

# Special theme: from Labs to Jobs: ensuring access and equity in Covid-19 vaccination

## SOLIDARITY AS A PRACTICAL CRAFT: COHESION AND COOPERATION IN LEVERAGING ACCESS TO MEDICAL TECHNOLOGIES WITHIN AND BEYOND THE TRIPS AGREEMENT \*

*Antony Taubman*

Email: antony.taubman@wto.org

The COVID-19 pandemic has precipitated an unprecedented call for global solidarity, which has included a proposal to waive key obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights. The governance of intellectual property in a global health crisis entails consideration of the effective and coordinated agency of domestic governments to foster solidarity through practical action. This paper presents the context for solidarity while taking in consideration its practical operation by focusing on the mechanism of interaction between the intellectual property system and access to medicines, historically and during the pandemic: authorization of the use of patented subject matter without right holders' consent.

*Keywords:* COVID-19, vaccines, public health, TRIPS Agreement, intellectual property.

*JEL classification:* O38, I14, H87

---

\* This article was written in the author's personal capacity and does not present any views or interpretations that can or should be attributed to the WTO, its members or its secretariat.

## **I. INTRODUCTION: GLOBAL SOLIDARITY AND INTERNATIONAL GOVERNANCE OF INTELLECTUAL PROPERTY IN A PANDEMIC**

The devastating COVID-19 pandemic has resulted in a crisis in global governance and international cooperation, as well as posing a direct, and at times overwhelming, challenge for individual governments. Calls for global solidarity,<sup>1</sup> and enormous efforts to promote a connected and effective international response has competed with the inevitable pragmatic political impulses termed as “vaccine nationalism” (Bollyky and Bown, 2020), the reactive prioritization of domestic over foreign needs, and constraints on the export of finished vaccines and of inputs for vaccine production (WTO, 2021). Given the direct linkage between access to vaccines in particular and societies’ capacity to contain and ultimately overcome the social and economic impact of the pandemic (Skegg and others, 2021), the development, adaptation and dissemination of vital medical technologies – vaccines, therapeutic treatments, diagnostic tools and personal protective equipment – have been in the forefront of the national and international response. This has spurred a range of intensive debates, integrated policy analysis (WTO and others, 2022) and strong encouragement to move beyond “business as usual” to accelerate and diversify medical innovation and access to the fruits of this innovation, notably in ensuring access to vaccines (Ghebreyesus 2021). The remarkable diversity and rapidity of technological innovation is encouraging. The World Health Organization (WHO) has reported the submission of 369 candidates for vaccines at various stages of development<sup>2</sup>, and the roll-out of vaccines has occurred at an exceptional, unprecedented pace overall (Glassman, Kenny, and Yang 2022). Yet, globally, effective access to this technology – in the form of actual doses delivered – has been highly uneven and inequitable, due to a complex array of factors (WTO and others, 2022); the rate of vaccine doses received reportedly ranges from more than 225 per cent of a country’s population to a scant 2 per cent.<sup>3</sup>

The COVID-19 pandemic, therefore, has raised fundamental questions for national governments and international cooperation about the effectiveness, the timeliness and, above all, the equity of systems for innovation and for access to the fruits of innovation in necessary medical technology. These questions hinge on the operation of the intellectual property (IP) system, especially the interplay between

---

<sup>1</sup> Concretely, COVID-19 initiatives associated with WHO are the Solidarity Call for Action ([www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action](http://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action)), a number of “solidarity” clinical trials, and the COVID-19 Solidarity Response Fund ([covid19responsefund.org/en/](http://covid19responsefund.org/en/)).

<sup>2</sup> WHO, COVID-19 Vaccine Tracker (accessed 1 September 2022); Airfinity.org reports 788 candidates in all, including 552 at various stages of active development, and 236 abandoned, inactive or rejected (accessed 1 September 2022).

<sup>3</sup> UNICEF (n.d.) (“COVID-19 Market Dashboard | UNICEF Supply Division n.d.).

that system's international rules and principles and the scope of action available and the actual choices taken by governments at the domestic level. Despite the historically unprecedented creation and development, and swift regulatory approval of a suite of vaccines on diverse technological platforms,<sup>4</sup> delays in universal access and stark, seemingly structural inequities in access to medicines has prompted many governments to question the adequacy and fitness of current international IP rules in the face of a pandemic.

Calls for global solidarity in response to this unprecedented crisis are well founded: manifestly on moral (Gayle and others, 2020) and human rights grounds, accentuated in a pandemic;<sup>5</sup> on public health grounds, given the threat to all posed by continuing circulation of the SARS-CoV-2 virus and the epidemiological impact of the resultant new variants; and on economic grounds, given the devastating, and shockingly regressive, economic hardship imposed by the pandemic on individual communities, and the consequent regressive effect on those least able to shoulder the burden (Gollier, 2021).

For solidarity to have a tangible effect as a guiding principle, it must give impetus and direction to practical action. Indeed, a complex set of intricately interconnected steps must be carried out to ensure the development of new medicines, rigorous testing for safety and effectiveness, sustainable production to necessary standards, transportation across borders, distribution to diverse and remote locations with the necessary cold chain or other specialist handling, and finally dispensation, safely and proficiently, to populations in need across the globe. This set of tasks is irreducibly complex and constantly evolving. As a result of the pandemic outbreak, engineering universal access to vaccines that until recently did not exist became a global imperative, imposing pressing, and fast evolving, needs for commercial players and for governance to depart from "business as usual". While there is an overwhelming argument for government intervention to accelerate this process and to ensure it is carried out equitably, the potential range of such interventions is diverse, as is their impact – ranging from humanitarian procurement for equitable access and donations of medicines to a global redistribution of production capacity and re-engineering of production and supply chains.

Despite the realpolitik inevitability of the impulse towards vaccine nationalism, and domestically focused access policies (Emanuel and others, 2021), governments around the world generally have accepted the call to solidarity and showed support for

---

<sup>4</sup> The WHO COVID-19 Vaccine Tracker identifies 171 vaccines in clinical development, classed in 11 distinct technological platforms.

<sup>5</sup> General Assembly resolution, Global solidarity to fight the coronavirus disease 2019 (COVID-19), A/RES/74/270.

partnerships with multilateral and regional organizations and international initiatives (Bump, Friberg and Harper, 2021). Their responses continue to take shape in a global context defined by almost 200 atomistic heterogeneous nation States, which can and will take divergent choices and will not achieve uniformity in action even if they accept solidarity in principle. Undertaking urgent practical action has inevitably entailed dealing with the potential tension between responding to the compelling and immediate domestic interests and the need for coordinated, connected and mutually beneficial action internationally, measurable in terms not of political expression but of actual public health outcomes equitably delivered – in short, solidarity as a practical craft.

This paper presents the context for solidarity in responding to health crises along with how government agency can operate in practice by focusing on the mechanism that has consistently been the cynosure of debate and criticism. In considering the interaction between the IP system and access to medicines, both historically and during the pandemic, suggested pathways of authorization of the use of patented subject matter without right holders' consent are given.

## **II. THE INTERNATIONAL LEGAL FRAMEWORK FOR GLOBAL SOLIDARITY**

The imperative for global solidarity has evolved within a complex, multifaceted international legal framework comprising an array of general principles, of which two are fundamental:

- The recognition within the framework of human rights law that “access to medicine is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health<sup>6</sup>;
- The principles, enshrined in the Constitution of WHO, that “[t]he achievement of any State in the promotion and protection of health is of value to all” and that “[u]nequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger”.<sup>7</sup>

---

<sup>6</sup> Human Rights Council Resolution A/HRC/RES/12/24, Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 12 October 2009.

<sup>7</sup> Constitution of the World Health Organisation, adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 (Off. Rec. World Health Organization., 2, 100), entered into force 7 April 1948.

The severe and inequitable impact of the COVID-19 pandemic demonstrates the practical context of these bedrock principles. Their aspirational, seemingly idealistic, character is in fact underpinned by realist and pragmatic qualities, pivoting on the obligation of governments to actively safeguard and promote public health of the populations they are responsible for, including through access to medicine, their responsibility to cooperate internationally in achieving this, and their ultimate self interest in doing so. Hence, in April 2020, the General Assembly framed the international response to the pandemic in terms of resolutions on global solidarity<sup>8</sup> and international cooperation on access to medicines.<sup>9</sup> Similarly, the World Health Assembly followed up with resolutions on the response to COVID-19<sup>10</sup> and on preparedness for health emergencies<sup>11</sup>, which underscored the need for cooperation and collaboration in the spirit of unity and solidarity. Later, as the development of COVID-19 vaccines showed promise but sparked concerns about uneven access, in March 2021 the Human Rights Council called upon “States and other relevant stakeholders to take appropriate measures to guarantee the fair, transparent, equitable, efficient, universal and timely access and distribution of safe, quality, efficacious, effective, accessible and affordable COVID-19 vaccines and to enable international cooperation” and called for “intensified international cooperation and solidarity to contain, mitigate and overcome the pandemic and its consequences.”<sup>12</sup>

For these general principles and calls for action, the normative context can be found within numerous overlapping and intersecting multilateral and regional international legal instruments that have bearing on public health, domestic law and policy, and their practical implementation through programmes and policies in a host of diverse fields, including regulation, trade policy and IP (WHO, WIPO and WTO, 2020). The specific linkages between governance of the IP system and governments’ responsibilities to promote public health were highlighted in the work of the then

---

<sup>8</sup> General Assembly resolution Global solidarity to fight the coronavirus disease 2019 (COVID-19) A/RES/74/270.

<sup>9</sup> General Assembly resolution, International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19, A/RES/74/274.

<sup>10</sup> World Health Assembly resolution, COVID-19 response, WHA73.1.

<sup>11</sup> World Health Assembly resolution, Strengthening preparedness for health emergencies: implementation of the International Health Regulations (IHR) (2005), WHA73.8.

<sup>12</sup> Human Rights Council resolution, Ensuring equitable, affordable, timely and universal access for all countries to vaccines in response to the coronavirus disease (COVID-19) pandemic,, A/HRC/46/L.25/Rev.1.

Human Rights Commission in 2000<sup>13</sup> and 2001,<sup>14</sup> and in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Most recently, in the context of the pandemic, in December 2021, the General Assembly reaffirmed:

The right of States to use, to the fullest extent, the provisions of the [TRIPS Agreement] and the flexibilities therein, as reaffirmed in the [Doha Declaration] which recognizes that intellectual property protection is important for the development of new medicines and also recognizes the concerns about its effects on prices and recognizes further that the Agreement should be interpreted and implemented in a manner supportive of the right of States to protect public health, in particular to promote access to medicines for all, to facilitate access for all to COVID-19 vaccines and to bolster coordination, including with the private sector, towards the rapid development, manufacturing and distribution of vaccines, while adhering to the objectives of transparency, efficacy, safety, equity, accessibility and affordability.<sup>15</sup>

The critical link between access to technologies and the public health response was evident in the Solidarity Call to Action under the aegis of WHO, which aimed at “equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data”<sup>16</sup> and envisaged action “to promote innovation, remove barriers, and facilitate open sharing of knowledge, intellectual property and data necessary for COVID-19 detection, prevention, treatment and response, including through national legal and policy measures, and international collaboration on regulatory practices, to ensure availability, affordability and assured-quality of the concerned products.” Health innovation and access to medical technologies were aligned with target 3b of Sustainable Development Goal 3, specifically to “support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines” in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirmed the right of developing countries to use flexibilities under the WTO Trade-Related Aspects of Intellectual Property Right Agreement (TRIPS Agreement) to protect public health and to provide access to medicines for all”.

---

<sup>13</sup> United Nations Economic and Social Council, Commission on Human Rights, Sub-commission on the Promotion and Protection of Human Rights (2000).

<sup>14</sup> United Nations Economic and Social Council, Commission on Human Rights, Sub-commission on the Promotion and Protection of Human Rights (2001).

<sup>15</sup> General Assembly resolution 76/175, Ensuring equitable, affordable, timely and universal access for all countries to vaccines in response to the coronavirus disease (COVID-19) pandemic.

<sup>16</sup> <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>.

Consequently, governments have a legal and moral responsibility to take action to safeguard public health through assuring equitable access to essential medicines (Rueda-Barrera, 2021; United Nations, 2021); they also have a self-interested prudential reason to do so, given the economic and social impact of the pandemic, and the virtual inevitability that untreated cases and low vaccination rates even in remote locations will spur the development of mutations of the novel coronavirus. Solidarity – an equitable and inclusive global response – is, therefore, an overarching obligation. However, achieving tangible results is a complex practical matter, involving the convergence of multiple tangible and intangible inputs, and diverse government actions that range from public financing of drug development to accelerated regulatory approval. The complex role of trade policy settings was highlighted in June 2022 by the WTO Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics.<sup>17</sup> Covering a diverse array of policy domains and exemplifying the complex interrelationship between public health outcomes and trade policy, the Declaration recognized “the role of the multilateral trading system in supporting the expansion and diversification of production of essential goods and related services needed in the fight against COVID-19 and future pandemics” and “the importance of a stable and predictable trading environment for the provision of goods and services in accordance with WTO rules to facilitate manufacturing, and supply and distribution, of COVID-19 vaccines, therapeutics, diagnostics, and other essential medical goods”

The role of the IP system was framed in the Declaration through recalling the affirmations of the Doha Declaration and recognizing that “increasing the level of global preparedness to COVID-19 and future pandemics requires strengthened productive, scientific and technological capacity across the world.” Furthermore, that capacity was recognized in the Declaration for its instrumental role in “developing solutions to public health crises beyond COVID-19, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, as well as neglected tropical diseases, and for diversifying manufacturing locations”, which underscores “the importance of promoting technology transfer that contributes to building capacity in related sectors”.

In parallel with this overarching Declaration, the WTO Decision on the TRIPS Agreement,<sup>18</sup> addressed certain aspects of the IP system, and the patent system, in particular. It was negotiated to deal with concerns that the TRIPS Agreement as it stood, as a legal text, or as it was understood and implemented in domestic IP law, potentially posed obstacles to a robust and timely response to the pandemic, especially

---

<sup>17</sup> WT/MIN(22)/31, adopted 17 June 2022.

<sup>18</sup> WT/MIN(22)/30, adopted 17 June 2022.

in ramping up and above all diversifying vaccine production as a prerequisite for more equitable access in the immediate term and greater resilience in the medium term. The Declaration confirmed and clarified the right of WTO member Governments to override patent rights through direct government authorization of the use of patented subject matter. It brought into force a targeted waiver of a provision of TRIPS to streamline urgent production of vaccines for export and to facilitate the development of dispersed production chains, especially in regions that had limited vaccine production capacity. The scope of the Decision was, however, well short of the original and revised TRIPS waiver proposal, first tabled by India and South Africa in October 2020 and subsequently co-sponsored or otherwise supported by a large number of developing countries. That proposal, if adopted, would have effectively led to a temporary suspension of TRIPS obligations for all WTO members applicable to the recognition and enforcement under their domestic laws of rights in the fields of patents, designs, copyright and undisclosed information in relation to members' response to the pandemic.<sup>19</sup>

### **III. SOLIDARITY AND TERRITORIALITY: NAVIGATING THE INTELLECTUAL PROPERTY DIMENSION**

International action on the IP dimension of the pandemic response was a widespread demand. The impact and potential roles of IP had been under close scrutiny virtually from the outset of the pandemic, given its critical role in the innovation of and access to essential technologies. At one level, attention turned to the ways in which right holders exercised the agency that their portfolios of IP rights gave them, in particular the extent to which they licensed their exclusive rights in an inclusive and humanitarian manner,<sup>20</sup> or indeed expressly to waive<sup>21</sup> their legal entitlement to exercise those rights,<sup>22</sup> as these choices help determine public health outcomes. Accordingly, the Solidarity Call for Action has directly encouraged holders of knowledge, IP and data, alongside governments, other research funders and researchers to leverage open access to IP. The COVID-19 Technology Access Pool (C-TAP) was launched in May 2020 to provide “a single global platform for the developers of COVID-19 therapeutics,

---

<sup>19</sup> WTO, TRIPS Council, Waiver from Certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 - Communication from India and South Africa, IP/C/W/669, October 6, 2020; subsequently circulated in a revised version on May 25, 2021 (IP/C/W/669 Rev.1).

<sup>20</sup> For an overview of the range of potential choices, see Taubman (2010).

<sup>21</sup> The commonly understood concept of a “waiver” of IP rights being closer to the general legal sense of “waive”, that is to “relinquish (a right, claim, or contention) either by express declaration or by doing some intentional act which by law is equivalent to this; to decline to avail oneself of (an advantage)...”, OED Online. Oxford University Press. <https://www.oed.com/view/Entry/225159>.

<sup>22</sup> See, for example, Reuters (2020).

diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data with quality-assured manufacturers through public health-driven, transparent, voluntary, non-exclusive and transparent licences” as well as “support for technology transfer agreements”.<sup>23</sup> As envisaged, voluntary licensing and patent pooling would enable patent holders to “reach new markets and scale up production using untapped capacity of manufacturers around the world, while securing appropriate royalties”.

In practice, the response was disappointing: the first technology made available under C-TAP was only licenced in November 2021, followed by 11 more, but from the one licensor, in May 2022.<sup>24</sup> In parallel, a diverse array of IP right holders pledged open licensing or non-assertion undertakings or waivers that would ease access to their IP-protected content in responding to the pandemic.<sup>25</sup> However, these initiatives – and the tardy and modest response to C-TAP – did not dispel concerns on the part of many governments that IP barriers would still impede the pandemic response, leading to probing questions about the scope, legitimacy and effectiveness of international IP rules, particularly the WTO TRIPS Agreement, especially at a time of global crisis. Accordingly, referring to the “urgent call for global solidarity, and the unhindered global sharing of technology and know-how in order that rapid responses for the handling of COVID-19 can be put in place on a real time basis”, India and South Africa tabled the proposal to “waive”, through the general WTO waiver provision,<sup>26</sup> a wide array of WTO members’ obligations under the TRIPS Agreement that set core standards for granting, defining and enforcing IP rights under their domestic legal systems:<sup>27</sup> “waiver” in this context referring to the exceptional temporary suspension of their international legal effect,<sup>28</sup> in contrast with a voluntary choice to renounce or disclaim the right to pursue a claim or interest.

---

<sup>23</sup> WHO (n.d). COVID-19 technology access pool, 2022.

<sup>24</sup> WHO, US NIH licenses to C-TAP, at <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses> (visited 6/6/2022).

<sup>25</sup> Contreras and other (2020); many pledges are listed under the WIPO COVID-19 Policy Tracker ([www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/voluntary-actions-text](http://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/voluntary-actions-text)), including the Open COVID Pledge.

<sup>26</sup> Agreement Establishing the WTO, Article IX.3.

<sup>27</sup> WTO, TRIPS Council, Waiver from Certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 - Communication from India and South Africa, IP/C/W/669, October 6, 2020; subsequently circulated in a revised version on May 25, 2021 (IP/C/W/669 Rev.1).

<sup>28</sup> The WTO Appellate Body has clarified that “the function of a waiver is to relieve a member, for a specified period of time, from a particular obligation provided for in the covered agreements, subject to the terms, conditions, justifying exceptional circumstances or policy objectives described in the waiver decision”, Appellate Body Reports, EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US), paras. 381-382.

The technical nature of the proposed TRIPS waiver was not always clearly expressed in the subsequent, widespread and urgent policy debate. At times it was characterized (by advocates and by critics) as leading directly to the cancellation of IP rights as such, or in some way bringing about a suspension of the exclusive effect of IP, possibly in a way more direct and expeditious than conventional mechanisms under domestic law. Yet to the extent to which this assumption prevailed, it risked deflecting attention from the key questions of how national governments can and should exercise their full agency most effectively in the governance of their domestic IP systems. IP rights are territorial in character, defined and governed under domestic law (and to some extent through regional systems). Adherence to or suspension of TRIPS obligations could only influence and partially define the scope for necessary action on the domestic plane. While such a waiver would be significant and pathbreaking, at best, it would only open up further options for individual governments' action, potentially also lending them political legitimacy; equally, while possibly clearing obstacles and giving momentum to a solidarity programme, the temporary absence of certain international rules could not engender a solidarity response in itself. It may open up new pathways, but governments would need to choose among them and then take the necessary steps forward, most effectively in concert with like-minded international partners.

Accordingly, the call for solidarity, when applied in practice to the management and governance of the IP dimension of the pandemic response, including at the global level, translates into questions about the action that can and should be taken by individual right holders concerning IP held in different jurisdictions, and by national governments, including legislatures, courts and other authorities. The effective agency on the part of national governments, therefore, retains the central position in the response to the pandemic, bridging between the general principles applied – or waived – at the multilateral level, and the actual governance of specific, applicable IP rights under domestic law. Waiver proposals form part of a wider consideration of the need to clarify, streamline and, if necessary, to extend, possibly in unprecedented ways, the latitude for direct government action either to encourage or more forcefully to leverage access to IP-protected technologies, or more directly to authorize and implement the suspension of the exclusive effect of IP rights. The essential controversy, then, is not whether IP rights should be “waived” or their exclusionary effect suspended under domestic law – as this is consistent with the principles and practice of IP law and its governance – but rather how, when and according to what procedural and equitable safeguards. IP rights are not absolute; it is an embedded principle – a design feature of balanced IP law, not just a safeguard or afterthought – that governments may override their exclusive effect in the public interest, including through direct

authorization of the use of patented technology for public purposes,<sup>29</sup> of which the protection of public health is an exemplary case. International law on this matter is essentially confined to setting out the broad principles and procedural safeguards that should apply in doing so, principally in the form of the TRIPS Agreement, at least at the multilateral level. The principles established and given international level effect through the TRIPS Agreement thus frame the policy space for domestic authorities to determine the actual mechanisms for overriding the exclusive effect of patent rights and the substantive grounds for giving effect to it. Hence, the 2001 Doha Declaration on the TRIPS Agreement and Public Health served to strengthen and clarify the effective agency of WTO members to apply these principles in their domestic systems in line with their right “to protect public health and, in particular, to promote access to medicines for all.”<sup>30</sup>

In the context of the pandemic response, a critical question was whether those principles were still inherently too restrictive to enable an effective and equitable response to the pandemic, or whether they impeded, delayed or frustrated the necessary response. This was the essence of the debate over the TRIPS waiver, given that no such waiver would have any immediate effect on the scope and application of actual IP rights in domestic law. And yet the question of the legitimacy and appropriateness of the existing TRIPS rules leads directly to further, equally pressing questions, which are linked to the two dimensions of national government agency. First, looking internally, what actions could and should governments take within their domestic systems, either by pushing the envelope of the existing TRIPS framework, or by making use of the wider freedom to operate that a waiver of TRIPS obligations would permit?<sup>31</sup> Second, looking externally, to what extent – and how – could such domestic measures be taken in a coordinated or connected way in order to leverage equitable global access, in line with the spirit of solidarity?

The proposal to waive TRIPS obligations was generally cast in terms of a stand-alone multilateral, international response, an outcome in its own right conceived as a means of eliminating IP barriers to access and of expressing global solidarity. This would set the waiver proposal implicitly or explicitly in contrast with self-sufficient individual action taken by governments at the domestic level, especially through the use of existing flexibilities under domestic law, which were often described

---

<sup>29</sup> The legal and policy background to this principle as developed in English law was recently elaborated by Justice Arnold – illuminatingly setting it in the context of the law of agency - in *IPCom v Vodafone* [2021] EWCA Civ 205 (discussed *infra*).

<sup>30</sup> WTO, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (November 14, 2001), 4.

<sup>31</sup> The potential range of mechanisms that a wide-ranging TRIPS waiver could make available, beyond existing options, is discussed in Mitchell, Taubman and Samlidis (2022).

as cumbersome and unwieldy. Less attention was paid to what concrete actions governments actively planned or would choose to do should they be freed of certain obligations under TRIPS. The international and domestic layers of IP law were often conflated, thus framing a waiver of international obligations under TRIPS as a waiver or suspension of IP rights as such under domestic law. Hence, the merits and shortcomings of the waiver proposal were generally debated not in terms of the expanded scope of potential national government agency, but rather in terms of the consequence of the continued effect or temporary suspension of IP rights as such. This conflation of international and domestic levels of action was evident in numerous accounts in the analytical, advocacy and academic literature: a characteristic example is the statement that South Africa and India had proposed at the WTO “that intellectual property rights on Covid-19 vaccines and related drugs and treatments be waived ...” (Loft, 2022) Much analysis and advocacy conflated a TRIPS waiver in international law with firms’ freedom to operate without IP constraints, bypassing the necessity domestic implementation, and omitting vital consideration of the scope and potential forms of exercise of national governments’ agency: for instance “The proposed TRIPS waiver would provide more companies with the freedom to operate in order to produce COVID-19 vaccines and other health technologies without the fear of infringing another party’s IP rights and the attendant threat of litigation” (Kang and others, 2021).

However, a TRIPS waiver could only temporarily suspend the binding effect of international principles. It would not in itself suspend or negate IP rights as such, nor curtail their exclusive effect, without specific action at the domestic level in each separate jurisdiction.<sup>32</sup> Achieving global solidarity in practice entails more positive steps than the simple absence of one set of international rules, including concrete steps well beyond the scope of IP law, to bring about the necessary diversification of production and equity in access:

---

<sup>32</sup> The modes of interaction between the TRIPS Agreement as international law and domestic IP law are discussed elsewhere (Taubman, forthcoming). The general principle is set out in TRIPS Art 1, which affirms the freedom of WTO members “to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” While there are specific instances of the TRIPS Agreement being construed as having direct effect in municipal law, these have essentially concerned the interpretation of the application of TRIPS principles within existing domestic legal frameworks, and it seems improbable that even in the most firmly monist of jurisdictions a waiver of international obligations would translate immediately into the effective suspension, cancellation or unenforceability of IP rights without some distinct domestic action to give effect to the waiver. (Mitchell, Taubman and Samlidis, forthcoming; Cottier and Schefer, 1998).

In the jurisprudence of the European Court of Justice, see *Parfums Christian Dior SA*, Joined cases C-300/98 and C-392/98, [2000] ECR I-11307 (availability of provisional measures); *Hermès International and FHT Marketing Choice BV*, Case C-53/96, [1998] ECR I-3603. *Merck Genéricos – Produtos Farmacêuticos Lda v. Merck & Co. Inc., Merck Sharp & Dohme Lda*, Case C-431/05 [2007] ECR I-7001. (patent term).

A WTO waiver ... combined with ensuring vaccine know-how and technology is shared openly ... through the [WHO C-TAP] ... should be accompanied by coordinated global investment in research, development, and manufacturing capacity to tackle this pandemic and prepare us for future ones, as part of a more robust international health architecture. If this last year has taught us anything, it is that threats to public health are global, and that strategic government investment, action, global cooperation, and solidarity are vital. The market cannot adequately meet these challenges, and neither can narrow nationalism (People's Vaccine Alliance, 2021).

Taking together the centrality of governments' effective agency, and connection and coordination of national actions in the spirit of solidarity frames the IP dimension of the pandemic response in a more productive, enabling manner. It illustrates, in practice, continuity and synergies between robust deployment of options under existing rules and the potential scope for action beyond the TRIPS Agreement. The waiver debate, in essence, was centred on how, and to what extent, TRIPS rules could be construed as a constraint on the effective exercise of national governments' agency for necessary action to address the pandemic. In turn, concerns were expressed over transaction costs and cumbersome procedural characteristics of mechanisms established under domestic laws to curb IP rights in the public interest. The temporary removal of international obligations under TRIPS was expected to enable national governments to overcome such constraints on their agency; in itself, it would neither instigate positive action nor build a positive programme of solidarity, but it could in principle broaden the potential scope for such action. Yet some of the domestic options for which a waiver was sought can be undertaken within existing TRIPS rules – notably, emergency government authorization to use all IP-protected subject matter necessary to produce and supply vaccines without the consent of right holders. Furthermore, it is only through the lens of actual domestic practice in different jurisdictions that there can be a full understanding. Such insights from domestic practice strengthen effective government agency by demonstrating the possibilities for action and illuminating how the general principles in TRIPS apply in concrete situations. In turn, understanding of the options clearly not available to governments in the absence of a waiver illuminates the full scope of options that are available, and would continue to be available within the TRIPS framework, furnishing a more powerful toolkit for future public health crises. Equally, if solidarity in a time of global crisis is understood to comprise a set of interventions undertaken through coordinated action across jurisdictions, the existing rules provide considerable scope, and an established framework for a range of practical options for the effective and expeditious exercise of government agency as a cooperative endeavour.

#### **IV. FRAMING NATIONAL GOVERNMENTS' AGENCY: EFFECTIVENESS AND CONNECTEDNESS**

It follows that whatever is agreed at the international level, currently and in the event of future health crises, the question of how to translate the call to solidarity into effective action, and, in particular, how governments should respond to the demand for collective action on the IP dimension of access to medical technologies, pivots on two critical, practical considerations that underly all proposals:

- (i) The need for effective agency on the part of national governments, in the general sense of agency as the ability or capacity to act or exert power;
- (ii) The need for coordinated and connected practical action by governments working in concert with international and regional organizations and initiatives.

The first point is articulated in the preceding section. That is, despite the intensive and necessary concentration on the international dimension of the IP system, national governments retain agency, and how they deploy and combine that agency remains critical: the range of options available, and the choices made and implemented within that range, ultimately shape the impact, for better or worse, of the IP system. The TRIPS Agreement remains an agreed set of principles governing relations between WTO members and influencing domestic law, but it is not an IP law as such. Hence the global IP system remains a patchwork of diverse national legal systems, interconnected and to some extent harmonized or convergent at the level of principle, but ultimately in the hands of national governments (and some regional authorities) when it comes to determining its actual impact.

On the second point, coordination of national governments' action is key to ensuring that solidarity is a practical reality. Interdependence is inevitable, given that all countries depend, to greater or lesser extent, on inputs from elsewhere, whether in tangible form, such as inputs to vaccine production or finished products, or in intangible form, such as patented technology, know-how or regulatory data.

National governments' agency can be greatly enhanced through the coordinated use of policy options. Governments with the greatest freedom to operate under international rules have frequently had least effective agency in practice. Hence, least developed country members of the WTO have no substantive obligations under TRIPS until at least 2034, and thus are already entitled under the TRIPS Agreement at least to take drastic action under domestic law not only to blunt the exclusive effect of IP rights in the public interest, but also to exclude the availability of IP rights. But plainly this state of affairs could not, in itself, confer on such countries a privileged level of effective agency, when considered in atomistic isolation: this wide freedom

to operate and the absence of international obligations seemingly had scant effect in practice for most such countries and in the many in which applicable IP rights were not in effect (Chiang and Wu, 2022) in the absence of a positive programme of collaboration in a spirit of practical solidarity.

## **V. THE PANDEMIC: A CRISIS FOR NATIONAL AGENCY AND THE LEGITIMACY OF INTERNATIONAL RULES**

The very call – by a wide cross-section of governments – for a sweeping suspension of core elements of international rules in the area of IP has raised critical questions about the suitability of these very rules, at the very least the immense stresses and humanitarian catastrophe of the COVID-19 pandemic putting their legitimacy under close and critical scrutiny. Accordingly, the waiver proposal has served as a fundamental critique of the legitimacy and effectiveness of TRIPS principles at a time of a health emergency, and a concerted bid for greatly enhanced scope for domestic agency to take action relating to the pandemic.

Yet the essential character and ultimate effect of the international rules on IP and the means of achieving the public health outcomes within their framework are ultimately only discernible through the prism of the domestic laws, which apply the broad international principles,<sup>33</sup> or – in the event of a waiver -- would reach beyond them. A false dichotomy lies, therefore, between a global, international or multilateral response to the IP dimension, on the one hand, and action taken domestically, on the other. The scope of available government interventions may be roughly arrayed across a spectrum: one end would entail no government intervention at all in the regular operation of the IP system, hence a reliance on voluntary licensing; the other end would be defined by the current range of options open to least developed countries, the freedom not to recognize IP rights at all and for all relevant content to lie in the public domain. Midway would be the recognition – articulated but not created by the Doha Declaration – that it is perfectly legitimate for governments to override the exclusive effect of IP rights in the public interest. No WTO member has advocated an exclusive reliance on voluntary licensing as the sole legitimate response to the pandemic; nor could they, with any consistency, given that all domestic laws provide for some form of non-voluntary use authorization and that a pandemic represents among the most compelling scenarios in which such a mechanism should be available if needed: of 117 patent jurisdictions surveyed by the World Intellectual Property Organization (WIPO), all had some form of mechanism for authorizing the use of a patented technology without the patent holder's consent (WIPO secretariat, 2010).

---

<sup>33</sup> Fully elaborated in Taubman (forthcoming).

The proposed TRIPS waiver can be placed towards the latter end of the spectrum, but would not go as far as the current freedom to operate of least developed country governments under TRIPS. An alternative, or parallel, proposal tabled by the European Union, clarifying the scope and nature of international rules, is closer to the former end of the spectrum, reflecting an understanding that tools to curb the exclusive effect of IP rights should be clearly available and understood, while their use would still be guided by the framework of the international principles of TRIPS.

Another factor potentially constraining government action – and itself a further argument for the waiver proposal – was concern that even when taking legitimate, TRIPS-compliant measures to leverage access to necessary technologies, developing countries may be subject to adverse political and economic pressure on the part of major trading partners and private sector players. Pakistan referred in the TRIPS Council to “reports surfacing that the same pharmaceutical companies are lobbying with their governments to impose sanctions to countries that adopt compulsory license[s]”.<sup>34</sup> South Africa maintained that, although members point out that TRIPS flexibilities are available and should be used, “this is not a reality for many developing countries [since] whenever such flexibilities are invoked, political and other sanctions are used to counter such efforts.”<sup>35</sup>

Dealing with such pressures is inherently a broader political matter beyond the formal scope of agreed international legal standards and the formal means for resolving differences, but it may be decisive in determining the scope of effective agency. This concern has been a consistent thread, reaching back to the negotiation and implementation of the TRIPS Agreement:

The multilateral turn represented by TRIPS was impelled in part by the actual and feared impact of unilateral action – essentially, pressure from the US Special 301 process, which expressly envisaged trade sanctions against countries that did not provide adequate and effective standards of IP protection and enforcement to US entities. For some negotiators, this was a spur to advancing negotiations to ensure that IP trade matters would fall within the multilateral trade dispute settlement system (Taubman, 2015).

This concern has arisen most consistently in relation to prospective or actual uses of measures to override the exclusive effect of patent rights to leverage access to pharmaceuticals (’t Hoen 2009). It is, therefore, no coincidence that this was one of the few specific flexibilities expressly addressed in the 2001 Doha Declaration, which

---

<sup>34</sup> WTO, TRIPS Council, Minutes of Meeting held on 10-11 March, 2021, document IP/C/M/98/Add.1, at 251.

<sup>35</sup> *Ibid.*, 287.

responded to misconceptions at that time that “compulsory licensing” of patent rights was in some sense illegitimate, and instead articulated that WTO members had a positive right to take such measures and freedom to determine the substantive grounds for them, this political declaration effectively strengthened governments’ agency in combatting public health challenges. The proposal for a pandemic waiver of TRIPS obligations took this logic further, broadening the debate over the legitimate scope of domestic action in the face of the pandemic. Ideally, this might have led to a closer, focused review of the specific measures governments could or should take individually or collectively within the framework of the waiver, as against options for robust actions pushing the envelope of the existing rules. Yet much of the analysis and public debate had focused on the legitimacy and value of, and the need for, a waiver of TRIPS obligations as an end in itself, with less attention paid to domestic implementation. Advocates also had argued that a waiver – framed as an act of global solidarity – could lend wider political legitimacy and momentum to steps to suspend or override IP rights, while easing hesitation based on potential dispute settlement action.

This contrast and interaction between a clear understanding of formal legal and legitimate options, and the actual, practical scope of realistic and viable action to be taken by governments is absolutely critical. Strengthened agency on the part of national governments in addressing the IP dimension of enhanced and sustainable vaccine production requires a firm foundation for governments to use the full array of legitimate options under TRIPS or under any waiver of TRIPS provisions. It would be naïve, reductionist and impractical to see this as purely a matter of the operation of international law, or for that matter its suspended effect. National governments’ agency in this sense is better understood as a combination of the following elements:

- A clear, objective understanding of the full range of options realistically available;
- Capacity to set these in the context of a broader strategy context (shaped by a vaccine and medicines strategy);
- Political confidence to take choices that may attract criticism and political pushback;
- Administrative and legislative capacity to deploy choices effectively and expeditiously (how to overcome domestic hurdles to effective implementation has been one of the less commented, but no less telling and instructive, issues arising from the pandemic response).

Ultimately, focus on government agency should recognize that the choices taken, and the insights then derived from practical experience, can, in turn, shed light

on how best to translate the principles of TRIPS into effective practice. National government agency, therefore, has greater impact when it can inform and guide others' choices. A formalistic reading of treaty text, even in the context of dispute settlement, does not necessarily give positive guidance on how to give practical effect to the very public policy principles that the TRIPS Agreement itself ascribes to the IP system, notably in its Article 7. By contrast, understanding of diverse, actual practice at the domestic level, and lessons shared through policy dialogue and cooperation, are likely to be more instructive as to how to achieve the intended social and economic welfare outcomes: what can be termed "the collective management of TRIPS".<sup>36</sup> This analysis of real-world agency can be taken further, given that no actions within or beyond the existing international IP framework can deliver public health outcomes – an integrated view of effective agency would embrace measures taken to ensure access to material inputs, financing, the regulatory dimension, and the necessary technical and industrial capacity. An exclusive focus on the IP system and the scope of international rules in this area does not yield the capacity to produce and supply vaccines or other COVID-19 technologies. The absence of applicable IP rights does not generate this capacity, while upheaval in the IP system may impede the garnering of the necessary resources and the structuring of beneficial technological and commercial partnerships. However, political debate centred on whether effective government agency in a health crisis necessitates the curtailment of the exclusive effect of IP rights, or even the suspension of them, as part of a broader strategy to leverage access and even to build production capacity for urgently needed medicines. This is, in part, an empirical question, dependant on the actual landscape and territorial scope of IP rights applicable to a certain needed output. In principle, governments unquestionably have considerable scope for action and agency to override or curtail the exclusive effect of legitimate patent rights in the public interest, and in particular to take steps to protect public health. These interventions are often collectively termed "compulsory licences" (and are referred to as such in the Doha Declaration), but this term can create an impression that governments' options are more limited than they actually are, while fuelling an assumption that procedural restrictions and administrative obstacles encountered in some domestic systems are actually required by TRIPS. The term "non-voluntary use authorizations (NVUAs)" is broader and more descriptive, referring to "conscious interventions by an administrative or judicial authority, on the grounds of failure of effective competition or on other public interest grounds, that permit third parties or government agencies to make significant use of patented technology without the authorization of the patent holder, subject to remuneration" (Taubman, 2008). NVUAs in actual domestic laws comprise a diverse array of measures entitling governments

---

<sup>36</sup> A view expounded in Taubman (2011), and further elaborated in Taubman (forthcoming).

to authorize the use of patented subject matter directly by government agencies, or by third parties on behalf of governments, without the consent or involvement of the patent holder, and provide avenues for third parties to seek compulsory licences. A review of how some 135 jurisdictions have implemented TRIPS discloses not only the diversity of mechanisms available, but also the options for their robust use to meet public health needs.<sup>37</sup>

The two main forms of NVUAs are (a) compulsory licenses that effectively regulate the competitive relationship between firms, typically sought by a firm affected by another's restrictive licensing practices, and (b) authorizations directly permitting use of patented technology for government use or for public non-commercial purposes, or for emergencies or cases of extreme urgency, directly serving the public interest, regardless of the competitive environment between firms.<sup>38</sup> The 2022 TRIPS Decision clarified that government authorizations could take such diverse forms, tailored for an emergency, such as the pandemic. From that perspective, the wider waiver debate shed light on a major systemic limitation that many countries faced. In a survey of 117 patent jurisdictions (WIPO, 2010), only 52 or 44 per cent expressly provided for government use authorizations, with no evident pattern in terms of geography, development status or legal tradition. This does not altogether exclude the possibility of such authorizations in other jurisdictions, but the mere fact that the matter is not clearly expressed in the law can be an impediment to effective agency, as can the absence of a clear procedure for initiating such a measure even when expressly provided for.

Several other obstacles to the effective use of NVUAs for patented technology cited in the debate over access to medicines in the context of the pandemic have been construed as TRIPS Agreement obligations. However, combining a careful reading of the treaty text with an objective survey of comparative practice in domestic laws, confirms that most such obstacles result from domestic choices. This paves the way to a more sustained and systematic removal of such obstacles, and even greater convergence between like-minded countries – such as those working together on a regional strategy for access to medicines – that eases the transaction costs of cross-border cooperation. Among the measures already in place in national jurisdictions that may help overcome identified obstacles are the following:

---

<sup>37</sup> Laws and Regulations under TRIPS Art. 63.2, available at [e-trips.wto.org](http://e-trips.wto.org).

<sup>38</sup> The New Zealand negotiator in the TRIPS negotiations helpfully distinguished: “[a] safeguard measure to maintain the correct functioning of the market despite the temporary monopoly accorded to the patent holder [that would not apply if the patent holder] acted in line with normal commercial practice and assumed his responsibilities as an actor on the market’ from interventions responding to ‘an overriding public interest . . . a situation of necessity where rapid action was required, such as the case of an epidemic.”

- Specific measures entitling the government directly to authorize the production and supply of medicines;<sup>39</sup>
- Exclusions of injunctive relief in the event of government-authorized use, including limitations of compensation for government use to subsequent remuneration as a remedy in infringement proceedings;<sup>40</sup>
- Clarification that government authorized use may include commercial activities and may serve the interests of the government in a broader sense;<sup>41</sup>
- Provisions for remuneration subsequent to government authorization of production and use, thus ensuring no procedural delay on that account;
- Streamlined procedures that bypass the need to consult, advise or negotiate with right holders in appropriate circumstances;<sup>42</sup>
- Authorizations that take the form of general authorization to produce or supply a specific product, without necessarily identifying any or all of the patents involved;<sup>43</sup>
- Provision for retrospective authorization<sup>44</sup> and for the authorization of the use of subject matter of patent applications;<sup>45</sup>
- Clarifying that protection of clinical trial data as provided under TRIPS Article 39.3 does not impede authorized production and supply;<sup>46</sup>
- Avoidance of double compensation, through a provision that compensation is not required for the import of a health product if the right holder has already or will separately receive remuneration.<sup>47</sup>

---

<sup>39</sup> Such as UK Patents Act 1977, s55(1)(a)(ii) and (c), and.

<sup>40</sup> Expressly provided for in Article 44.2 of the TRIPS Agreement; see also 28 U.S. Code § 1498.

<sup>41</sup> Under English and Welsh law, see *IPCom GmbH v Vodafone* [2020] EWHC 132 (Pat).

<sup>42</sup> Foreseen in Article 31, TRIPS Agreement.

<sup>43</sup> *IPCom GmbH v Vodafone* [2020] EWHC 132 (Pat).

<sup>44</sup> India, Patents Act 1970, s100(4).

<sup>45</sup> UK, Patents Act, ss 55(4) and 55(5).

<sup>46</sup> Malaysia, 2011 Directive of Data Exclusivity, s5(i) and (ii); Chile, Law 19.039 (as amended) on Industrial Property, Art. 91; see also 2022 Decision on TRIPS, para 4.

<sup>47</sup> Singapore, Patents Act (Chapter 221), s 62(2).

Such mechanisms offer prospects for overcoming obstacles cited during the debate, such as procedures for judicial review that may have a suspensive effect, retarding or impeding the capacity for authorized use of the patent subject matter in a timely manner; and concerns regarding the scope and nature of actual authorizations, such as the assumption that authorizations must be in the form of single, “case by case” compulsory licensing of individually identified patents. These are not TRIPS requirements, and the burdensome character of some choices under domestic laws have been incorrectly attributed to the corresponding provisions of the TRIPS Agreement, reinforcing an overly limited and cumbersome reading of the scope for government agency within the TRIPS framework. Hence, to analyse, practically and objectively, the reported or perceived impediments to deploying NVUAs for public health under domestic law remains a compelling task. The call for a TRIPS waiver was driven, in part, by the perceived need for streamlined and facilitated direct government authorization of deployment of patented technology in the public interest. Such government-authorized use of patented technologies may be achieved in one of two ways: the temporary or conditional absence of international obligations, opening up the possibility of implementing additional domestic options that would otherwise have been constrained solely by international legal obligations under the TRIPS Agreement; or the robust use of existing mechanisms, guided by a pragmatic understanding of the full range of current legitimate options, informed by the full breadth of actual practice. The notion of stronger government agency spans and unites these apparently discrete forms of action.

The suspension of international obligations does not, by definition, give positive guidance on what practical steps may be taken, whereas a systematic and pragmatic grasp of actual mechanisms provided under domestic law across the full WTO membership not only provides positive practical guidance as to how to implement such a measure to blunt the effect of patent rights, but also a bulwark against political criticism and legal challenge in the event that such a measure provoked criticism or retaliation. Hence, the 2022 Decision on TRIPS was crafted as a direct practical response to the specific problems members identified in using the existing system to respond to the pandemic, especially in ramping up and diversifying vaccine production. This included positive guidance on legitimate measures that directly accorded robust agency to developing country governments, and addressed issues that had been identified as practical constraints on their effective agency. It provides practical tools for diversifying COVID-19 vaccine production across the developing world by confirming and clarifying the right of members to override patent rights through direct government authorization, and by bringing into force a TRIPS waiver to streamline urgent production of vaccines for export and to facilitate the development of dispersed production chains especially in regions which have had

limited vaccine production capacity. Similar to a broader TRIPS waiver, the decision is not self-executing; its effective use depends on national and regional action, in two senses:

- It facilitates and enables national and regional initiatives for diversified vaccine production and distribution, including by doing away with IP obstacles, but it does not stand in for such initiatives nor precipitate them in itself; accordingly, its implementation must be part of concrete plans to diversify vaccine production.
- As IP rights are granted and administered at the domestic level, it requires domestic steps to be implemented (ideally coordinated among like-minded and cooperating members, such as through coordinated national or joint decisions to authorize production and import of vaccines).

## **VI. DRAWING THE THREADS TOGETHER: SOLIDARITY IN PRACTICE**

If the expectations of solidarity and collective action are to bear fruit – and the harsh lessons of the COVID-19 pandemic are to be applied – the individual and collective agency of national governments is of paramount concern, not only concerning governance of the IP system. International outcomes – whether in the form of positive normative guidance, such as the 2021 Doha Declaration and the 2022 Decision, a broad-brush waiver as proposed in 2020, a more targeted waiver, or an amendment of the TRIPS Agreement, such as the one entered into force in 2017 – will only have a practical impact for public health when governments, preferably in cooperation, authorize them through policy, legal and administrative measures. The “collective management of TRIPS” would build a wider practical understanding of the full array of tools deployed under domestic law that enable governments to ensure that public interests prevails, when necessary, over the exclusivity of patent rights. This understanding is likely to be more fruitful in practice than focusing exclusively on treaty language as such, given that it is only under domestic law that the legal and policy principles of TRIPS are effectively followed. Progressive convergence, for example on a regional or subregional model, can proceed without coercive intrusion into domestic regulatory autonomy.

A regional or subregional model may also enable more effective use of existing public health tools within the TRIPS framework, including the more systematic and workable implementation of the mechanism for export of medicines under the new Article 31*bis*, and the 2022 Decision. Such IP governance tools would be more effective when associated with the coordination of procurement of medicines and the aggregation of cooperating countries’ demand to create economies of scale

and, if needed, reassurance against political retaliation. A single compulsory licence or government use order issued in a single, small country as an isolated measure would typically have little practical effect; and governments may be reluctant to have to deal with political pushback by taking an isolated step. Countries facing similar unmet needs or access issues – and, ideally, working on coordinated or pooled procurement and regulatory convergence – can enhance the effect of NVUAs by coordinating issuance of authorizations. This is one simple step that would give more routine practical utility for the export compulsory licence mechanism introduced into TRIPS (31bis): a routine practice of joint notifications of unmet need of medicines at an early stage in procurement. The need be no more than a single email sent as soon as a specific need for a certain medicine is identified, and can be a single joint notification by several countries combining their needs. The 2022 Decision provides a more streamlined approach to ramping up pandemic vaccine production for export by doing away altogether with the requirement for import needs to be notified in advance, thus enabling production capacity to be developed and implemented, and vaccines supplied, for export following a single government authorization. Once the waiver provision of the 2022 Decision comes to an end, either in 2027 or when extended, this arrangement may be immediately transitioned to a more regular, systematic mechanism for supply of vaccines. By that time, the continuing matching of supply and demand can be managed more smoothly, and the authorized production for export can transition to supply in response to the ongoing demand notified by importing countries.

Access to a specific medicine can be streamlined by issuing a government use authorization at an early stage in procurement – thus opening up a wider range of potential suppliers, whether the government use authorization of the patent is ultimately used as the preferred procurement option. The same can be done by importing countries: they could notify their needs for medicines through the TRIPS Article 31bis mechanism at an early stage in procurement, whether the system is actually used in the end. Again, this simply entails incorporating into procurement procedures the despatch of an email notifying the number and name of a medicine being procured, ideally at an early stage of procurement. International agencies, such as the WHO, MPP, the Global Fund to Fight AIDS, Tuberculosis and Malaria or GAVI, cannot indicate needs through this official channel, but they could facilitate coordination with potential recipient governments and assist with notification needs, in order to include those countries' notification of identified needs as a routine step early in the procurement process, and aggregate demand across different countries to leverage economies of scale

Solidarity is a high legal and moral imperative; it is also a practical craft. Agency of national governments is central to the effective implementation of the full array of tools provided for in the international IP system. That agency can be amplified through

cooperative action, notably across a region, which would aggregate demand and create economies of scale, make more effective the use of TRIPS options, flexibilities and waivers, and put to work the lessons of comparative experience with a view to convergence on the most effective means of using the full array of domestic tools to ensure that the policy outcomes espoused in principle by the TRIPS Agreement are achieved in practice: the collective management of TRIPS.

### **NOTE ON CONTRIBUTOR**

Antony Taubman, Director, World Trade Organization Intellectual Property, Government Procurement and Competition Division, formerly diplomat and patent attorney, held senior policy roles in national government and in the World Intellectual Property Organization, taught, researched and published widely on IP law and policy issues.

## REFERENCES

- Bollyky, Thomas, and Chad Bown (2020). The tragedy of vaccine nationalism: only cooperation can end the pandemic. *Foreign Affairs*, vol. 99, No. 5.
- Bump, Jesse, Peter Friberg, and David Harper (2021). International collaboration and COVID-19: What are we doing and where are we going?. *British Medical Journal*, vo. 372, No. 180.
- Chiang, Ting-Wei and Xiaoping Wu (2022). Innovation and patenting activities of COVID-19 vaccines in WTO members: analytical review of medicines patent pool COVID-19 vaccines patent landscape, (VaxPal), WTO Staff Working Paper ERSD-2022-01, 18 January. Available at [https://www.wto.org/english/res\\_e/reser\\_e/ersd202201\\_e.htm](https://www.wto.org/english/res_e/reser_e/ersd202201_e.htm).
- Contreras, Jorge, and others (2020). Pledging intellectual property for COVID-19. *Nature Biotechnology*, vol. 38, No. 10, pp. 1146–1149.
- Cottier, Thomas, and Krista Schefer (1998). The relationship between world trade organization law, national and regional law. *Journal of International Economic Law*, vol 1, No. 1, pp. 83–122.
- Emanuel, Ezekiel, and others (2021). On the ethics of vaccine nationalism: The case for the Fair Priority for Residents Framework. *Ethics and International Affairs*, vol. 35, No. 4. pp. 543–562.
- Gayle, Helene, and others (eds.) (2020). *Framework for Equitable Allocation of COVID-19 Vaccine*, Washington, D.C.: The National Academies Press.
- Ghebreyesus, Tedros (2021). Five steps to solving the vaccine inequity crisis. *PLOS Global Public Health*, vol. 10, no 10, e0000032.
- Glassman, Amanda, Charles Kenny, and George Yang (2022). COVID-19 vaccine development and rollout in historical perspective. Center for Global Development Working Paper 607, June 2022. Available at <https://www.cgdev.org/publication/covid-19-vaccine-development-and-rollout-historical-perspective>.
- Gollier, Christian (2021). The welfare cost of vaccine misallocation, delays and nationalism. *Journal of Benefit-Cost Analysis*, vol. 12, No. 2, pp. 199–206.
- Kang, Hyo Yoon, and others (2021). Academic open letter in support of the TRIPS Intellectual Property Waiver Proposal. LSE Law - Policy Briefing Paper , No. 46 (July 2021). Available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3885568](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3885568).
- Loft, Philip (2022). Waiving intellectual property rights for Covid-19 vaccines. House of Commons Library Research Briefing Number 9417 (July 13, 2022). Available at <https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf>.
- Mitchell, Andrew, Antony Taubman, and Theodore Samlidis (2022). The Legal character and practical implementation of a TRIPS waiver for COVID-19 vaccines. *Fordham Intellectual Property, Media & Entertainment Law Journal*, Vol XXXIII No 1.
- People's Vaccine Alliance (2021). Open letter: former heads of state and nobel laureates call on President Biden to waive intellectual property rules for COVID vaccines. 15 April. Available at [peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704](https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704) (accessed on 17 August 2022).

- Reuters (2020). Mylan waives exclusive U.S. distribution rights for potential COVID-19 therapy, 26 March 2020. Available at <https://www.reuters.com/article/health-coronavirus-mylan-lidINL4N2BI4NS>.
- Rueda-Barrera, Eduardo (2021). The waiver of COVID-19 vaccine patents: a fairness-based approach." *Journal of Global Ethics*, vol. 17, No. 3, pp. 367–374.
- Skegg, David, and others (2021). Future scenarios for the COVID-19 pandemic. *The Lancet* vol. 397, No. 10276 pp. 777–778.
- 't Hoen, Ellen (2009). *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*. Diemen, Netherlands: AMB Publishers.
- Taubman, Antony (2008). Rethinking TRIPS: 'adequate remuneration' for non-voluntary patent licensing. *Journal of International Economic Law*, vol. 11, No. 4, pp. 927–970.
- \_\_\_\_\_ (2010). A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policymakers. *Open AIDS Journal*, vol. 4, pp. 4–24
- \_\_\_\_\_ (2011). *A Practical Guide to Working with TRIPS*. Oxford, UK: Oxford University Press.
- \_\_\_\_\_ (2015). Thematic review: negotiating "trade-related aspects" of intellectual property rights. In *The Making of TRIPS*, Jayashree Watal and Antony Taubman, eds. Geneva, WTO.
- \_\_\_\_\_ (forthcoming). Towards the "collective Management" of TRIPS, Ph.D. dissertation, University of South Australia.
- United Nations (2021). Secretary-General calls vaccine equity biggest moral test for global community, as Security Council considers equitable availability of doses. Press release, 17 February. Available at <https://press.un.org/en/2021/sc14438.doc.htm>.
- United Nations Children's Fund (UNICEF) (n.d.) COVID-19 Market Dashboard. Available at [www.unicef.org/supply/covid-19-market-dashboard](http://www.unicef.org/supply/covid-19-market-dashboard) (accessed on September 4, 2022).
- United Nations Economic and Social Council, Commission on Human Rights, Sub-commission on the Promotion and Protection of Human Rights (2000). Intellectual Property Rights and Human Rights (Resolution 2000/7).
- \_\_\_\_\_ (2001). The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights: Report of the High Commissioner (E/CN.4/Sub.2/2001/13, 2001).
- World Health Organization (WHO) (n.d.). COVID-19 Technology Access Pool. Available at [www.who.int/initiatives/covid-19-technology-access-pool](http://www.who.int/initiatives/covid-19-technology-access-pool) (accessed on 9 September 2022)
- \_\_\_\_\_, World Intellectual Property Organization (WIPO), and World Trade Organisation (WTO) (2020). *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*. 2nd ed. (Geneva, WHO, WIPO and WTO).
- \_\_\_\_\_, and others (2022) Accelerating COVID-19 Vaccine Deployment: Removing obstacles to increase coverage levels and protect those at high risk, Submission to G20 Finance Ministers, Washington, April 2022. Available at <https://www.who.int/publications/m/item/accelerating-covid-19-vaccine-deployment>
- World Intellectual Property Organization (WIPO) secretariat (2010). patent related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels, CDIP/5/4 Rev.

World Trade Organization (WTO) (2021). Indicative list of trade-related bottlenecks and trade-facilitating measures on critical products to combat COVID-19: Information Note, 8 October. Available at [https://www.wto.org/english/tratop\\_e/covid19\\_e/bottlenecks\\_update\\_oct21\\_e.pdf](https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf).