INTELLECTUAL PROPERTY RIGHTS AND FAIR VACCINE DISTRIBUTION: A NEW PERSPECTIVE ON THE TRIPS AGREEMENT

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Abstract

The COVID-19 pandemic has highlighted inequities concerning global vaccine distribution, as well as issues surrounding patents and intellectual property rights for these vaccines. This paper addresses the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) regarding vaccines. Adhered to by all state members of the World Trade Organization (WTO), the agreement sets minimum regulatory standards for governments on intellectual property, including vaccines. Our contribution is a new analysis of TRIPS Art. 31 Bis concerning flexibilities in its terms of use on global vaccine distribution. We consider existing solutions for fairer vaccine distribution, such as governments enforcing a compulsory vaccine licence, and governmental/individual charitable efforts. We then focus on issues with know-how distribution and access to knowledge in the TRIPS context. We conclude that the enhanced provisions of TRIPS are ill-suited to global pandemics. To ensure fairer global vaccine distribution, we argue that patent pools and further TRIPS amendments are needed to endow less and least-developed countries with the ability to implement government-use compulsory licenses and to negotiate compensation terms later under judicial review. Further, to enable countries lacking the technical manufacturing capabilities to produce vaccines under license, TRIPS needs to be amended to permit technology and know-how transfer (Holder, 2023).

Keywords: TRIPS Agreement, Patent, Pandemic, Ethics, Vaccine Distribution, TRIPS Art. 31 Bis

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1. INTRODUCTION

Since innovation and development are incentivized by economic returns, patents have a clear economic aspect which is manifest not only in how they are employed to deal with a new product, technology, or process but also in the limited monopoly given to the inventor. When patents are used under government license, they can help resolve a health crisis, market failure, or any other major global problem. Despite these potential economic benefits, intellectual property rights (IPR) and the pathologies

of power have exposed inequalities in global health and vaccine distribution. Indeed, the global response to the need for expensive medications due to COVID-19 confirms that under-resourced nations are unequally affected in comparison to the better resourced (Engebretsen & Ottersen, 2021). This most recent global public health crisis has shed light on attempts to improve the ethicality of a key element of the IPR system, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement); these attempts are focused on the ability of developed and less developed countries to obtain vaccines and the importance of vaccinating a significant portion of a nation's population.

Intellectual property (IP) laws give patents and their holders exclusive rights to prevent mass distribution, in line with the United Nations (UN) International Covenant on Economic, Social and Cultural Rights of 1966 (the Covenant[1]). According to Art. 15 of the Covenant, the States Parties to the present Covenant recognize the right of everyone:

"… (b) To enjoy the benefits of scientific progress and its applications;

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" (United Nations, 1966).

From a theoretical perspective, as noted in the provisions of the Covenant, the IPRs specified in Art. 15 are human rights. This includes patents and access to knowledge and medical patents, especially those for high public interest priorities such as medications for HIV/AIDS in most underdeveloped countries, or major pandemic situations ('t Hoen, 2002). Because of the need to balance the exclusivity of patents — as the incentive to innovation and development — against their beneficial social elements, contradictory views have been espoused by those who respectively represent the interests of human rights and IP. As such, we have seen the evolution of the TRIPS Agreement from its early days through to the Doha Conference. The IP international legal framework especially patent exclusive economic system either before the WTO TRIPS system pre-Doha Conference amendments or after have been intensely safeguarded via geopolitical severe procedures as shown in situations undermining the exclusive rights of pharmaceutical patentees. As seen, in measures taken by the United States and European Union (EU) against breaches of Thailand in 2008 (Igbokwe & Tosato, 2023). Or in external Free Trade Agreements (FTAs) which provide stricter provisions than that stated in TRIPS as noted in provisions of the US–Jordan FTA. That is considered amongst the main TRIPS Plus Agreements[2].

The COVID-19 pandemic highlighted failings in global efforts to achieve a wide-ranging and fair distribution of vaccines, as shown by the huge variation in the percentage of vaccinated persons per country according to domestic vaccine availability (Holder, 2023). This availability is connected to TRIPS in the context of countries being importers or exporters of IP and technology transfer. Some philanthropic efforts, such as COVAX[3], show there is a will to distribute vaccines to lower-middle-income countries (LMIC) for future pandemics. Indeed, potential pandemics, for example, monkeypox, are likely to impact LMICs more severely if exemptions on IPRs and patents do not permit the transfer of technology as required. Moreover, even if the technology is transferred, its proper application may be hindered by the host countries' lack of technical capabilities (Raslan, 2021). A more permanent solution is therefore needed which is capable of dealing with such public health/pandemic situations.

The provisions of TRIPS Art. 31 Bis per se have not resolved the issue of fair vaccine distribution in the context of a public health crisis such as a global pandemic. As noted in the latest COVID-19 all means of transportation were shut down.

We, therefore, objectively evaluate the present situation regarding TRIPS, before proposing potential solutions to the current issues. As such, the paper considers why the current global distribution of vaccines is unbalanced, and how the present IP legal framework/TRIPS Art. 31 Bis should be modified to address this imbalance. To answer these questions, our adopted method is an analytical examination and interpretation of the related provisions of the international IP legal system, mainly the TRIPS Agreement, Art. 31 Bis, as well as the practical implementation of the suggested solutions during a public health pandemic.

This research paper aims to answer the following research questions:

RQ1: Is vaccine distribution balanced?

RQ2: Is the current IP legal framework (TRIPS Art. 32 Bis) efficient to the subject matter?

The lack of efficiency with the main legal text does not create favorable situations for fair distribution of vaccinations during public health crises.

Even though, many previous studies have examined the nature of Art. 31 Bis complex procedural implementation which predicted the difficulty to truly implement the flexibilities stated within the provisions of Art. 31 Bis realistically in a global wide spreading pandemic. The previous studies that addressed the problematic implementation of Art. 31 Bis and the complex application of its procedural rules have never taken into account the possibility of such an extreme public health situation as occurred during the COVID-19 recent pandemic leaving Art. 31 Bis and the studies regarding completely and utterly useless (Gervais, 2021; Igbokwe & Tosato, 2023). While other previous studies examined the politics ruling the concept of distribution of vaccines based on a transfer of technology and the divide of the south and north global separation raising the issue of the control patent legal system may have on the matter while not addressing the problematic issue of Art. 31 Bis inability to a global pandemic (Raslan, 2021).

[1] Entered into force on January 3, 1976, in accordance with Art. 27.

[2] The US-Jordan FTA entered into force December 17, 2001. The US-Jordan FTA have included certain provisions that exclude the ability to maximize the use compulsory licenses concerning patented pharmaceutical products. The US-Jordan FTA agreement restricts the ability to grant compulsory licensing policy with the Jordanian Patents Act. For more on the issue in the Agreement between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area which was finally implemented in 2010, see at https://ustr.gov/sites/default/files/Jordan%20FTA.pdf

[3] COVAX is an attempt by the Centre for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance, and the WHO to create more equitable access to vaccines regardless of income.

The paper is structured as follows. Section 1, an introduction, addresses the subject matter under study. Section 2 reviews the previous studies that addressed the topic. Section 3 presents the research methodology. Section 4 provides the research results. Section 5 tackles the subjective content of the research dealing with the inscuffency of TRIPS Agreement Art. 31 Bis to handle the distribution of vaccinations during the COVID-19 pandemic. Section 6 introduces potential solutions. Section 7 addresses the possible modifications of the TRIPS Agreement Art. 31 Bis. Section 8 concludes the paper.

2. LITERATURE REVIEW

Numerous recent studies, especially those conducted during the COVID-19 pandemic, have tackled issues related to the impact of intellectual property patents on the distribution of vaccines and vaccine know-how. Most notably, Gervais (2021, pp. 142–145) examined the evolution of the patent system within TRIPS and the progress of compulsory licensing within the provisions of Art. 31 and 31 Bis. Gervais (2021) and later Moens (2022), addressed the global south-north dramatic and positive change regarding the distribution of vaccines and transfer of knowledge between the EU and Africa. Other authors, such as Gurgula and Lee (2021), have addressed potential individual solutions to vaccine distribution issues, while Pilkington et al. (2022) considered the complications and difficulty of adapting particular solutions, such as patent waivers and TRIPS provisions. However, previous studies have not sufficiently addressed the fair distribution of vaccines and the legal framework of TRIPS Art. 31 Bis.

More importantly, the progressive development of the legal provisions related to the subject-matter understudy. Still, the progress was not sufficient or complete However, certain recent studies have addressed the issue of complexities of Art. 31 Bis the complex nature of its procedures some addressed the development of the Doha Conference and the lengthy negotiations that led to the implementation of Art. 31 Bis system in 2017. That lengthy period and the meetings the discourse that marred the meetings shed light on the gapping standpoints towards vaccination distribution transfer of technology between the North and the South (Raslan, 2021; Gervais, 2021). The most recent study that analyzed the progress of Art. 31 Bis system in depth examined its complex procedural aspects and its clear lack of flexibility (Igbokwe & Tosato, 2023).

The problematic issue regarding the subject-matter is that previous studies were theoretical and descriptive. The legal nature of the TRIPS Agreement, the role IP legal framework, Art. 31 Bis has in the vaccine distribution process its positive flexibilities, its procedural, and complexities provided certain analytical studies of Art. 31 Bis (Gervais, 2021). Its role in easing the vaccine distribution during pandemic situations was a bit of a theoretical nature rather than a practical theoretical examination of a critical public health situation that showed that Art. 31 Bis and its legal framework were found lacking in providing essential change or modification on the procedural elements that complicate the proper implementation of Art. 31 Bis during the recent COVID-19. In addition, the data collection via the World Health Organization (WHO) its definition of universal health coverage (WHO, 2022). The previous literature on the matter as stated has predated examinations of Art. 31 Bis its possible problematic implementation yet the concept of lack of legal practical application of the flexibilities that may ease the distribution of vaccinations during wide spreading health crises that have a global impact. However, there has been certain elaboration from the EU concerning the possible partial implantation of Art. 31 Bis via wavering the negotiation process and the role of COVAX facilities while ensuring the exclusive rights of pharmaceutical companies that have invested in research and development (R&D) on a massive scale (World Trade Organization [WTO], 2021a). However, this solution was more of a regular transaction of pharmaceuticals rather than a straightforward application of Art. 31 Bis other than a possible weaver of the negotiation process, which has not been adopted during the COVID-19 pandemic. The demand for the dismissal of TRIPS entirely during COVID-19 has been prominent among certain voices (Omino & Kahumbu, 2022).

3. RESEARCH METHODOLOGY

The subject matter is distribution of vaccines, its previous status and its current legal, and humanitarian perspective. The impact of the pharmaceutical industry's intellectual property especially patents on the subject matter is analyzed. The research adopted a comparative analytical in-depth examination of the international legal framework of intellectual property law in general and patents per se, its connection with the distribution of vaccines during extreme public health crises in line with the recent COVID-19 pandemic. The efficiency of the main legal international documentation to address a global spreading outburst suddenly within the current legal provisions of WTO TRIPS Agreement Art. 31 Bis. Analyzing the conditions/circumstances that led to drafting the provisions within the above-mentioned article in such fashion the WTO Doha Ministerial Conference which is known as the Doha Declaration. The extensive discourse surrounds its subject matter[4].

3.1. Data collection

The collective process of information was based on specialized journals (Igbokwe & Tosato, 2023) and books (Gervais, 2021) that addressed the vaccination distribution failure during the COViD19 pandemic on a global level showed the legislative gap in TRIPS Agreement.

3.2. Documents analysis

The provisions of WTO TRIPS Agreement Art. 31 Bis were thoroughly examined for possible practical implementation during the health public pandemic (COVID-19). Indicating the difficulty of properly implementing it within LDCs due to the complexities related to the lengthy process of applying Art. 31 Bis system and its procedural aspects (Igbokwe & Tosato, 2023).

[4] The Doha Declaration on TRIPS Agreement and public health was adopted the WTO Ministerial Conference of 2001 in Doha.

The methodology adopted seemed to be the most logical approach toward the subject matter of the study, its nature and examination of the most dominant international legislative document addressing the topic (Art. 31 Bis of the TRIPS Agreement), and its application within national legal texts. In addition to the lack of national implementation of the liberties granted within the legislative framework of Art. 31 Bis (Igbokwe & Tosato, 2023). The method approached the recent ongoing COVID-19 pandemic and the diminishing role application of Art. 31 Bis liberties system during a public health crisis as it was theoretically intended.

The method chosen to address the subject matter was most suitable to address the practical or lack of use of TRIPS Agreement Art. 31Bis as the examination of the realistic implementation of Art. 31 Bis. It requires shedding light on the nature of the legal provision under the study of its concept drafting history of the Art. from the various stances of the different delegations (Gervais, 2021; Raslan, 2021). The previous implementation of TRIPS Art. 31 Bis provides a comprehensive understanding of the provisions stated in Art. 31 Bis, flexibilities, procedural complications, and the hardship that may arise during a global wide-spread pandemic making the potential application of Art. 31 Bis the lack of ability to implement during as noted the COVID-19 pandemic which let the possible implementation of Art. 31 Bis unfeasibile.

4. RESULTS

The in-depth examination of previous studies that handled similar topic matters was not sufficient to address the distribution of vaccines and the legal framework TRIPS Agreement Art. 31 Bis. Even though, the progressive legal development of the provisions that have undertaken the issues, understudy, has not solved entirely the issue of distributing vaccines properly within public health crises as showed during the global pandemic recently.

The paper addressed the lack of balance required to deal with distribution during lengthy global pandemics. It addressed the need to modify the procedural aspects of Art. 31 Bis which is an additional sub-paragraph that reverses procedural aspects to a later period that allows the least developed countries (LDCs) to obtain much-needed medical aid. The national IP law that is in line with the provisions of the TRIPS Agreement reviews the availability of the extreme public health crisis and the need for a compulsory license issuing Art. 25 of the United Arab Emirates (UAE) Federal Law No. (11) of 2021 regarding the Protection of Industrial Property Rights. The national judicial procedures shall be under the complete supervision of the Council for TRIPS to ensure the accuracy of the procedures and the fairness of the compensation awarded by the designated national court. In addition, the length of the period and the quantity of the vaccines shall be under scrutiny by the revision of the Council.

5. THE INADEQUACY OF THE CURRENT LEGAL FRAMEWORK

5.1. The stance of TRIPS Agreement on decolonizing human rights: IP laws and unequal access to COVID-19 vaccines

The WTO TRIPS Agreement sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. However, it has been fiercely criticized because of the predicted effects that increased levels of patent protection will have on drug prices. The TRIPS Agreement has created certain safeguards that protect the exclusive rights granted to the IP/patent holder and the patentable subject matter covered within the range of protection. However, conceptual fairness between consumers and owners/producers is not straightforward. According to the trade law approach, related instruments have tended to favor IP owners, on behalf of consumers, according to TRIPS[5]. This theoretical approach takes a more distant standpoint between the previously mentioned rights discussed during the drafting of the TRIPS Agreement, and later when amendments were tabled, as to whether the Agreement accords with human rights (Helfer, 2003; Reiss, 2011). The conflicting position of consumers from LDCs and the IP holders of pharmaceuticals is coincidental and yet inevitable, as the TRIPS Agreement intends to reach a suitable solution that not only protects the economic rights of the IP holders as a legitimate exclusive monopoly but also provides certain limited leverages to consumers. In this regard, the TRIPS Agreement provides the minimum standards of protection that member countries can implement, with the possibility of stricter standards for IPRs via bilateral international trade agreements.

The significance of the controversies related to the WTO TRIPS Agreement is that it is a manifestation of the Global North's IP legal system seeking its almost implementation in the South and the patents legal framework within TRIPS Agreement provisions and its compulsory licensing system is just that. The WTO TRIPs Agreement's amendments especially via the Doha Conference led to the enactment of Art. 31 Bis even though it has taken a prolonged period to enter into force. This amendment to the TRIPS Agreement, the current legal framework, is to bridge the gap between IP rights holders (pharmaceuticals) exporter members and importing members' legal rights regarding the use of compulsory licenses. However, Art. 31 Bis acts more as a means to utilize the flexibilities granted in the TRIPS Agreement to its fullest practical extent while taking into consideration maintaining the fragile balance between the contradicting interests of IP owners (exporting) and the benefits of the patented medicines (import). Especially, the exemptions on implementing Art. 31 (f and h). It is that the eventual current legal framework of the TRIPS Agreement is a result of

[5] Art. 31 Bis which has been introduced in the Doha Ministerial Conference 2001 has addressed the main issue related to procedures to create the needed balance between right holders and importing members. It entered into force on January 27, 2017. It has to be mentioned that WTO TRIPS Agreement addressed patents within Art. 27–34, however, the crux of the paper is Art. 31 Bis and its implementation, its possible application in global public crises or pandemic situation.

provisions before the Doha Conference and after the conference and Art. 31 Bis with its attempts to properly apply the TRIPS Agreement flexibilities via the measures or procedural method within the texts of the agreement or the procedures related to Art. 31 Bis system regarding the role the exporting and importing members concerning the implementation of the provisions of para. 2 and 3 of Art. 31 Bis of the TRIPS Agreement dealing with the conditions of adequate remuneration according to Art. 31 (h)[6]. Art. 31 Bis para. 3 addresses the implementation of the flexibilities of the TRIPS Agreement, the most favored nation, and favorable treatment[7]. As Art. 31 Bis, in its current phrasing, its implementation would be extremely problematic to implement on exporting members of the TRIPS Agreement taking into account the number of WTO TRIPS members that are included in the UN LDC's list. While the understanding of the terms developing countries and least developed countries are interpreted in favor of developing countries[8]. The implementation of the flexibilities of the TRIPS Agreement within the line of the wording of the General Agreement on Tariffs and Trade (GAAT) provisions is more in favor of importing members who are included within LDC's list, which, could be undermining the exporting members, especially regarding the monetary ruminations. The main issue, which is the proper implementation of Art. 31 Bis, is the procedural prolonged measures that undermine the speedy process of providing an equitable rumination of the fair value of the patented vaccines, which is considerably lengthy. In addition, the procedures related to that member country that is among (LDC's) list or that may not be within the list still may not have the manufacturing capabilities the inability to certify this manufacturing in addition to sending these procedural requirements and more than are sent to the Council for TRIPS. Furthermore, prior agreement of the monetary compensation, the quantity of the vaccines that will be taken under consideration will be utilized within the provisions of Art. 31 Bis system. These procedures are extremely lengthy and within normal health crises might be adaptable during normal situations. However, an extreme public health situation that may include a lack of mobility delayed the distribution of vaccines as it has been so recently in the COVID-19 pandemic. The procedural elements of Art. 31 Bis would not have been thoroughly successful in the speedy distribution of vaccines with the Art. 31 Bis system.

5.2. The TRIPS Agreement before the Doha Conference: Art. 31

The TRIPS Agreement Art. 31 contains exemptions such as those applied when a patented item is used without the authorization of the right holder. However, provisions that identify others' or third parties' use of patents without authorization have always been problematic. Both during the creation of the Agreement and later when it was amended, the negotiating parties expressed conflicting views, primarily represented by the two extremes of those importing or exporting IP and technology. Their widely varying opinions, especially on protective measures for ensuring IPR holders' rights, undermined efforts to distribute lifesaving vaccinations. The opinions discussed fall into three categories — those of the most developed nations, less developed nations, and least developed nations — based on their stance toward public health and the exclusive rights of the pharmaceutical companies owning the patents. Two key issues require discussion at this point: 1) government use or compulsory licenses on public health grounds, and 2) know-how distribution or lack of access to knowledge.

Since Art. 31 of the TRIPS Agreement does not permit the unauthorized use of patents, the idea of a compulsory license is somewhat unrealistic, which is influenced by the Paris Convention for the Protection of Industrial Property[9]. Unauthorized use is limited in scope by time and place, for example within the borders of a member state. Such use is deemed inside the scope of the domestic market of the member state and not beyond it. The principle that patent holders are paid adequate usage fees for unauthorized use via a compulsory license has been taken into consideration within the international community and by global international economic institutes such as the WTO. This approach was seen at the WTO Ministerial Conference in 2001 in Doha, Qatar, at which a declaration was adopted on the TRIPS Agreement and Public Health (the Doha Declaration or Declaration) to affirm the sovereign right of governments to take measures to protect public health. The Doha Declaration was and is considered a breakthrough by public health proponents. However, although the principled concept of Art. 31 is in general valid and fair, there are, understandably, conflicting opinions of its wording on the specific conditions granting a non-voluntary license. As such, Art. 31 provides an exhaustive list of circumstances or defined cases for granting a license by a member state. The authorization

[6] Art. 31 Bis (2): "Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member" (Art. 31 Bis of the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994).

[7] Art. 31 Bis (3): "With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question". A swift underling of the provisions above mentioned indicates the certain complexities related to the implantation of Art. 31Bis system.

[8] L/U903 General Agreement on Tariffs and Trade 1979 (GATT 1979) has elaborated in clear-cut manner that any special treatment for least developed countries is to be explained in favour of developing countries. The same spirt was sensed in the document regarding deferential and more favourable treatment (Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries, 1979).

[9] The Paris Convention for Protection of Industrial Property of 1883 and many revisions of Art. 5A: "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of exclusive rights conferred by the patent, for example, failure to work".

granted must be in line with WTO practices and those of neighboring countries regarding anti-competitiveness, freedom of movement, and free trade. This requirement was given special consideration in the negotiations before the Doha Conference regarding different approaches to public health crises concerning certain infectious illnesses, such as HIV/AIDS, and malaria inter alia (World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, 2001).

The Doha Declaration also permits exemptions regarding this requirement in cases of national emergency if the patent/right holder is informed within a reasonable time period. Therefore, there is a need to understand whether the modifications to the requirement have enhanced the situation by bridging the gap between the conflicting opinions. Among the flexibilities provided for in Art. 31 is the concept of compulsory licenses for public health, by which governments can grant access as necessary for the production of pharmaceutical medications and vaccines for their ultimate purpose. These notions are addressed next.

The second issue concerns know-how distribution or lack of access to knowledge. The practical application of Article 31 requires the ability to understand the concepts and knowledge that led to the invention addressed in the patent. Indeed, most attempts to implement Art. 31 have not in actuality been comprehensive implementations of the patent due to pharmaceutical companies' lack of interest in distributing their technical knowledge or, to a lesser extent, their know-how, without the patentable process. Therefore, the ability to implement Art. 31 appropriately in LDCs and LMICs will not be fruitful or beneficial. This can be seen in the lack of attempts to implement a compulsory license within the provisions of Art. 31 by LMICs, possibly due to economics, politics, and reputation within the international economic/commercial sector, or a lack of technology; this, in turn, is likely due to the non-fulfillment of the element in Art. 31 on providing importing countries with access to information technology. The European "side", for example, has stood firmly against the full waiver of IPRs, with Ursula Von Der Leyen reiterating that "the bloc is willing to support the use of compulsory licensing of vaccines which enables a country to produce vaccines without the license holder's consent" (Moens, 2022).

5.3. The post-Doha Ministerial Conference and the evolution of the Declaration's applicability and its impact on the TRIPS Agreement (Art. 31 Bis)

Although the Declaration addressed various issues such as traditional knowledge, a balance is required between controlling resources and the interests of multi-national pharmaceuticals, especially in situations when local substantive laws lack legislative solutions. The Declaration was influenced by various procedures before the initiation of the TRIPS Agreement. Moreover, certain issues remained that had been in the background of the drafting of the Agreement (Gervais, 2021), including the ongoing discourse surrounding adequate remuneration for, and identification of, pandemic crises. While pharmaceutical companies have continued to proclaim that it is not "business as usual" anymore, the reality is different as COVID-19 has not altered the industry's operations. Pharmaceutical companies engage in proprietary research that generates proprietary data, the outcomes of which remain protected IP (Gurgula & Lee, 2021; Médecins Sans Frontières, 2020; Wu, 2020). The Doha Conference negotiations and the introduction of Art. 31 Bis led, in turn, to the introduction of a new variation of compulsory license; however, despite its adoption within the TRIPS Agreement, there has been critical discourse on the license's reliability and applicability (Gervais, 2021, pp. 142–145; Moens, 2022; Regional and National Development Sector, the Office of Deputy Director General, 2021). Although the amendment led to the integration of more morality into TRIPS and the IPR legal framework in general, the debate on aspects of IPRs and morality is ongoing, especially on the issue of technology transfer and know-how in public health crises. Until this point, the LDC bloc had not agreed to a proposal for the transfer of technology.

5.4. Opposing views on licensing

The technical legal understanding of a compulsory license is not as restricted as a patent; the license is a descriptive legal document that covers certain technical elements that enable a legitimate patent user to manufacture the invention into a final product since patentability requires industrial applicability. A compulsory license may overcome certain aspects of patents to include technical knowledge or know-how (Raslan, 2021). However, manufacturing pharmaceuticals still needs to provide member countries suffering a health crisis with the technical ability to produce a vaccine. Some manufacturers such as Moderna have addressed this issue by allowing the manufacture and licensing of COVID-19 vaccines in nations enduring a public health pandemic (Moderna, 2023). Nevertheless, in this regard, Art. 31 Bis may be critiqued for potentially being unable to provide a working solution to the issue of technical knowledge. The insufficient manufacturing capacities LDCs must provide certain evidence to self-certify the lack of capabilities.

As a progressive yet flawed effort, Art. 31 Bis is a significant improvement on the moral aspects of TRIPS and IPRs integration. A possible solution to its flaws might include allowing collective compulsory licenses for neighboring countries suffering under a pandemic situation. This would permit a collective effort to fulfill the requirements of Art. 31 Bis more beneficially for those countries applying for the collective compulsory license. The proposed attempt to modify Art. 31 Bis was a prolonged discourse on the substantive provisions, indicating the opposing views of member countries on the dispute over the list of diseases. The importing members are covered by the terms of the Doha Declaration regarding the effectiveness of the use of a compulsory license, in line with Art. 31(f). This takes into consideration the eligibility of countries, the diseases covered, and a timeline for permanent solutions (Gervais, 2021). The less than progressive implementation of the Doha Declaration via Art. 31 Bis system has drawn complications regarding the applicable use of the flexibilities of TRIPS undermining the normal form

compulsory licensing approach toward numeration regarding the interests of the exporting members concerning the fact the members who might impact the outcome their exclusivity. Furthermore, damaging the situation taking into account it is considered common knowledge that beneficiaries from the TRIPS Agreement Art. 31 Bis system are still among the UN LDCs. Notwithstanding, that wording/ phrasing in addition to the explanatory notes of the TRIPS Agreement Art. 31 Bis reveres the concept of Art. 31(f) and (h) while undermining the compulsory licensing policy ingrained in the North exporting members before TRIPS Art. 31 Bis (Doha Conference Declaration, para. 6). This could be noted clearly within the legal framework of the United States, Canada, Japan, and other countries which are in line with the TRIPS legal general framework and patents protection including compulsory licensing (Igbokwe & Tosato, 2023, p. 1804; Gaudillière, 2008). The procedural content of Art. 31 Bis has created practical complications in implementing the provisions of the understudy article. That could be noted via dwindling numbers of either exporting or importing members who are interested in registering in the Art. 31 Bis system. The exporting members have even taken though approving the Doha Conference Declaration para. 6 or reaching what seemed to be a middle ground between the interests of pharmaceutical exporting members and that of the importing members into consideration via the Doha Conference Declaration, para. 6[10].

6. POTENTIAL SOLUTIONS

The provisions of Art. 31 of the TRIPS Agreement are of great significance since they have effected certain changes to the rules on compulsory licenses. One of these allows the government of an importing country to apply for a compulsory license when there is a public health crisis, without gaining the pre-approval of the pharmaceutical right-holders. In return, a certain fixed compensation is paid and a judicial authority can review the agreement. This government-use license includes the conditions of manufacturing capacity and know-how. These amendments to the TRIPS Agreement regarding Art. 31, and the new modified version, have been of huge significance for turning IPRs generally and the TRIPS Agreement into a more moralised legal framework; however, although it is morally a step in the right direction, it remains insufficient on the grounds of manufacturing capacity and knowledge distribution. The current implementation of Art. 31 Bis system in line with possible practical extreme public health certain proportional solutions within the complicated procedural measures might be problematic. This was noted during the COVID-19 global pandemic in which the transactions sector globally ceased to exist making the process of implementing the procedural aspects of Art. 31 Bis system more complicated. This shows during the pandemic that the compulsory license imposed via Art. 31 Bis during the pandemic to certain success via member countries that obtained manufacturing capacity as showed in the attempts of Israel, Russia, and Germany among a few countries that utilized Art. 31 Bis system effectively during the pandemic (Pilkington et al., 2022; WTO, 1994).

Manufacturing capacity is the ability to manufacture pharmaceutical products based on certain technological abilities and to apply for the license satisfactorily according to the needs of the importing country suffering from the public health crisis. During the COVID-19 pandemic, however, only highly developed countries with a thriving pharmaceutical industry succeeded in delivering/outsourcing the active pharmaceutical ingredient, and this obstructed certain countries lacking progressive manufacturing ability, such as China and India, from doing the same (Garrison, 2020). The inability to create a fully functioning pharmaceutical industry to produce vaccines/ pharmaceuticals undermines the ability of LDCs to implement Art. 31 from a manufacturing perspective.

Solutions have been presented in the legal/ health literature and by the jurists who introduced morality into IPRs. Current potential solutions concerning widespread public health crises require urgent measures to support those LMICs/LDCs that lack the financial resources to access lifesaving vaccines quickly. Such solutions may help create a balanced response that takes into consideration the best interests of both IPR holders (i.e., the pharmaceutical corporations) and the LMICs/LDCs by, on one hand, rightfully providing a guaranteed financial reward for the former, even if it may be delayed and partial, and, on the other, distributing vaccines to the latter. Moreover, the vaccination of the largest number of individuals is best from a global humanitarian perspective, as well as being in the best interests of LMICs (Sariola, 2021). With the drastic change in views among higher-income countries (HICs) concerning IPRs and LMICs in the context of the pandemic, collective governmental and humanitarian efforts have been made to distribute vaccines more fairly.

More advanced global R&D efforts include bringing in experts and scientists from importing countries into patent pools, to introduce the expertise required for making the end product. There has also been progress in some regions between medical institutes and world-renowned research institutions, such as the Centre of Excellence for Biomedicine (CEBM), which is a recent collaboration between King Abdulaziz City for Science and Technology and Brigham and Women's Hospital, Harvard Medical School. Similarly, the Chinese Sinopharm vaccine forms the cornerstone of vaccination campaigns in the UAE and other countries, and the Pfizer vaccine is distributed in Jordan (Woertz & Yellinek, 2021).

These efforts, however, have not created legal modifications that will effect a real global change in the legal framework of patents (i.e., in the TRIPS Agreement). The solutions to the current COVID-19 pandemic which have introduced aspects of morality have their drawbacks, for example, the arguments in defense of IPRs simply cannot be upheld. The commonly presented claim that IP rights protect innovator companies from market failure and financial risk is inapplicable for COVID-19 vaccines, as the research was funded by governments worldwide, primarily in North America and Europe. When observing the motives of these governments

[10] For more detail on the initial approval of the Doha Conference, para. 6, General Council of TRIPS WT/GC/M/82 on November 13, 2003 (WHO, 2003).

and pharmaceuticals, there is a question as to whether they are purely IPR-related. Recent meetings between the General Director of WHO and representatives from the US, EU, UK, and Canada to discuss the relaxation of patent protection reached an impasse regarding the tight grip that IP holders/ pharmaceuticals have on vaccine distribution.

Another potential solution that may strengthen the moral element of patents is the implementation of a compulsory license within local/national IP legislation for public emergencies. As we have seen, although such a right is granted to WTO members, not all member states have the ability to implement a compulsory license according to Art. 31, especially subparagraphs (f) and (h) regarding local use and adequate compensation. Due to the COVID-19 pandemic, this lack has driven certain countries to employ a more varied concept of the license for government use, for example, in the German Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance of March 2020 (Gurgula & Lee, 2021). The rules and conditions of a government-use license are certainly within the reach of countries with the technical capacity for pharmaceutical manufacturing and the ability to process the know-how (via access and transfer of technology). However, despite many countries having updated their patent-related regulations and laws, only two developed countries (Germany and Israel) managed to apply for government-use compulsory licenses during the COVID-19 pandemic. Thus, even though compulsory licenses were introduced into the TRIPS Agreement via Art. 31, and by some LDC legislations, there are no examples of the application of the flexibilities of Art. 31 in these countries. It should also be noted that many HICs have reservations about Art. 31, including Australia, Canada, and the European Union, as well as TRIPS member states such as Iceland, Japan, New Zealand, Norway, Switzerland, and the US (Pilkington et al., 2022; WTO, 1994).

Regarding the waiving of IPR patents during a global public health crisis, the ongoing COVID-19 pandemic has led to calls for the abandonment of the TRIPS Agreement as linked to public health, medical sciences, medications, and the pharmaceutical manufacturing process. Patent waiving is considered a major, and also moral, solution supported by such prominent voices as the WHO General Director, who met with representatives from the US, UK, EU, Canada, and other countries at the WTO. They addressed the dismissal of exclusive economic outcomes for patent rights holders in favor of helping humanity survive the COVID-19 pandemic (Boseley, 2021). Even though the concept of waiving IP patents as per TRIPS has so far only led to discourse on what is achievable, it is nevertheless an improvement in emergency circumstances (Moens, 2022). Nevertheless, this approach may not be the most appropriate for regular conditions, as it may undermine the initial basic rights of patent right holders and their motivation to innovate, as well as reduce the ability of LDCs to evolve their pharmaceutical manufacturing capacity and improve their resilience during emergencies, which the EU addressed the Council of TRIPS concerning Art. 31 Bis its partial application during COVID-19 (WTO, 2021a). That response to certain demands to waver the main provisions related to Art. 31 Bis that makes its application during the COVID-19 pandemic more realistic was in line with the WHO point of view regarding the weaver of intellectual property economic outcomes these WTO members the delegations include (Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe) regarding the flexibilities and limitations of the TRIPS Agreement Art. 31 Bis. The delegation demanded preserving the flexibilities while placing limitations on the right holders' exclusive rights in situations of extreme public health crises as Art. 31 Bis requires certain conditions to be met during a public health crisis that may not be realistically applicable such as; providing proof of experience in certain areas such as industrial designs, trade secrets, algorithms, and copyright, applying compulsory licenses to such areas may be legally complicated and novel (WTO, 2021a, 2021b).

Recognition of these weaknesses has led to more emphasis being placed on global philanthropic and governmental efforts to introduce equal distribution of COVID-19 vaccines to in-need countries. Indeed, many developed countries such as Germany, Canada, and the US, as well as the EU, have poured funding into the R&D of cures and vaccinations to provide a sufficient amount of these (Global Health Centre, 2021). These global efforts provide a platform for R&D to tackle future pandemic-related crises on various levels, including vaccine science, and which diseases or viruses should take priority for R&D. The main issue with these solutions, however, remains the inability of LDCs to make effective progress with their domestic pharmaceutical industry, despite such a solution being of a higher ethical standard than global humanitarian efforts by developed countries seeking to give lower-income countries handouts.

The waiving of the exclusive protections provided by patents over vaccines for countries suffering from their lack is unlikely to accelerate their distribution in a pandemic, and will not be a long-term solution. Rather, it is likely to be a temporary solution for specific health crises instead of a longer-term solution for future situations if the know-how and transfer technology is an essential part of the solution within the TRIPS Agreement and a compulsory license system. Therefore, the proper application of technology transfer should be a durable solution for lower-income countries, in cooperation with vaccine manufacturing countries and pharmaceuticals, hand in hand with patent pools. COVAX, for example, shares its manufacturing process via a clear-cut solution that involves a truthful application of technology transfer between itself and its receivers wavering the TRIPs Agreement patent-related provisions entirely (Balestriero, 2022).

As implemented during the COVID-19 pandemic, this solution reveals that some cooperation in the distribution of vaccines is possible, regardless of the nature and type of this cooperation. However, it cannot be said that the cooperation is either comprehensive or complete as it does not cover the manufacturing process or any advanced transfer of technology. Despite this, more recently there has been a shift in perspective regarding the practical and comprehensive transfer of technology to those

in need in terms of providing a long-lasting solution that includes training and building factories in the benefiting country. For example, agreements have been set between the EU and several African countries such as Senegal, where a COVID-19 vaccine factory has been built (European Commission, 2021). There are also likely upcoming agreements between BioNTech and Rwanda and Senegal to enable them to manufacture up to 50 million COVID-19 vaccines (Agence France Presse [AFP], 2022).

The lack of grit in the current solutions stresses the lack of intent to address the vast gap between the Global North compared to Global South regarding the transfer of technology let alone the distribution of vaccines. The staggering difference between the number vaccinated during the pandemic among member countries of the North and that of member countries of the South. The current solutions are subsidiary in nature as they do not address the clear complex nature of Art. 31 Bis system either the patents-pool, wavering the IP-Patents exclusive rights and R&D are not actually addressing the obvious problem.

7. TOWARD A NEW VERSION OF THE TRIPS AGREEMENT ART. 31 BIS

To resolve the issue of insufficient amendments to the TRIPS Agreement via the Doha Declaration, it is important to deal with para. 6 of the Declaration on the transfer of ready-to-use vaccines to deal with public health crises (Correa, 2018). Also, it must be said that Art. 31 Bis is likely to be hindered by tedious and unnecessarily cumbersome authorization processes, meaning that procedural details and formalities may discourage generic drug manufacturers from exploiting its provisions. To provide the required flexibility, specific changes need to be made to national patent laws. However, LDCs suffer from a lack of technical expertise concerning IP, and most have failed to incorporate its complexities into their national patent laws. As of February 2017, the waiver flexibility has been used only once, demonstrating that it is not a workable solution to the problem highlighted in para. 6 of the Doha Declaration (Abbas & Riaz, 2017). Finally, the provisions of Art. 31 Bis of the TRIPS Agreement should be amended or extended to include public health crises/global pandemics (WTO, 1994a, 1994b). However, the main drastic modification of Art. 31 Bis system should be on the concept of the complex procedural aspects. The lengthy complicated procedures related to Art 31. Bis of the TRIPS especially regarding the compensation process in advance. Therefore, the proper application of Art. 31 Bis by LDCs would be problematic in reality especially during wide-spreading pandemics.

The novel view towards Art. 31 Bis procedural aspects should be reversed to take into consideration the extreme public health pandemic-like situation, the negotiations to identify adequate compensation and providing a lack of manufacturing capabilities and the quantities needed in addition to the period of compulsory license in a later stage when the crises are over rather than wasting valuable time during the pandemic while lives massive numbers of patients are under threat.

As stated previously, although Art. 31 Bis provides some solutions, it remains conceptually flawed, especially regarding cumbersome procedural details for which LDCs may be unprepared when stricken by a pandemic or health crisis. Additionally, its terminology requires considerable rewording, particularly on eligible importing members, as some are presently excluded due to their insufficient or lack of pharmaceutical manufacturing capacities. Despite the progressive flexibilities added to Art. 31 Bis, especially in subparagraphs (1) and (2), the application of its provisions during a global pandemic is — as seen with COVID-19 — unachievable by an importing member of the TRIPS Agreement. However, for public health emergencies restricted to certain regions (i.e., not global pandemics), the provisions of Art. 31 Bis could be applicable. The most suitable long-term solution is thus likely to be one related to the transfer of technology such that the manufacturing capabilities of LDCs are enhanced. A modified version of Art. 31 Bis (2) and (3) should delay the procedural leading to a compulsory license. However, a nationally designated court will supervise the conditions to identify the urgency of the public health situation, the availability of the conditions of the modified Art. 31 Bis could be reviewed through the TRIPS Council that the compensation, time limitation period, and the quantities required.

8. CONCLUSION

In this paper, we have determined how the current legal framework governing the IPR system and medical R&D provides inadequate access to technology and, more importantly, public health-related medications and vaccines. The COVID-19 pandemic has intensified a long-running debate on IPRs and access to medications and public health. Gurgula and Lee (2021) note that the struggle is not solely between patent rights holders and access to affordable medications, but there is an added dimension regarding equitable mass production and the distribution of vaccines to billions in urgent need (Holder, 2023). Thus far, wealthier countries have received vaccinations before LMICs; however, manufacturing capacity may no longer be the most significant barrier to equitable access, as exclusive patent rights are also hindering access to much-needed public health medications. The modifications to the TRIPS Agreement in 2017 and the adaptations made at the Doha Conference have had the significant effect of introducing morality to IPRs, especially the legal framework of patents. This is in addition to the global efforts to provide solutions to the current pandemic through voluntary attempts to provide affordable vaccines to countries in distress. Public funding of R&D, pool patents, and even the failed attempt to waive patent holders' exclusive rights, are further moral additions to the patent framework. A long-lasting solution that allows countries under the jurisdiction of the legal framework of IPRs and the TRIPS Agreement includes endowing LDCs at risk of widespread health crises with the ability to implement and seek government-use compulsory licenses and to negotiate compensation terms later under judicial review.

As stated in Part III B from TRIPS Agreement regarding the potential solutions and the much-needed suggested major changes in the modified Art. 31 Bis procedural system in addition to a strict national framework that addresses that provides enough warranties for the patentee pharmaceutical

right holders that the compensation will adequate ex. Art. 25 of the UAE Federal Law No. (11) of 2021 on the Regulation and Protection of Industrial Property Rights. The conditions of Art. 25 and its subparagraphs 25 (1/a-h) fall in line with the provisions of the TRIPS Agreement. The provisions of Part Two of the Law that addresses mandatory licenses allow for certain humanitarian cases. Art. 28 of the UAE Federal Law No. (11) of 2021 states: "The Court may not accept the requirement provided for in Article (25) of this Law if the mandatory license application is resulting from a case of emergency, crises, disaster, public". The exceptions on Article 25 of the law related to mandatory licenses which both the procedural aspects of Article 25 and its possible exceptions are under the watchful eye of the judicial review. In addition to an exception mentioned in Article 30 of the same law which is in line with the provisions of Article 35 excluding the 3-year time limit: "A mandatory license to exploit an invention protected by a patent or utility certificate may be issued by a decision of the Minister or his authorized deputy if such invention is important for the public interest, in accordance with the conditions provided for in Article (25) of this Law, with the exception of the time limit condition and Clause (a) (1) therein. Such decision by the Minister shall be published in the Industrial Property Bulletin".

Art. 25 of the UAE Federal Law No. (11) of 2021 states: "If the holder of patent or utility certificate does not use it at all or has made insufficient use of it during the following three years after granting the same, any interested party may apply for a mandatory license in accordance with procedures provided for in Art. (29) of this Law if such interested party meets the following conditions:

a. The applicant shall demonstrate making efforts during reasonable period to obtain a license from the patent or utility certificate holder against reasonable price and under reasonable commercial conditions. The Executive Regulations of this Law shall provide for the procedures required in this regard.

b. The applied license shall not be exclusive.

c. The license shall be intended to meet the needs of the local market. The Executive Regulations of this Law shall provide for the guarantees that the applicant shall be obliged to offer with respect to the sufficient use of the invention, remedy the deficiencies, or meet the needs that have led to the application for the mandatory license.

d. The licensing resolution shall determine the scope and duration of the license in accordance with the purpose for which it has been granted. It may include also commitments and controls applicable to licensor and licensee.

e. The holder of patent or utility certificate shall be entitled to a fair compensation.

f. The use of the invention shall be restricted to the licensee and shall not be transferable to third party unless the ownership of the establishment or the ownership of the part thereof that uses the invention is transferred and the Court approves such transfer of license.

g. Provisions of Art. (29) and (35) of this Law shall be applicable to mandatory license transfer application.

h. If the invention is related to semi-conductors, mandatory license may be granted only for public and non-commercial purposes or to rectify practices that has been decided to be non-competitive based on judicial or administrative proceedings.

2. Mandatory license shall not be granted if the holder of patent or utility certificates offers plausibly justifies his position".

We conclude that, although the progress highlighted regarding Art. 31 Bis, especially in its opening paragraph on the non-applicability of rights given to importing members, may be theoretically sound, it is the practical application of such flexibilities during a pandemic that matters. The recent global pandemic has highlighted that the lack of technical manufacturing abilities in LDCs, combined with the process of applying Art. 31 Bis (1) and (2), led to their ineligibility under these provisions. There is also the additional difficulty of implementing the flexibilities of Art. 31 Bis in global pandemic situations. Therefore, the potential solution is to amend the legal framework (the TRIPS Agreement Art. 31 Bis) for handling critical public health situations so that it provides more balance.

To conclude, the enhanced provisions of the TRIPS Agreement are lacking with respect to global pandemics. However, certain amendments to Art. 31 Bis make its provisions more adapted to such situations as explained regarding the proposed modifications that include the reversal of the procedural elements such as the delayed fair and adequate remuneration to the right holder under guaranties provided by the importing member under the supervision and mentoring of the TRIPS Council. These modifications in addition to the strict yet fair national framework could provide the attempts of the current solutions to provide more access to vaccinations that may tackle possible future global pandemics. The complication regarding the lack of practical implementation and implications arising from the lack of practicality within the provisions of the TRIPS Agreement Art. 31 Bis to operate properly within public health crisis on a wider global range. The suggested modification of Art. 31 bis may provide certain much-needed simplicity during pandemics that ease the transfer of technology and vaccinations during breakout pandemics.

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