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Does Compulsory Licensing Mechanism Facilitate the Supply and Distribution of COVID-19 Vaccines?

-- A Critical Analysis of Article 31 And 31bis

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Abstract

In the context of the COVID-19 epidemic, the availability of vaccines has become one of the significant factors affecting public health. The compulsory licensing mechanism established through the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 31 has long played an essential role in international health affairs. However, the spread and prevalence of the COVID-19 epidemic are much faster and more widespread than other infectious disease epidemics in the past. The public health interests of the underdeveloped and least developed member states of the United Nations are subject to significant challenges. Although the amendment to TRIPS 31 has expanded the scope of application of the compulsory licensing mechanism, many scholars still question its flexibility. This paper objectively analyses the obstacles to the compulsory licensing mechanism based on the analysis of relevant legislative practices of Canada, the EU, China, Swiss, and Korea and the accessibility of the COVID-19 vaccine. According to the research, the existing compulsory licensing mechanism cannot maintain the balance of interests between the patentee and public health. Lack of vaccine production capacity in countries that obtain compulsory licenses, onerous conditions for vaccine exports, and excessive debt on the scope of use authorized by compulsory licenses are barriers to reducing vaccine accessibility. This paper suggests that the speed of spread of the COVID-19 epidemic conflicts with the cumbersome compulsory licensing process, and the interests of the patentee should perhaps make appropriate concessions to the public health interest to reduce the time costs of compulsory licensing proceedings. Nevertheless, as one of the most widely used patent licensing systems in the international arena, the compulsory licensing system still needs to be utilized more effectively and efficiently.

Keywords

Compulsory licensing; COVID-19 vaccine; TRIPS Article 31 & 31*bis*.

1. Introduction

Article 31 of TRIPS was established in 1995 to ensure that a government could compulsorily license a national institution or company to produce a pharmaceutical product protected by a patent in another country in the interests of that country's public health in an emergency. The purpose of the compulsory licensing (CL) of Article 31 is originally, therefore, to balance the interests of the patent owner with the public health interest [1]. In order to ensure that compulsory licenses can be effectively implemented internationally and that people in developing countries have access to some of the essential medicines, Article 31 of TRIPS provides a range of measures for WTO member countries to follow and allow the national authority to issue compulsory licenses. For example, the definitions of the terms in some

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provisions are vague. Article 31(h) stipulates that the 'right holder shall be paid adequate remuneration' but does not provide specific criteria for its calculation [2]. Article 31(b) provides that the 'user has made efforts to obtain authorization from the right holder,' but the definition of 'made efforts' is more ambiguous [3]. Article 31(f) states that medicines 'shall be predominantly for the supply of the domestic market.' However, for developing countries without manufacturing capacity, even if they could obtain a license, they would still have to rely on imports from other authorized exporting countries under a license. These severe shortcomings of Article 31 were controversial in academic circles, social organizations, and political circles. In response to these severe deficiencies, TRIPS was revised in 2005 to improve the compulsory licensing mechanism and ensure access to essential medicines for the most vulnerable. It aims better to protect access to medicines for people in developing countries and better promote public health without damaging the legitimate interests of patentees. However, Article 31bis does not effectively address some of the critical issues in the CL regime. Article 31bis made amendments to balance the protection of IP owners with the interests of public health in developing countries. Article 31 of TRIPS grants CL in a relatively cursory manner [4]. The WTO Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) was agreed to improve the health situation in developing countries and fixed into Article 31bis of TRIPS which relaxes the restrictions on the export of patented CL for pharmaceutical products. Although the establishment of Article 31bis aimed to address the problems of flexibility caused by Article 31, the situation in practice is still unsatisfactory [5].

According to Article 31 (f), CL should be adopted primarily in the domestic market. This restriction is a hurdle to some developing countries that cannot produce generic medicines. They rely on importing emergency medicines from other members under CL. To effectively tackle the growing public health crisis faced by developing countries, Article 31bis has amended Article 31 and established procedures to allow the importation of compulsory licensed medicines from a third member country. The content of Article 31bis consists of two parts. The first part is an additional clause to Article 31 of the TRIPS. The second part is an annex, which contains an appendix assessing production capacity in the pharmaceutical sector. By allowing a WTO Member to export compulsorily licensed medicines to eligible importers, the member is exempted from the obligation under paragraph (f) to primarily supply the domestic implementation market. Secondly, when an exporting member implements CL under this amendment, it shall pay the patentee adequate remuneration in accordance with Article 31(h) of the TRIPS Agreement. The eligible importing party is exempt from the obligation to pay remuneration to the patentee. In addition, the provision of generic medicines under CL is no longer limited to the domestic market as defined in Article 31(f), benefiting developing countries that meet the corresponding requirements. Although Article 31bis has been amended to address the severe shortcomings of Article 31, which was too flexible and ambiguous in some provisions, it still does not meet the needs of some developing countries that do not have pharmaceutical capacity. Particularly in the current COVID-19 epidemic context, Article 31bis does not strike a good balance between patentees and public health [6].

This essay will analyze in detail some of the problems with Article 31 bis by examining the practical case of the production and distribution of the COVID-19 vaccine under the current CL mechanism of TRIPS, and thus put forward the argument that the implementation of Article 31bis and ANNEX has not achieved its intended purpose. The current TRIPS compulsory licensing regime is unbalanced and does not effectively contribute to protecting the public health interest. In order to better support the argument, the next section will firstly review some of the mainstream views of scholars on compulsory licensing theory to illustrate the rationale of CL concerning protecting public health and safety in the international context to establish a theoretical basis for the whole essay. Section three will then analyze the issues of Article 31bis in terms of supporting the production and distribution of sufficient quantities of

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vaccines to tackle the COVID-19 pandemic worldwide. Although imports from third countries are permitted, the current CL regime is not feasible in practice.

2. The Academic Debate On Compulsory Licensing: An Overview

The debate among scholars has focused on protecting the Right to Health and IP rights. The scholars who support the Right to Health have argued primarily about the ability to innovate, access to medicines, and human rights. For example, some scholars examined whether CL would affect the innovation and price of medicine and argued that CL is not likely to reduce the ability of companies affected by CL to innovate in their products [7]. Moreover, CL could be effective in reducing drug prices [8]. CL might therefore be a win-win measure. Due to this, developing countries are encouraged to improve their science technology innovation capacity and use CL as an industrial policy to increase its efficiency.

On the other hand, two recommendations were put forward to address the procedural issues and maintain the right of the public's health better in practice. The first is the establishment of mandatory patent pools globally, regional, or even national, such as 'Licensing Facilities' [9]. The second recommendation is the establishment of Regional Pharmaceutical Supply Centers (RPSCs) to collectively procure products and coordinate the issuance of the necessary compulsory production or import licenses [10]. RPSCs could help overcome the difficulties that individual countries may encounter in dealing with the administrative and technical aspects of sourcing supplies and can effectively improve the ability to negotiate prices (bargaining leverage) with potential suppliers [11]. Moreover, legal arguments about the relationship between human rights and IP rights and practical debates about access to medicines in developing countries point to a potential conflict between introducing patents on medicines and the realisation of the Right to Health in developing countries [12]. In the current global pandemic situation, the flexibility of existing TRIPS could not afford the corresponding time costs[13].

However, the scholars who support CL have proposed some alternatives to CL that would better protect patent holders. For instance, the main argument is that the rewards of patent protection are necessary to support continual innovation [14]. Some scholars proposed that with guaranteed market separation, originator companies could offer prices comparable to those of local generic companies for differentiated pricing based on Ramsey pricing principles [15]. Additionally, by reviewing the shortcomings of the CL system in terms of economic growth, cost, and quality control, CL may only make generic companies more profitable and not reduce the price of medicines available to the public [16]. Moreover, if taking a long-term view of patent development in developing countries, while CL may reduce the cost of access to medicines, it would lack incentives for patent research. It may ultimately lead to higher costs of access to medicines [17].

3. Some Issues Of Article 31bis In Dealing With The COVID-19 Pandemic

The COVID-19 pandemic poses a considerable challenge to the international community. It reveals that current systems of access to medicines cannot effectively address the devastating impact of the pandemic on a global scale. There is an urgent need to accelerate the production and equitable global distribution of the COVID-19 vaccine to overcome the pandemic. This will not be an easy task. There is currently not enough manufacturing capacity to rapidly produce the billions of doses of vaccine needed to vaccinate the entire world population. In addition, there is another, perhaps more severe, obstacle: in order to accelerate vaccine production, access to vaccine technologies is required. However, these technologies are protected by various intellectual property rights owned by pharmaceutical companies. Various proposals have been put forward to remove this IP barrier, including voluntary technology banks (C-TAP

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and other initiatives), CL, and TRIPS IP exemptions. However, each of these solutions has a significant drawback. As far as the mechanism for access to CL is concerned, as currently established by Article 31*bis*, it still does not meet the needs of international public health.

3.1. Obstacles to the Production of COVID-19 Vaccines

Article 31*bis* of TRIPS has placed an obstacle to the production of COVID-19 vaccines due to the requirement of a special CL authorization from the patent holder to produce a patent product. For instance, the TRIPS Council received a general notification from Bolivia in February 2021. Bolivia has indicated that it intends to become an importing country in accordance with the procedure laid down in Article 31bis. Canada's vaccine manufacturer Biolyse released a statement in March 2021. It requested to enter into an arrangement with Johnson & Johnson Company for commercial purposes. It is the regulation that Canada has established in Section 6 (now Article 31bis of the TRIPS Agreement). At the end of April, a Canadian committee requested the addition of the 'COVID-19 vaccine' to the list in Schedule 1 of the Patent Act. Step required to undertake the procedures necessary to obtain a compulsory license under the Canadian Access to Medicines Regime (CAMR). 2021 On 10 May 2021, Bolivia signed an agreement with Biolyse to produce and supply 15 million doses of the vaccine if a voluntary license or a compulsory export license issued by Canada is obtained. However, two months after the launch by Biolyse of the necessary procedures for obtaining the CL. The Canadian government has made no progress or decision. These challenges and evidence demonstrate that the process is inadequate to authorize the production of sufficient vaccines in an emergency.

Additionally, for the eligibility of producing a patented product, Article 31bis 1(b) has defined 'eligible importing Member' as 'any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS' [18]. With the COVID-19 epidemic, the demand for vaccine imports is not only present in least-developed countries. Even developed countries like the UK, US, and Canada may increase their demand for vaccine imports due to the development and changes in the epidemic. However, these countries with a need for the vaccine may not be eligible for import or production. It would lead to the result that even countries with vaccine production capacity would need to import vaccines from the patent holder's country and not be able to produce and use them independently. This may not have had severe consequences in the past, but the extent to which the new crown epidemic is a severe public health crisis unprecedented. Considering COVID Pandemic's practice, the definition of 'eligible importing Member' may need to be redefined. The fact that vaccines can only be imported from the country of the vaccine holder will create enormous production pressure, while production in other countries is left untouched. The inequitable distribution of vaccine production will result in lower production efficiency, detrimental to the global fight against the COVID-19 epidemic and public health security.

Article 31 of the TRIPS Agreement empowers WTO members to grant compulsory licenses under permissive conditions. Paragraph 5(b) of the Doha Declaration further clarifies the right of members to grant compulsory licenses on their own and decide on the grounds for granting them. According to Article 31(b) of TRIPS, WTO members should, in principle, first seek to obtain a voluntary license from the patentee, a license negotiated diligently by the right holder on reasonable commercial terms. However, this requirement may be waived in times of national emergency or another extreme urgency. However, Article 31bis still does not clarify what constitutes the 'national emergency' or 'other circumstances of extreme urgency. Paragraph 5(c) of the Doha Declaration allows States to decide what constitutes such a situation. Generally speaking, major public health events such as neonic pneumonia and other outbreaks can be understood as falling into this category. In the US, the Obama administration declared a state of emergency concerning the H1N1 swine flu, which some scholars have argued should

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fall under the state of emergency to grant compulsory licenses for patents [19]. As long as it constitutes a state of emergency, a compulsory license can be issued directly without negotiation of a voluntary license to avoid delaying the effective control of the epidemic.

Considering the urgency of the development of an epidemic, it may be controversial whether a compulsory license can be granted at this point, as there are different views on whether it constitutes a significant public health threat. Some scholars have proposed the 'precautionary principle' as one of the principles for granting compulsory licenses for pharmaceutical patents in the event of an outbreak [20]. According to them, the following four factors have been identified as criteria for applying the precautionary principle [21]. Firstly, the inevitability of severe or irreversible damage to public health if no action is taken [22]. Secondly, there is uncertainty about the risk associated with such a threat [23]. Third, there must be a good-faith assessment of that risk [24]. Fourthly, measures must be taken to achieve the desired health objectives [25]. In this case, a domestic emergency need not arise for a compulsory license to be granted for a patented medicine at an earlier date. Under this principle, the conditions for compulsory licensing under TRIPS and the Doha Declaration are in effect further broadened to facilitate the early production and use of medicines through compulsory licensing in countries where an epidemic occurs to address an imminent public health threat.

3.2. Obstacles to the Distribution of COVID-19 Vaccines

Article 31bis also has placed another obstacle to the distribution of COVID-19 vaccines due to the limitations and conditions posed on exporting countries. Exports and imports to countries without sufficient manufacturing capacity is not realistic to enforce in practice. Doha Declaration tasked the Council of TRIPS with developing a fast-track solution to facilitate CL for both exports and imports [26]. The aim was to address the challenges faced by countries whose manufacturing capacity is inadequate or non-existent in the effective use of the CL under Article 31(f) [27]. However, the consequential amendment, TRIPS Article 31bis, does not address the identified challenges promptly. On the other side, Article 31bis introduces unnecessary and cumbersome procedures for exporting CL, which is inappropriate for dealing with sanitary emergencies. For example, the Annex to the TRIPS Agreement calls for a notification procedure for countries because CL must permit the production of a certain quantity of products [28]. The designated product needs to be in a different color and packaging prior to shipment. These requirements of Article 31bis are impractical in a pandemic such as COVID-19 when the pressure to mobilize all capacity at a record pace continues to grow.

Furthermore, the significant price differential between generic and patented medicines creates a high risk of trade diversion for high profits. It would seriously defeat the purpose of the TRIPS amendment, as cheap generic medicines would not reach patients in the Member States facing a public health crisis and would become a means for unscrupulous individuals to make a profit. To avoid this, the amendment requires Members to take adequate measures to prevent trade diversion. It specifies that exporters should use unique markings, including special packaging, colors and shapes, to distinguish generic medicines clearly and that importers and exporters should comply with transparency obligations such as notification and information disclosure. Therefore, since the implementation of TRIPS Article 31bis, many countries worldwide have legislated anti-trade diversion measures concerning CL exports. For instance, Section 21.06 of the Canadian Patent Act provides that the licensee shall create a web page that discloses the name of the licensed product, the distinctive features, the importing member party's organization, and the quantity manufactured and sold of the exported product [29]. Subsection 6 of section 21 provides that the licensee shall give notice of export to the patentee, the importing member, and the seller [30]. Section C.07.008(c) of the Canadian Food and Drug Regulations provides that the exported product must be marked with the 'XCL' mark and that the product's color should be distinguishable from the batch of the drug product sold in Canada

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[31]. All markings on the product should bear certain information that distinguishes the product from proprietary products of the same type sold in the Canadian market [32]. The product label must indicate the quantity of product approved for export by the Public Health Agency of Canada [33]. Article 10(5) of the EU Regulation provides that all products must be labeled as having been produced in accordance with the regulation and that these products should be distinguished from the patentee's products by special packaging or unique colors or forms [34]. Article 10(6) provides that the licensee must produce a web page prior to the export of the product and should publish the relevant information on that web page [35]. Article 40(d)(4) of the Swiss Federal Act on Patents for Inventions provides that a product must be distinguished from a patented product by unique means such as packaging, color, and form, as long as these means do not have a significant impact on the product [36]. Article 23(2) of the Chinese Patent Enforcement CL Scheme provides that medicines manufactured under a compulsory license shall use specific labeling or markings to indicate that the medicine is manufactured under the compulsory license; where feasible and without significant impact on the price of the medicine, unique colors or shapes shall be used for the medicine itself, or unique packaging shall be used for the medicine [37]. Article 23(3) provides that, prior to the shipment of a medicinal product, the entity obtaining the compulsory license shall publish on its website or the relevant website of the World Trade Organisation information on the quantity of the medicinal product destined for the importing party and on the identifying characteristics of the medicinal product referred to in Article 23(2) [38]. Article 110(2)(3) of the Korean Patent Act provides that in the case of an award under Article 107(1)(5), the patentee, exclusive licensor, or non-exclusive licensor (excluding the holder of a non-exclusive license issued through an award) shall provide externally identifiable packaging and markings for the pharmaceutical product of the patented invention in question and the address of the website where the information of the award is published [39]. The responsive legislation of these countries to Article 31bis on the external packaging of products implementing CL represents a widespread trade risk caused by CL. At the same time, this also reveals a side-effect of the inadequacy of Article 31bis. This mechanism is intended to protect the interests of patent holders but accordingly complicates granting the CL. Without commenting on the effectiveness of the patent holder's protection, the complication of the procedure brings a high cost in terms of time. This means that a country wishing to obtain a drug through the CL will spend more time on procedural matters. However, given the severity of the current COVID-19 epidemic, this is not in the public health interest.

Assume that the applicant has filed an application under Article 31bis, specifying the type and quantity of drug required, and has contacted a generic manufacturing company willing to produce the drug. The manufacturing company does not agree during negotiations with the patentee, and the patentee rejects the voluntary license application. The manufacturing company must apply for two compulsory licenses in such a case. One is to apply for the medicine export in the pharmaceutical company's country. The other is that the pharmaceutical company must also apply for a compulsory license in the country where the medicine is exported if the patent is protected. This places a significant additional human and financial burden on the generic manufacturing company, particularly when it applies for a compulsory license in the export destination country. Its position and the subsequent outcome will be more uncertain if it has no prior experience there. All these procedures are time-consuming and do not guarantee final success. If voluntary licensing negotiations are prolonged, the export of life-saving medicines can be extended indefinitely or even eventually canceled. If all the procedures set out in Article 31bis are completed, then a compulsory export license will be granted or achieved. The procedures set out in Article 31bis are complex, time-consuming, and cumbersome. In contrast, the export of medicines requires a simple, quick, and easy procedure under some extremely urgent worldwide crises such as the COVID-19 pandemic [40].

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3.3. Obstacles to the Sufficient Quantity of COVID-19 Vaccines

TRIPS establishes several procedural and substantive conditions for using CL by governments to limit the quantity of authorized patented products [41]. Some of these can be boundaries within the context of a global pandemic. First, the TRIPS provisions require a compulsory license with 'non-commercial use' [42]. It is recommended to proceed on a case-by-case basis and a product-by-product basis. Second, as a first step, prospective licensees must apply for a voluntary license under commercial conditions. It does not include emergencies and other requirements, non-commercial public use, or competition breaches [43]. Finally, the review of the levy rate and the rationale for the CL is unrealistic. This could result in several legal disputes against the licensed generic drug company or the government agency granting the license.

In the context of a worldwide pandemic, the creation of a patent-free supply chain for products has numerous ingredients and complex patent landscapes. For instance, certain vaccines would create a considerable coordination crisis, as CL procedures may need to be initiated and won in several jurisdictions. Some governments may have other legislation which may be detrimental to the CL. The operation of granting CL defined by Article 31bis exhibits a one-issue operation from drug to drug, from country to country, and from case to case. The process by which CL decisions are taken determines the demand for medicines. This is because the application for a compulsory license must specify the quantity and destination of the medicines to be purchased and exported. Suppose the demand for medicines increases and the number of patients applying for medicines is much greater than the number of patients counted in the compulsory license application. In that case, the only way to obtain more medicines under Article 31bis is to start again and again with another compulsory license application and again and again with voluntary license negotiations with the patentee and the generic manufacturer. If a WTO member overestimates the demand for medicines and has a large number of unused medicines, but a third country needs a large number of these medicines, the process of obtaining medicines in that third country would have to start again from scratch, and it would not be possible to obtain these unused medicines immediately. Article 31bis is ineffective and inefficient in the face of these practical complications. Therefore, Article 31bis must provide for flexibility and speedy measures to deal with the rapidly changing complexities of the situation.

4. Concluding Remarks

While TRIPS Article 31*bis* allows for the export of generic medicines produced under compulsory licenses under certain conditions, significantly reducing the relevant medicines' market price, the aim is to balance the high standard of protection afforded by the TRIPS Agreement to pharmaceutical patents with the need to alleviate and address the growing public health problems faced by developing countries. This will help control and mitigate public health crises more quickly and effectively and ensure that the fundamental human right to life and health is respected and protected. However, the many obstacles encountered in practice have revealed the limitations of Article 31*bis* to fulfill its purpose. In particular, in the current COVID-19 pandemic, the cumbersome procedures set out in Article 31*bis* and the resulting high time costs have become a barrier to access to the COVID-19 vaccine for the vulnerable group.

The constraints imposed on the CL suggest a practical requirement for more legal alternatives. This should be fully recognized in the current TRIPS exemption proposal for COVID-19. Some countries have already indicated their interest in improving the future CL system. This is a welcome proposal to modify the CL regime to be more suitable for the long-term protection of public health. However, it should not be an excuse for countries not to support a more direct response to the outbreak through a proposed TRIPS waiver. It would alleviate TRIPS-related restrictions on CL and ensure more accessible access to medical tools on a global scale.

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India and South Africa proposed an exemption that gives countries the option to withdraw. It has failed to enforce patents, and protect undisclosed information, industrial designs, and copyright-related to drugs, vaccines, diagnostics, and other relevant technologies and health documents related to COVID-19 at this time. If enacted, countries would not be sued by the WTO dispute settlement body for failing to implement the TRIPS Pandemic Agreement. When implemented at the national level, the exemption may alleviate the restrictions of existing CL rules. At the same time, it could provide an accelerated approach to exporting and importing generics. It also provides advice on IP disputes related to medical equipment related to COVID-19, which would offer more certainty and raise operational freedom for manufacturers and suppliers. Departments of Health and government procurement agencies will not be required to exhaust the full range of IP status analyses to prevent their activities from infringing on any person's IP rights.

As a result, the proposed exemptions for relevant IP provisions are a timely solution globally. It could allow governments to deal with uncertainties and legal impediments that could prevent more flexibility in the production and supply of medical technologies related to COVID-19. It is more effective than waiting for obstacles to arise before rushing to take action. While negotiations on CL waivers are ongoing, countries should insist on protecting public health rights through the TRIPS flexibilities as deemed appropriate.

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