Development and Challenges of Infectious Disease Control Measures in Trade Policy: Using COVID-19-related Medical Resources as a Case Study *[*]

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Abstract

Triggered by the global spread of COVID-19 (hereafter, "COVID-19 pandemic"), the relationship between international trade rules and infectious disease control measures with access to medicine that constitutes an element of such measures, has once again been tabled for discussion in domestic and foreign forums, and the appropriateness of conventional responses and future direction have come under review. A wide range of trade measures were adopted to secure medical products that contribute to COVID-19 diagnosis, treatment, and immune-boosting, ranging from export and import restrictions as well as bilateral trade that was criticized as "vaccine nationalism," to free donations to other countries/regions or to multilateral international organizations such as the COVAX Facility (hereafter, "COVAX"), exemption from protection for some intellectual property rights related to medical products based on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and further, application for import of vaccines based on Article 31bis of the TRIPS Agreement. International organizations, including the World Trade Organization (WTO), are gathering and analyzing information on the various measures implemented at the national level and providing feedback on such measures, and at the same time, considering international rules such as the WTO Ministerial Conference decision on the exemption of the protection of COVID-19 vaccine-related patent rights, and World Health Organization (WHO)'s proposed convention on infectious disease control measures. This paper aims to shed light on the development and challenges of infectious disease control measures in trade systems through the COVID-19 pandemic.

Keywords: COVID-19, medical products, infectious disease control measure, access to medicine, intellectual property rights, IPRs, patent rights, import / export restriction, TRIPS Agreement, WIPO, WHO, WTO, vaccine nationalism, vaccine diplomacy, compulsory licensing, governmental use of IPRs

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I. Introduction

In May 2023, WHO declared that they changed their policy approach toward the COVID-19 pandemic from the emergency version after the declaration of public health emergency of international concern (PHEIC) to a more long-standing version keeping necessary measures while pursuing fruits of this pandemic and made public the outline of the approach afterward[1]. The COVID-19 pandemic has brought effects worldwide far greater than the ones caused by previous pandemic such as the SARS which had finished relatively quickly in 2002, pandemic influenza in 2007 and 2008, and the Ebola fever which rises in limited area. Infectious disease control at each country / area -level and multi -level trade measures toward the above-mentioned diseases and legal analysis of these control[2] are parts of the contemporary international public health policy, sometimes called "global health."[3] For example, in April 2020, the ACT-Accelerator was established as an international system in which World Health Organization (WHO) becomes the hub networking with other Intergovernmental Organizations (IGOs) and Non-governmental Organizations (NGOs) related to infectious diseases control[4]. ACT-Accelerator placed four pillars. The COVAX Facility is one of them, aiming to develop, manufacture and allocate COVID-19 vaccines for the progress of immunization and other pillars have tried to procure and allocate therapeutic medicines, medical devises, and test kits. In parallel, Medicines Patent Pool (MPP) negotiated with holders of Intellectual Property Rights (IPRs) registered worldwide regarding these products, asking for voluntary licensing and making progress in expanding manufacturing ability and increasing supply. It is assumed that these schemes have certainly affected international trade of medical products that reflects differences in affordability among countries/areas.

Furthermore, exceptions to the obligations under existing trade agreements aiming to improve access to medicine, e.g., the special compulsory licensing system provided by the art.31*bis* and the Protocol (in effect in 2017) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), establishing a waiver of art.31 making possible for a World Trade Organization (WTO) member to give compulsory licensing and export generic medicines to another member with poor or no ability to manufacture these medicines, have been evaluated as under-utilized because of their severe requirements and burdensome procedures. Since 2003, this system has been available, however, there has been only one case utilizing this system: Rwanda imports Canadian antiretroviral. In the COVID-19 pan-

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[1] WHO (2023b), (2023c).

[2] As the initial research on Japan, e.g., Iwasawa & Nakatani (2022); Kagiyama (2022); The 21st Century Public Policy Institute (2022) etc.

[3] As the initial research based on the situation until mid-2021, Nakayama, I. (2021a) and Nakayama I. (2021b).

[4] On the structure of the ACT-Accelerator, Kato (2021a) and Kato (2021b).

demic, in 2021, Bolivia and Antigua & Barbuda made submissions to the WTO to use this system. A Canadian generic pharmaceutical company replied to application by the Bolivia government and asked the Canadian government to amend Canadian patent law to make it possible to manufacture the COVID-19 vaccine and fulfill Bolivian needs; however it has not yet been realized. These cases provide us the opportunity to verify the availability of the existing international trade system.

It is also noteworthy that these applications were made during the strict controversy on the draft decision of the WTO General Council proposed by India and South Africa in October 2020 to make a temporal waiver of obligations to protect IPRs under the TRIPS Agreement. This proposal resulted in the Decision adopted in June 2022 at the WTO 12th Ministerial Conference stating that WTO members recognize developing countries' right to waive the protection of patent rights relating to the COVID-19 vaccine only and that they continue the discussion on whether to recognize to do so relating to other IPRs relating to other medical products or not. Now the discussion and evaluation are required on these new exceptional measures to the protection of IPRs.

In face of the pandemic, governments have made efforts to implement their obligations to protect the right to health of their nationals and to preserve and improve public health within their territory, through the limitation / ban of exportation / importation and conclusion of buy-out agreements with manufacturers. Without international adjudication, such measures would inevitably compete with other governments' ones, leading to a scramble[5]. In this COVID-19 pandemic, especially from 2020 to 2021, the world had faced serious shortage of COVID-19 vaccines, and governments of developed countries and vaccine manufacturers concluded buy-out agreements and were strictly criticized for their "vaccine nationalism"[6]. However, in the global pandemic, it has been pointed out that the success of only a specific country / region in acquiring herd immunity is not enough. Continuous countermeasures against the pandemic would be required as long as there is the existence of a potential risk of a pandemic and the rise of variants. Under these circumstances, some commentators have insisted that

[5] For example, Kagiyama explained that the EU, in May 2020, and the U.S. in April 2020, introduced export licensing systems on PPE, meaning a *de facto* ban of exportation to non-EU countries or foreign countries and the governments asked domestic / regional industries to prioritize fulfilling domestic / regional supply. He also mentioned that other countries / regions have enforced similar export banning / limiting measures on these products until mid-year of 2020, and through the adjustment of global supply chain, scarcity had certainly been solved, and measures were abolished. Kagiyama (2022) pp.44-45.

[6] As for the concepts of vaccine diplomacy and vaccine nationalism, Kelly & McGlasson explained that the relationship between vaccine diplomacy and vaccine nationalism has not been fully explored yet and is evaluated as mutually exclusive, and cited the definition of Owusu-Antwi (2021) that vaccine diplomacy consisted of three continuous and supplementary elements. Here are the three elements 1) predatory vaccine nationalism; enclosure of vaccine is its characteristic; 2) benign vaccine nationalism which prioritizes domestic needs, hence international distribution is limited; 3) ultra vaccine diplomacy, which places non-nationalistic needs to center, and beyond donations, prefers pluralistic vaccine manufacturing. Based on this definition, they evaluated that the COVAX had been constructed based on the benign vaccine nationalism; however, its function had been undermined by predatory vaccine nationalism. See Kelly, M. & McGlasson, M. A. (2023) pp.113-133. Considering these concepts more is a future challenge.

the system to protect IPRs, originally authorized by the independent decision of each country / region under the doctrine of territoriality, should be controlled by appropriate global normative guidelines. The decision of the WTO Ministerial Conference could be situated as one of them. Furthermore, in the period of pandemic, both on the global and domestic dimensions, in a variety of industries, right holders have opened and shared publicly IPRs such as copyrighted works or designs for facemasks and ventilators[7]. However, it is doubted that measures legally taken by governments in the medical industries are appropriate for the role division between public / private sector aimed at the preservation of public health. Relating to this discussion, the pros and cons of the system have been discussed that on the one hand private persons acquiring and utilizing IPRs needed to deal with public health emergencies and derived from public investment, and on the other governments should authorize the private persons to provide products based on the IPRs. A more enhanced argument places these IPRs as the global public goods needed in the global / domestic emergency and insists that public financing should be paid for their sharing.

Based on the above concerns, this paper aims to clarify the development and challenges of infectious disease control measures in trade policy, with using COVID-19-related medical resources as a case study. Section II will make a general observation on the relationship between infectious disease control measures and trade policy through analyzing tripartite studies provided by three Inter-Governmental Organizations named WTO, World Intellectual Property Organization (WIPO) and WHO. Next, Section III traces activities of these three organizations, Antigua & Barbuda and Bolivia that have made applications to use the special compulsory licensing system provided by TRIPS Art.31bis. Finally, Section IV will provide the findings and further agenda to be investigated.

II. Infectious Disease Control Measures and International Trade

From the 1990s to the 2000s, in line with the development of globalization, emerging infectious diseases like HIV/AIDS, Ebola hemorrhagic fever and Pandemic Influenza have brought serious damage to the economy of countries / regions and international trade and according to this, access to medical products needed to deal with diseases became one of the international concerns of the United Nations' activity[8]. The specific characters of these activities focused on combating diseases are the WHO and its member states as the leader since its establishment in 1948, and the style called "Public-Private Partnership (PPP)" within that various actors collaborate with each other notwithstanding their inter/inner-national, profit-

[7] Regarding the relationship between IP sharing and the COVID-19 pandemic, see KATO, A. (2024) pp.198-208.

[8] Goal 7 of the Millenium Development Goals (MDGs), adopted in September 2000; Goal 3 of the Sustainable Development Goals (SDGs), succeeded MDGs and adopted in 2015.

able/non-profitable, official/private status.

Specifically, the WTO, WHO and WIPO have progressed for 20 years their "Tripartite Cooperation" for adjusting among public health, intellectual property and trade and convened collaborative studies and events like symposiums[9]. Their recent report[10], summarizing their achievements towards the COVID-19 pandemic, is worth referring to as a framework on the relationship between infectious disease control measures and international trade.

First, the report describes 1) the dramatic impact on health systems and responses at the global level and their legal basis like many decisions by the UN and the WHO, International Health Regulation (IHR) and countermeasures towards the pandemic provided by each country / region; 2) policy challenges posed by the pandemic, from poverty to countermeasures toward virus variants. Second, based on this fact-finding, the report makes references to 3) meeting the demand for health technologies and medical services, with emphasis on creating sustainable regional and global partnerships, is essential to the development of local production capacity; 4) preserving effective international trade, with a description of the landscape of the medical products industry and trade-restrictive / -facilitating measures by country / region assessed by the WTO; 5) intellectual property aspects, such as user-friendly measures taken by country / region on patent application / examination process, collection and sharing of application / registration information of IPRs available for combating the pandemic, global controversy on the flexibility relating to the protection of IPRs obliged by the TRIPS Agreement (TRIPS flexibility) like compulsory licensing or governmental use and proposals to waive the above obligations temporarily, voluntary sharing of IPRs by IP holders and promotion of sharing by international organizations; 6) international initiatives to support Research and Development (R&D) and equitable access to the technologies relating to the COVID-19 pandemic, such as the global sharing of genetic sequences of viral samples and governments' investment; 7) regulatory responses to encourage use, sale of medical products and enforcement of clinical trials; 8) ensuring transparency by collecting and sharing of information regarding the above-mentioned issues. The report sorts country / regional measures to the above category and 9) tries to provide a view.

Against the backdrop of this landscape, the next section analyzes the activities of three international organizations and two countries making applications to use the special compulsory licensing scheme provided by the Article 31bis of the TRIPS Agreement.

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[9] For the tripartite collaboration, see, for example, WIPO (2023b).

[10] WTO, WHO & WIPO (2023). This is the updated version as of May 2023, of the version from October 2021 summarized for public understanding of the part describing the COVID-19 pandemic in the tripartite report published in 2020 (WTO, WHO and WIPO (2020).

III. Infectious Disease Control Measures towards COVID-19 and International Trade

III-1. Measures on the international face

III-1-1. WTO, WHO and WIPO

The WTO, WHO and WIPO have developed activities alongside their coherent roles and in parallel, made them functional as part of their tripartite activity.

The WHO has established the ACT-Accelerator and COVAX as its one pillar to develop, produce, and procure the COVID-19 vaccine, by evolving the network among various actors contributing to the improvement of access to medicine since the 1990s. By May 2023, COVAX had allocated 20 billion doses of COVID-19 vaccines to 92 Advance Market Commitment (AMC) countries which have received vaccines in support by international fund procurement. Furthermore, COVAX enforced special vaccination programs in 34 countries in which vaccination was specifically delayed and drove their vaccination rate from 4% in January 2022 up to 28% in May 2023. By the end of 2023, COVAX's activities had moved towards a form that member states had agreed upon[11].

To date, the above-mentioned global procurement of the COVID-19 vaccine by COVAX and bilateral deals / donations[12] between governments and vaccine manufacturers have provided 13.4 billion doses of vaccines worldwide[13]. Approximately 70% of the world's population completed at least one vaccination, and a substantial number have acquired immunity through infection. On the other hand, a certain number have been left yet behind at infectious risk, unevenly distributed in low-income and lower-middle- income countries. The coverage of the primary series of COVID-19 vaccination is 76% at high-income countries, and in contrast, 27% in lower-income countries[14], 52% among health workers and 35% in older population[15]; obviously, risk has clearly remained. Furthermore, there is also a risk for the data preservation. Some governments, particularly those of high-income countries who made progress on immunization, have changed their policy on the collection and reporting data on the number of infectious people, inspection and hospitalization. In accordance with it, understanding the infection status becomes relatively difficult both domestically and internationally, and besides all that many information sharing systems provided by international

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[11] WHO, *supra* footnote 1, p.10.

[12] Government-to-government donations are categorized as donations from vaccine manufacturers to recipient governments in the IMF-WHO COVID-19 Vaccine Tracker, that the IMF and WHO had jointly provided detailed information on the origin of procured vaccines. See IMF-WHO (2023).

[13] WHO (2023d), p.2.

[14] *Ibid*.

[15] WHO, *supra* footnote 1, p.2.

organizations like WHO and United Nations Development Programme (UNDP) have stopped updating[16]. Responding to this trend, WHO recommends member states to continuously adopt strong data collection and reporting systems[17].

Apart from the issue of weakened data collection and reporting systems, global sharing and analysis of the above-mentioned data by many international organizations themselves were one of the fruits of worldwide countermeasures. For example, WIPO has collected information on not only preferential / exemptional measures on the application / examination procedure of IPRs by governments but also legal measures such as governmental use or compulsory licensing and voluntary declaration by IPR holders to provide their IPRs use or not to enforce their rights to third parties' use.

In addition, since 2020, the MPP has also watched patent application / registration activity relating to the medical products available to fight with the COVID-19 pandemic and made them public through their existing database "Meds-Pal". MPP was established in 2010 under the UNITAID, which was set up by part of the WHO member countries in 2006. Also, MPP has succeeded in concluding voluntary licensing agreements with multiple patent holders on several therapeutic medicines like Remdesivir and Molnupiravir. These agreements gave many developing countries, including Bangladesh that permitted to waive the patent protection obliged by TRIPS Agreement as a Least Developed Countries (LDCs), submission making it possible to produce, sale and export the generic medicines. On the other hand, C-TAP[18], established as an IPR pool towards the COVID-19 pandemic in April 2020, earlier than MPP's response to COVID-19, has acquired little participation from governments and IPR holders and has not substantially operated.

Finally, the WTO has received notifications from governments on their trade measures aiming to deal with the pandemic and made them open through its website[19]. Governments have deployed measures both trade-restrictive like tariff hikes and quantitative restriction or bans on import/export, and trade-facilitating such as tariff reductions and cost / burden reductions of customs procedures. According to the analysis of the WTO Secretariat, trade-restrictive measures have been gradually withdrawn, and, at the point of December 2022, governments of WTO member states and observers took 443 such measures on trade in goods, with the ratio of trade-restrictive versus facilitating scored 44% and 56%.

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[16] For example, COVID-19 Vaccine Tracker (*supra* footnote 11) had come to a standstill at the end of August 2022 and we cannot grasp the recent origin of procured vaccines and their volumes etc. UNEP (2023) has also been stopped. Continuously updated sites, e.g., UNICEF (2023), are very few.

[17] WHO, *supra* footnote 1, p.7.

[18] For the C-TAP, including its relationship between WHO and ACT-Accelerator, see KATO, A. *supra* footnote 2, p.172.

[19] WIPO, *supra* footnote 9, p.9. See also the columns titled as "COVID-19 and Trade" in *the Reports on Compliance by Major Trading Partners with Trade Agreements*, published after 2020 by the Ministry of Economy, Trade and Industry.

III-1-2. Proposal to waive worldwide the obligations to the protection of IPRs

Despite the above-mentioned activities, it is difficult to evaluate that the global procurement of medical products needed to deal with the pandemic has made progress in time and effectively responding to the pandemic. Especially from 2020 to 2021, during the global emergency, the scarcity of such products had already been apparent[20]. This shortage derived an argument that insisted to regard these products, and furthermore, the IPRs of the products, as global public goods[21]. In October 2020, India and South Africa jointly proposed to the WTO TRIPS Council a draft decision to waive the obligations of the TRIPS Agreement to protect IPRs regarding medical products if they are necessary to deal with COVID-19 pandemic. At that time, the development and market approval of COVID-19 vaccine had been pushed forwarded in an unprecedently short period. Governments with economic power had concluded buy-out agreements and global procurement by COVAX had stagnated. Resultantly, most Low and middle income countries (LMICs) agreed to the proposal. Developed countries persuaded that not the IPR protection but the structure of vaccine manufacturing and distributing must be discussed and arouse controversy at the Council. It is also noteworthy that, different from the case of therapeutic medicines available for COVID-19, vaccine developers holding the IPRs hesitated to give voluntary licenses to third party. Behind the trend are the fact that, a large part of IPRs remains under long period of patent protection in each country / region for certain, or, in case that the IPs were applied, they are so fresh and innovative that they have not reached to 18 months from patent application and are not subject to the laid-open publication. Furthermore, they had to select the dealing partners carefully regarding mRNA vaccine especially because the products require a cold chain in stock and transportation.

In the first half of 2022, India, South Africa, the US and the EU had intensive and closed negotiations on the proposal, with hearings from their domestic industries / academia. The outcome draft decision was discussed at the TRIPS Council meetings and afterward at the WTO 12th Ministerial Conference in June 2022. Below is the text adopted in the Ministerial Decision on the TRIPS Agreement[22], permitting the waiver for developing countries from obligations on the patent rights protection regarding COVID-19 vaccines for 5 years after adoption, meaning until June 2027.

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[20] About the first half of 2021, see KATO, A. (2021b), p.170.

[21] Nickerson, J. W. & Herder, M. (2020) criticized the recent approach as one that permits publicly invested IPs to be privately owned and insisted that COVID-19 vaccines should be treated as global public goods. They mentioned the details of the Canadian case on the development of Ebola vaccine and listed policy options: inserting a contract clause copying the march-in-right clause; exploring the potential availability of a newly legislated compulsory licensing clause on patent rights, and more, the possibility to extend its subject to manufacturing know-how, as a threat and pressure for voluntary licensing by vaccine manufacturers. Hein, W. (2020) etc. also considered the applicability of the global public goods.

[22] WTO (2022).

Ministerial Conference
Twelfth Session
Geneva, 12-15 June 2022

MINISTERIAL DECISION ON THE TRIPS AGREEMENT
ADOPTED ON 17 JUNE 2022

The Ministerial Conference,
Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization;
Noting the exceptional circumstances of the COVID-19 pandemic;
Decides as follows:

1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member[23] 1 may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of the subject matter of a patent[24] 2 required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.
2. For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.
3. Members agree on the following clarifications and waiver for eligible Members to authorize the use of the subject matter of a patent in accordance with paragraphs 1 and 2:
   (a) An eligible Member need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder as set out in Article 31(b).

[23] For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.

[24] For the purpose of this Decision, it is understood that the 'subject matter of a patent' includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine.

(b) An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members, including through international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.

(c) Eligible Members shall undertake all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with this Decision that have been imported into their territories under this Decision.[25] Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.

(d) Determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate remuneration in these cases, eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances.[26]

4. Recognizing the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.

5. For purposes of transparency, as soon as possible after the adoption of the measure, an eligible Member shall communicate to the Council for TRIPS any measure related to the implementation of this Decision, including the granting of an authorization.[27]

6. An eligible Member may apply the provisions of this Decision until 5 years from the date of this Decision. The General Council may extend such a period taking into consideration the exceptional circumstances of the COVID-19 pandemic. The General Council will review annually the operation of this Decision.

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[25] In exceptional circumstances, an eligible Member may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes, as long as the eligible Member communicates in accordance with paragraph 5.

[26] This includes the remuneration aspects of the WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation (2020) (WTO, WHO & WIPO (2020)), and the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1) (Love, J. (2005)).

[27] The information provided shall include the name and address of the authorized entity, the product(s) for which the authorization has been granted and the duration of the authorization. The quantity(ies) for which the authorization has been granted and the country(ies) to which the product(s) is(are) to be supplied shall be notified as soon as possible after the information is available.

7. Members shall not challenge any measures taken in conformity with this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994.
8. No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.
9. This Decision is without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice to their rights and obligations under the TRIPS Agreement, except as otherwise provided for in paragraph 3(b). For greater certainty, this Decision is without prejudice to the interpretation of the above-mentioned flexibilities, rights and obligations outside the scope of this Decision.

This decision establishes a system like the special compulsory licensing system provided by Article 31bis of the TRIPS Agreement, as to, for example, the duty to notify its intention to use the system to WTO Secretariat. Compared with the first proposal by India and South Africa, most critical feature of the adopted decision is the limitation to the "patent rights" concerning "COVID-19 vaccines" as the subject matter of compulsory licensing. The 8th paragraph of the decision says that whether to extend to other IPRs of other products or not will be discussed and decided within 6 months following the adoption of this decision; however, it has not yet been decided even in April 2024. In September 2023, member states discussed this issue in a regular meeting of the TRIPS Council, and at an irregular meeting held in October, the delegate of the US government introduced a summary of the United States Trade Representative (USTR) report[28], including a domestic investigation conducted by the United States International Trade Commission (USITC). In addition, the above Ministerial decision differs from the primary proposal in that it clearly permits the re-exportation of the generic products manufactured under compulsory licensing to other member states to the extent needed to combat the COVID-19 pandemic.

Initially, voluntary licensing agreements concluded between the MPP and IPR holders have made it possible for pharmaceutical industry in developing countries to manufacture, sell, and export some of the therapeutic medicines for COVID-19. In addition, this decision made it possible for them to do so with the COVID-19 vaccine too with no fear and cost of infringement. Responding to this, several developing countries which have domestic pharmaceutical industry and have exported generic products to the world could actively manufacture, sell and export COVID-19 vaccines commissioned by patent holder (India[29]) or through domestic R&D (China, India). On the other hand, there exists also several countries that even

[28] USITC (2023).

[29] Relating to the response of India towards medical products including COVID-19 vaccines, see KATO, A. et al. (2022).

have their domestic industry but not dealing with manufacturing of the vaccines. For example, Bangladesh[30] is one of the LDCs which are exempted from the obligations to protect IPRs under the transition period provided by the TRIPS Agreement Art. 66. In recent years, Bangladesh has acquired economic power over the UN standard of LDCs, and the UN agency recommends its "graduation" from LDCs in 2026. Pharmaceutical industry of Bangladesh fulfills almost all the domestic demand and export their generics to many countries / regions, including developed countries. However, procurement of the COVID-19 vaccine by Bangladesh has relied on COVAX (45%), bilateral deals such as Bangladesh pharmaceutical companies acquired Indian vaccines through purchase and delivered them to the government of Bangladesh (24%), and bilateral donations (7%), and the government of Bangladesh has not bought domestically produced vaccine at all (based on the data until the end of August 2022 by the WHO & International Monetary Fund (IMF)). Bangladesh has been a typical case among developing countries and until recently most COVID-19 vaccines have been provided by the EU, U.S., India, China, and Russia[31]. However, in the face of an extreme spread of infection within their territory in upper half of 2021, India made the shift to domestic provision and from April to September 2021 banned exportation notwithstanding bilateral or multilateral through the COVAX. As a result, the government of Bangladesh had no choice but depend on bilateral deal of Chinese vaccines and bilateral donations, including bilateral donations of Pfizer vaccines that the U.S. government designated which countries will receive, and the provision of vaccines to their people had been delayed seriously. The policy change in India had a huge effect on vaccine procurement of COVAX and made a cause of delay of the spread among developing worlds.

III-2. Utilization of the TRIPS flexibility on the County / Region face

Articles of the TRIPS Agreement aiming to permit member states to make the exemptions and limitations to the obliged IPRs protection have been understood as the "TRIPS flexibility," in line with the progress of the access to medicine discussions since 1990s. In the fight with the COVID-19 pandemic, governments have taken measures referred as several types of "flexibility" as shown below, closely linked to the above-mentioned global discussions and exercises, to procure needed medical products.

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[30] Why Bangladesh had not tried to manufacture COVID-19 vaccines domestically under the TRIPS transitional waiver from IPRs protection would have occurred in the context of the fact that the country had been subject to vaccine diplomacy from both of India and China. Most recently, Bangladesh has tackled to build their capacity necessary to provide their medical products domestically and for developing countries. Bangladesh is also one of the candidates scheduled to protect IPRs in line with TRIPS minimum standards corresponding to their graduation from LDCs; therefore, it is a noticeable case. See KATO A. et al. (2023).

[31] Based on data until the end of May 2022, the counties / regions manufacturing COVID-19 vaccines and their ratios of exported vaccine volume / total volume are 1) EU (39.0%), 2) China (32.2%), 3) U.S. (15.7%), 4) South Korea (3.9%), 5) India (2.3%), 6) South Africa (1.8%), 7) Russia (1.7%), 8) Japan (1.1%), and others (1.8%). See WTO-IMF (2023).

III-2-1. Governmental Use of IPRs

One such "flexibility" is the so-called "governmental use" which makes it possible for government agencies to use the IPRs of the medical products to deal with, for example, public health emergency like the COVID-19 pandemic. Not long after the outbreak of the pandemic, several developed countries including Germany, France and Canada enacted emergency legislations[32]. Some of them supplement or revise existing laws and others were incorporated into their legal systems as perpetual. Learned from the terrorism by anthrax in 2001, the U.S. has situated public health policy as a pillar of national security and permitted the use of IPRs regarding the development, manufacture and procurement of medical products for the pandemic by federal laws. Israel admitted the effectiveness of Kaletra (lopinavir / ritonavir) of Abbott Laboratories in the therapy of not only HIV/AIDS, etc., but also COVID-19, and give the governmental use license to import Indian generic medicine. It could be said that in these countries the relationship between the policy of infectious disease control, trade and intellectual property has become sophisticated. In contrast, few developing countries have taken the above-mentioned measure and the disparity between these country groups would have expanded.

III-2-2. Compulsory Licensing system

Compulsory licensing is another type of "flexibility," in common with governmental use at the point that governments put certain limitations on a part of the right to business of IPR holders. On the other hand, both are different from the point that, under the compulsory licensing, governments give the license to use IPRs to a third person not permitted by IPR holders. In the COVID-19 pandemic, several governments gave the license on the Remdesivir of Gilead Sciences, aware as the effective therapeutic medicine and anti-retroviral medicines[33].

Article 31 of the TRIPS Agreement establishes many conditions on the authorization of compulsory licensing, for example, the requirement on the consultation for the voluntary licensing between the patent holder and a third party demanding licensing in advance of the application to the government (clause (b), the obligation would be exemplified in case of emergency or correction of unfair competition); the principle of domestic consumption meaning that generic products under the license shall be provided mainly within the territory (clause (f)). Furthermore, to solve the issue that these conditions would disrupt the deals between the exporting member and the importing member which does not have a sufficient pharmaceuti-

[32] The cases mentioned below are cited by WIPO, *supra* footnote 9, pp.11-12; KATO, *supra* footnote 2, p.170; WIPO (2023a), collecting and publishing the measures by each country / region.

[33] Compulsory licenses were given by Russia for domestic manufacturing and sales, Hungary and Italy for the importation of Indian generic pharmaceuticals.

cal industry to provide generic medicines domestically under compulsory licensing, in 2005 member countries adopted Protocol amending the TRIPS Agreement (in effect in 2017) and established a special compulsory licensing system under Article 31bis. In the COVID-19 pandemic, Antigua & Barbuda and Bolivia had applied to use this system, however, not succeeded yet.

Two countries joined to the WTO as original members. On May 12, 2021, Antigua & Barbuda ratified the Protocol and notified its intention to use the system under Article 31bis[34]. Bolivia, which had already ratified the Protocol on January 30, 2018, made first notification to use it on February 17, 2021[35]. On May 10, 2021, Bolivia sent a second notification explaining that it had prepared to give compulsory licensing since it needed approximately 150 million doses of COVID-19 vaccine[36].

(1) Antigua & Barbuda

Antigua & Barbuda has 97,000 people in spanned 4.4 million square meters, the same as the Tanega-Shima island of Japan, and still one of the members of the Commonwealth Nations despite its independence from British self-governing territory in 1981[37]. Antigua & Barbuda had experienced three infection waves from February to March, July to October of 2021 and December to January 2022. Until July 5, 2023, infection cases of the country have counted 9,106, equating to 10% of its population, and 146 have died[38]. To complete the first vaccination to the population, excluding people who cannot inject by health condition and don't wish to do so, it required 194 thousand doses[39]. It had procured 250 thousand doses, meaning 258% of its population[40]. 60% of these doses were provided by bilateral donations, 24% by COVAX, and 16% by other sources (see Figure 1). From February 2021 to August 2022, it had received 9 times bilateral donations; 3 times of British AstraZeneca vaccine, 3 times of U.S. Pfizer, 1 time of Chinese Sinopharm, Indian SII and Russian Sputnik-V vaccine. On the other hand, there is no record of bilateral business deal and domestic supply in the country. It is also unique that the country had not taken any trade measures addressing to vaccine procurement[41].

Has the immunization in Antigua & Barbuda made substantial progress? 63.7% of the

[34] WTO (2021e). Antigua & Barbuda, same as Bolivia, had been obliged to notify the kind, figure, volume and IPRs information relating to the vaccine to the WTO.

[35] WTO (2021b).

[36] Refer to the notification by Bolivia (WTO (2021c)) and WTO news on this notification (WTO (2021d)).

[37] See Ministry of Foreign Affairs (2021).

[38] See the Country Data of WHO (2023a).

[39] Here presumes that all the first vaccinations used the kind of vaccine which completes the first vaccination with two injections. Below is based on the same presumption. WTO (2023a).

[40] Author extracted from the IMF-WHO COVID-19 Vaccine Tracker and figured.

[41] WTO (2023a).

population has completed the first vaccination[42], however, only 10.05% has done their first booster vaccination[43]. These numbers show that the first vaccination has consumed less than 124 thousand doses and booster vaccination has done 10 thousand, suggesting that approximately 116 thousand have been left unused. Apart from the success of vaccine procurement, the issue of enough immunization using the fully the procured vaccine is left unresolved. In addition, when Organization of East Caribbean Countries (OECS), of which Antigua & Barbuda is one of the members, reviewed their trade policy at the WTO Trade Policy Review Mechanism (TPRM), it appeared that no mention was made as to the procurement of medical products for the COVID-19 pandemic or application for the use of special compulsory licensing[44].

(2) Bolivia

In Bolivia, until July 19, 2023, 1.2 million people, equating to a tenth of one of 11.51 million nationals living in about three times larger than Japan, have been infected with COVID-19 and 2.2 thousand people died. Until the end of August of 2022, the country had procured the vaccine through the bilateral deals (39%), bilateral donations (15%) and COVAX (46%) (see Figure 2). Bilateral deals from the end of December of 2020 to May 2021 were taken 3 times on 1.17 million doses from Russia and China. A part of these deals was overlapped with 6 bilateral donations of 4.65 million doses from February to December of 2021, containing of 4 times of Chinese Sinopharm and 2 times of British AstraZeneca. Adding 1.367 million doses by COVAX, total procurement reached 30 million doses. Same as Antigua & Barbuda, Bolivia has no record of domestic procurement. Different from Antigua & Barbuda, Bolivia had taken measures temporarily eliminating the import tax for the COVID-19 vaccine and some medical products[45].

On the use of the procured vaccine, as of June 1, 2023, Bolivia had implemented inoculation of 1.6 million doses, covering 137.21% of its population. At that point, 6.3 million nationals had completed the first vaccination (53.9%) and 2.49 million nations done booster vaccination (21.3%). Same as Antigua & Barbuda, Bolivia is reminded of the low rate of booster vaccination.

The application by both countries to use the special compulsory licensing scheme started at the beginning of 2021. Parallel to these applications, WTO members had discussed TRIPS waiver proposed by India and South Africa, and Bolivia stepped forward as one of joint pro-

[42] Given that every vaccine is different in terms of the completion of initial immunization by one or two injections, we cannot directly know the volume of consumed vaccine from vaccination rates.

[43] IMF-WHO (2023), *supra* footnote 39.

[44] WTO (2023b); WTO (2023c); WTO (2023d); WTO (2023e).

[45] WTO, *supra* footnote 41.

posers of it. Responding to the questionnaire by developed countries expressing skepticism about effectiveness of proposed waiver, Bolivia provided an answer persuading that existing TRIPS flexibility could not provide significant measures to the pandemic[46]. Bolivia had negotiated with Canadian pharmaceutical company Biolyse on the vaccine manufacturing and provision and exchanged draft contracts. Until that time, Biolyse had asked Johnson & Johnson (J&J) to give it voluntary licensing. In case that the government of Canada gave compulsory licensing to Biolyse on the Canadian patent rights of J&J, Biolyse could manufacture generic vaccines. Canadian Patent Law has the compulsory licensing system (CAMR) to domestically implement Article 31bis of the TRIPS Agreement[47]. CAMR requires approval by the government of Canada in advance to manufacture the medicine under the license. Biolyse, researchers and influential individuals had asked the government to approve it[48], however, the government of Canada has not accommodated the request, and vaccine deal between Bolivia and Biolyse has not been realized yet[49].

The Bolivian case shows again the difficulty in using the special compulsory licensing system. Bolivia, like Antigua & Barbuda, has fulfilled the doses for the first vaccination with increased bilateral donations and allocation of COVAX; however, delayed countermeasures inevitably made the loss of many lives.

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[46] WTO (2021a).

[47] Regarding the CAMR, see KATO (2004).

[48] Biolys pharma (2021): BioNiagara (2021).

[49] Brown S. & Rosier, M. note that notwithstanding that since the 1990s Canada has adopted global health under multilateralism as one of its diplomacies, in the face of the COVID-19 pandemic, Canada has prioritized domestic procurement and concluded bilateral agreements, provided monetary funding to COVAX and procured Indian and English vaccines, resulted in much redundant vaccine. They also write that the reason why it has not accepted the requirement by Biolys based on the special compulsory licensing system, despite expectations of a return to Canadian manufacturing. See Brown, S. & Rosier, M. (2022), pp.228-231, pp.236-238.

Figure 1 Origin of the COVID-19 vaccine procured by Antigua & Barbuda

(million dose)

	total	Bilateral Deal	Bilateral Donation	COVAX total	EU Deal	Other sources	Domestic supply
Antigua Barbuda	0.250000	0	0.15	0.06	**0**	0.04	0
	%	-	60	24	-	16	-

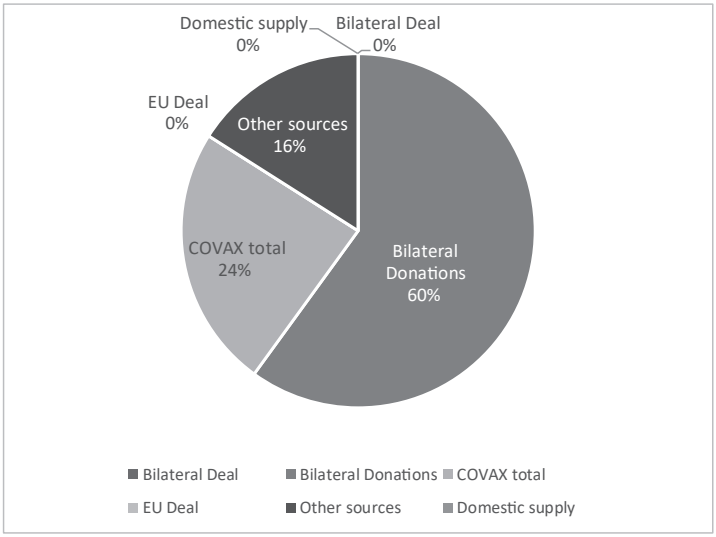
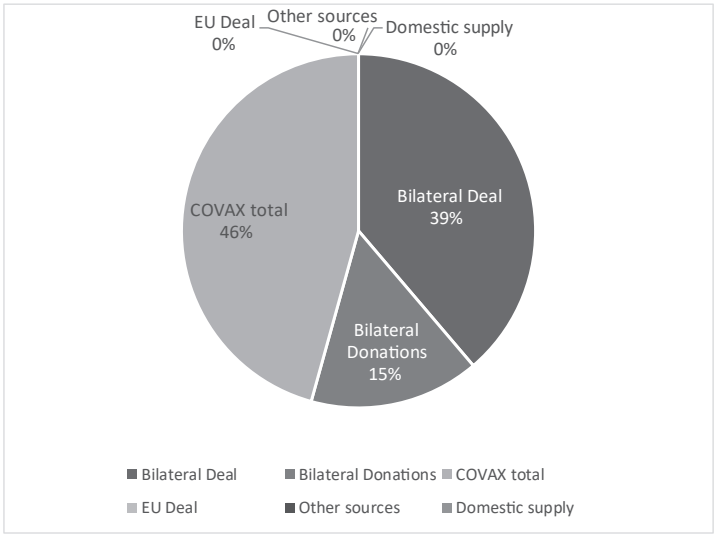


Figure 2 Origin of the COVID-19 vaccine procured by Bolivia

(million dose)

	total	Bilateral Deal	Bilateral Donation	COVAX total	EU Deal	Other sources	Domestic supply
Bolivia	30	11.6	4.65	13.67	0	0	0
	%	38.64	15.49	45.54	-	-	-



*Reference: Author extracted data from the IMF-WHO COVID-19 Vaccine Tracker[50] and created the figure.

[50] IMF-WHO (2023).

IV. Discussions - What is the obligation of governments?

Clearly, COVID-19 pandemic is the most recent public health emergency, and governments must protect the right to health of both their nationals and people worldwide alongside to correct the negative aspects of vaccine diplomacy and vaccine nationalism and to reach global infection inhibition.

Firstly, the use of IPRs by governments and the compulsory licensing system are established based on market division provided by the principles of territoriality and the independence of each IPRs per countries and the TRIPS Agreement also adapts these premises. However, as seen in COVID-19, global pandemic makes the phenomenon in which fulfilling one area's demand leads to others' scarcity and results in a scramble for medical products. For that reason, EU, for example, has begun to discuss a regional compulsory licensing system, making it possible to ask for a license available in the whole area and on all IPRs related to the product[51]. Now it is pointed out that the existing international trading system like the Article 31bis of the TRIPS Agreement is difficult to use in reality. Therefore, it is not appropriate to evaluate this regional system inherent to the EU, as the entity that have finally enforced a unitary patent system after a long-standing discussion.

Furthermore, we have witnessed many legislative proposals extending in and out of the IPR system. Correa writes that regarding IPRs of the essential medical products for the pandemic as a global public good requires change of existing R&D models and re-interpretation and/or revision of the TRIPS Agreement[52]. Accordingly, the waiver of IPR protection, as mentioned above, would figure out one but incomplete step and there should be another step prepared, e.g., the use of IPRs for national security, admitted by Article 73 of the TRIPS. Dreyfuss shares with Correa the awareness that compulsory licensing is not effective for a global pandemic and proposes a general exemption to the protection of trade secrets[53]. The need for this exemption is increasingly pointed out domestically and internationally, however, it has not yet been introduced systematically. She persuades also that the COVAX system is not enough to expeditiously proliferate vaccines to developing countries and that bold proposals such as governments' obligation of annual expenditure for securing revenue and the manufacturers' obligation of contribution for securing products are important. We should not hesitate to get out various proposals, including the above-mentioned legislative ones, on the negotiating table to find appropriate measures for the next pandemic.

Secondly, it should be explored to foster industries relating to pharmaceutical products in minimum at each country / region, in normal times when supply and demand is certainly

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[51] European Commission (2023).

[52] Correa, C. M. (2021). For the relationship between COVID-19 pandemic and exception of national security, see Abe (2023).

[53] Dreyfuss, R. C. (2022).

balanced under functioning of the international labor division, supply chain and good neighboring relationship among countries, and in emergency times of public health, to establish the capacity to be able to manufacture these products through optimizing the system and resources prepared in normal times and receiving international technology transfer[54]. One of the initial trials is sharing technological information including not only patents but also know-how, through the C-TAP scheme. Firstly U.S. NIH, and later, vaccine manufacturers, Spanish national research institute and University of Chile, have provided based on the voluntary licensing agreement with MPP[55]. In addition, since 2021, focusing on the technology transfer to developing world regarding mRNA vaccine, on which voluntary licensing has been quite limited, WHO and part of its member countries have invested and prepared to establish an institute for manufacturing and technical training. In August 2022, WHO announced that this institute was scheduled to enforce technology transfer to 15 countries[56]. These trials reflect the academic discourse on the access to medicine issue like above-mentioned proposals and researchers' long-standing analysis provided by, for example, Reichman[57] or Drahos[58], and even part of their considerably legislative arguments has been expeditiously incorporated and realized. Japan, that has failed to develop effective therapeutic medicines or vaccines expeditiously in face of COVID-19 pandemic, is not totally unrelated to these trials. Several Japanese companies have engaged to receive technology transfer relating to COVID-19 vaccine by foreign initial companies, manufacture and export their own products[59], and others have succeeded to develop, manufacture and receive marketing approval by governmental authority on vaccine[60], or develop and manufacture therapeutic medicine and conclude voluntary licensing agreement with MPP permitting to manufacture and export the medicine to developing countries[61]. In support of these private engagements, Japanese government is required to make and implement the policy on the cooperation between industry-government-academia and join in an affirmative way to the discussion on the full application of the Article 31 and 31bis schemes of the TRIPS Agreement, and if not enough, reformation of surrounding inter-

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[54] This perception is not only limited to the industries surrounding medical products. For example, one expert in the apparel industry notes that due to its highly globalized characteristics, it has become more than likely that trade measures provided by countries / regions in emergencies would create significant influence on national industries, the risk of too much globalization, the need to enhance the supply chain and to nationalize the production of the core materials have been widely recognized. See Kagiyama (2022) p.45.

[55] WHO (2023e).

[56] KATO, A. (2024) supra note 7, p.19. Countries subject to the technology transfer are Argentina, Bangladesh, Brazil, Egypt, India, Indonesia, Kenya, Nigeria, Pakistan, Serbia, Senegal, South Africa, Tunisia, Ukraine, Vietnam.

[57] Reichman J. H. (2022).

[58] Drahos, P. (2022).

[59] Takeda Pharmaceutical Company Limited has imported and distributed the mRNA vaccine made by Moderna, Inc. Furthermore, Takeda has received technology transfer from U.S., Novavax Inc., with a concluding voluntary licensing agreement and after getting marketing approval, began sales. See Takeda Pharmaceutical Company Limited (2022) and Ministry of Health, Labour and Welfare (2022).

[60] NHK (2023); Medicines Patent Pool (2022).

[61] Shionogi & Co., Ltd. (2023).

national scheme[62].

Thirdly, it is required as preparing for next pandemic, with organically combining these components and improving, developing the functions of COVAX and MPP sparked under COVID-19 pandemic, to establish international scheme covering from conducting the development, manufacturing, allocating needed medical products to dealing with relating IPRs. To propel the preparation, it is worth noting that WHO members have negotiated on the international covenant (so-called pandemic treaty) before and after the World Health Assembly (WHA) in May to June 2024.

Finally, it is also required to revisit legal obligations of governments with regard to infectious diseases control and corresponding access to medicine issue in international trade. This discussion will ask for the integrated approach on human rights, especially right to health, extending to personal self-determination of with or without vaccination and selection of the vaccine kinds. We witness the emergence of this approach[63] that is expected to be well explored in near future.

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[62] One of the issues to be discussed is whether Article 93 of the Japanese Patent Law and "Guideline for enforcing adjudicative licensing system" are enough as to use the special compulsory licensing system under Article 31bis of TRIPS Agreement as the exporting member or not. Many member countries like Canada and India have already taken legal measures to implement this system. Furthermore, it is truly fortunate that Japan has not faced with the status to use that system as an importing member in the COVID-19 pandemic because it had already made legal declaration not to use it as an importing member, along with other developed country members, at the General Council Decision in 2005 that made this system available prior to the effectuation in 2017 of the Protocol amending the TRIPS Agreement (see footnote 3 of WTO(2005)). Reminding Japanese situation, author agrees to some commentators who brought up this declaration as the risk of the national security (Dreyfuss (2022) etc.).

[63] Singh, J.A. (2022) mentions this approach in brief.

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