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TRIPS Decision on COVID-19 Vaccine Patent Waiver: Old Wine in a New Bottle?

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As the latest international legislative achievement of TRIPS system in response to the global public health crisis, *Ministerial Decision on the TRIPS Agreement* adopted by the 12th WTO Ministerial Conference provides a legal basis for exempting members from the obligation of patent protection in relation to the acquisition of COVID-19 vaccine. Compared with the previous Doha Declaration system and Article 31*bis* of the TRIPS Agreement, the feasibility of the *Ministerial Decision* has been enhanced. However, in contrast to the TRIPS waiver proposal presented by India and South Africa and the subsequent discussion texts, both the scope and extent of the waiver in the *Ministerial Decision* have been considerably reduced. In the face of COVID-19, the approach of restricting intellectual property rights to address public health crises still faced challenges. However, given the difficulties and even crisis that have befallen the WTO, despite its inherent flaws, the decision makes a special contribution to the hope of sustaining a multilateral approach to public health crises.

Keywords: TRIPS Agreement, the *Ministerial Decision*, patent, COVID-19 Vaccine

Introduction

On 17 June 2022, the 12th Ministerial Conference of the World Trade Organization (WTO) reached a package of outcomes, including *Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics* (hereinafter referred to as the *Ministerial Declaration*) (WTO, 2022e) and *Ministerial Decision on the TRIPS Agreement* (hereinafter referred to as the *TRIPS Decision*) (WTO, 2022f) that constitute the latest international law-making efforts made by the WTO to deal with the global public health crisis. In particular, the *TRIPS Decision* became the latest international legislative outcome of the TRIPS system in response to the global public health crisis, following *Declaration on the TRIPS Agreement and Public Health* (hereinafter referred to as the *Doha Declaration*) (WTO, 2001) adopted at the 4th WTO Ministerial Conference in 2001, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (hereinafter referred to as the *Implementation of Paragraph 6 of the Doha Declaration*) (WTO, 2005) made by the General Council of the WTO in 2003, and *Amendment to the TRIPS Agreement* (WTO, 2017) entering into force in 2017.

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Ever since the adoption of the TRIPS Agreement, the debate about intellectual property rights and public health has never stopped (Mercurio & Upreti, 2022). Either the unresolved HIV or the COVID-19 highlights the fact that the effective response time of a country in epidemic management is influenced by the patent holder (Drahos, 2021). To address such dilemmas, the *Doha Declaration* and its *Implementation of Paragraph 6* reaffirm the rights of WTO members to protect public health and promote access to pharmaceuticals in the interpretation and implementation of the TRIPS Agreement and particularly make it clear in the partial clarifications concerning the Article 31 of the TRIPS Agreement that public health crises are national emergencies or other circumstances of extreme urgency as defined in Article 31(b), and that members have the autonomy to determine the conditions for granting compulsory licensing while maintaining their commitments under the TRIPS Agreement. The revised TRIPS Agreement permanently fixes the special compulsory licensing of pharmaceutical exports as a solution for members without pharmaceutical production capacity to use compulsory licensing under the TRIPS Agreement, namely Article 31*bis* of the TRIPS Agreement. Although various flexibility adjustments have been introduced by WTO members in the area of access to pharmaceutical products, in practice, the limitations of the case-by-case approach, pressure from trading partners and geographical and procedural constraints can still lead to the complex process and eventually limited effect of compulsory licensing, that is, the inability to respond quickly and effectively to an epidemic (WTO, 2021c).

In view of the conflict between the government's domestic obligation to safeguard the health of its citizens and its international obligation to protect the patent right of pharmaceuticals, as well as the fact that the flexibility of the existing TRIPS Agreement has not been properly adjusted, the outbreak of COVID-19 in early 2020 has quickly become a pandemic causing a global public health crisis after the World Health Organization (WHO) declared it a "Public Health Emergency of International Concern" (PHEIC) (WHO, 2020b). The special control measures and the threat of viruses to human life and health associated with the large-scale outbreaks have hindered global communication and shone a spotlight again on the international response to public health crises. Accordingly, global concerns and discussions have returned to the questions like whether intellectual property protection impedes the realization of global public health, what deficiencies exist in the flexibility provisions of the TRIPS Agreement, compulsory licensing included, and what barriers exist to access to medical products such as vaccines (Ma & Lu, 2022). Given the severity of COVID-19 and the lack of international mechanisms to respond effectively to it, in October 2020, India and South Africa submitted to the WTO *Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19* (WTO, 2020a) (hereinafter referred to as the *Initial Waiver Proposal*), attempting to promote waiver from pandemic-based intellectual property protection obligations. The proposal, which had gone through several revisions and 20 months of negotiations since it was put forward, including the *Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text* pertaining to the Initial Proposal (hereinafter referred to as the *Revised Waiver Proposal*) (WTO, 2021c), the *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic* by European Union (hereinafter referred to as *EU Proposal*) (WTO, 2021a), and the *Quad's Outcome Document* initiated and negotiated by EU, India, South Africa, and the United States (WTO, 2022b), was finally adopted in the form of the *TRIPS Decision*. What are the similarities and differences between the *TRIPS Decision* and the

existing institutional tools in the TRIPS system to deal with the public health crisis? How to evaluate its significance? These are the main issues of this paper.

Origin and Evolvement of *TRIPS Decision*

The process of the *TRIPS Decision*, from the *Initial Proposal*, the *Revised Proposal*, the *EU Proposal* to the *Quad's Outcome Document*, fully reflects the fierce strategic interactions or game among the parties on the issue of intellectual property waiver. The *Initial Proposal* is the most radical of the changes of TRIPS flexibility. The intellectual property waived as proposed in Article 1 of the annex to the proposal covers copyright, industrial design, patent and undisclosed information relating to COVID-19 prevention, control and treatment. India made it clear at the TRIPS Council Meeting that the reason for requesting the waiver from these four types of intellectual property is that they may be involved in health products and technologies such as testing reagents, vaccines, medicines, and ventilators (WTO, 2020c). With regard to the duration of the waiver, Paragraph 13 of the proposal clarifies that the waiver should be extended until most of the world's population has been vaccinated and immune to the virus. The broad scope and the vague duration of waiver had sharply divided supporters and opponents of the *Initial Proposal*, which led to a stalemate in the waiver negotiations. It was not until May 2021, when the United States switched from a staunch opposition to a limited support for vaccine-related intellectual property waiver, that the negotiations took a turn for the better (USTR, 2021).

India and South Africa, along with other proponents of the waiver proposal, submitted the *Revised Proposal* after the United States announced that it would join the negotiations. Taking into account the above-mentioned conflicts over the scope and duration of the waiver, the future mutation of the virus, and the uncertainty regarding the efficacy and actual production of an effective vaccine and treatment, the proposal further specifies the products, technologies, and production methods covered by the waiver and limits the duration to three years. However, the EU remained dissatisfied with the proposal and believed that intellectual property rights (protection) play(s) an important role in vaccine research, innovation, and equitable access (WTO, 2021b). As a result, the EU has put forward the *EU Proposal* in response to the crisis of COVID-19. The proposal is more a clarification of Article 31*bis* of the TRIPS Agreement than a new draft waiver. The heading of the *EU Proposal* replaces "Decision" with "Declaration" to highlight that it is not an exemption or amendment of existing obligations under the TRIPS Agreement. The annex to the *EU Proposal* not only covers epidemics in the national emergencies or other circumstances of extreme urgency defined in Article 31 of the TRIPS Agreement, recognizes the right of members to waive the efforts of prospective users in the use of Articles 31*bis*, specifies compensation requirements, and allows one-time notification to the exporting supplier country, but mentions for the first time to integrate with international joint initiatives, for example, the COVID-19 Vaccines Global Access Facility (COVAX[1]) to promote equitable access to vaccines. The emergence of the *EU Proposal* represents the beginning of a shift in the focus of the waiver negotiations from broad waivers from intellectual property to revisions solely modeled on existing TRIPS flexibility provisions, with a direct impact on subsequent waiver texts.

[1] COVAX, which is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization (WHO), alongside key delivery partner UNICEF, aims to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

With the support of the WTO, an informal group of EU, Indian, South African, and US ministers had been formed since December 2021 to negotiate further on the waiver text with a view to reaching a consensus, after the key participants had been unable to reach an agreement (TWN, 2021). In May 2022, the *Quad's Outcome Document* was reached through negotiations which later became the prototype of the *TRIPS Decision*. The document focuses only on the discussion of vaccine patents waiver, no longer dealing with other related intellectual property rights, which means the negotiations on the production and distribution of COVID-19 diagnostic and therapeutic products other than vaccines will be postponed. Paragraph 3(c), which allows for the export of any proportion of vaccines to eligible members under the authority of the document, is the document's main highlight. The document also has two main points of contention. One is the exclusion criteria for eligible members. The other is the requirement for eligible members to list all patents covered when issuing a single authorization for the use of multiple patent objects. The former gives two possible exclusion criteria for eligible members in Footnote 1: either encouraging developing members with export capacity to withdraw from the decision, or simply excluding developing members with more than 10% of the world's COVID-19 vaccine exports in 2021. This approach, which takes export capacity or share as the exclusion criterion, in effect discourages members to export and is not conducive to the acquisition of vaccines by developing members through imports and exports or to the containment of the spread of the epidemic (Yu, 2022). Meantime, the export share criterion is extremely discriminatory, basically aimed at China (Access Campaign, 2022), not just because China had so far been the only developing member, apart from the developed EU and US, to share more than 10% of the world's COVID-19 vaccine exports (WTO, 2022g), but because the United States had been working hard in the document negotiations to exclude China from obtaining waivers (Priti, 2022). The U.S. Congressional Research Service Report once revealed in depth that the United States did so mainly out of concern that it would lose its comparative advantage over countries like China, which may reap the economic benefits of America's advanced technology (Congressional Research Service, 2021). This clause imposes an exorbitant cost on eligible members in terms of requiring that all patents covered be listed during the authorization. Not only are patent filings related to COVID-19 unusually active (WIPO, 2022), but the patent system for some vaccines can be quite complex (Love, 2022). The requirement to list all patents covered may add to the time cost of authorization. The two major disputes were eventually resolved in the *TRIPS Decision* by no longer requiring eligible members to list all covered patents during the single authorization and only encouraging those developing members with vaccine production capacity to opt out voluntarily.

Progress on Enforceability of *TRIPS Decision*

The *TRIPS Decision* consists of nine paragraphs, including specific circumstances of waivers (Para. 1), clarification of authorization methods (Para. 2), waivers from proposed user's efforts (Para. 3(a)), waivers from restrictions on domestic market supply and exports (Para. 3(b)), restrictions on re-exportation and importation (Para. 3(c)), determination of adequate remuneration (Para. 3(d)), protection of undisclosed test data (Para. 4), transparency and communication (Para. 5), limitation period and review (Para. 6), non-challenging clause (Para. 7), possible extension (Para. 8), and without prejudice to existing flexibility and rights and obligations under the TRIPS Agreement (Para. 9). Compared with Article 31*bis* of the TRIPS Agreement, the *TRIPS Decision* has

improvements to different degrees in terms of the conditions, restrictions, and procedures of applicability, thus enhancing its feasibility.

First, in terms of application conditions, the least developed members do not belong to eligible members of the *TRIPS Decision*, as compared to Article 31*bis* of the TRIPS Agreement, which is mainly because they will not be obliged to implement or apply the patent-related provisions in the TRIPS Agreement on pharmaceuticals until 2033 (WTO, 2015). Thus, there is no need to include them in the eligible members if they are not subject to the duty of patent protection on medicines that can be waived. There is no material difference between the *TRIPS Decision* and Article 31*bis* in terms of the coverage of the least developed members. In addition, according to Article 31*bis*, members of the TRIPS agreement shall only "notify" if they need to prove that their pharmaceutical industry lacks the relevant drug production capacity (WTO, 2021e). That whether WTO members are developing members or not also adopts the self-declaration approach. As a result, the *TRIPS Decision* and Article 31*bis* of the TRIPS Agreement are more lenient with regard to the certification requirements of eligible members. Considering, however, that developing members constitute the vast majority of WTO members and that the *TRIPS Decision* places greater emphasis on the local production and export of vaccines within eligible members than on the import of generic drugs, as opposed to Article 31*bis*, the *TRIPS Decision* is therefore more conducive to the development of the pharmaceutical industry in developing member countries from the perspective of the membership and diversified production.

Second, in terms of application effect, the *TRIPS Decision* has the advantage of scale economies over conditional exports under Article 31*bis* of the TRIPS Agreement. For one thing, the export of any proportion of the product means that vaccines produced under compulsory licensing can be exported as much as possible, as long as both import and export members are eligible. This effectively addresses the problem of differential treatments between the domestic use of products and the export to eligible importing members for different purposes, contributing to the realization of scale economies in production. For another, vaccines produced under the *TRIPS Decision* no longer require special labeling and packaging. But it is still required in Article 31*bis* as long as such differentiation is feasible and does not have a significant effect on prices. While taking into account the affordability of drug prices and minimizing the impact of compulsory licensing on competition in the pharmaceutical market, it ignores the fact that a limited number of drugs are produced under each compulsory licensing. Moreover, special packaging discourages large-scale production, which can reduce costs, and the extra cost of distinguishing products makes generic drug makers less willing to apply for compulsory licensing (Zhang, 2022).

Third, the international initiatives supported by the *TRIPS Decision* are more responsive to international needs than the mutual assistance of specific regional trade agreements under Article 31*bis*. In practice, COVAX is faced with a variety of problems, including unexpected vaccine delivery, delivery delays, and delivery of vaccines approaching the expiration date (Goldhill, Furneaux, & Davies, 2021). The reason is that COVAX supplies rely more on a limited number of global manufacturers who have always prioritized the delivery of vaccines to rich countries, regardless of whether the vaccination needs of poor countries are more urgent (OXFAM, 2021). Such problems can be solved by compulsory licensing of vaccine patents by a number of eligible members of the *TRIPS Decision* so that mass low-cost vaccines can be produced and exported to COVAX.

In addition, the mutual assistance under specific regional trade agreements is not so feasible. In part, this is because it requires that at least half of its members belong to the least developed countries ascribed by UN and suffer from common public health problems, which has left few regional trade agreements meeting the conditions. The practice of applying the provision is very limited, as the EU has stated at the time of negotiation that it should apply only to Sub-Saharan Africa (Abbot & Reichman, 2007). On the other hand, even in areas that meet the application requirements such as East African Community, high production and financing costs and poor use of technology make locally produced generic drugs more expensive and unaffordable than imported drugs (Russo & Banda, 2015). Moreover, Article 31*bis* requires that the territoriality of the patent right not be affected. As a result, when a country wants to import or locally produce generic drugs, the remaining countries in the East African Community still need to issue their own compulsory licensing of obtaining the drug through import, and the compulsory licensing procedures in each country are complex, which eventually causes a great limitation on the effectiveness of Article 31*bis* (Adekola, 2022).

In addition, the two "reasonable" requirements of Article 31 of the TRIPS Agreement, on the one hand, make commercial negotiations between the prospective user and the right holder time-consuming, which can lead to unnecessary delays in the fight against pandemics during the public health crises. On the other hand, both sides are likely to disagree on what constitutes "reasonable commercial terms and conditions" and whether it has passed a "reasonable period of time", so that in the absence of objective criteria, the burden of proof on the prospective user will greatly reduce its incentive to try to apply for compulsory licensing. The direct waiver of the prospective user from the required efforts in the *TRIPS Decision* could significantly reduce the lengthy time and burden of proof needed to apply for a compulsory license. In addition, in comparison with the economic value criterion for authorization considered in compensation and the value criterion for importing members in Articles 31 and 31*bis* of the TRIPS Agreement respectively, the *TRIPS Decision* also takes into consideration humanitarian and non-profit purposes of specific vaccine distribution schemes aimed at providing equitable access to COVID-19 vaccines, so as to support production and supply at affordable prices by eligible member manufacturers. The new considerations can be divided into two parts: the humanitarian and non-profit purposes of compensation and the bias towards eligible member manufacturers. The call for a humanitarian and non-profit compensation fee promotes local production in support of eligible exporting members and affordable price purchases by eligible importing members (Watal, 2022) and clarifies the value orientation to be given by the compensation fee. The reports and guidance contained in Footnote 4 to the *TRIPS Decision* provide a number of cases of compulsory royalty pricing and guidelines for export royalties (Xu & Chen, 2022), so the practical guidance is offered to eligible members for specifying compensation for the authorized production of vaccines under the *TRIPS Decision*.

Arguments on Necessity of *TRIPS Decision*

Skepticism and Criticism

As far as the content of the *TRIPS Decision* is concerned, there is a view, from the perspective of developing members, that the provisions, on the one hand, facilitate the import and export of vaccines without the authorization of the right holder. On the other hand, they have more or less created more legal uncertainty or ignored some provisions of Article 31*bis*, which still needs to be clarified by the WTO (Watal, 2022).

Furthermore, the *TRIPS Decision* has made adverse changes to the existing system of compulsory licensing, including more difficult application of TRIPS Agreement flexibility provisions, only a slight relaxation of export restrictions on vaccines (People's Dispatch, 2022), too limited waivers, contradictions between eligible member standards and Article 31(f) of the TRIPS Agreement, and re-export barriers (Syed, 2022). In view of the practical effect of the *TRIPS Decision*, some think that patent waivers are only one of the tools for addressing inequities in vaccine management, and other factors, such as COVAX donations, the ability of countries to manage vaccines and of manufacturers to scale up production, will all affect global vaccine production and distribution (Loft, 2022). The current oversupply of vaccines and the shrinking of production lines mean that weakening intellectual property protection will no longer help to further expand vaccine production in the future and will not achieve vaccine equality (IFPMA, 2022b).

Indeed, the dispute over the necessity of the *TRIPS Decision* has been ongoing since the start of the waiver negotiations, primarily around the question of whether the existing flexibility provisions and voluntary licenses in the TRIPS Agreement have met the needs of addressing COVID-19 pandemic. Opponents of the waiver proposal argue that the TRIPS Agreement already provides sufficient flexibility, entitling countries to issue compulsory licenses in the face of a public health crisis to produce cheaper medicines and to allow countries lacking productive capacity to import (Labonte & Johri, 2020). This is evidenced by the widespread use of flexibilities including compulsory licensing between 2001 and 2016, which have had the effect of reducing drug prices and ensuring equitable access for all (Hoen, Veraldi, Toebes, & Hogerzeil, 2018). In cases where existing flexibility is not available, it is usually because of the complex procedures of domestic application of the mechanism concerned, rather than the shortcomings in international mechanisms (Mercurio, 2021). In terms of voluntary licensing, this mainly includes direct licensing by drug patentees (pharmaceutical companies) and through international mechanisms such as C-TAP[2] and COVAX. Opponents also argue that voluntary licensing has been already working and that the international community has been actively promoting it. In May 2020, for example, Gilead granted a voluntary non-exclusive patent license to generic drug companies in Egypt, India, and Pakistan for the COVID-19 drug *Remdesivir*, allowing these generic drug manufacturers to distribute the drug in more than 100 countries (Jerving, 2020). By November 2020, 18 generic drug companies have openly joined C-TAP to increase access to COVID-19 health tools, according to WHO (WHO, 2020). As of February 2022, relying on vaccine donations from high-income countries and some pharmaceutical companies, COVAX has delivered more than 500 million doses to 105 countries or territories (Gavi, 2022). As of 2021 December, Gavi and Moderna have already reached an agreement on additional vaccine supply to COVAX, agreeing to provide the Moderna COVID-19 vaccine at the lowest graded prices in the second and third quarters of 2022 (Gavi, 2021). With the use of voluntary licensing and the advancement of global initiatives, there is no need to give up intellectual property rights to ensure equitable access to affordable medicines (Mercurio, 2021).

Advocacy of the *TRIPS Decision*

With regard to the content, there is a view that the *TRIPS Decision* clarifies the application of the flexibilities

[2] In May 2020, WHO, the Government of Costa Rica, and other partners launched the project of COVID-19 Technology Access Pool (C-TAP) to provide an access for people in all countries to obtain COVID-19 health products which is more efficient, equitable, and affordable.

of existing TRIPS agreements and its implications should not be limited to the exceptional cases of the COVID-19 pandemic (Hilty et al., 2022). There is another view that while the *TRIPS Decision* does not address all epidemic-related issues, it makes useful changes at the level of scope of eligible members, implied recognition of national emergencies, and arbitrary proportions of exports (Mercurio & Upreti, 2022). In her closing statement to the *12th Ministerial Conference*, the Director-General of the WTO takes a positive view on whether the *TRIPS Decision* can promote global vaccine production and distribution, feeling that it could advance decentralization and diversification of vaccine production capacity (WTO, 2022a). Developed countries such as the US and the UK also see the *TRIPS Decision* as a way to provide safer and more effective vaccines for those who need them most (USTR, 2022), as well as to improve vaccine exports under existing flexibilities (Trevelyan, 2022). A broad intellectual property waiver could help other countries invest in developing their own manufacturing capacity to serve the current and next pandemics (Amin & Kesselheim, 2022).

Comparing the *TRIPS Decision* with the existing flexibility provisions of the TRIPS Agreement, proponents of the waiver proposal believe that the TRIPS Agreement is not flexible enough to address a public health crisis of this magnitude. The flexibilities in TRIPS Agreement do provide policy room for public health, but they are not a viable option for dealing with COVID-19. The reasons include the infrequent use of flexibilities other than patents, the lack of enforcement capacity in many countries, the impediment to international cooperation by compulsory licensing on a case-by-case basis, the complex procedures of Article 31*bis*, and the pressure from trading partners and other stakeholders (WTO, 2021c). In the case of compulsory licensing of vaccines, exclusive data rights are not licensed to the manufacturer along with the patent rights, making it impossible for generic drug makers to use existing data to obtain approval of marketing in a timely manner (Thambisetty et al., 2022). For other ways of obtaining vaccines, such as voluntary licensing, supporters, on the other hand, believe that voluntary licensing not only limits catch-up and innovation among generic competitors, but lacks transparency. Some pharmaceutical companies may limit the production, number, and export territory of licensed products to exclude most of the world's population. Further, COVAX focuses only on limited access to vaccines in the short term compared to the waiver proposal, with shortcomings such as the inability to meet diversity needs (WTO, 2021c). Determining the clause of voluntary licenses, pharmaceutical companies grant them only to affordable least developed countries, leaving poorer regions out of the picture (Erfani et al., 2021). As of May 2022, only two R&D entities in the United States and Spain were willing to share COVID-19-related health technologies with C-TAP (WHO, 2021).

Ostensibly, the debate over the necessity of the *TRIPS Decision* is a reflection of the divergent evaluation of existing measures or institutional instruments, but in fact it is a further reflection of the tension or even conflict between the protection and the limitation of intellectual property rights, which ultimately comes down to the expansion and maintenance of interests. For intellectual property right holders, voluntary licensing is the most acceptable form of self-restraint. Under the framework of freedom of contract, they can still maximize the protection of their intellectual property rights through the design of licensing clauses. However, it must be admitted that such licenses on a case-by-case basis cannot form a scale effect. In response to the global public health crisis, using international mechanisms to limit intellectual property rights so as to achieve the sharing of knowledge products is necessary. Such external restrictions would be naturally resisted by the intellectual

property right holders, and this resistance would be reflected in the negotiations through the will of the government, eventually softening or even weakening the restrictiveness of the international mechanism. Hence, C-TAP under the WHO and COVAX can only stay at the initiative level where there is no restriction to intellectual property right holders. In comparison, the flexibility clause under the WTO is more mandatory, but it is also limited to an acceptable range through deep and intense game. This has also become the position that intellectual property right holders represented by pharmaceutical companies try to hold fast to. Thus, that "flexibility clause is sufficient" is more like a bottom line for intellectual property restrictions than an important argument against the necessity of the *TRIPS Decision*.

Contribution With Imperfections

Limitations of Realism

The debate over the necessity of the *TRIPS Decision* has once again revealed that the international community remains deeply divided on the path to addressing the public health crisis by restricting or even waiving from intellectual property rights. At the heart of this disagreement is a dispute among relevant stakeholders about the role of intellectual property. Regarding the role of intellectual property rights in the epidemic, the international community represented by developing countries believes that intellectual property rights impede the production and equitable access to other health products such as vaccines. Potential intellectual property rights violations and disputes in the early days of COVID-19 over therapeutic products, diagnostic products, vaccines, and other products demonstrate the complex legal implications of producing life-saving medical replicas and their impact on access (WTO, 2021c). In South Africa, intellectual property rights holders have been unable to meet vaccine demand and transfer enough technology, hampering the prospects for local scale-up (Vawda et al., 2021). For its part, the pharmaceutical industry, which acts as an intellectual property spokesperson, believes that intellectual property protection is essential in the prevention and control of the global pandemic, and it is other barriers that are to blame for the lack of equitable access to global vaccines. Intellectual property rights can be effective in facilitating rapid research and development of vaccines and strengthening voluntary partnerships, while trade is the biggest factor affecting access to vaccines (IFPMA, 2022a). It can also promote inter-agency cooperation and turn research into real outcomes, while logistics, raw materials, and manufacturing techniques in production are the main barriers to vaccine acquisition (Moore, 2021).

This controversy reflects the scarcity of drug patent as a resource endowment and the resultant reality that it becomes a national interest. Although the TRIPS Agreement characterizes intellectual property as a private right, this characterization cannot resolve the public interest nature of intellectual property and the resulting tension between protection and restriction. This internal tension is inherent in intellectual property rights as the right with specialty. The more relevant intellectual property is to the public interest, the stronger the internal contradiction will be. Especially when certain intellectual property rights, such as pharmaceutical patents, have made the leap from private interest to industrial interest with national interest afterwards, this tension and even conflict will take on more complex multi-polarization and multi-layered nature. The involvement of stakeholders, including sovereign states, multinational companies, and non-governmental organization, has made disputes more irreconcilable. In this extremely complex game, any compromise will be time-consuming and will continue to be wrapped up in endless dispute. In this sense, the *TRIPS Decision* still fails to break the shackles of the

existing institutional tools of TRIPS system for coping with public health crises. This is not only a true portrayal of realistic international relations, but also a reappearance of the inherent tension between protection and restriction of intellectual property, which reflects the inherent limitation of the *TRIPS Decision*.

Contributions of Multilateralism

Nevertheless, the contribution of the *TRIPS Decision* should not be denied. The positive significance of the *TRIPS Decision* as a legislative outcome of international law cannot be overlooked, particularly in the light of the current challenges and even crises faced by multilateralism. Since entering the Doha round, the process of WTO trade negotiation has been blocked repeatedly. This is mainly reflected in the past two decades, when WTO members have reached only two major multilateral agreements, namely *Agreement on Trade Facilitation* and *Agreement on Fisheries Subsidies*. Additionally, United States has blocked the appointment of new members to the Appellate Body, which makes the decision-making and dispute settlement mechanism of WTO to be marginalized from the center of international trade system. On the one hand, this phenomenon results from the consensus decision-making mechanism adopted by the WTO, and the recent trade issues that are more and more controversial and involved in the core interests of the members (Ma & Lu, 2022). On the other hand, it is because the development pattern of a multi-polar world makes the wealth gap between countries narrower, so that national voters and public opinion will pay more attention to the relative welfare gains and losses between countries, rather than an increase in the overall welfare of the international community (Cohen, 2019). The ideal multilateral system should be able to respond efficiently to the common challenges facing human society, effectively realize the joint efforts of its members, and equitably benefit its members and the international community (Che, 2020). The *TRIPS Decision* not only demonstrates the determination of countries to reach consensus at the WTO negotiating table, but also shows that developing members are no longer passively accepting the reality of an inadequate supply of vaccines and seeking donations from developed members and pharmaceutical companies when a public health crisis arises; instead, they are actively looking for cooperation to promote local production of vaccines in order to achieve equitable distribution of vaccines globally.

The priority relationship between public health and intellectual property protection has also undergone a long policy shift within the WTO. In the Indian patent case, the TRIPS Agreement was interpreted by the Panel and the Appellate Body in a manner that strictly protects patent rights (WTO, 1997). In the *Doha Declaration*, the right of members to take flexible measures to protect public health and the right of all persons to health with access to medicines were emphasized. In the case of the tobacco plain packaging, treaty interpretation in a manner consistent with the public health policy objectives of the TRIPS Agreements was stressed by the Panel and the Appellate Body (WTO, 2020b). The amendment to Article 31*bis* was not formally adopted until 2017. It is after more than two decades that the internal decision-making and Dispute Settlement Body of the WTO finally have made a definite shift in their attitude towards the relationship between the two. Nevertheless, the norms of international law on public health-related intellectual property rights remain seriously lacking, with Articles 8.1 and 31*bis* of the TRIPS Agreement being the only explicit provisions, while the significance of the *Doha Declaration* in international law level is not yet clear (Zhang, 2020). Therefore, the *TRIPS Decision* not only reinforces the tendency within the WTO to attach more importance to public health than to the protection of intellectual property rights, but also makes up for the absence of international law norms on public health-related

intellectual property rights in the multilateral regime. In the context of the latest developments in temporary waivers, the TRIPS Council has established a detailed meeting schedule for the discussion on extending the *TRIPS Decision* to COVID-19 diagnostics and therapeutics, and some members have been actively preparing materials (WTO, 2022c), which also reflects the determination of WTO members to continue to improve international law norms on public health-related intellectual property rights in a multilateral order.

Conclusion

Compared with the TRIPS waiver proposal put forward by India and South Africa, the object, scope, and extent of waivers in the *TRIPS Decision* are greatly reduced. Despite the fact that the *TRIPS Decision* is more implementable than Article 31*bis* of the TRIPS Agreement, doubts and even criticism about its necessity remain. This is not so much a pity as a true reflection of the inherent conflict between intellectual property protection and the response to the public health crisis. In particular, when pharmaceutical-related intellectual property rights are transformed from a private right into a national interest through the promotion by pharmaceutical companies and their industries, any restrictions on them will provoke fierce resistance from the private sector to national governments. With this in mind, the *TRIPS Decision* remains of positive practical significance in the longer term of history. Especially when the multilateral system represented by the WTO is facing challenges and even crises, the adoption of *TRIPS Decision* has kept a crack for the closing door of multilateralism. In accordance with Paragraph 8 of the *TRIPS Decision*, no later than six months from the date of this decision, members would decide whether to extend the vaccine patent waiver to cover the production and supply of COVID-19 diagnostic and therapeutic drugs. In view of the failure of the members to reach an agreement as scheduled, the Council of TRIPS has recommended the extension of the deadline to the General Council the day before. WTO members finally agreed to suggest extending the 17 December 2022 deadline to the General Council, so as to decide whether the *TRIPS Decision* should be extended to COVID-19 diagnosis and treatment (WTO, 2022d). Discussions at the WTO on this topic are still predictably difficult. Regardless of the final outcome, however, the *TRIPS Decision* offers a glimmer of hope for the international community in exploring the path of international law in response to the pandemic. In this sense, the *TRIPS Decision* still has its special contribution different from the existing institutional tools of the TRIPS system.

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