Journal of
Intellectual Property Rights Law

ISSN: 2582-9742
Volume 6, Issue 2, 2023
DOI (Journal): 10.37591/JIPRL
(July–December)

http://lawjournals.celnet.in/index.php/jiprl/index

Research JIPRL

The North-South Divide in Pharmaceuticals: Analyzing the Role of TRIPS Agreement Within the Sphere of Public Health in Developing Countries

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Abstract

This study explores the impact of the Intellectual Property Rights Agreement (TRIPS) on access to pharmaceuticals in developing countries, particularly in the context of the COVID-19 pandemic. While promoting innovation and investment, the TRIPS Agreement has been criticized for creating barriers to affordable healthcare in developing countries. The study discusses the limitations of compulsory licenses and the adverse effects of TRIPS Plus provisions, which impose stricter intellectual property protection. It also explores the Doha Declaration, which recognized the flexibility of TRIPS for public health purposes. The study further examines the COVID-19 waiver proposed by South Africa and India, which sought to waive IP rights related to COVID-19 health technologies. It highlights some of the features of the COVID-19 waiver. It provides comprehensive approaches that need to be made in order to address the challenges of access to medicines and emphasizes the importance of technology transfer and data exchange. Finally, the study calls for measures to bridge the North-South divide in the pharmaceutical industry and ensure equitable access to essential medical products.

Keywords: Intellectual property rights agreement (TRIPS), intellectual property protection, Doha declaration, health technologies

INTRODUCTION

The COVID-19 pandemic sparked an ongoing debate regarding the issue of global health and inequality, particularly in the context of the developed and developing countries of the Global North and South respectively. The race to develop and distribute vaccines has highlighted the disparities between the Global North and South. The role of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPs) has become a key point of discussion with regard to access to pharmaceutical products in developing countries [1]. Even though the TRIPs Agreement has been acknowledged for prompting innovation and research in the pharmaceutical sector, it has also been criticized for creating significant obstacles to affordable healthcare, specifically for individuals living in developing nations [2].

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Received Date: May 22, 2023
Accepted Date: June 26, 2023
Published Date: July 11, 2023

Citation: Deah Rose Neeliyara. The North-South Divide in Pharmaceuticals: Analyzing the Role of TRIPS Agreement Within the Sphere of Public Health in Developing Countries. Journal of Intellectual Property Rights Law. 2023; 6(2): 1–8p.

Furthermore, the reluctance of developed nations to share essential data and medications, as well as the rampant hoarding of essential medicines and vaccines in the middle of a global shortage, hampered global efforts to combat the pandemic [3]. This has prompted concerns about the influence of the TRIPs agreement on access to vital treatments and essential vaccines. Where, despite the development of vaccines and treatments for COVID-19 at a record pace, many developing countries still lack access to these life-saving tools [4].

Through this study, the aim shall be to analytically assess the impact of the TRIPs Agreement on the access to pharmaceuticals to the countries in the global south, especially within the larger context of the COVID-19 pandemic. Furthermore, this study examines the efforts of the covid waiver and provides possible solutions to combat the growing North-South divide of the pharmaceutical industry.

TRIPS AGREEMENT

This Agreement was established between the years 1986 and 1994 in the trade negotiations which took place in the Uruguay Round. It consisted of an elaborate multilateral trade agreement on the relatively unexplored field of intellectual property rights (IPRs) [5]. Prior to the agreement, there were no comprehensive regulations governing IPRs as they were not associated with trade [6]. The TRIPS Agreement went on to set certain foundational standards of protection and guidelines on enforcement for IPRs that all WTO member states are required to implement, regardless of their level of economic or social development [7]. The agreement aims to establish a harmonized international legal framework for IPRs to promote innovational ideas and investment in the same, facilitate the transfer of technology, and protect creators' rights [8]. In principle, the TRIPS Agreement's intention was to create a "level playing field" of mutually recognized IPRs among all member states, with the added emphasis on encouraging trade and commerce. However, often the patent holder monopolies the patents which creates exorbitant prices that cannot be borne by most governments and individuals from developing nations [9].

Therefore, the issue of IP was highly controversial during the Uruguay round, particularly for countries that were still in the stages of developing [10]. These countries were in opposition to laying down substantive standards alongside important enforcement rules for IP, arguing that such rules were "marginally trade-related" and would negatively affect access to affordable medicines [11]. This opposition was fueled by the fact that developed countries owned most copyrights, patents, and trademarks while developing countries primarily imported and used intellectual property for the creation of generic products. Despite initial resistance, developing countries felt the need to comply with the TRIPS Agreement due to a lack of choice owing to pressure from a powerful group of developed nations amid drastic geopolitical changes in the year 1989 and the shift seen in domestic economic policies [12].

However, the TRIPS Agreement recognized that WTO members have the authority to take measures that are necessary for public health and additional public interest causes and to prevent intellectual property rights abuse. It contains provisions that allow for members to exercise flexibility in balancing the protection of IPR alongside the protection of public health, including the exception of compulsory licensing under Article 31 [13]. This provision allows WTO members to grant licenses to the government or other third parties without having to take authorization from the patent holder for certain specific reasons specified in Article 31, thereby enabling access to affordable medicines [14].

DOHA DECLARATION

However, even with the provision of a few exceptions in the TRIPS agreement, the inefficiencies of the TRIPS agreement to deal with public health became apparent during the AIDS crisis. During the Crisis, South Africa was one such country that was significantly affected by the epidemic. In order to deal with the crisis, they allowed the parallel importation of products coming withing the purview of the pharmaceutical sector in an effort to minimize the cost of the medication. However, subsequently, 39 pharmaceutical companies challenged the decisions of South Africa [15].

Since this issue became a global topic of discussion, it was brought to WTO's attention, which led to the adoption of the 'Doha Declaration' on November 14, 2001. This declaration reaffirmed that point of the TRIPS Agreement not preventing member countries from taking necessary measures to safeguard public health [16]. It recognized the severity of public health challenges, particularly those related to diseases such as malaria, HIV/AIDS, tuberculosis, and other such serious epidemics that

affected developing countries. The Doha Declaration clarified the flexibility that WTO members possess under the TRIPS Agreement to be able to take measures in order to protect their public health, which includes granting compulsory licenses for pharmaceuticals and determining the reasons for doing so. However, it was only in 2003 that WTO members were able to reach an agreement on allowing member states to export pharmaceutical products which have been produced under the category of compulsory licenses, which was previously limited to domestic supply [17]. Furthermore, in 2005, the amendments which were introduced to the TRIPS Agreement were approved by WTO members, although it did not come into effect until 2017. Prior to the ratification of the amendment, the 2003 waiver continued to apply [18].

TRIPS PLUS PROVISION

Despite the provisions and objectives established in the Doha Declaration to promote public health, many of these measures have proven to be ineffective [19]. Developed countries, with the United States and the European Union being notable leaders, have aimed to establish stricter regulations through bilateral free trade agreements, leading to the emergence of TRIPS Plus provisions [20]. Trips Plus provisions are clauses in trade agreements that require countries to adopt more stringent intellectual property protection than those specified in the TRIPS agreement. These provisions have forced developing countries to take measures such as adopting more restrictive patent laws, making it harder for generic drug manufacturers to produce and distribute affordable medicines [21]. The lack of flexibility in these provisions has made it challenging for countries to balance public health concerns and the protection of intellectual property rights. Unlike, TRIPS, the countries are not obliged to set the requirements in their domestic laws, but due to the push of the developing countries, they have very little choice but to implement such regulations.

For instance, there have been many free trade agreements made by the United States where they have requested national drug authorities from registering a generic drug without receiving the prior consent of the patent holder. This is a radical shift from the traditional method of operations where the market approval for a drug was granted based on the safety and efficacy of a drug and not on the basis of the patent status of a particular drug [22]. This system has created a lot of confusion since the persons in charge of the patents and regulatory market approvals are separate bodies in most nations. Furthermore, the issue of the legality of compulsory licenses remains unclear due to this change.

Furthermore, some bilateral agreements have requested the provision of data exclusivity. Where when a generic drug manufacturer aims to submit a drug for approval, they need to re-conduct tests of the clinical trials. Previously, they simply needed to prove that the drug they sought to distribute was of similar quality and had equivalent efficacy to the patented drug [23]. This process substantially reduces the time and resources that are required to introduce a new drug in the market. However, the new shift creates a huge financial burden on the generic drug company, forcing them to conduct their own clinical trial and submit their data. This will also impede the manufacturers from getting the drugs out in the market in a reasonable time [24].

Furthermore, the US has made efforts to ensure the inclusion of provisions in certain FTAs which creates a phase of data exclusivity, starting from the approval date of another country, even in cases of the manufacturer not having had sought the registration of the drug in a particular country. What this means is that a generic manufacturer would nevertheless be prohibited from relying on data for a certain time period, the end result of which will be that the country will not have access to that specific drug up and until the expiration of the data exclusivity period [25]. Additionally, many such bilateral agreements have also been requested, including provisions to extend the duration of a patent beyond the 20 years mentioned in the TRIPS Agreement [26]. These TRIPS-plus provisions have hindered any positive changes brought about by the Doha Declaration.

LIMITATIONS OF COMPULSORY LICENSE

Furthermore, the limitations and challenges associated with compulsory licenses have been demonstrated in numerous cases. The first issue is the provision of compulsory license merely has

persuasive value since developing countries have often been deterred from using this option due to pressure being exerted from pharmaceutical companies and the possibility of trade sanctions from international bodies. For instance, the US Trade Representative's (USTRs) Special 301 Report has threatened trade sanctions against nations like Brazil, Chile, India, Malaysia, Thailand, and South Africa for the grant of compulsory licenses for offering versions that are priced lower for essential medicines that are still under patents [27].

In India, the compulsory license provision was only used once in 2012, in *Bayer v. NATCO*, causing a stir worldwide [28]. However, regulators have since dismissed all attempts to grant compulsory licenses, including in cases such as BDR Pharmaceuticals International Pvt Ltd.'s 2013 application for a compulsory license for the drug SPRYCEL used for cancer purposes produced by Bristol Myers Squibb [29] and Lee Pharma's 2015 application regarding a compulsory license for the diabetes drug Saxagliptin made by AstraZeneca [30]. The Indian Patent Office cited insufficient justification by both companies, but there has been speculation that the rejection of all compulsory patents since 2012 may be a result of international pressure to maintain trade relations with the United States [31]. To effectively remove political and trade pressures, there must be a permanent cessation of pressure on countries to grant compulsory licenses for free access to generic vaccines, medicines, and other medical products. This should not just be an exception because of Covid-19.

Moreover, in times of crises such as pandemics, simply providing compulsory licenses to override patents is inadequate. Instead, to expedite the production and regulatory approval of essential medical products, alternative producers require immediate access to other types of intellectual property protections, including trade secrets, confidential information, copyrights on software, and industrial designs related to equipment [32]. However, under the flexibility of the compulsory license, it is only limited to the usage of patents. In addition to patents, diagnostics also involve other types of IP protection, which means that producers need access to regulatory data, quality control know-how, cell lines, and other biologic resources. Copyright protections may also apply to industrial blueprints, manuals, and software used for production equipment, diagnostic tools, and medical devices [33]. In the case involving the COVID-19 pandemic, a range of products, including treatments, diagnostics, vaccinations, ventilators, and protective equipment, are protected by various forms of IP rights, not just patents. Furthermore, certain vaccines are protected by multiple patents, adding further complications since patents are granted on a case-by-case basis and are product-specific [34].

Finally, it is pertinent to note that compulsory licensing has limited utility in countries with limited capacity to research and develop vaccines, particularly during a pandemic when large numbers of vaccines are required to meet the demand. Therefore, a comprehensive approach is needed to address the complications involved in the development and production of medical products that also provides a robust mechanism ensuring that alternative producers have access to all relevant information and resources [35].

COVID-19 WAIVER

In 2020, India and South Africa put forward a proposal to the WTO seeking a waiver of all four categories of intellectual property rights under the TRIPS Agreement for COVID-19 health technologies and materials until the majority of the global population is vaccinated and immune to the virus [36]. The proposal received official co-sponsorship from Eswatini, Kenya, Mozambique, and Pakistan and gained support from 100 countries [37]. The objective of the Waiver was to exempt countries from facing legal action before the WTO dispute settlement body for not fully complying with the TRIPS Agreement during a pandemic and to facilitate the rapid import and export of COVID-19 products manufactured by generic companies.

However, a small group of WTO members, the EU, the UK and Switzerland, have withheld their support for the proposal, stating concerns about the potential impact on innovation and investment in

the pharmaceutical industry, even though in the case of COVID-19 a large percentage of vaccines were developed through public funding [38]. The United States initially withheld their support but changed its position under the Biden Administration agreeing to a narrow scope for providing support only or waiving vaccine patents [39]. These countries have traditionally supported the interests of their pharmaceutical corporations through a proprietary IP system. After nearly 2 years since the TRIPS Waiver was first proposed, the TRIPS Waiver Decision was finally adopted at the 12th WTO Ministerial Conference in June 2022. However, the adopted TRIPS Waiver Decision is a diluted version of the original proposal after compromises were made to accommodate the developed countries' concerns during the "Quad" negotiations.

The approved Covid Waiver has a narrower scope compared to the original proposal made by India and South Africa, which covered a broad range of intellectual property rights, including patents, trade secrets, copyright, and confidential information related to the prevention, control, or treatment of COVID-19, such as diagnostic kits, medical masks, personal protective equipment, ventilators, vaccines, and medicines. However, the current Waiver only applies to COVID-19 vaccine patents, excluding other forms of IP rights and Covid-19-related medications or treatments. This exclusion shall be reviewed within 6 months to determine whether to extend the Waiver's coverage to include COVID-19 diagnostics and treatments [40]. The TRIPS Waiver Decision will be valid for a period of 5 years starting from the date of the decision, and the WTO General Council shall review it on an annual basis, and may extend its duration, taking into consideration the unprecedented and exceptional circumstances of the COVID-19 pandemic [41].

ANALYSIS OF TRIPS EXEMPTIONS

While the TRIPS waiver is an extremely important step towards ensuring that access is provided to COVID-19 vaccinations for developing countries, it is not a complete solution to the issue of medical accessibility. Firstly, it took almost 2 years for the TRIPS Waiver to be adopted because the WTO requires unanimous agreement from all member countries, which undermines the urgency of an emergency measure. Meanwhile, during the initial and subsequent attempts at the waiver, many developed countries were struggling to obtain vaccines and treatments, making the delay even more frustrating.

Furthermore, the lack of ability to manufacture vaccines in some developing countries is a significant challenge that cannot be fully addressed through the Waiver of patents alone. The production of vaccines requires trade secrets to obtain details regarding the production, process, and mechanism of the vaccines, which are not covered by this TRIPS Waiver. Therefore, additional intellectual property rights should be waived to support developing countries' manufacturing capabilities [42].

Moreover, the TRIPS waiver covers merely the COVID-19 vaccination patents, and there are other critical tools needed to combat the virus, such as diagnostics and therapeutics. Therefore, more progressive measures are needed to ensure that developing countries are given the chance to have equitable access to these essential tools [43]. Focusing solely on patents and encouraging compulsory licensing is not sufficient. While these measures can assist developing countries in utilizing pharmaceutical patents, they do not guarantee their ability to produce medicine. To overcome this issue, a strong technology transfer and data exchange system should be implemented to ensure the aforementioned equitable access to COVID-19 vaccinations and medications is extended to developing countries as well. This system should not rely upon the goodwill of companies in the pharmaceutical industry, but rather should be established through a collaborative effort between countries that are both developed and developing.

VACCINE HOARDING

The lack of collaborative effort and reluctance of developed countries have been major contributors to the current disastrous situation of the pandemic. In April 2020, the UN General Assembly passed a

resolution which directed the UN secretary general and WHO to create a framework for the fair distribution of vaccines [44]. Subsequently, the direction was followed by a World Health Assembly resolution, which gave the WHO Director-General the responsibility to develop an equitable framework for global vaccine distribution. The framework prioritized 20% of the population, including health workers, senior citizens, and those with underlying health conditions [45]. However, most developed countries failed to follow this framework and instead used advanced market commitments to acquire bulk orders of vaccines before they were even developed. For instance, Canada ordered enough vaccines to provide nine doses per person. This disregard for the global framework left developing countries without sufficient doses to cover even 20% of their populations. As a result, Russia, China, and India were forced to fill the gap and supply vaccines in developing countries, even though the vaccines created by these countries were not in power in terms of the efficacy rate as the ones created by United States.

CONCLUSION

Even though the TRIPs Agreement played a pivotal role in the promotion of innovation and research in the pharmaceutical industry, it has also created significant barriers for developing countries to access affordable healthcare. The Trips Agreement has allowed major pharmaceutical companies from the global north to monopolise the sale and distribution of life-saving medicines, driving up costs and limiting access to governments and individuals from developing countries.

It is imperative to recognise that the unequal footing of countries that are both developed and developing have resulted in developing nations from being unable to enjoy the full advantages of the agreement, despite being parties to the same agreement along with the developing nations. This dichotomy has compelled many developing nations to accept terms that are not in their best interest. To resolve this issue, there is a pressing need to move the focal point of international forums towards the assistance and welfare of developing countries to ensure that developing nations can be independent and sustain themselves. One approach of doing this is by forming more robust international forums, similar to the Doha declaration, to ensure that the necessities of healthcare do not trump the profit-making schemes of the patent holders. Furthermore, Compulsory licenses must be extended to other forms of intellectual property rights, including trade secrets and copyrights. Such a decision would enable and encourage developing nations to manufacture and distribute the generic versions of life-saving medicines, making them widely accessible and affordable.

Such a goal requires a fundamental shift in the way we approach intellectual property rights in the pharmaceutical industry. Therefore, to make a real difference in ensuring healthcare access for all, it is critical to work together with a commitment to putting the welfare of people ahead of corporate profits ensuring that everyone has access to life-saving drugs. By doing so, a more fair and just healthcare system can be created, which would be of equal benefit to everyone regardless of their socio-economic background or geographical location.

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