significantly hampered by the procedural aspect of the "Article 31bis System". Unfortunately, efficiency, simplicity, and expediency for the pertinent stakeholders are not given priority in the rules under review. The lengthy and burdensome multi-step process that governs the Article 31bis System is interrupted with various restrictions. When it is required to notify the "TRIPS Council", the Importing State is required to adhere to a number of information disclosure requirements (Annexure II, WTO. Special Compulsory Licensing for Export of Medicines). In addition, the Exporting State is required to compensate the impacted patent

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holder, grant extremely precise obligatory licenses, and provide the TRIPS Council with adequate updates. Additionally, the licensee must provide information about the manufactured drugs to the public (WTO, 2018). The procedural aspect of the “Article 31bis System” is extremely challenging for emerging members, and it is usually called "labyrinth" (Brook, 2003). Critique say that the procedure is too drawn out and requires an unreasonably high level of coordination between the participants when viewed as a whole.

It has been criticized that the requirement to negotiate with patent holders prior to issuing an ECL is likely to cause major delays, particularly when there are several patentees involved. Strong concerns have also been raised by commentators over the need that pharmaceutical items made under an ECL be distinguished from one another by unique coloring and shape. These changes take time and frequently entail a biomolecular analysis of the proprietary medication to make sure the generic version being produced has the same bioequivalence and bioavailability (Chow, 2014). The Doha Declaration aimed to address the challenges that Members with inadequate pharmaceutical manufacturing capabilities experienced while attempting to effectively utilize the Article 31 mechanism for compulsory licensing which seems hard to achieve with current scenario. In such circumstances to comprehend the extent to which these procedural requirements discourage the use of Article 31bis is difficult to measure.

Financial Difficulties

It is also big hurdle in the way of using Article 31bis system for poor countries who neither have enough pharmaceutical manufacturing capacity nor do they have sufficient finance to support it. These challenges are many types starting from pharmaceutical manufacturing, distribution, and sales under ECLs are capital-intensive operations requiring significant upfront investment (Basu et al., 2008). Production cost are huge in every type of medicines. If it is chemical based then it is necessary to ascertain the compound's composition and create a stable formulation. In case of biologics the inherent challenges is in creating biosimilars, this reverse-engineering approach is even more complex in the case of biologics (ROGER, 2006). Costs associated with regulations are also high. The costs associated with acquiring the required permits from the appropriate regulatory bodies in the countries where they wish to market and sell their goods must be borne by all pharmaceutical producers.

Financial limitations also exist on the importing state's end to ensure the sustainability of this endeavor. The path to financial success is difficult and limited for export compulsory licensees. The Importing States are least developing countries who can only afford low prices for a particular pharmaceutical product. Additionally, the export compulsory licensee would have to produce in large scale quantities in order to realize economies of scale (Silberston, 1972). Over time, this would lower marginal production costs, allowing the manufacturer to reach a price point that is both profitable for the manufacturer and affordable for the Importing State. But in reality, such a tactic is not always practical. Importantly, if the Importing State only requests a modest amount of pharmaceutical items in its submission to the TRIPS Council, the required licensee will not be able to achieve economies of scale (WHO, 2020).

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Apart from the above, economic challenges for this system will be enhanced in case of litigation threats posed by patentees or other stake holders.

How to Maximize the Potential of Article 31bis in Medical Emergencies

The Article 31bis System's dormant state has not gone unnoticed. It is widely believed that the limits imposed by developed members have sentenced ECLs to failure, making them an unsuccessful experiment (Wade, 2003). In order to support developing members in their efforts to provide their citizens with adequate public health standards, including access to medications, they suggest focusing both human and financial resources on securing inexpensive voluntary licenses from patentees, strengthening medicine patent pools, and organizing humanitarian aid campaigns. In fact, these strategies have not brought the intended results evidently from the past. On the other hand export compulsory licensing promising more effective and better solution toward the achievement of medicine recourse on the following grounds:

First, cooperation from the patent holders or outside the organizations are essential to compulsory licensing, medical patent pools and more importantly humanitarian relief initiatives. On the other hand, in the case of export compulsory licensing, member states of WTO can act independently and according to their own conditions if they have access to an efficient export compulsory licensing mechanism especially in the case of national health emergency like Covid-19.

Second, when faced with the threat of compulsory licensing, pharmaceutical patent holders are much more willing to make concessions in the way of lowering prices, transferring know-how, and granting compulsory licenses. This strategy is only open to members who are unable to rely upon their own domestic compulsory licensing while it is still in growth stage, provided that the Article 31bis System is viewed as a functional mechanism rather than a hypothetical threat.

Third, domestic compulsory licensing is frequently used by members with adequate pharmaceutical production capabilities to gain access to patented medications that would otherwise be unavailable. This data has the conclusion that compulsory licensing with patent holders and assistance initiatives are not always practical or feasible. In these situations, Members without a developed domestic pharmaceutical sector have no choice except to use ECLs.

Fourth, in the past, countries have used compulsory licensing as an inward-looking tool to either advance domestic policy goals or limit patentee behavior that disrupts local markets. The Article 31bis System seeks to broaden and change the functional profile of this legal tool in order to give it a new dimension. Despite the patent system's territorial nature, ECLs are meant to give Members access to a tool whose reach transcends national boundaries. They represent a cooperative system that enables poor nations to profit at reasonable costs from the technological superiority of international pharmaceutical industries.

Undeniably, Article 31bis has not yet produced results, but it has enormous potential. It shouldn't be dropped because of a bad execution. Rather, we think that the Article 31bis System should be used to its fullest capacity.

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Some Suggestions for Pakistan in Accessing cheap and Affordable Medicines

Although Pakistan is not in the list of least developing countries under Article 31bis of TRIPS but still Pakistan is a poor country categorized as a developing nation. It is strong need of Pakistan to think how it can provide cheap and affordable medicines to its citizens using some permissible and legal strategies, in the context of current legal regime of intellectual property laws, which might be as follows:

- Pakistan has not issued any compulsory licensing in the past which is available right under article 31 of TRIPS. Compulsory licensing proved many times an effective tool for accessing cheap and generic version of high priced medicines. India issued a compulsory licensing on March 9, 2012 against 'Natco Pharma' for generic production of 'Nexavar' a lifesaving medicine against cancer. After issuing compulsory licensing Bayer agreed to sell at price of monthly medicine at 160$ per month which it was initially selling against the price of 5000$ (PMLiVE, 2013).
- Pakistan can also update its patent law while limiting patentability qualifications like India's section 3(d) which proved an effective tool to restrict evergreen patent.
- The grounds for issuing compulsory licensing have been provided under section 59(1) of Pakistan Patent Ordinance 2000 are not sufficient as compare to India or alike other states. Conversely, section 84 of Indian Patent Act 1970 provides three grounds: two grounds are same to Pakistan but one is that if the patented invention not available to public at reasonable or affordable price whereas such ground is not available in Pakistan Patent Ordinance 2000.
- India has become world's largest exporter of generic drugs but Pakistan is not even producing to meet its domestic needs. It is interesting to know that the India and Pakistan are under the same international obligations regarding intellectual property laws but the difference is that India had shown strong priority toward access of affordable medicines through taking different measures like restraining evergreen patents, pre and post-grant-opposition, parallel importation, using of TRIPS flexibilities and health priorities while dealing with IP rights but it does not reflect in Pakistan IP policy.

Conclusion

There are solid grounds to assume that the underutilization of the flexibilities is neither the result of deficient national practices nor their intrinsic inefficiency, given the well-known history of the Doha Declaration and the TRIPS Agreement. Instead, because of the political pressure they face when they do utilize them and the excessive complexity of the legal requirements and patent landscapes, countries do not include these exceptions in their laws. As an additional example, consider the fact that India has not granted any compulsory license since its first in 2012, which sparked excessive criticism from the US government. Pakistan has not considered it yet which the other mostly countries are availing in their

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difficult times. The developing countries must be ready to defend their proactive approaches and strategies towards accessing easy and affordable medicines for their citizens in difficult times. India also faces huge pressure upon the making hard criteria of patentability but it always defends that the legislation is under the limits of TRIPS and international obligations.

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