Mitchell, Andrew D.; Taubman, Antony

Working Paper

Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production

ARTNeT Working Paper Series, No. 225

Provided in Cooperation with:
Asia-Pacific Research and Training Network on Trade (ARTNeT), Bangkok

Suggested Citation: Mitchell, Andrew D.; Taubman, Antony (2023) : Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production, ARTNeT Working Paper Series, No. 225, Asia-Pacific Research and Training Network on Trade (ARTNeT), Bangkok

This Version is available at:
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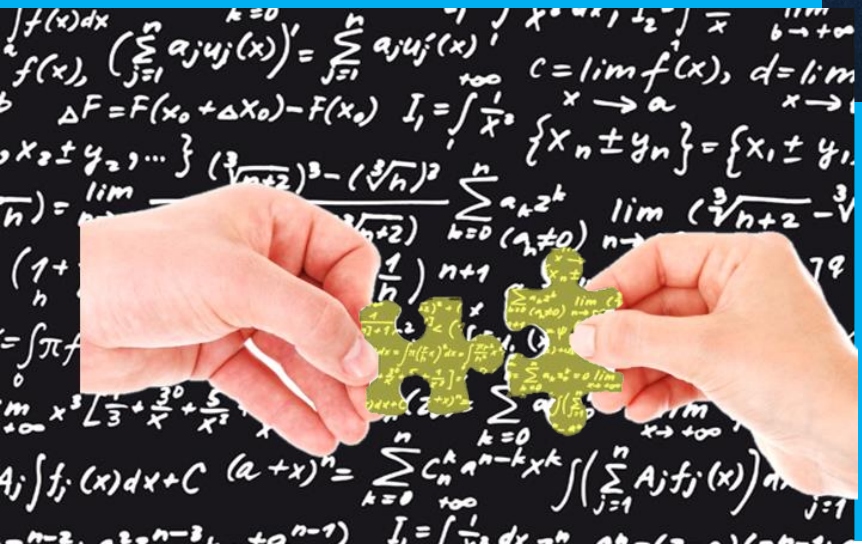
Special Series on Trade and Health

Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production



Andrew D Mitchell
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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

Working Paper

No. 225 | 2023

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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

WORKING PAPER

Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production

Andrew D Mitchell[1], Antony Taubman[2]

Please cite this paper as:

Andrew D Mitchell and Antony Taubman (2023). "Practical means of applying the TRIPS Agreement's flexibilities to spur vaccine production", **ARTNeT Working Paper Series** No. 225, January 2023, Bangkok, ESCAP.

Available at http://artnet.unescap.org

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Abstract

Timely and equitable access to vaccines and other health technologies is vital in effectively responding to pandemics and treating other communicable diseases. This paper shows how countries might overcome real or purported intellectual property (IP) barriers to regional COVID-19 vaccine production. In particular, it examines how countries can utilise IP flexibilities to increase and diversify the manufacture and distribution of COVID-19 vaccines. It provides concrete examples of how these flexibilities are practised in various domestic jurisdictions in Asia and the Pacific and sets out practical recommendations for different policy areas.

Keywords: COVID-19, vaccines, intellectual property rights, regional cooperation, Asia-Pacific

JEL Codes: F13, O34

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1. Introduction

Equitable and effective access to COVID-19 vaccines is an essential means of curbing the pandemic and easing its grave social and economic impact. Despite their rapid development and global scale-up in production, gross inequities in access to vaccines are likely to continue. This is due to multiple causes, including export restrictions, supply chain constraints, inadequate health infrastructure, and insufficient manufacturing capacity.[3] For most vaccine technologies, this manufacturing capacity remains highly concentrated in a handful of countries. The demand for booster shots in countries with significant access to first- and second-dose vaccine supplies[4] and continuing concerns about emerging new variants[5] are also potential contributors. Countries with less purchasing capacity have benefited from international donation facilities such as COVID-19 Vaccines Global Access ('COVAX'). However, such programs have, to date, proven largely inadequate in the face of massive global demand, procurement and stockpiling (generally by wealthier nations), supply chain disruptions, constraints on vaccine exports, and logistical barriers to distribution.

Many have concluded that inequitable and delayed distribution of vaccines is at least partly attributable to the concentration of production capacity in very few locations.[6] An effective response to the immediate pandemic and continuing resilience in the face of future potential health crises requires mapping the pattern of current and projected future needs more closely and diversifying production and distribution centres accordingly.

Along with other factors (such as sustainable financing, regulatory clearance and logistical capacity), expanding and diversifying vaccine production entails leveraging access to a wide range of technologies: the 24 COVID-19 vaccines subject to the WHO Emergency Use Listing and Prequalification evaluation process include entirely novel mRNA technologies, as well as viral vector and recombinant protein vaccines.[7] Working such technologies entails access to manifold inventions, knowhow and regulatory data as part of a broader process of technology transfer and capacity building for sustained and more diversified production capacity. Much of this subject matter is protected by intellectual property ('IP') rights in multiple jurisdictions.[8] Content protected by copyright and industrial designs may also come into play.

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[3] World Trade Organization, 'Members discuss intellectual property response to the COVID-19 pandemic' (Media Release, 20 October 2020) < https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm>

[4] Australia, which has enough vaccines to vaccinate 495 per cent of its population, began its booster campaign in November 2021: International Monetary Fund, 'IMF-WHO COVID-19 Vaccine Supply Tracker' <https://www.imf.org/en/Topics/imf-and-covid19/IMF-WHO-COVID-19-Vaccine-Supply-Tracker>

[5] At the time of writing, the Omicron strain is the latest of five variants of concern ('VOC') recognised by the World Health Organization ('WHO'): https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/

[6] See e.g. United Nations, 'Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting' (*United Nations*, 16 April 2021) <https://www.un.org/press/en/2021/ecosoc7039.doc.htm>

[7] WHO, 'Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process' (Guidance Document, 11 November 2021) <https://www.who.int/teams/regulation-prequalification/eul/covid-19>

[8] Ting-Wei Chiang and Xiaoping Wu, 'Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytic Review of Medicines Patent Pool (MPP) COVID-19 Vaccines Patent Landscape (VaxPaL)' (Staff Working Paper, WTO, 2021).

Thus governments and intergovernmental organisations have partly directed their focus toward strategies for leveraging access to critical IP through a range of mechanisms, including promotion of voluntary licensing, creation of technology sharing platforms such as the World Health Organisation ('WHO') COVID-19 Technology Access Pool ('C-TAP'),[9] humanitarian licensing programs such as the Medicines Patent Pool ('MPP'),[10] targeted technology transfer initiatives,[11] and various means of curbing or removing the exclusive effect of applicable IP rights.

Two decades ago, World Trade Organization ('WTO') members responded to concerns about potential obstacles to access to medicines posed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement' or 'TRIPS') by the consensus adoption of the Doha Declaration on the TRIPS Agreement and Public Health ('Doha Declaration' or 'Declaration'). Among other things, the Declaration identified a number of policy options, or 'flexibilities', open to WTO members to leverage access.[12] Faced with the current pandemic, acute concerns about potential IP obstacles have led a number of WTO member governments to press for a temporary waiver[13] of certain obligations under the TRIPS Agreement ('TRIPS waiver').[14] The proposed waiver would entitle members to take a wider range of measures than those available under the TRIPS Agreement, to address IP barriers to a range of COVID-19 technologies, including vaccines. Others have called for clarification or reinforcement of existing policy options and flexibilities under TRIPS to override the exclusive effect of IP rights in the public interest.[15] A complex matrix of overlapping regional trade and economic agreements is a source of further IP protection standards that may have a bearing on vaccine manufacture and distribution options.[16]

In particular, developing and least-developed countries ('LDCs') have sought guidance on the practical implementation of TRIPS flexibilities both before and during the

[9] World Health Organization, 'WHO COVID-19 Technology Access Pool', World Health Organization <https://www.who.int/initiatives/covid-19-technology-access-pool>

[10] Medicines Patent Pool , 'MPP's contribution to the global response to COVID-19', Medicines Patent Pool <https://medicinespatentpool.org/covid-19>

[11] See below Section 2.1.1.

[12] The 'flexibilities' explicitly identified in the Declaration are illustrative and not exhaustive of the potential policy options that Members can take while complying with the TRIPS Agreement. WIPO has identified four clusters of TRIPS flexibilities, comprising flexibilities as to the method of implementing TRIPS obligations, flexibilities as to substantive standards of protection, flexibilities as to mechanisms of enforcement and flexibilities as to areas not covered by the TRIPS Agreement: WIPO, 'Public Policy-related Assistance – Flexibilities' <https://www.wipo.int/ip-development/en/policy/flexibilities.html)>

[13] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, WTO Doc IP/C/W/669/Rev.1 (25 May 2021).

[14] Marrakesh Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 3 (Marrakesh Agreement) Annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) ('TRIPS').

[15] Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from the European Union to the Council for TRIPS, WTO Doc IP/C/W/681 (18 June 2021).

[16] R Valdés and M McCann, 'Intellectual property provisions in regional trade agreements: Revision and update' in R Acharya (ed), Regional Trade Agreements and the Multilateral Trading System (Cambridge University Press, 2016) 497-607.

pandemic and have foreshadowed a need for greater assistance in giving domestic effect to a TRIPS waiver.[17] At the same time, many criticisms of the IP system and its implications for public health are concerned not with the principles of TRIPS itself, but choices made in giving effect to those principles at the national level. This has led to claims that domestic procedures for implementing legitimate pro-access policy measures are overly restrictive, inefficient and bureaucratic.[18] Policy debate and scholarship has primarily concentrated on the international dimension. Still, there is an urgent need to clarify and illuminate how national governments can use existing and potential future options to address the critical shortfall in vaccine access — both for the current pandemic, and future health needs.

The Asia-Pacific region, particularly South Asia and South-East Asia, is a natural focus of technology transfer and manufacturing initiatives, given its relatively well-developed industrial base[19] and large populations needing affordable and reliable access to vaccines. The COVID-19 pandemic has underscored the vulnerability of Asia-Pacific populations and the strategic need for more substantial vaccine production activity in the region. This study examines the extent to which IP protection acts as a barrier to regional production of COVID-19 vaccines in the Asia-Pacific, and reviews the range of IP rights involved in increasing and diversifying production capacity. To ensure a concrete and pragmatic focus, we consider a representative sample of countries, including developing countries and LDCs: Bangladesh, Cambodia, Fiji, India, Indonesia, Malaysia, Mongolia, Nepal, Thailand and Vietnam.

We selected these countries to illustrate the distinct potential roles of different economies in building more diverse vaccine production capacity: some may serve as regional hubs for vaccine production; others may play an intermediate role in the production of vaccine inputs and regulatory approval processes; while others would more likely benefit from vaccines imported from the region. Ultimately, diverse countries may have common interests in coordinated or pooled procurement and in regulatory coordination or convergence,[20] to expedite and streamline regional access to vaccines.

Bridging between the international and domestic layers of IP law and related regulation, we assess these countries' existing IP constraints and flexibilities and identify practical options for overcoming or utilising them. We draw on existing regional practice to help guide pragmatic choices both for domestic and coordinated regional

[17] World Trade Organization, 'Members discuss intellectual property response to the COVID-19 pandemic' (Media Release, 20 October 2020) <https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm>

[18] Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang, Graham Dutfield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID- 19 Pandemic' (LSE Law, Society and Economy Working Papers 06/2021) 27; James Bacchus, 'An unnecessary proposal: a WTO waiver of intellectual property rights for COVID-19 vaccines' (CATO Institute, 16 December 2020); Poku Adusei, 'Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa' (2011) 14(1) Journal of World Intellectual Property 1, 11.

[19] Matthias Helble and Susann Roth, 'Asia should lead the way in producing a novel coronavirus vaccine' (Asian Development Blog, 23 April 2020) <https://blogs.adb.org/blog/asia-should-lead-way-producing-novel-coronavirus-vaccine>

[20] See e.g. ASEAN Secretariat, *ASEAN Common Technical Dossier* (December 2016) <https://asean.org/wp-content/uploads/2016/12/68.-December-2016-ACTD.pdf>

access. The study recognises the need to balance distinct approaches tailored to different technological capacities and legal regimes on the one hand, with a degree of coordination and cooperation on the other hand — to aggregate demand, build economies of scale, and provide for collective action that would reinforce the agency of individual countries.

The current literature is lacking in comprehensive and geographically inclusive assessments of the full range of IP issues in the COVID-19 or public health context that also take full stock of how TRIPS flexibilities have been implemented practically in a range of Asia-Pacific countries. Much of the debate has considered the adequacy and effectiveness of available flexibilities, with a particular focus on the patent system, and to a lesser extent, the protection of knowhow and clinical trial data. The scope of other IP rights and flexibilities in a public health context is comparatively less examined, corresponding with the lesser degree of practical experience reported at the domestic level. This limited analysis has contributed to the view that the full range of existing TRIPS flexibilities is limited, and choices for overcoming barriers posed by a range of IP rights are constrained.[21] To be sure, some level of ambivalence about the exact nature and scope of IP flexibilities may mean that they are not fully implemented in domestic laws or, when present in those laws, not effectively utilised. Therefore, we attempt to provide some guidance on the full scope of flexibilities available across several categories of IP rights, contrasting the principles established under the TRIPS Agreement at the international level with actual practice in a range of domestic jurisdictions. As our analysis aims to be comprehensive in its scope, it is less in-depth than it would be if individual issues and provisions were treated in isolation. However, we adopt this approach in the interests of providing comprehensive, practically-informed, timely and pragmatic policy and legal recommendations to address an ongoing practical health crisis.

[21] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Responses to Questions, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, WTO Doc IP/C/W/672 (15 January 2021) [18] ('WTO Doc IP/C/W/672').

2. Overview

2.1 The Asia-Pacific Vaccine and Manufacturing Landscape[22]

2.1.1 Vaccine Distribution

Vaccine consumption in Asia is achieved by 'a complex mix of bilateral and multilateral donations, purchase orders … emerging local production, home-grown vaccine development, and … private sector fund-raising.'[23] The data suggests that for most countries in the Asia-Pacific region, the bulk of vaccines supplied up to April 2022 has been through bilateral and multilateral agreements and government procurement, with donations and supply under COVAX providing for significant but not predominant amounts for the most part (Table 1).

Table 1: Vaccine procurement in surveyed Asia-Pacific countries

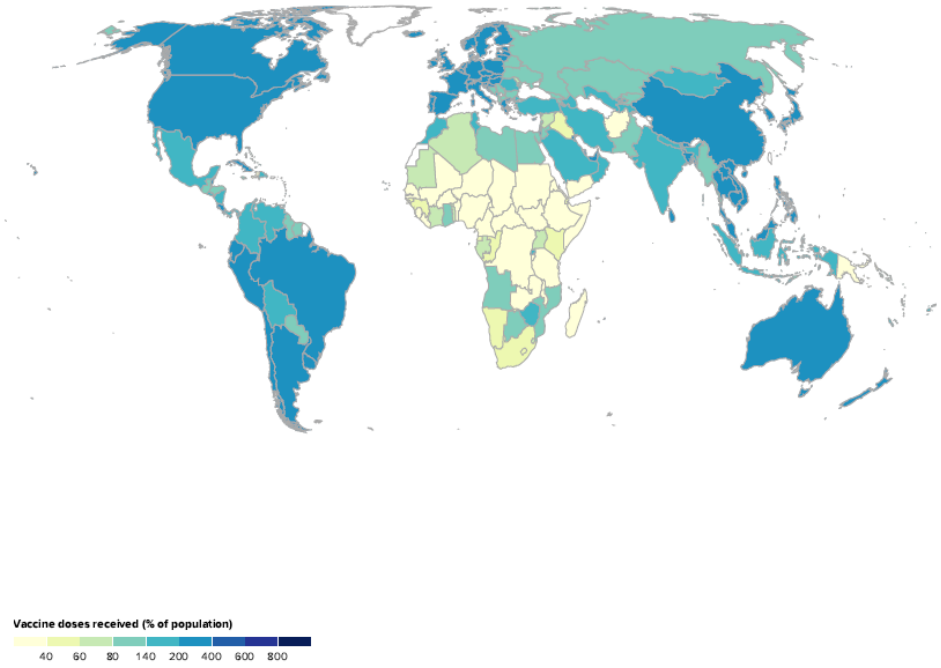
Surveyed country	Purchase agreement	Donations	COVAX	Unknown (uncategorised)	Total
Bangladesh	322,926,828	28,758,090	187,758,900		539,443,818
Cambodia	24,510,000	12,191,000	3,926,960	231,722	40,859,682
Fiji		1,249,500	501,280		
India	1,165,176,072		100,000,000	777,862,842	2,043,038,914
Indonesia	231,539,640	20,835,330	103,898,830	69,857,374	426,121,174
Malaysia	7,5934,848	6,415,000	1,387,200		83,737,048
Mongolia	3,026,060	450,000	1,327,260	1,240,868	6,044,188
Nepal	2,800,00	5,355,420	31,919,650	6,275,327	46,350,397
Thailand	48,781,250	7,560,870		86,767,917	144,110,037
Vietnam	30,418,940	17,017,560	68137050	113,031,124	228,604,664

Source: UNICEF Vaccines Dashboard (15 April, 2022), Authors' compilation

[22] This section provides a general overview. A parallel study reviews the vaccine landscape in more detail: Pavida Pananond and Alvaro Cuervo-Cazurra, 'Vaccine Global Value Chains and Regional Production Capacity in Asia and the Pacific' (*ARTNeT Working Paper Series*, No. 217, October 2022, Bangkok, ESCAP)

[23] Richard Maude, 'Southeast Asia and COVID-19 Vaccines Explained' (*Asia Society Policy Institute*, 21 June 2021) <https://southeastasiacovid.asiasociety.org/southeast-asia-and-covid-19-vaccines-explained/>

Figure 1: Vaccines delivered as a percentage of population



Source: UNDP Vaccine Equity Dashboard (accessed 14 April 2022)

Various reasons exist for uneven distribution of and access to COVID-19 vaccines within and outside the Asia-Pacific region. Certain developing and least-developing countries lack the purchasing power and economies of scale to purchase vaccines in bulk. However, purchase data reveals that some developing countries are buying a significant share of the COVID-19 vaccines that are available. Yet developed countries purchase a more significant proportion of mRNA vaccines.[24] Even for those countries willing and able to purchase vaccines at affordable prices, there has been concern about the continuing implications of highly localised production for effective and sustainable capacity to meet global demand.[25] Despite massive increases in production capacity, the demand for ever more frequent booster shots — accentuated by the response to the Omicron variant and consequent stockpiling — is exacerbating concerns that even the projected growth in production capacity will continue to be marked by disparities, and will not guarantee equitable, let alone universal, access.[26] In addition, many countries report supply chain and logistical issues associated with

[24] Duke Global Health Innovation Centre, Issue Brief: Deciphering the Manufacturing Landscape for Covid-19 Vaccines (19 March 2021) <https://launchandscalefaster.org/covid-19/vaccinemanufacturing>

[25] The United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP) estimates that planned production for authorized vaccines covers around 40 per cent of the world population under a two-dose regime in 2021: UNESCAP, 'Asia-Pacific Trade Facilitation Report 2021: Supply Chains of Critical Goods Amid The Covid-19 Pandemic – Disruptions, Recovery, and Resilience' (October 2021) 42. See Boniface Chimpango, 'Vaccine nationalism and equitable access to COVID-19 pharmaceuticals: TRIPS Agreement under trial (again)' (2021) Journal of International Trade Law and Policy, ahead of print, 12-13.

[26] World Trade Organization, 'Interim statement on booster doses for COVID-19 vaccination' (WHO, 22 December 2021) <https://www.who.int/news/item/22-12-2021-interim-statement-on-booster-doses-for-covid-19-vaccination---update-22-december-2021>

vaccine input procurement and last-mile, cold-chain storage transportation to remote communities.[27]

Thus increased, and more geographically dispersed, manufacturing capacity is needed to address insufficient vaccine supply and access issues, as well as to maintain longer term capacity and thus resilience against future health crises. An UNCTAD publication notes that 'with discussions focused on the issue of patents and profits, a fundamental issue is being overlooked: the lack of productive capacity in developing countries.'[28] Various locations in Africa, Asia and South America have since each been identified as sites for local production in the developing world.[29]

Accordingly, the WHO has launched a South African COVID mRNA Vaccine Technology Hub,[30] to complement and benefit from the MPP and other initiatives. Workstream 3 of the COVAX Manufacturing Taskforce is focused on expanding capabilities of existing manufacturers in low-middle income countries in these regions, and establishing sustainable capacity in regions with no significant capacity.[31]

Fisher, Okediji and Sampath identify four elements for building manufacturing capacity: (i) legal authority; (ii) technological knowhow; (iii) financial resources; and (iv) reliable demand for products.[32] As the third shares only an indirect link with intellectual property law and policy, and the fourth is satisfied within the COVID-19 context, our focus is on the first two elements.

2.1.2 Mapping Contributors and Beneficiaries

Local production facilities have long been suggested as a solution to high-priced low-cost medicines.[33] Local or regional manufacturing hubs may also be established to address an inadequate supply of lower-price medicines that are in high demand. Such initiatives have positive spin-off effects for the local industry involved, including increased research and development ('R&D') activity and the development of an industrial base.[34] Local production frameworks can and should be structured to achieve maximal efficiencies and economies of scale,[35] which is particularly important for regions largely constituted by developing countries and LDCs, such as the Asia-

[27] UNESCAP (n 25) 43-46.
[28] UNCTAD, 'COVID-19 heightens need for pharmaceutical production in poor countries' (27 May 2020) <https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries>
[29] World Health Organization, WHO Director-General's opening remarks at the media briefing on COVID-19 – 5 February 2021 (5 February) <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-5-february-2021>. See also G20, Rome Declaration (21 May 2021) 4.
[30] World Health Organization, 'WHO supporting South African consortium to establish first COVID mRNA vaccine technology transfer hub' (World Health Organization, 21 June 2021) <https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>
[31] World Health Organization, 'COVAX Manufacturing Taskforce' (Meeting Report, 12 May 2021) <https://www.who.int/publications/m/item/covax-manufacturing-taskforce>
[32] William Fisher, Ruth Okediji and Padmashree Gehl Sampath, 'Fostering Production of Pharmaceutical Products in Developing Countries' (2021) forthcoming, Michigan Journal of International Law, 25.
[33] Frederick M Abbott, 'Managing the Hydra: The herculean task of ensuring access to essential medicines' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 393, 419.
[34] Abbott (n 33) 419.
[35] Abbott (n 33) 419.

Pacific. A number of developing countries and LDCs in the Asia-Pacific have managed to develop such local production facilities, and have in turn developed well-functioning generic pharmaceutical industries. The development of such manufacturing capacity has resulted in well-performing vaccine hubs for influenza viruses in the Asia-Pacific region, creating potential candidates for the production of other vaccines — either through independent R&D-based novel vaccine development or technology transfer.

Pharmaceutical manufacture typically involves the production of active pharmaceutical ingredients ('APIs'); the combination of an API with excipients (inactive ingredients that act as the drug's medium); and the fill-and-finish stage of production, which involves placing the drug in final dosage form and packaging it for distribution.[36] For vaccines, the relevant API is an antigen that must be synthesized or extracted, isolated and purified, and then combined with adjuvants, stabilisers and preservatives to ensure the vaccine's efficacy, stability and longevity.[37] Such processes are highly technical and differ significantly depending on the vaccine technology being developed.

The manufacturing landscape for COVID-19 has been described as 'opaque', leading to uncertainty surrounding the practical, IP-related implications for vaccine manufacture.[38] However, current data allows us to map and identify the strongest candidates for primary and secondary manufacturing processes in the region. Drawing on the data in Table 2 below, we identify India, Vietnam and Thailand as manufacturing hub candidates. Indonesia and Malaysia's capacity for influenza vaccine production also makes those countries promising candidates as regional COVID-19 vaccine producers.[39] Indonesia was the seventeenth leading vaccine exporter in the world in 2019, in front of Switzerland and Singapore; India was seventh.[40] In each of these countries, state-operated manufacturing enterprises play an instrumental role in national pharmaceutical and vaccine production.[41] Indonesia — where currently there is no end-to-end COVID-19 vaccine production — has announced the domestic production of locally developed COVID-19 vaccines.[42] India, Nepal Vietnam, Indonesia, and Malaysia have also been the site of clinical trials for vaccines developed

[36] Fisher, Okediji and Sampath (n 32) 12.
[37] United Nations Industrial Development Organization and World Health Organization, 'Establishing Manufacturing Capabilities for Human Vaccines: Key cost drivers and factors to consider when planning the establishment of a vaccine production facility' (White Paper, 2017) 6-7.
[38] Duke Global Health Innovation Centre, 'Issue Brief: Deciphering the Manufacturing Landscape for Covid-19 Vaccines' (19 March 2021) 1.
[39] Mahendra Suhardono, Dori Ugiyadi, Ida Nurnaeni, Imelda Emelia, 'Establishment of pandemic influenza vaccine production capacity at Bio Farma, Indonesia' (2011) 29S *Vaccine* A22; Surichan et al, 'Development of influenza vaccine production capacity by the Government Pharmaceutical Organization of Thailand: Addressing the threat of an influenza pandemic'(2011) 29S *Vaccine* A29-A33.
[40] mClinica, 'Southeast Asia's role in the quest for a COVID-19 vaccine' (26 August 2020) <https://www.mclinica.com/southeast-asias-role-in-the-quest-for-a-covid-19-vaccine/>
[41] E.g. the Government Pharmaceutical Office in Thailand, Research Institute for Tropical Medicine in the Philippines, Biofarma in Indonesia, the National Institute of Hygiene and Epidemiology in Vietnam and the Central Research Institute in India: Theodore F Tsai, Raman DSV Rao, and Zhi Yi Xu, 'Immunization in the Asia-Pacific Region' (2018) 7 *Plotkin's Vaccines* 1466, 1478.
[42] mClinica (n 40).

elsewhere. For example, India has conducted 15 clinical trials for 12 countries, including many from the European Union and the United States.[43]

In contrast, other developing countries and LDCs with no significant pharmaceutical production base — such as Cambodia, Fiji, Lao, Myanmar and Nepal — are likely to remain reliant on imports.[44] Bangladesh has a relatively strong and dynamic pharmaceutical sector for an LCD.[45] Nevertheless, there is a lack of expertise surrounding the development of APIs in Bangladesh, demonstrating the limited potential for manufacturing capacity for novel vaccines even amongst countries with an otherwise well-established industrial base.[46]

Table 2: Number of COVID-19 Vaccine Facilities in the Asia-Pacific

Country	End-to-End	Excipient	API	Fill-Finish	Total
India	19	2	4	2	27
China	14	1		4	19
Japan	1		3	3	7
Viet Nam	3			2	5
Pakistan	2				2
Australia	1				1
Thailand	1				1
Philippines	1				1
Malaysia				1	1
Bangladesh				1	1
Singapore				1	1
Sri-Lanka				1	1
Cambodia					0
Fiji					0
Indonesia					0
Nepal					0

Source: UNICEF Market Dashboard, Authors' compilation (accessed 6 December 2021)

Table 3: Vaccine Manufacturers in the Asia-Pacific

Country	Manufacturers
India	India Bharat Biotech International Ltd Biological E Ltd Cadila Healthcare Ltd Serum Institute of India Pvt. Ltd Dr Reddy's Laboratories Wockhardt Limited
Vietnam	Vabiotech
Australia	CSL
Thailand	Pharmaceutical Organization (GPO) Bionet Asia Co.Ltd

[43] Chiranjib Chakraborty, 'Asian-Origin Approved COVID-19 Vaccines and Current Status of COVID-19 Vaccination Program in Asia: A Critical Analysis' (2021) 9 *Vaccines* 600, 609.
[44] mClinica (n 40).
[45] Bangladesh accounted for 47.4 per cent of total exports of pharmaceuticals by LDCs in 2016: Mustafizur Rahman and Sherajum Monira Farin, 'WTO Decision on TRIPS and Public Health: A Window of Opportunity for Bangladesh's Pharmaceutical Industry' (Advancing LDCs' Trade Interests, Centre for Policy Dialogue, May 2018) 10.
[46] Rahman and Farin (n 45) 11.

	Siam Bioscience
Malaysia	Clinical Research Malaysia Malaysian Genome Institute National Public Health Laboratory Institute for Medical Research Universiti Malaya
Indonesia	Bio Farma Limited Kalbe Farma

Source: Author's Compilation

2.2 Intellectual Property Issues

2.2.1 Significance of the IP system for vaccine access

Increasing and diversifying manufacturing capacity for developed vaccines requires effective transfer of technology, particularly for more novel vaccine platforms such as mRNA. Technology transfer may take a wide range of forms in practice: from making use of public domain information (including publications of patents not in force in the countries concerned), to a diverse range of technology licensing and contractual arrangements, to close cooperative technology partnerships entailing human capital development and direct knowledge transfer. These different mechanisms often involve assuring effective access to IP-protected technologies. The development and production of novel vaccines may also require access to IP rights covering other technologies, such as technology platforms, production inputs and delivery technologies. These may be held by other firms not directly involved in the development of a specific vaccine. The IP dimension of technology transfer processes may therefore entail licensing or transfer of patent rights, sharing of knowhow and confidential information, and access to or reliance on clinical trial data required for market approval of the finished product. The production and distribution of vaccines may involve technologies that utilise copyright and industrial design rights.

This section maps out the potential issues involving these types of IP rights with a specific focus on the Asia-Pacific region. Each subsection outlines the nature of the category of IP, and its relevance to vaccine production and distribution. This is followed, in section 3, by an analysis of corresponding policy options available to WTO Members under the TRIPS Agreement, as a core element of the international legal framework that codifies the key principles and standards for the recognition, administration, enforcement and governance of IP rights in these Members' domestic laws. The accounts in this section are necessarily brief and focussed for the purpose of this paper; a comprehensive account of the interplay between these IP rights and innovation of and access to medical technologies can be found elsewhere.[47]

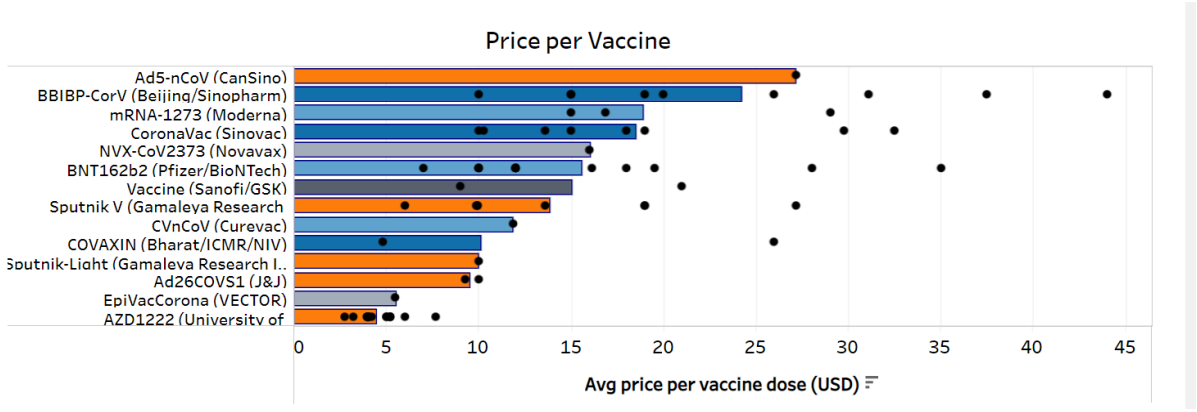
[47] See e.g. WHO, WIPO & WTO, Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, Second edition (2020) <wto.org/trilateralstudy2020>

2.2.1.1 Patents

A patent gives its owner the exclusive right to make, use or sell an invented product or process that is specified in the patent. Vaccines and vaccine manufacturing processes are often subject to the protection of one or more patents.[48] Firms in the Asia-Pacific wishing to manufacture developed vaccines may encounter barriers to production where the vaccine and its production processes are protected by patents under the domestic law of the country where the firm seeks to exploit the invention. Equally, patent rights can prevent the importation of finished vaccines or of inputs for their production where this occurs without the patent holder's authorisation.

The market exclusivity over a particular drug that a patentee acquires by virtue of their patent, and the ensuing absence of market competition, sometimes allows that patentee to set high prices for products covered by a patent. This may be an issue for developing countries and LDCs that lack the purchasing power to import vaccines. However, what data are available suggests that vaccine inequity in the COVID-19 context (illustrated by Figure 1 above) is caused primarily by insufficient manufacturing levels that fail to meet demand, procurement and stockpiling initiatives, and the high concentration of production facilities, rather than the price of vaccines alone (as Figure 2 and Figure 3 illustrate).

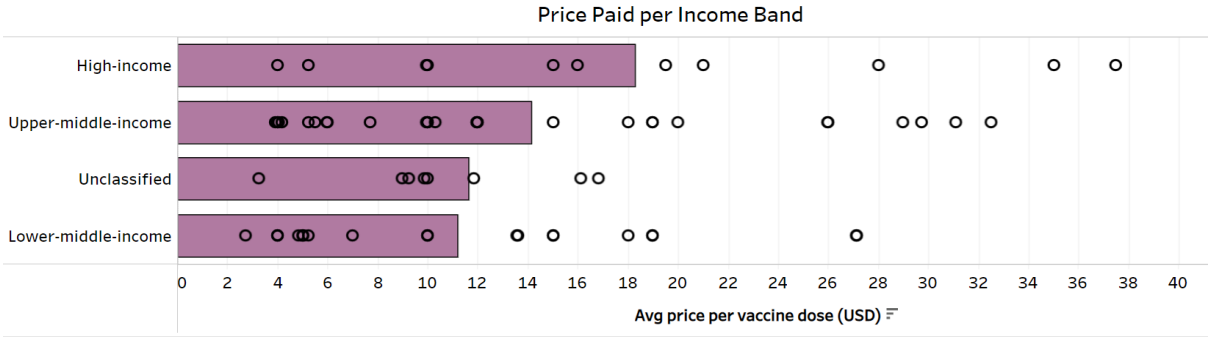
Figure 2: Reported price per vaccine dose



Source: Airfinity (accessed 16 April 2022)

[48] Patent Analytics Hub identifies 1,422 applications and 290 unique patent families filed globally since 2000 relating to human coronavirus vaccines, with 50% of these patent families either being sought or in force: IP Australia, Patenting of Human Coronavirus Vaccines (Tableau Public, 21 September 2020) <https://public.tableau.com/app/profile/patent.analytics.hub/viz/Humancoronavirusvaccines/Vaccines> (accessed 23 December 2021). See also Mario Gaviria and Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' (2021) 39 Nature Biotechnology 546 <https://doi.org/10.1038/s41587-021-00912-9>

Figure 3: Reported price per dose by income level



Source: Airfinity (accessed 16 April 2022)

It is a critical practical consideration in charting options for access to medicines that, upon publication of a patent application, an invention passes immediately into the public domain in those jurisdictions where a patent is not sought, because of the strictly territorial scope of patents under national and regional systems. Thus most patented technology information becomes publicly available in most WTO Members as soon as it is published, and early in the vaccine development process (publication generally taking place 18 months after the first filing data).[49] The key impediment to utilising an invention in cases where an invention is known but not protected is obtaining the necessary technical information to carry out the invention. In principle, a patent document must fully teach the person skilled in the art how to implement the invention,[50] and a patent can be invalidated for insufficient disclosure. However, further knowhow is typically needed to make effective use of patented technology, especially in the complex area of pharmaceutical technology, where it is difficult to replicate or reverse engineer detailed manufacturing knowhow.

When patents do present a barrier in countries where they are in force, governments have considerable scope to override their exclusive effect in the public interest. One flexibility that receives frequent attention is the possibility of issuing compulsory licenses or other forms of non-voluntary use authorisation ('NVUA') such as government use orders and emergency decrees — interventions by government authorities conferring on third parties the right to use or sell an invention without authorisation of the patentee, subject to remuneration.[51]

Compulsory licences and other NVUAs can be issued on various grounds and for a range of policy reasons. Broadly speaking, they fall into two general categories: to address concerns regarding anti-competitive or restrictive business practices specifically, or to address more general public interest concerns, such as greater access to medicines. This mechanism has been advocated where the pricing of

[49] According to WIPO data, approximately 47% of 3,276,700 patent applications filed in 2020 were filed in high-income countries, 46% were filed in China, and only 7% were filed in LMICs (excluding China): WIPO, 'WIPO IP Statistics Data Center' <www3.wipo.int/ipstats/> accessed 15 December 2021.
[50] TRIPS art 29.1.
[51] Antony Taubman, 'Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing' (2008) 11(4) Journal of International Economic Law 927, 932.

medicines is a key issue. Removing the patentee's exclusive rights over the product helps to introduce competition into the market, in the expectation that prices will be lowered,[52] an effect that has been extensively studied in relation to HIV/AIDS treatments since the time of the Doha Declaration.[53] Moreover, some have suggested that compulsory licences can and should be used to incentivise (or pressure) patent owners to license their inventions at reasonable prices voluntarily.[54]

The procurement scenarios that do not call for a compulsory licence or NVUA are wide-ranging, including:

(i) where the product is not patented;
(ii) where products are appropriately priced and effectively and equitably available;
(iii) where a voluntary licence or licences have been granted, or other initiatives have been taken, such as non-assertion undertakings by the patent holder.

However, compulsory licensing may also be used to allow third parties to manufacture or import a product where the original patentee refuses to licence it voluntarily, at least in those circumstances where refusal to licence is viewed as anticompetitive in character, or where there are other grounds for overriding the exclusive effect of the patent, such as public health interests. Compulsory licensing in such cases is an effective way of expanding manufacturing capacity beyond the originator firm's own production chain — not necessarily to introduce competition and lower-priced medicines into the market, but with a view to maximising the use of available production capacity in order directly to expand the available supply of high-demand medicines, including as a specific public initiative (the public non-commercial or urgent use foreseen in TRIPS Article 31(b)).

Patents may also cover technologies and devices used to administer vaccines,[55] as well as technologies used for storage and delivery, so these also may need to be addressed in ensuring effective access to vaccines.

2.2.1.2 Copyright and Industrial Designs

Copyright issues in respect of written material on product information documents, product labelling and inserts, as well as software and data compilations utilised in the vaccine manufacturing and distribution process have been highlighted as distinct

[52] There is evidence that compulsory licensing can successfully achieve this goal: WIPO, Standing Committee on the Law of Patents Thirtieth Session Geneva, June 24 to 27, 2019, Draft Reference Document on the Exception Regarding Compulsory Licensing, SCP/30/3 (21 May 2019) 56.

[53] Ellen 't Hoen, Jonathen Berger, Alexandra Calmy, Suerie Moon, 'Driving a decade of change: HIV/AIDS, patents and access to medicines for all' (2011) 14(1) Journal of International AIDS Society 15 <https://doi.org/10.1186/1758-2652-14-15>

[54] Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (Kluwer Law International, 2001) 328; Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10(1):010358 Journal of Global Health 1, 2.

[55] Hilde Stevens, Koenraad Debackere, Michel Goldman, Richard T Mahoney, Philip Stevens and Isabelle Huys, 'Vaccines: Accelerating Innovation and Access' (Report, WIPO, 2017) 19.

possibilities in the pandemic context.[56] Article 10(2) of TRIPS requires that 'compilations of data or other material … which by reason of the selection or arrangement of their contents constitute intellectual creations' be protected. As clarified by Article 9(2), copyright protects expressions, and not ideas. It would not normally protect individual items of data in themselves, such as raw statistics.

Industrial design protection protects the outward appearance of manufactured products, but not the product *per se*. Thus an industrial design holder has the exclusive right to produce and sell products incorporating its design, but cannot prevent others from producing and selling the same product incorporating a different design.[57] Industrial designs are likely less relevant to the manufacture and distribution of COVID-19 vaccines than the development and distribution of other medical products, such as diagnostic tools, ventilators, and personal protective equipment ('PPE').[58]

Moreover, vaccines are primarily delivered through diluent containers, single- and multidose vials and pre-filled syringes, and transported using refrigerators, freezers and cold boxes. Industrial designs have been registered in some jurisdictions for items such as vaccine transportation containers and freezer, syringes and other delivery items. These may be procured at several points on the vaccine distribution and delivery by both private and public entities. However, no specific IP obstacles for access to such devices have currently come to light (by contrast with supply chain scarcity for vaccine inputs generally[59]). Nevertheless, in Section 3 below, we outline the flexibilities available under TRIPS relating to these forms of IP.

2.2.1.3 Confidential Information

The protection of confidential or undisclosed information (also termed 'knowhow' or 'trade secrets') may affect access to knowledge or information necessary to undertake the steps required to produce a vaccine, such as technical methods of production or use of the equipment involved, including their precise settings and arrangement, and biological and other materials used in vaccine development.[60]

Such information and knowhow constitute core components in the production of any vaccine, such as tacit knowledge about production methods. While much information required may be in the public domain, some specialist knowledge is more likely to be protected as confidential in the context of newer technology platforms, such as mRNA

[56] Council for the Trade-Related Aspects of Intellectual Property Rights, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19', WTO Doc IP/C/W/684 (30 September 2021) [40] ('IP/C/W/684'). See Doris Estelle Long, 'The Overlooked Role of Copyright in Securing Vaccine Distribution Equity' (infojustice, 6 September 2021) <http://infojustice.org/archives/43621>

[57] Edson Beas Rodrigues Jr, The General Exception Clauses of the TRIPS Agreement (Cambridge University Press, 2012) 266.

[58] See e.g. WTO Doc IP/C/W/672 (n 21) [89], [91]; WTO Secretariat, the TRIPS Agreement and COVID-19, Information Note (15 October 2020) 11.

[59] WTO, 'Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19' (October 1, 2021)
<https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf>

[60] Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets' (2021) 16(11) Journal of Intellectual Property Law & Practice 1242, 1246.

vaccines, compared with more established vaccine technologies.[61] Vaccine technologies are best understood as a package of various inputs, comprising both patented inventions and/or knowhow, some of which may be confidential.[62] Hence, even if there is no patent in force in a particular jurisdiction, or a compulsory licence or other NVUA is granted under a patent, access to confidential information and related knowhow may still be necessary to ensure the effective implementation of the technology platform. Removing barriers and obtaining access to confidential information is therefore critical to technology transfer and generic vaccine production.

2.2.1.4 Clinical trial data

Clinical trial or test data that demonstrates the safety and efficacy of new pharmaceuticals (including vaccines) is, in some countries, required to be submitted to regulatory authorities as a condition of approval for new products and new applications. Such data may also include sensitive information regarding the manufacturing process, formulation, dosage, delivery method, indicated uses and general safety information.[63] These regulatory procedures are distinct from protection of IP as such, and many countries in the Asia-Pacific region do not maintain entirely independent approval processes that call for submission of data. Many of these countries base domestic approval on approval in other countries, or to WHO emergency use or prequalification procedures, particularly in the context of urgent pandemic responses.

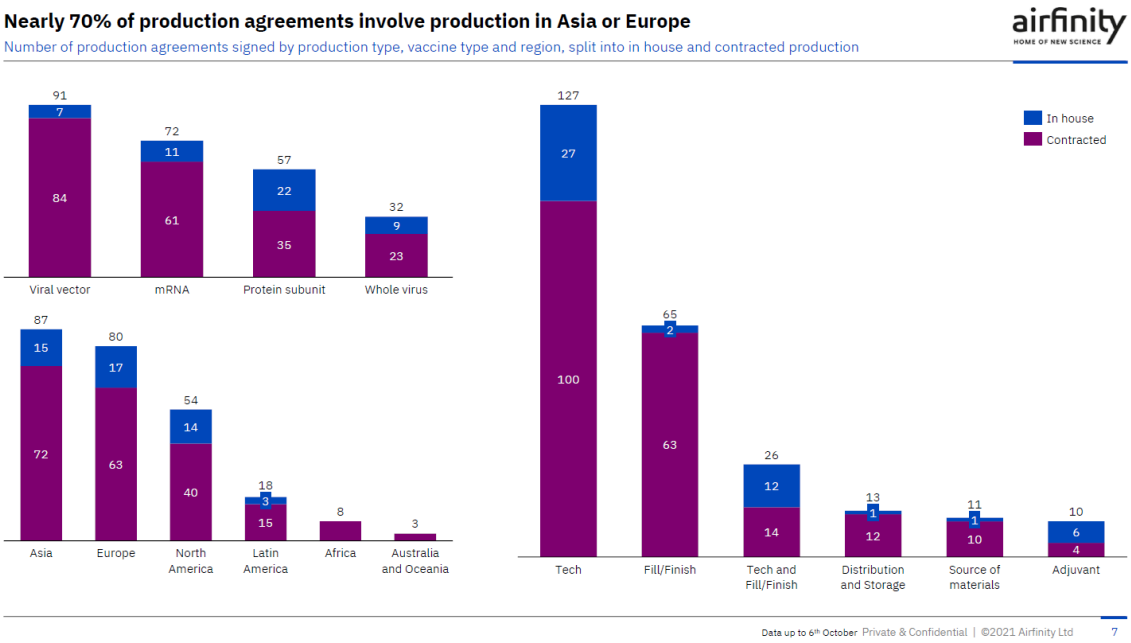
However, in those countries where test data are required to be submitted, such data are required — under TRIPS — to be protected against disclosure or unfair commercial use, provided they are undisclosed, relate to a new chemical entity, and require considerable effort to generate. This requirement may constrain Asia-Pacific firms from producing follow-on COVID-19 vaccines if they are required to submit clinical trial data or required to rely on the originator's data to gain approval to distribute the vaccine. The TRIPS standards in this area apply when the domestic authorities undertake a distinct review of clinical trial data as a condition of regulatory approval. Some bilateral and regional agreements provide for more extensive protection, which may expressly set a term of exclusivity over the originator's data, may apply to reliance on data submitted for approval in other jurisdictions, or may set limits over reliance on the originator's earlier regulatory approval.[64] Regulatory systems and processes in the Asia-Pacific have in the past reportedly slowed or blocked the introduction of novel vaccines developed externally.[65] Due to relatively low costs, and growing technical

[61] Gurgula and Hull (n 60) 1246.
[62] Geertrui Van Overwalle, 'Uncorking trade secrets: sparking the interaction between trade secrecy and open biotechnology' in Rochelle Dreyfuss and Katherine Strandberg (eds), The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research (Edward Elgar, 2011) 246, 250.
[63] IP/C/W/684 [35].
[64] See e.g. Comprehensive and Progressive Agreement for Trans-Pacific Partnership (signed 8 March 2018) ('CPTPP') incorporating the Trans-Pacific Partnership Agreement (signed 4 February 2016) art 18.50 (Protection of Undisclosed Test or Other Data).
[65] Theodore F Tsai, Raman DSV Rao and Zhi Yi Xu, 'Immunization in the Asia-Pacific Region' (2018) 7 Plotkin's Vaccines 1466, 1478.

expertise, recent years have seen an increasing trend for clinical trials to be conducted in the region, including for COVID-19 vaccines.[66]

As outlined in Section 3.5 below, countries in the Asia-Pacific region currently maintain a diverse range of approaches both to regulatory approval of vaccines (and reliance on approval in other jurisdictions or by the WHO), and to the protection of clinical trial data. Divergent regulatory mechanisms and cumbersome regulatory procedures have, in themselves, been identified as an obstacle to the timely production and distribution of vaccines.[67]

Figure 4: Breakdown of announced vaccine production agreements



Source: Airfinity, as of 6 October 2021 (accessed 14 December 2021)

2.2.1.5 Voluntary Licensing in the context of production and access

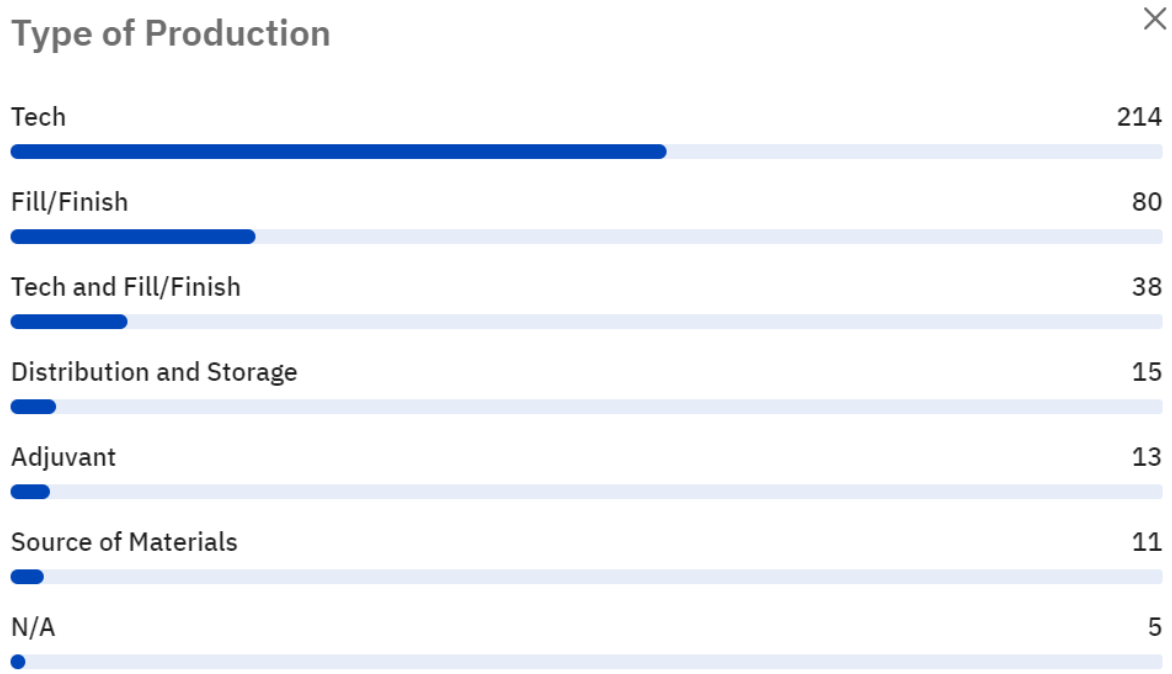
While IP rights are generally exclusive in character, licensing those rights is often the most effective way to derive benefits both for producers and users of technology and for society's overall welfare, as foreseen in the objectives of IP protection set out in Article 7 of the TRIPS Agreement. Article 28 confirms the right of '[p]atent owners … to assign, or transfer by succession, the patent and to conclude licensing contracts.'[68] Mechanisms for IP licensing to promote public health outcomes cover a spectrum of

[66] Sheraz Ali, Oluwaseun Egunsola, Zaheer Ud Din Babar and Syed Shahzad Hasan, 'Clinical trials in Asia: A World Health Organization database study' (2019) 10(3) Perspectives in clinical research 121 < https://doi.org/10.4103/picr.PICR_109_18> . See above n 43.
[67] OECD, 'Regulatory responses to the COVID-19 pandemic in Southeast Asia' (Report, 11 October 2021) <https://read.oecd-ilibrary.org/view/?ref=1112_1112857-ojsehuakia&title=Regulatory-responses-to-the-COVID-19-pandemic-in-Southeast-Asia>
[68] TRIPS art 28.2. See also, TRIPS arts 14.2, 21, 26.1 and Berne Convention arts 9, 11-14bis.

options,[69] including concerning degree of openness or exclusivity, geographical coverage and safeguards for access and equity.

In practice, the distribution of vaccine production has been enabled by a wide range of agreements between different players. These agreements may be categorised as 'in-house' or 'contract production' on the one hand (where the technology originator retains overall control), and as 'technology transfer' on the other (which a greater legal separation between technology provider and user), although there is no absolute distinction between these categories. These agreements are naturally diverse in their subject matter and cover several steps along the production and supply chain. Airfinity data provides a breakdown of publicly announced agreements covering technology transfer, fill-and-finish, distribution and storage, source of materials and adjuvants (Figure 5). Such agreements entail various forms of voluntary licensing of IP, and the reported practices vary considerably across the range of vaccines currently under production. UNICEF data, for instance, illustrates this diversity: some lead vaccines are reportedly the subject of numerous technology transfer agreements and others are predominantly or exclusively covered by contract production (Figure 6). Across different regions, reported production in North America and Europe has been mostly in-house or under contract, whereas Asia shows a more mixed pattern (Figure 7).

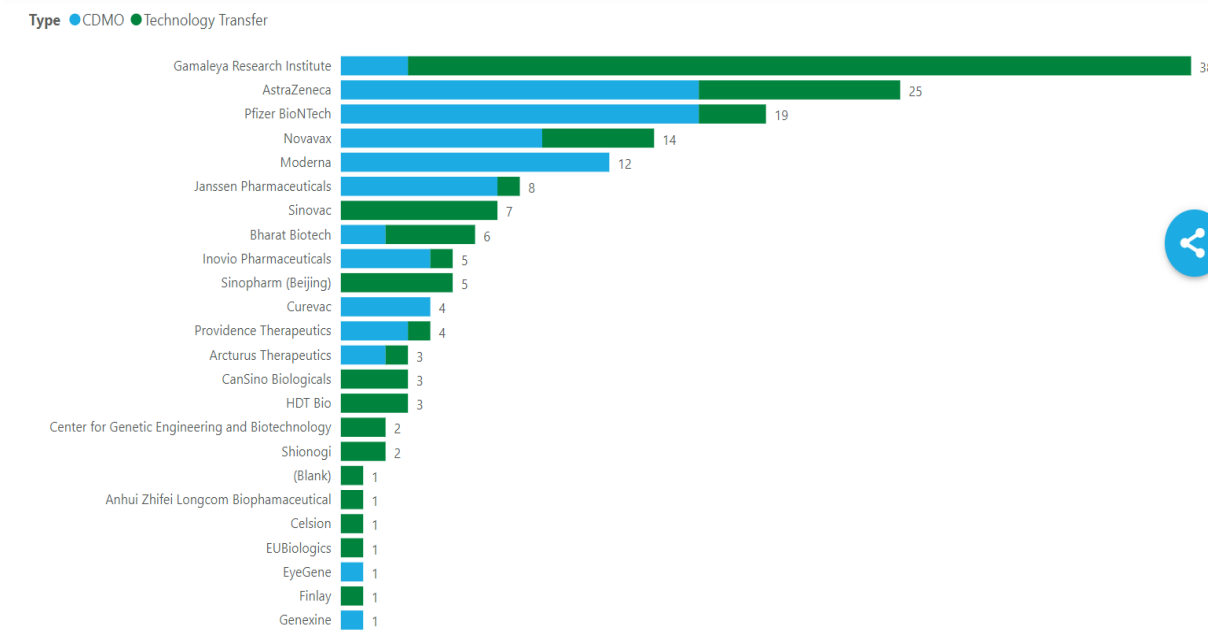
Figure 5: Breakdown of announced production agreements



Source: Airfinity (accessed 15 April 2022)

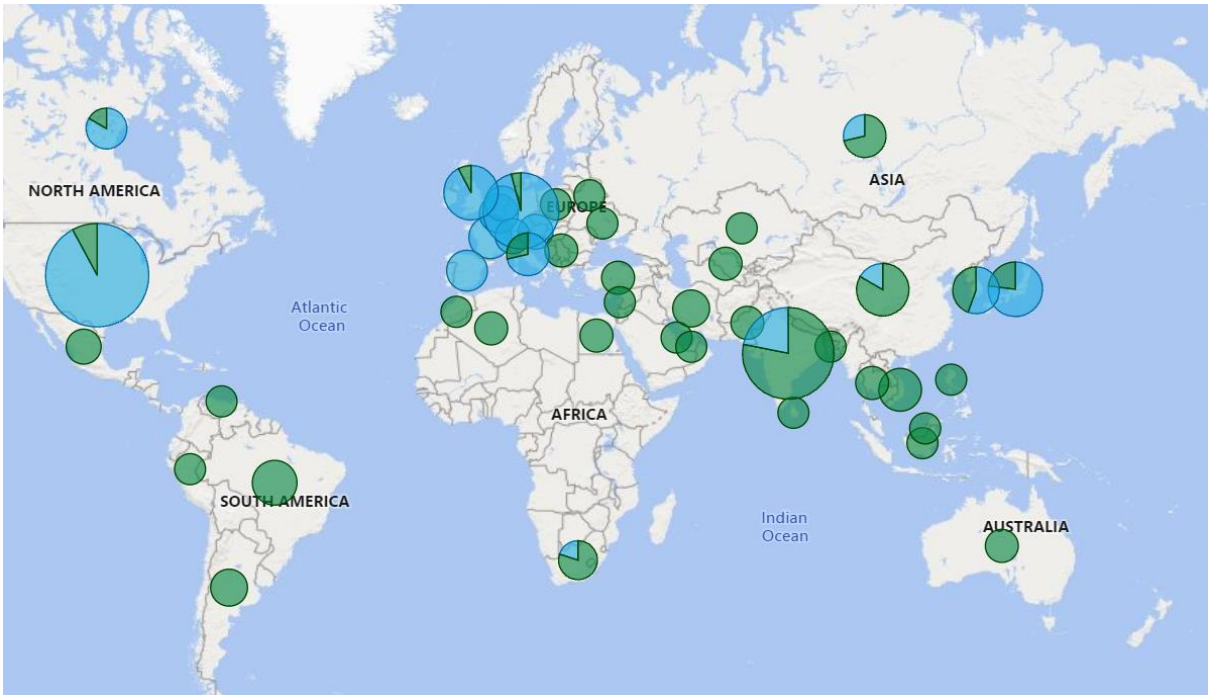
[69] Antony Taubman, 'A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policymakers' (2010) 4 The Open Aids Journal 4 <https://ssrn.com/abstract=2604570>

Figure 6: Announced production agreements



Source: UNICEF Dashboard (accessed 14 December 2021)

Figure 7: Breakdown of reported production



In-house agreements are represented in blue and technology transfer are represented by green.

Source: UNICEF Dashboard (accessed 14 December 2021)

Understanding these trends in licensing, however, is complicated by limited transparency as to their specific terms, and this has been the subject of criticism.[70]

[70] E.g. by India, TRIPS Council minutes, IP/C/M/101/Add.1, 262.

Licences negotiated and published by the MPP and other licence databases[71] have helped to reinforce a trend toward greater transparency. A lack of intervention by Members with regard to restrictive licensing practices has been criticised by proponent Members of a TRIPS waiver.[72] Equally, the overwhelming majority of licensing arrangements have been bilateral in character, despite widespread calls for more open licensing structures. The May 2020 WHO Solidarity Call for Action aimed to 'realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data.'[73] It was operationalised through the creation of the COVID Technology Access Pool ('C-TAP')[74] which concluded its first global, transparent, non-exclusive licence for a diagnostic technology in November 2021.[75]

Voluntary licensing — provided it is on reasonable terms, and consistent with enhanced and more equitable vaccine access — has generally been welcomed as a default means to transfer and disseminate vaccine technologies. As has been noted elsewhere, 'adopting a non-confrontational approach to promote access to medicines will ensure cooperation among governments and pharmaceutical patent holders'.[76] From that point of view, voluntary licensing has been somewhat successful in the COVID-19 context thus far, although showing the considerable diversity in licensing practices described above.

Agreements covering collaboration in the area of vaccine production include AstraZeneca's license for its technology to the Serum Institute of India ('SIIPL')[77] as well as to the Thai firm Siam Bioscience (alongside licenses to the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi the Vaccine Alliance (Gavi)).[78] An additional AstraZeneca licensing agreement with the Brazilian public health research institute, Fundação Oswaldo Cruz (Fiocruz), covering the production of 100m vaccine doses, was concluded in October 2021.[79] AstraZeneca also concluded deals with the Argentinian biotechnology company mAbxience of the INSUD Group, and with the Mexican Carlos Slim foundation for the production of vaccine doses to be supplied in Latin America. Furthermore, a Pfizer–BioNTech collaboration agreement covered

[71] E.g. Global Healthcare Innovation Alliance Accelerator (GHIAA), 'MAPGuide' <https://ghiaa.org/mapguide-home/>

[72] Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, WTO Doc IP/C/W/673 (15 January 2021) 3 [21].

[73] World Health Organization, 'Solidarity Call to Action' (World Health Organization, 29 May 2021) <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>

[74] World Health Organization, 'WHO COVID-19 Technology Access Pool' (World Health Organization) <https://www.who.int/initiatives/covid-19-technology-access-pool>

[75] World Health Organization, 'WHO and MPP announce the first transparent, global, non-exclusive licence for a COVID-19 technology' (World Health Organization, 23 November 2021) <https://www.who.int/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology>

[76] Poku Adusei, 'Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa' (2011) 14(1) Journal of World Intellectual Property 1, 6.

[77] Chakraborty (n 43) 621; AstraZeneca, 'AstraZeneca takes next steps towards broad and equitable access to Oxford University's COVID-19 vaccine' (Press Release, 4 June 2020)

[78] Marimi Kishimoto, 'Thai king-owned biotech starts production of AstraZeneca vaccine' (Nikkei Asia, 4 June 2021)

[79] Available at <https://agencia.fiocruz.br/sites/agencia.fiocruz.br/files/u34/contrato_etec.pdf>

collaborative R&D of vaccines and their launching and commercialization, each maintaining exclusive rights in its respective territory.[80] Novavax and the SIIPL have concluded their COVID-19 Vaccine Supply and License Agreement, which grants SIIPL exclusive rights to commercialize the vaccine in India and non-exclusive rights to commercialize in other LMIC countries. Moderna has concluded two agreements with Lonza, for the manufacturing of the former's COVID-19 mRNA vaccine. CureVac AG (CureVac) and Glaxosmithkline Biologicals SA ('GSK') entered into a COVID-19 collaboration and licensing agreement for the research, development and commercialization of mRNA based COVID-19 vaccines, which builds on an existing relationship under an earlier collaboration and licensing agreement. Ocugen concluded a co-development, supply, commercialization agreement with Bharat Biotech (Bharat), to serve as the Indian company's partner in the US and Canada for Bharat's Covaxin. Merck, a major US pharmaceutical company, entered an agreement with fellow US firm Johnson & Johnson to increase the production of the latter's vaccine.[81]

With regard to therapeutics, attempts to increase production of repurposed medicines investigated for their efficacy in treating COVID-19 patients, such as remdesivir and kaletra (LPV/r), were initiated in the early stages of the outbreak, including through several voluntary licenses by Gilead and NVUAs by government agencies. The voluntary licenses most notably include Abbivie's sublicenses for LPV/r (an antiviral used initially in the treatment of HIV/AIDS) through MPP that covers 102 countries of which more than 65 are classified as middle-income nations. This licensing predated the pandemic but was expanded in light of it and once the compound was nominated as an effective COVID-19 treatment. Furthermore, Gilead's May 2020 non-exclusive voluntary licenses on remdesivir signed with a number of generic pharmaceutical manufacturers based in Egypt, India and Pakistan.[82] With regard to newly developed medicines, Pfizer announced voluntary licenses for its oral antiviral Paxlovid to the MPP,[83] shortly after Mercke agreed to licence its Molnupirarvir to MPP.[84]

2.2.2 IP and the wider context of access

Some have criticised the disproportionate emphasis placed on IP in the debate regarding access to medicines.[85] In the COVID-19 context, Members arguing against

[80] See Pfizer-BioNTech agreement (March 2020), available at: https://www.keionline.org/misc-docs/Pfizer-BioNTech-Collaboration-Agreement-17March2020.pdf.
[81] Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 18) 7. However, see Ashleigh Furlong, 'Big Vaccine Makers Reject Offers to Help Produce More Jabs' (POLITICO, 14 May 2021) <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/>
[82] See Ellen 't Hoen, 'Remdesivir developed country price announced' (Medicines Law & Policy, 30 June 2020) accessed 1 September 2020.
[83] Grady McGregor, 'Pfizer pledges equitable access to COVID-19 pill through new licensing agreement' (Fortune, 16 November 2021) <https://fortune.com/2021/11/16/pfizer-covid-pill-equitable-access-generic-manufacturing-low-income-countries/>
[84] Adam Taylor and Claire Parker, 'U.S. drug company Merck to share license for experimental covid-19 treatment with non-profit organization' (The Washington Post, 27 October 2021) <https://www.washingtonpost.com/world/2021/10/27/merck-license-ip/>
[85] Hans Morten Haugen, 'Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?' (2021) 24 The Journal of World Intellectual Property 195, 196-197 citing United Nations, Report of the United Nations Secretary-General's High-Level Panel On Access To Medicines: Promoting Innovation and Access to Health Technologies (September 2016).

a TRIPS waiver have pointed to other barriers that a waiver alone is unlikely to alleviate: underfunded health care and procurement systems, spiking demand, and lack of manufacturing capacity.[86] Implicit in these claims is that manufacturing capacity is a broader issue in respect of which IP rights can only play a limited role. Manufacturing capacity requires, amongst other things, adequate levels of investment, strong physical infrastructure systems, and suitable systems of labour. Maskus, Saggi and Puttitanun note that technology transfer — which is often the sole avenue to the local manufacture of complex pharmaceuticals — can be impeded by 'weak domestic absorption capacities, poor infrastructure, restrictions on inward technology, trade, and investment flows, and inadequate regulatory systems'.[87]

Indeed, some of the barriers listed by TRIPS waiver opponents, such as spiking demand, have precipitated the need to ramp up manufacturing capacity. IP rights only form part of the picture, and a conducive regulatory and infrastructural environment for boosting manufacturing capacity of either novel or developed vaccines is likely to be achieved by addressing IP-related impediments as part of a broader suite of policy measures.[88]

2.3 Tailoring IP systems to domestic needs

The TRIPS Agreement is not in itself a model IP law with provisions at the level of detail and precision of those found in domestic legislation; it is better conceived of as a set of agreed general principles intended to be adapted and applied in a manner that responds to domestic needs and circumstances.[89] TRIPS itself stipulates that governments are 'free to determine the appropriate method of implementing [its] provisions … within their own legal system and practice.'[90] Accordingly, a challenging but vital practical issue — extending well beyond the scope of this paper — is how to shape domestic systems in a manner that responds to the domestic legal, economic and developmental context. The approach taken to addressing pharmaceutical needs may differ depending on: whether a country seeks to build capacity as a pharmaceutical innovation or production centre; whether it is maintaining an independent regulatory regime; and whether it aims to rely primarily or even exclusively on imported pharmaceuticals produced and regulated elsewhere. A robust IP regime can act as an incentive for foreign firms to engage in technology partnerships with

[86] World Trade Organization (n 3).
[87] Keith E Maskus, Kamal Saggi and Thitima Puttitanun, 'Patent rights and international technology transfer through direct investment and licensing' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 265, 266.
[88] Carlos M Correa, 'Can the TRIPS Agreement foster technology transfer to developing countries?' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 227, 256.
[89] Antony Taubman, A Practical Guide to Working with TRIPS, (Oxford University Press, 2011) 92. See in particular the author's forthcoming Ph.D. dissertation, entitled Towards the 'Collective Management' of TRIPS, due for conclusion in 2022 at the University of South Australia.
[90] TRIPS art 1.1.

domestic firms, either through licensing arrangements or foreign direct investment.[91] This is particularly the case for complex biotechnologies where access to IP-protected technologies is critically important,[92] such as mRNA vaccines.

Adjusting the settings and policy balance of the domestic IP system is just one element of creating the necessary enabling environment for technology transfer and the successful implementation of pharmaceutical technologies. Other, non-IP-related means of managing technology transfer can be employed, such as licensing arrangements with strong contractual protections. Some countries do not attract technology transfer for reasons unrelated to IP, demonstrating that there are other factors at play.[93] Maskus, Saggi and Puttitanun note that 'simply strengthening IPRs alone cannot suffice to improve access significantly' and that this 'needs to be buttressed by appropriate infrastructure, governance, and competition systems in order to be effective.'[94] A report on the experience of transferring influenza vaccine technology to Brazil concludes that:

> Technology transfer is complex. It entails a great deal of responsibilities on the part of the technology provider and technical and managerial capability on the part of the recipient. Above all, technology transfer is a joint venture based on mutual trust and commitment. A major objective must also be for the project to be sustainable, which implies incorporation of new developments into the process and, ultimately, technology independence for the recipient.[95]

It follows that individual countries will need to apply and adapt a range of policy options depending on their specific strategy relating to longer-term upgrading of manufacturing and innovative capacity for vaccines and other medicines, recognizing also that the IP system in isolation is not the sole or even primary determinant of vaccine access. The current WHO-COVAX project to establish an mRNA technology hub in South Africa — guided by the practical lessons of establishing technology hubs for the influenza virus[96] — offers a real-time case study in technology transfer in association with the development of technical skills and absorptive capacity.

Box 1: Lessons learned from the South African mRNA Vaccine Hub

The South African mRNA vaccine hub – issues faced and lessons learned

Access to, and capacity to use, mRNA vaccine technologies have become critical not merely for the global response to the COVID-19 pandemic but also for their potential to provide for vaccines for other endemic infectious diseases, on which investigation was already under way prior to the outbreak

[91] See generally, Ashish Arora, Andrea Fosfuri and Alfonso Gambardella, 'Markets for technology, intellectual property rights, and development' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 321; Maskus, Saggi and Puttitanun (n 87) 272-273. However, the theoretical and empirical evidence in this respect is somewhat mixed or has not always been watertight: Maskus, Saggi and Puttitanun (n 87) 271.
[92] Correa (n 88) 231; Maskus, Saggi and Puttitanun (n 87) 272-273.
[93] Correa (n 88) 228.
[94] Maskus, Saggi and Puttitanun (n 87) 266.
[95] Cosue Miyaki, Mauricio Meros, Alexander R Precioso, Isaias Raw, 'Influenza vaccine production for Brazil: A classic example of successful North–South bilateral technology transfer' (2011) 29 Vaccine A12.
[96] Martin Friede, Laszlo Palkonyay, Claudia Alfonso, Yuri Pervikov, Guido Torelli, David Wood, Marie Paule Kieny, 'WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: Supporting developing country production capacity through technology transfer' (2011) 29 Vaccine A2.

of SARS-CoV-2.[97] The novel vaccine technology, together with a novel form of production and delivery, created significant challenges, including from the perspective of technology transfer, capacity to absorb and deploy the new technology, manufacturing processes and knowhow for production at scale, and access to critical inputs such as bioreactor bags and the lipids used to produce the nanoparticles that deliver the mRNA vaccine. The previous development of the mRNA as a platform technology[98] also means that there is a relatively complex patent landscape.[99] These factors, together with the originating firms' approach to licensing and technology sharing, has resulted in relatively concentrated manufacturing capacity for mRNA COVID-19 vaccines, a situation sparking concern that knowhow and production capacity should be shared more widely with a view both to vaccine equity and longer term resilience.

The WHO and partners sought to address this situation by announcing in June 2021 the launch of the mRNA Vaccine Technology Hub, to 'build capacity in low- and middle-income countries to produce mRNA vaccines through a centre of excellence and training.'[100] Based at Afrigen, a biotech firm in Cape Town, South Africa, the hub will disseminate technology and knowhow through an array of spokes, technology recipients based in low- and middle-income countries so as to enable beneficiary countries to produce safe and effective vaccines in the near future. It has reportedly already commenced production of COVID-19 vaccines.

The mRNA hub initiative has lessons for the wider efforts to disseminate vaccine technologies and progress more diversified vaccine production capacity. For instance:

- Partnerships are key: the launch is a collaboration between the WHO, the Medicines Patent Pool (MPP), Afrigen Biologics (Pty) Limited, the Biologicals and Vaccines Institute of Southern Africa (Biovac), the South African Medical Research Council (SAMRC) and Africa Centres for Disease Control and Prevention (Africa CDC).
- Technology transfer requires both specialist training and the indigenous capacity to absorb and deploy a new technology, including a skilled workforce able to make use of production knowhow, and to manage quality control and product regulation.
- Effective establishment combines financing, developing human capital, meeting regulatory and quality control standards, and concluding any necessary licenses, as well as sourcing the necessary inputs for production.
- Analysis of the patent landscape can guide pathways to effective access to technologies, even in the absence of cooperation by the technology originator companies.

In sum, for the effective deployment and diversified global production of this vital technology, it is necessary to ensure freedom to operate in light of background and foreground IP – whether through voluntary licensing, patent non-assertion pledges, public domain status of technology not patented in relevant countries, or non-voluntary use authorisations such as approval for public non-commercial use or compulsory licensing. However, other equally significant factors must also play a role: human capital, transfer of technology and production know how through direct training, financing, regulatory capacity, and access to critical inputs.

3. TRIPS Flexibilities and their Implementation in Asia-Pacific Intellectual Property Law and Policy

A multilateral trade agreement concluded as an Annex to the Agreement Establishing the World Trade Organisation, the TRIPS Agreement sets standards of IP protection

[97] Norbert Pardi, Michael J. Hogan, Frederick W. Porter & Drew Weissman, 'mRNA vaccines — a new era in vaccinology' (2018) 17 Nature Reviews Drug Discovery 261.
[98] Elie Dolgin, 'The tangled history of mRNA vaccines' (Nature, 14 September 2021) <www.nature.com/articles/d41586-021-02483-w>
[99] See generally, Chiang and Wu (n 8).
[100] World Health Organization, 'The mRNA vaccine technology transfer hub Credits' <www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub>

for WTO Members. In comparison to other WTO Agreements, TRIPS largely sets down a 'floor' of positive, minimum standards at the level of general principles for how national systems protect IP. These general principles cover eligible subject matter, the consequent rights, and the manner of their enforcement. In imposing these obligations, TRIPS — explicitly through its terms, and implicitly within its structure and context — confers on WTO Members some room for manoeuvre or flexibility, allowing them to go beyond the minimum standards imposed,[101] and also to provide defined exceptions and limitations to these standards in certain circumstances.

Importantly, TRIPS is not a self-executing treaty, meaning that Members must give it effect by implementing it into their legal systems through domestic laws and regulations. This process of treaty implementation allows Members to adopt and adapt TRIPS standards to their own national legal regimes and judicial and administrative systems, provided that these systems remain compliant and consistent with the treaty's more general standards. Thus, WTO Members' national IP laws are the operative means by which TRIPS' inherent flexibilities can be realised.[102]

This section examines and analyses how the countries selected for this study have implemented TRIPS provisions so far, so that recommendations can be made for leveraging the treaty's flexibilities to increase manufacturing capacity in the Asia-Pacific region. In interpreting TRIPS provisions, we adopt the analytical framework of treaty interpretation under the disciplines in Articles 31-32 of the *Vienna Convention on the Law of Treaties* ('*VCLT*'). The *VCLT* requires that a treaty be interpreted in good faith in accordance with the ordinary meaning to be given to its terms in their context and in light of the treaty's object and purpose, which includes the treaty text, its preamble, and annexes.[103]

In adopting this interpretative framework, we employ a 'practical jurisprudence' approach that is consistent with *VCLT* rules and principles. This approach has been developed and previously elucidated by one of us as 'a systematic and coherent approach to reading the text of TRIPS in the light of its full legal context, but with certain practical needs in mind, when weighing choices for domestic IP law'.[104] As previously explained, this straightforward and objective reading of TRIPS text enables greater legislative freedoms than an overly political or theoretical approach would otherwise allow.[105] We apply this approach in light of the practical demands created by the current global health situation.

[101] See TRIPS art 1.1.
[102] WIPO, Committee on Development and Intellectual Property (CDIP), Fifth Session Geneva, April 26 to 30, 2010, Patent Related Flexibilities In The Multilateral Legal Framework And Their Legislative Implementation At The National And Regional Levels, Cdip/5/4 (1 March 2010) 8 [23].
[103] Vienna Convention on the Law of Treaties, opened for signature 23 May 1969, 1155 UNTS 331 (entered into force 23 January 1980) arts 31.1-31.2. See also art 31.3.
[104] Antony Taubman, A Practical Guide to Working with TRIPS (Oxford University Press, 2011) 43. The elaboration of this approach is the subject of the author's concurrent Ph.D. dissertation (n 89), which has been drawn on substantially for relevant passages of the present paper.
[105] Antony Taubman, A Practical Guide to Working with TRIPS (Oxford University Press, 2011) 43.

3.1 Least-Developed Countries

'In view of the special needs and requirements of [LDC] Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base', least-developed Members were not required to apply TRIPS (other than non-discrimination provisions) for 10 years.[106] That transition period was extended in respect of pharmaceutical products two times by the TRIPS Council before 29 June 2021,[107] when it was extended again until 1 July 2034.[108]

The LDCs in our survey and other LDCs in the Asia-Pacific — Bangladesh, Cambodia, Nepal, and Myanmar[109] — need not comply with such provisions until at least 2034, leaving them with the greatest latitude available to implement IP-related measures to address the pandemic and future health crises. Thus, for example, LDCs with an existing industrial base (notably, Bangladesh, which has a vibrant pharmaceutical industry) can potentially produce generic medicines to meet national demand and export to other LDCs or countries where no relevant patent is in force, subject to manufacturing capacity for the medicines concerned.[110] As noted above,[111] manufacture of more recent vaccine technologies is considerably more complex than for other pharmaceuticals, which may limit the options available to LDCs in this regard. For example, LDCs — in addition to becoming involved at the excipient production and fill-and-finish stage — may receive imported vaccines while dispensing with the requirements in Article 31 and 31bis, even where the imported vaccine was produced and exported under a compulsory licence.

3.1.1 Implementation in the Asia-Pacific region

Bangladesh has diverged from TRIPS standards in its patent law, which provides patent protection for only 16 years, allows the issue of compulsory licenses by non-government entities, and permits the cancellation of foreign patents after four years if the product is not manufactured domestically.[112] Similarly, Nepal only grants patents with terms of seven years, and provides wider grounds for refusing to patent an invention.[113] Cambodia has availed itself of the decision to extend the transition period

[106] TRIPS art 66.1.
[107] Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products, WTO Doc IP/C/73 (6 November 2015); Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products, WTO Doc IP/C/25 (1 July 2002).
[108] Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition Period Under Article 66.1 for Least Developed Country Members, Decision of the Council for TRIPS of 29 June 2021, WTO Doc IP/C/88 (29 June 2021).
[109] Samoa and Vanuatu were LDCs on accession to the WTO, but have since graduated from LDC status.
[110] Mahmud-Al-Rafat, Abdullah et al, 'COVID-19 vaccine inequity, dependency, and production capability in low-income and middle-income countries: the case of Bangladesh' (2022) 22(3) The Lancet Infectious Diseases 310, 310; Rahman and Farin (n 45) 9.
[111] See above n 46.
[112] Padmashree Gehl Sampath, 'Pharmaceutical Manufacturing in Bangladesh – A Success Story: What can we learn?' (FEAPM Advocacy Series No. 1, no date) 23. Some of these measures are arguably TRIPS compliant as nothing precludes patent revocation on particular grounds, including a failure to work an invention domestically.
[113] A patent 'shall not' be registered if it is likely to 'adversely [a]ffect the public health, conduct or morality or the national interest': The Patent, Design and Trade Mark Act, 2022 (1965) (Nepal) s (1).

in respect of pharmaceutical products.[114] However, it is noteworthy that Cambodia's current patent and industrial design law only excludes such products from patentability until 2016, notwithstanding the TRIPS Council's 2015 decision.[115]

Countries that have acceded to the WTO since its inception in 1995 have entered into additional agreements as part of the accession package, at times creating additional obligations on IP protection beyond the specific provisions of the TRIPS Agreement (since the ensuing accession protocols form part of the WTO Agreement for such acceding members).[116] Several acceding LDCs have entered into such 'TRIPS-plus' accession commitments, creating some ambiguity as to their current obligations, although subsequent TRIPS Council decisions have referred to extensions of the implementation period for all LDC members without qualification.[117]

3.2 Patents

3.2.1 Patentability

3.2.1.1 Scope of Patentability

Article 27 of TRIPS requires Members to make patents available for any inventions — whether products or processes — that are 'new', 'involve an inventive step' and are 'capable of industrial application'.[118] TRIPS itself does not define these terms, beyond clarifying that 'the terms "inventive step" and "capable of industrial application" may be deemed to be synonymous with the terms "non-obvious" and "useful" respectively.'[119] In practice, 'novel' is also often used as a synonym of 'new.' It follows that Members have considerable latitude in determining the application of these terms, in their domestic patent laws, through judicial decisions and in the application of examination guidelines by patent grant authorities.

The threshold question is the definition of an 'invention' as such, and there is a wide practice among WTO members. This includes various approaches to defining 'invention' in inclusive terms and through exclusions of certain subject matter (including, but not limited to, the specific exclusions provided for expressly in Article 27 (see the following subsection). A common positive approach to defining the term is to refer to a solution to a problem in a technical field; scientific principles and mere scientific discoveries are examples of common exclusions of subject matter. To some extent, the definition of 'invention' is clarified further in many jurisdictions through judicial decisions. Similarly, WTO members determine the specific criteria for patentable inventions by setting standards for novelty, inventive step and utility or

[114] Law on Patents, Utility Models and Industrial Designs (Cambodia) arts 4(iv), 136.
[115] However, see Law on Compulsory Licensing for Public Health (Cambodia) art 23.
[116] Antony Taubman, 'How Post-TRIPS Negotiations Reframe the 'Trade-Related Aspects' of Intellectual Property After TRIPS: The Lessons of WTO Accessions' in Alexei Kireyev and Chiedu Osakwe (eds), Trade Multilateralism in the Twenty-First Century: Building the Upper Floors of the Trading System Through WTO Accessions (Cambridge University Press, 2017).
[117] e.g. WTO document IP/C/88 (June 29, 2021), providing that 'Least developed country Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, until 1 July 2034, or until such a date on which they cease to be a least developed country Member, whichever date is earlier'.
[118] TRIPS art 27.1.
[119] TRIPS footnote 5.

industrial applicability, and again these are found both in legislation and in the jurisprudence arising from judicial decisions.

3.2.1.1.1 Implementation in the Asia-Pacific region

The legislation and actual practice of Asia-Pacific countries show considerable diversity in defining and applying these terms, and more generally, in setting the threshold criteria for determining whether a claimed invention is eligible to be patented. For example, Fiji's patent law defines an 'invention' as 'any manner of new manufacture and every new process of manufacture and every new method of application of known processes and improvements in any known process'.[120] Thailand includes under the definition of 'invention': 'any improvement of a known product or process'.[121] While often general in character, a number of definitions have specific application in the pharmaceutical field, and of these some have been formulated with the intention of raising the threshold for pharmaceutical patents and in particular curbing a practice termed 'evergreening' of certain inventions (gaining patent protection over minor improvements or changes to existing pharmaceutical formulations). Thus, Indonesia's definition of 'invention' expressly excludes a 'discovery in the form of: 1. new use of existing and/or known product; and/or 2. new forms from existing compound which does not generate significantly enhanced efficacy and contains different relevant known chemical structures to compound.'[122] India's patent law states that 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant' is not patentable.[123] Another provision, commonly found in other country's patent laws, excludes from patentability 'a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance'.[124] As noted elsewhere, this may provide the basis for refusing a patent over a mere vaccine composition.[125]

3.2.1.2 TRIPS exclusions from patentability

Along with general criteria for patentability, Article 27 of TRIPS expressly sets out permissible exclusions from the scope of patentable subject matter, some of which may be relevant to pharmaceutical technologies. These exclusions are optional for Members and therefore provide scope for domestic policy choices. Importantly, such exclusions do not provide exceptional circumstances in which the rights of a patent-holder are suspended.[126] Instead, they operate as limitations on patentability that

[120] Laws Of Fiji, Chapter 239, Patents (Fiji) s 2.
[121] Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 3.
[122] Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 4(f).
[123] Patents Act, 1970 (India) s 3(d).
[124] Patents Act, 1970 (India) s 3(e).
[125] Medicines Sans Frontiers, 'A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines' (September 2017) 17.
[126] This is the potential effect of TRIPS art 30.

operate *ex ante* before a patent is granted, hence effectively stripping all potential applicants of the ability to patent an invention captured by the exclusion.

Article 27.2 provides in part that 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'[127] This provision is unlikely to apply to vaccine technologies which would, in general, be considered highly desirable to be commercially exploited, although some jurisdictions may raise issues about the ethical basis of some biotechnologies.[128]

Article 27.3 allows Members to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. However, such methods — even if broadly construed — could not be argued to include processes and inputs for the production of vaccines, nor the finished vaccines themselves. Article 27.3 is concerned only with methods for treatment, which would arguably only include processes for the final administration of vaccines, should these be claimed as potentially patentable inventions.

3.2.1.2.1 Implementation in the Asia-Pacific region

Many Members incorporate the words of Article 27.2 directly into their patent legislation. For example, Cambodia's patent and industrial design law provides that 'inventions, the commercial exploitation in the Kingdom of Cambodia of which would be contrary to public order or morality, or would not be protected human, animal or plant life or health, or would cause serious prejudice to the environment, or prohibited by law, are excluded from patentability.'[129]

Some developing country Members have incorporated the 27.3(a) exclusion of diagnostic, therapeutic and surgical methods directly into their domestic legislation.[130] India goes further by excluding from patentability 'any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings'.[131] By excluding 'prophylactic … treatment' from patentability, India's provision may possibly exclude from patentability methods for actual administration of vaccines, which are not expressly encompassed within the methods of treatment specified in Article 27.3.[132] In any case, this does not exclude vaccines as such, as such products are clearly distinct from processes or methods for the prophylactic *treatment* of human

[127] TRIPS art 27.2.
[128] See e.g. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
[129] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 9. See also, Patents Act, 1970 (India) s 3(b); Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 9(5).
[130] See e.g. Law on Patents, Utility Models and Industrial Designs (Cambodia) art 9(iii); Patent Law of 25/06/1993 (Mongolia) art 4.7.5; Patents Act No. 291 of 1983 (Malaysia) s 13(d); Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 9(4); Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 9(b).
[131] Patent Acts, 1970 (India) s 3(i).
[132] See also, Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 9(4); Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 4(f).1 which states 'any method'.

beings. Our survey reveals that this option of excluding methods of treatment from patentability is not universally adopted by developing countries, which may reflect distinct IP policy choices around desired levels of technological innovation.

3.2.2 Patent Disclosure

It is a longstanding, central principle of patent law that the invention must be fully disclosed in sufficient detail for a skilled person to be able to put the technology into effect. Patent disclosure is at the heart of the patent function: the *quid pro quo* that permits interested parties to make use of the patented technology in return for the patentee gaining a defined period of market exclusivity over the invention.[133] It is, in principle, the guarantee that the protected technology passes fully and effectively into the public domain. Given the ready availability of patent information online, this assists in making full use of the technology in those countries — typically the majority of developing countries — where the patent has not been applied for. This mechanism can therefore have some effect on firms' ability to engage in technology transfer, including enabling an early review of available technologies still undergoing development even prior to exploring licensing possibilities.

Article 29 of TRIPS obligates Members to require patent applicants to disclose the invention 'in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art'.[134] Article 29 permits but does not compel Members to require patent applicants to 'indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.'[135]

Some argue that the requirement in the first sentence of Article 29.1 does not require disclosure of the invention in 'significant scientific or technical detail'.[136] In any case, there is evidence that, in some cases, disclosure does in practice fall short of technical disclosure,[137] although in principle this leaves a patent vulnerable for revocation on the grounds of insufficient disclosure. The preposition 'for' in the first sentence of Article 29.1 indicates that a disclosure need not be generally 'clear and complete', but only sufficiently 'clear and complete' *for the purposes of* enabling the invention to be carried out by a skilled person.[138] The question whether the words 'a person skilled in the art' engenders a requirement for the disclosure to be technically or scientifically detailed may not be necessary to answer, largely because Members can go beyond the requirements in Article 29.1 by requiring more than merely a 'clear and complete' disclosure.

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[133] Bingbin Lu, 'Disclosure Requirements for Patent Application: Article 29 of the TRIPS Agreement and a Dimensional Exploration' (2012) 35(4) European Intellectual Property Review 336, 336.
[134] TRIPS art 29.1.
[135] TRIPS art 29.1.
[136] Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 18) 18.
[137] Medicines Sans Frontiers, 'A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines' (September 2017) 17.
[138] This interpretation at the domestic level has been subject to widespread judicial and academic debate: see generally, Lu (n 133) 339.

Given the possibility of differing interpretations and applications of Article 29.1 by implementing Members, governments have the option of utilising the flexibilities conferred by Article 29.1 by requiring patent applicants to disclose the best known mode, which means the best way of carrying out the invention. In some jurisdictions, this requirement is not simply an added requirement, but acts as the 'linchpin … of the patent system',[139] ensuring that the invention is properly disclosed, and when appropriate, can be properly worked.

3.2.2.1 Implementation in the Asia-Pacific region

US patent law requires a description of the invention 'and … the manner and process of making and using it in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same …'[140] Many of our sample countries impose much narrower requirements. For example, Bangladesh's patent and designs law merely requires that a 'complete specification … particularly describe and ascertain the nature of the invention and the manner in which the same is to be performed.'[141] Similarly, Nepal's law requires disclosure of the '[p]rocess of manufacturing, operating or using the patent and … [t]he theory or formula if any, on which the patent is based.'[142]

Our survey indicates that the laws of Cambodia,[143] India,[144] Malaysia,[145] Mongolia,[146] and Thailand[147] include a requirement to disclose 'the best known mode', while those of Bangladesh, Fiji, Indonesia, Nepal, and Vietnam do not. The consequence of failure to meet disclosure requirements in a patent law is that it renders the patent invalid in principle and thus open to attack and revocation, or for the scope of the patented invention to be reduced.

3.2.3 Exceptions to Patent Rights

Article 28 of TRIPS requires that, under Members' domestic laws, patent owners must be given the right to exclude others from acts of making, using, offering for sale, selling, or importing patented products or products produced by a patented process, and from using a patented process. However, these 'exclusive rights' are not absolute and it is well established that they may be curtailed or overridden in view of the public interest or the legitimate interests of third parties, such as researchers and other firms. TRIPS Articles 30, 31 and the related 31bis, dealt with in the following Section 3.2.4, specify

[139] Dale L Carlson, Katarzyna Przychodzen and Petra Scamborova, 'Patent Linchpin for the 21st Century – Best Mode Revisited' (2005) 87 Journal of the Patent and Trademark Office Society 89, 92.
[140] 35 U.S.C. 112 cited in Lu (n 133) 337-338.
[141] The Patents And Designs Act, 1911 (Bangladesh) s 4(2).The law includes as a ground for revocation: 'that the complete specification does not sufficiently and clearly ascertain the scope of the invention claimed': s 26(h). Cf Patent Regulations 1986 (Malaysia) r 12, which is extensive.
[142] The Patent, Design and Trade Mark Act, 2022 (1965) (Nepal) s 4(1)(c)-(d).
[143] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 18.
[144] Patent Acts, 1970 (India) s 4(b).
[145] Patent Regulations 1986 (Malaysia) r 12(e).
[146] Patent Law of 25/06/1993 (Mongolia) art 7.3.1.
[147] Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 17(3); Ministerial Regulations No. 21 (B.E. 2542) Issued under the Patent Act B.E. 2522 (Thailand) r 3(6).

two broad classes of such exceptions and limitations to the rights provided for in Article 28. Article 30 allows Members to:

> provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[148]

Similar exceptions apply in respect of copyright protected works, trademarks and industrial designs.[149] Article 30 has formed the basis of exceptions to patent rights in the laws of many WTO Members, some of which have transposed the exact terms of TRIPS directly into their legislation. In practice, the range of specific exceptions implemented on the basis of Article 30 has been limited to several specific categories. In this subsection, we review only those most relevant to vaccine production and distribution.

3.2.3.1 Regulatory Review

In order to obtain regulatory approval to place a follow-on pharmaceutical product on the market, a generic producer may need to make use of the originator's patented technology (for instance, by producing sufficient quantities of the medicine to demonstrate its safety and efficacy or equivalence to the original product). In principle, this would violate the Article 28 right to exclude the 'use' of the patented technology. Yet delaying such regulatory use until a patent expires or lapses would unreasonably extend the effective term of the patent. Hence, it is in the public interest for the regulatory processes to be concluded by the time the patent term ends so that the generic producer can enter the market in a timely fashion and enhance access to the patented medicine.

It is now widely accepted that such use is a legitimate exception under Article 30 (commonly referred to as a '*Bolar* exception', with reference to an earlier case in the United States). The Panel in *Canada – Patents* confirmed Canada's regulatory review exception was consistent with Article 30. Since that finding, many WTO members have implemented this exception — even the EU, which had originally challenged its TRIPS-compliance.

The *Bolar* exception provides one avenue for accelerating market entry for generic pharmaceutical products, thus potentially diversifying production and reducing prices through the effect of competition. In particular, it may reduce the delay between a patent's expiry and the ability of local manufacturers to exploit the vaccine by producing and selling it domestically. It only comes into play, however, when a domestic regulatory authority is requesting data based on use of the patented technology in the course of approval of the follow-on generic product. This may not be the case, for instance, where products can be approved on the basis of regulatory clearance in other jurisdictions. In addition, it only applies where there is a patent in force over a vaccine

[148] TRIPS art 30.
[149] See TRIPS arts 13, 17 and 26. See Sections 3.3-3.4 below.

that a domestic producer wishes to manufacture; and no other flexibilities have or will be utilised to provide the local producer with access to relevant IP in the invention before the patent term expires.

3.2.3.1.1 Implementation in the Asia-Pacific region

The *Bolar* exception is widely implemented across the WTO membership, but less so amongst the countries surveyed in this study.[150] That said, it is possible for such an exception to be implemented by domestic courts in interpreting the general principle set out in Article 30, assuming Article 30 has been inserted into domestic patent law. However, it is clearly preferable for such an exception to be framed expressly in the patent legislation.

3.2.3.2 Research and Other Exceptions

Other exceptions accepted as generally being permissible under Article 30 (depending on their individual scope and parameters) include private, non-commercial use; prior use (the continued use of an invention initiated secreted prior to the priority or filing date); and temporary use on vessels, aircraft or land vehicles temporarily or accidentally entering the waters, airspace or land (a mandatory exception in Article 5ter of the *Paris Convention* incorporated into TRIPS).[151]

However, the most significant for access to medicines are exceptions for research and analysis, and for pharmacists to make up prescribed medicines. Generally, it is accepted that researchers can make use of a patented invention for investigation, study and experimentation, including for determining whether the invention actually produces the results claimed for it, provided this stops short of commercial exploitation. Research exceptions are likely to assist countries in undertaking relevant preparatory research and analysis, but would not alone permit the manufacture or sale of vaccines. Equally, it is a longstanding principle that, for public policy reasons, a pharmacist can make up a patented medicine on the prescription of a medical practitioner, without the patent holder's consent, but this is not applicable to large scale vaccine production and distribution.

3.2.3.2.1 Implementation in the Asia-Pacific region

The research exception has been expressly implemented in the laws of several of the countries surveyed,[152] although it is possible that such an exception may be allowed by the courts based on the wider principles of patent law, including as an exception to the remedies available for alleged patent infringement. That said, an express exception in domestic legislation would assist in providing clarity and confidence to those seeking to make use of this legitimate option and avoid the uncertainty and delay of litigation.

[150] See e.g. Laws Of Fiji, Chapter 239, Patents (Fiji) s 3A; Patent Acts, 1970 (India) s 107A; Patents Act No. 291 of 1983 (Malaysia) s 37(1A); Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 36(4).
[151] Antony Taubman, Hannu Wager and Jayashree Watal, A Handbook on the WTO TRIPS Agreement (Cambridge University Press, 2nd Edition, 2020) 118.
[152] See e.g. Patent Law of 25/06/1993 (Mongolia) art 18.2.2; Patent Acts, 1970 (India) s 47(3); Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) arts 6(1)(b), 19(3); Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 36(1).

Thailand's patent law provides express exceptions for 'any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner'[153] and for 'the compounding of a drug specifically to fill a doctor's prescription by a professional pharmacist or medical practitioner.'[154]

3.2.4 Government interventions to safeguard public health

It is a well-established general principle — within the TRIPS Agreement and in the field of patent law and policy more widely — that Member governments have considerable agency and scope of potential action 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. This includes an array of legal measures to authorise the use of patented subject matter — whether directly by government agencies, on behalf of governments, or by third parties — without the consent or involvement of the patent holder. These interventions are often collectively termed 'compulsory licences' (and are referred to as such in the Doha Declaration), but in some contexts this term has created the impression that governments' options are more limited than they actually are. Such interventions may, therefore, be termed more broadly and descriptively 'non-voluntary use authorisations' (NVUAs), which have been described as '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.'[155] These fall into two broad categories:

(i) Compulsory licenses that aim to preserve a healthy state of competition between firms, promote more competitive use of patented technology, or remedy anticompetitive practices; and
(ii) Other public interest NVUAs that directly permit use of patented technology for public non-commercial purposes, for emergencies, in cases of extreme urgency or directly in the public interest, regardless of the competitive environment.

When implemented within national legal systems, NVUAs take diverse legal and substantive forms, but they may be categorised broadly as follows:

(i) express authorisations to use the subject matter of a nominated patent(s) (including applications prior to patent grant);
(ii) broader authorisation to make use of a technology that may be covered by the subject matter of a patent, implicitly authorising acts that could otherwise infringe a patent right;
(iii) direct use by a government instrumentality of a patented technology, even in the absence of a specific authorisation as such;

[153] Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 36(2).
[154] Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 36(3).
[155] Antony Taubman, 'Rethinking TRIPS: "Adequate Remuneration" for Non-Voluntary Patent Licensing' (2008) 11(4) Journal of International Economic Law 927.

(iv) exclusion or limitation of remedies for claimed infringement of patents, so that a right holder would be limited, for instance, to a retrospective claim for adequate remuneration potentially after the use has been authorised.

Thus, in some contexts at least, NVUAs need not refer to a patent at all, and the consequences of infringing a patent may emerge only after the authorized activity. Government use authorizations may, therefore, take the form of a specific license under a patent (i.e. a compulsory licence), or a more general authorization rather than a license as such, and the formal link with a patent may be a limitation on available remedies for infringement. This diversity of approach is reflected both at the international level as framed in the TRIPS Agreement, and in the actual domestic practice of nations, including across the Asia-Pacific region, as documented in our survey below.

3.2.4.1 Article 8 and the Doha Declaration in context

The policy context for the development and actual implementation of NVUAs in the public health domain is partly framed by the TRIPS Agreement itself and the Doha Declaration. Negotiators were fully conscious of the need to safeguard domestic policy space, and, to that end, articulated the principles of Article 8 of TRIPS, confirming that, among other things: 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition … provided that such measures are consistent with the provisions of this Agreement.'[156]

The Doha Declaration further illuminated several aspects of this vital policy space and more concretely set it in practical context. For instance, it confirmed that each Member government 'has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'[157] While the term 'compulsory licence' is not defined or clarified further in the Declaration — and is not expressly limited to patent rights as such — there can be no doubt that this clarification extends to NVUAs in general, regardless of their precise legal formulation in domestic law. Similarly, the Declaration clarifies the right of each Member 'to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises … can represent a national emergency or other circumstances of extreme urgency.' The significance of this clarification has been misconstrued at times: it does not concern the substantive ground for a NVUA, and there is no obligation under TRIPS to establish that an emergency or circumstance of extreme urgency applies before overriding patent rights (as, indeed, the previous paragraph refers to freedom to determine such grounds). Rather, it is a procedural matter, concerning the situations in which governments can do away with a requirement for a potential user first to seek a voluntary licence from the patent holder. The significance for streamlined domestic practice is further discussed below.

[156] TRIPS art 8.1.
[157] Doha Declaration para 5(b).

3.2.4.2 The Doha Declaration and Article 31bis

Paragraph 6 of the Doha Declaration recognised the problem of members with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing. A country with the necessary domestic capacity could supply its needs through its own production under a compulsory licence. But other countries are by definition dependent on imports, and thus would need to import under a compulsory licence. This was possible to do already under TRIPS, as NVUAs can be issued for importation as well as for domestic production. However, if a country wished to *import* generic medicines produced under a compulsory licence, that would require a NVUA to be issued in the country of production for export. This was problematic because Article 31(f) of TRIPS requires that production under a compulsory licence be 'predominantly for the supply of the domestic market'; this would rule out a compulsory licence expressly for export.

The solution found was to create, in effect, a new category of NVUA — a special compulsory licence for production for export, to address needs identified by countries without their own production capacity. This led ultimately to the amendment of TRIPS in the form of the inclusion of a new Article 31bis and Annex, an amendment which entered into force in 2017, following formal legal acceptance by two thirds of the membership. In essence, this provides for a compulsory licence to be issued expressly for export to respond to unmet needs identified by eligible countries (LDCs, and countries with limited or no pharmaceutical production capacity). The operation of this special compulsory licensing system — and options for more effective use — are discussed below.

3.2.4.3 Political and industry pressure: bolstering national government agency

Some governments have, in the course of debate over the pandemic response (including in the WTO TRIPS Council), raised concern that even when taking legitimate, TRIPS-compliant measures, they may be subject to political and economic pressure on the part of major trading partners and private sector players. For instance, Pakistan has referred to 'reports surfacing that the same pharmaceutical companies are lobbying with their governments to impose sanctions to countries that adopt compulsory license[s]'.[158] South Africa has 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.'[159]

In the same vein, the fact that the protection of IP rights is potentially covered by numerous bilateral investment treaties ('BITs'), many with investor-state dispute settlement ('ISDS') mechanisms, has provoked concerns that even the threat of a challenge to a TRIPS-compliant NVUA might have a chilling effect on the willingness

[158] WTO, TRIPS Council, Minutes of Meeting held on 10-11 March 2021, WTO Doc IP/C/M/98/Add.1, 251.
[159] WTO, TRIPS Council, Minutes of Meeting held on 10-11 March 2021, WTO Doc IP/C/M/98/Add.1, 287.

and capacity of governments to make use of what are legitimate options in delivering an effective and timely response to public health crises.

Dealing with such pressures, where they exist, is inherently a broader political matter beyond the formal scope of agreed international legal standards and the formal means for resolving differences.[160] Yet this concern has been a consistent thread, not merely throughout the recent debate about the pandemic response, but also through 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.[161]

This concern has arisen most consistently in relation to prospective or actual uses of NVUAs that would override patent rights to leverage access to pharmaceuticals,[162] and it is no coincidence that this was one of the few specific flexibilities expressly addressed in the Doha Declaration, not least given misconceptions at that time that 'compulsory licensing' was in some sense illegitimate. Thus our analysis of various avenues of response in relation to Articles 31 and 31bis should also illuminate possibilities for guiding both domestic choices and coordinated regional responses that entail the robust and empowered use of existing options. Our analysis also extends to the use of extended possibilities under a TRIPS waiver — there being no guarantee that the more extensive suspension or limitation of IP rights under a waiver would not attract some form of pushback, compared with the use of existing legal and policy options under TRIPS.

A key element in establishing a firm foundation for governments to use the full array of legitimate options, under TRIPS or under a waiver of TRIPS provisions, is the critical need for strengthened agency on the part of national governments in addressing the IP dimension of enhanced and sustainable vaccine production. National governments' agency in this sense can be analysed as an amalgam of several components:

- a clear, objective understanding of the full range of options realistically available;
- capacity to set these in their strategic context (shaped by a vaccine and medicines strategy);
- the political confidence to take choices that may attract criticism and political pushback
- administrative and legislative capacity to deploy choices in an effective and expeditious manner (the need to overcome domestic hurdles to effective

[160] The analysis in this section is drawn from Taubman (n 69) and that author's current Ph.D. dissertation (n 89).
[161] Antony Taubman, 'Negotiating "Trade-Related Aspects" of Intellectual Property Rights' in Jayashree Watal and Antony Taubman (eds), The Making of the TRIPS Agreement Personal Insights from the Uruguay Round Negotiations (World Trade Organization, 2015) 15, 37.
[162] See Médecins Sans Frontières (MSF), Analysis of Communications from the European Union to the Council for TRIPS (24 June 2021); Ellen 't Hoen and Pascale Boulet, 'The EU proposed Covid waivers of certain TRIPS rules meaningless' (Medicines Law & Policy, 14 October 2021).

implementation has been one of the less commented, but no less telling and instructive, lessons from the debate about the pandemic response).

The critical aspect of reinforcing national government agency can be illustrated by practical examples of the need to focus not only on the formal range and scope of applicable rules and principles, but also on the wider and more practical governance challenge of how to exercise options in a robust, effective and strategic manner. These examples, elaborated upon in more detail below, concern the difficulties reported in making use of compulsory licensing and other NVUAs under existing laws that provide for TRIPS flexibilities. These obstacles have included the lack of an administrative procedure to give effect to the right, enshrined in national law, to override patents in the public interest; concerns about procedures for judicial review that may have a suspensive effect, retarding or impeding the capacity for authorised use of the patent subject matter in a timely manner; and severely limiting assumptions regarding scope and nature of actual authorisations, such as the assumption that authorisations must be in the form of single, 'case by case' compulsory licensing of individually identified patents.

None of these obstacles result from the TRIPS Agreement itself, and addressing them in a practical and objective way would also shed light on mechanisms for making use of the greater scope for domestic agency that would be available under a waiver of TRIPS provisions. Further, the call for a TRIPS waiver has been driven, in part, by the perceived need for streamlined and facilitated direct government authorisation of deployment of patented technology in the public interest. Hence, clarifying approaches to effective implementation of NVUAs under TRIPS will also facilitate the possibilities for effective government choices under a waiver of TRIPS provisions.

3.2.4.4 NVUAs as exceptions or limitations to IP rights

An essential part of the legal architecture of the TRIPS patent provisions is the relationship between the exceptions to patent rights provided for under Article 30, discussed above, and the 'other use' without the right holder's authorisation that is addressed by Articles 31 and 31*bis*.

Prior to the insertion of Article 31*bis* into TRIPS, it was suggested by some WTO Members that a broader interpretation of Article 30 would allow one Member to supply another Member with a product produced or sold under a compulsory licence, thus bypassing the requirement in Article 31(f) that the authorised use by predominantly for the supply of a Member's domestic market.[163] That exception is now seen as relying on an interpretation of Article 30 that is too broad, especially in view of *Canada – Patents*.[164]

[163] Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) Journal of International Economic Law 73, 89. See e.g. Communication of 4 March 2002 by EC and its Members States (IP/C/W/339); IP/C/W/355 24 June 2002.

[164] Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) Journal of International Economic Law 73, 90.

Footnote 7 to Article 31 — which clarifies that the words 'other use' used in Article 31 refer to 'use other than that allowed under Article 30' — makes clear that Article 31 operates outside the field of permissible exceptions under Article 30. It does not necessarily follow that Article 30 cannot form the basis for an exception to the obligations within Articles 31-31*bis*. This is because the likely function of footnote 7 is simply to clarify that Article 31 deals with compulsory licensing and other forms of 'NVUA', which are of a kind that would not ordinarily satisfy the requirements of Article 30, not least because they would typically — and even desirably in the case of access to medicines — entail large-scale and sustained production. However, this implicit recognition that compulsory licensing and other similar NVUAs would not usually satisfy the requirements of Article 30 indicates that any attempt to override the specific rules set out for such use in Articles 31-31*bis* would likewise fall short of satisfying the test in Article 30. Indeed, it was because of the inherently prejudicial nature of compulsory licensing that TRIPS negotiators felt it necessary to introduce peculiarly adapted rules in Articles 31-31*bis* for utilising this form of unauthorised use — rules that are accompanied by their own specific exceptions.[165] Thus the text and structure of TRIPS as far as Articles 30 and 31 (and now 31*bis*) are concerned reveals that these exceptions and compulsory licensing provisions within TRIPS are intended to be mutually exclusive.[166]

However, they may — and in our view ideally should — be viewed in a complementary way as part of a more systematic approach to the use of TRIPS flexibilities to address public health needs: Table 4 illustrates a practical scenario for their coordinated use.

[165] See e.g. TRIPS Article 31(b), (k).
[166] Andrew D Mitchell and Tania Voon, 'Patents and public health in the WTO, FTAs and beyond: tension and conflict in international law' (2009) 43(3) Journal of World Trade 571, 575.

Table 4: Practical scenario: Article 30 exceptions and Article 31/31bis authorised use

Practical step	Exception or limitation	TRIPS provision
Generic producer manufactures pilot supply of vaccines sufficient to seek regulatory approval in home jurisdiction or export destination. No authorisation necessary for this use of the patent.	Regulatory exception Examples: • e.g. 'any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product … shall not be considered as an infringement of patent rights.'[167] • 'it is not an infringement of patents in pharmaceuticals for any person to make, construct, use or sell the patented invention in respect of a pharmaceutical product or substance, solely for uses reasonably related to the development and submission of information required under any law of the Fiji Islands or of another country that regulates the manufacture, construction, use or sale of such pharmaceutical product or substance'.[168]	Article 30, as clarified in *Canada — Patents*.[169]
Regulatory approval sought to confirm safety and efficacy	Regulatory exception	Article 30. Seeking regulatory approval is not in conflict with right holder's normal exploitation of a patent
Obtain authorisation for full-scale production to meet public needs in domestic and/or export markets.	Non-voluntary use authorisation (e.g. compulsory licence, emergency use authorisation, public sector use authorisation). Potential fast-track, streamlined process for authorisation of production of vaccines already approved (as above), e.g. when required for pandemic or other health emergency, or humanitarian supply.	Article 31 for predominantly domestic needs. Article 31bis for needs in export destinations. Possible parallel/coordinated authorisations under both provisions to serve multiple needs through the same production facility.

Source: Authors' compilation

This suggests to us that the first avenue for pursuing large scale production of medicines without the right holders' authorisation, whether for domestic or export purposes or both, is to explore the full scope of mechanisms available under Articles 31 and 31*bis*. Equally as important is ensuring that their practical implementation can be streamlined and made more effective, including through simplifying and clarifying

[167] Patents Act, 1970 (India) s 107A.
[168] Laws Of Fiji, Chapter 239, Patents (Fiji) s 3A.
[169] Panel Report, Canada – Patent Protection of Pharmaceutical Products, WTO Doc WT/DS114/R (17 March 2000) ('Canada – Patents').

procedures, aggregating demand to build economies of scale, and making use of complementary options to address regulatory processes. This is not in any way to diminish the potential role of and impact of waivers or even future amendments or clarifications of TRIPS provisions. To the contrary, an analysis of how to overcome obstacles to the effective use of NVUAs under Articles 31 and 31bis, and a mapping of their full scope of application, directly illuminate the contours of the additional possibilities made available by a waiver, and the ways in which they may be more effectively put to use in diversifying and building up production capacity.

3.2.4.5 Making full use of NVUAs

The Doha Declaration has affirmed the right of members to determine the grounds for NVUAs, leaving their legitimacy as policy tools, especially at a time of public health crisis, beyond any reasonable challenge. As our survey demonstrates, Members have specified a wide range of grounds in their domestic systems, not viewing TRIPS as a form of model law or prescribing a specific legal mechanism. Hence, the TRIPS Agreement provisions for issuing compulsory licenses or other NVUAs on patent rights, as set out in Articles 31 and 31bis, can essentially be conceived as procedural safeguards, aimed at ensuring due process and an equitable balance, but set out in a broad and flexible manner. Given the widely expressed concerns that NVUA mechanisms are unduly cumbersome and thus unworkable,[170] we focus on specific means of applying these principles in a way that facilitates and simplifies their effective deployment, drawing both on a plain reading of the treaty text and on guidance from domestic practice across the Asia-Pacific region.

3.2.4.5.1 Implementation in the Asia-Pacific region

Compulsory licensing and government use authorisations in line with Article 31 have generally been used in the field of pharmaceuticals, although even in this priority area, their use in practice has been relatively infrequent.[171] The legal basis for their use is largely present: almost all jurisdictions provide in some way both for compulsory licencing to third parties, on a range of substantive grounds, and for government or public non-commercial use. Amongst the countries surveyed and other Asia-Pacific economies, Thailand has used it seven times,[172] Malaysia twice,[173] Indonesia twice,[174] India once,[175] Mongolia once, Taiwan (Province of China) once, and Pakistan once. While some countries have amended their compulsory licensing laws since the

[170] See below nn 234 and 240.

[171] For an up-to-date overview of its use, see South Centre, 'Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic' (2021).

[172] Siraprapha Rungpry and Edward J Kelly, 'Compulsory Licensing Developments in Thailand' (2008) Asia Law IP Review 16; Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10(1):010358 Journal of Global Health 1, 2.

[173] 'A comparison of patent law developments' (Asia Business Law Journal, 4 October 2021) <https://law.asia/comparison-patent-law-developments/>

[174] The Indonesian government issued licences in respect of seven HIV drugs in 2012: Chang-fa Lo, 'Compulsory Licensing: Threats, Use and Recent Trends' in Bryan Mercurio and Daria Kim (eds), Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options (Routledge, 2017) 144, 157.

[175] Raju KD, 'Compulsory Licensing Provisions to Deal with Access to Patented Medicines in India' (2012) 6 NUALS Law Journal 8, 8.

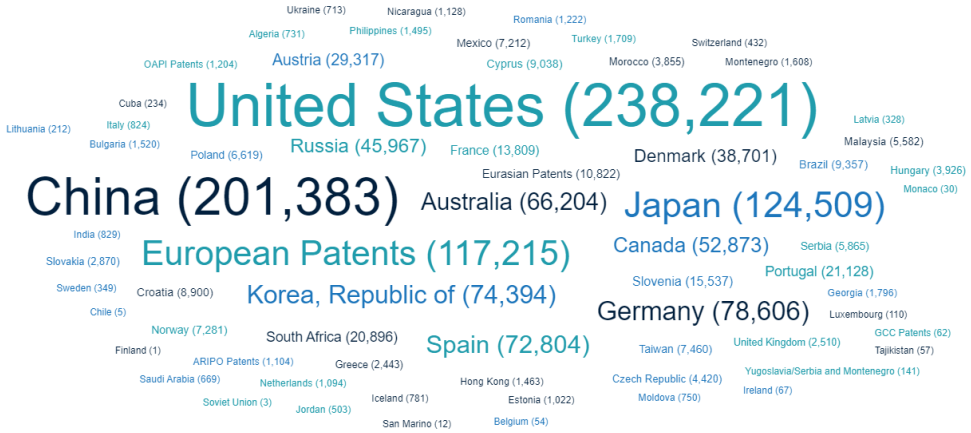
pandemic began,[176] our survey reveals that some Asia-Pacific countries maintain compulsory licencing and procedures that are unnecessarily burdensome or limited in scope, in light of what is required by Article 31. Notably, Fiji and Nepal altogether lack a compulsory licensing regime, which means that these countries — despite offering patents in their jurisdiction — are without a legal basis for issuing compulsory licences or streamlined processes for utilising Article 31*bis* as importers.[177]

However, Fiji has before its parliament a bill[178] that would introduce both forms of NVUA — a compulsory licence available upon application to a court (including for export in line with TRIPS Article 31bis), and a 'state use' provision that addresses the public interest and covers both patent applications and granted patents.

For some countries in the Asia-Pacific region, analysis of the practical use of NVUAs of either form should take account of the practical reality that there are relatively few patents in force in any field of technology, and so for such jurisdictions technology patented elsewhere is therefore likely to enter the public domain upon publication (Figure 8 illustrates the relative rates of patent grants since 2000 in the general field of preparations for medical, dental, or toilet purposes, IPC A61K).

[176] WTO Doc IP/C/W/672 (n 21) [99]; Medecins Sans Frontieres, 'The European Union's position on compulsory licensing and the TRIPS waiver in the COVID-19 pandemic' (May 2021) 3.
[177] See Laws Of Fiji, Chapter 239, Patents (Fiji).
[178] Fiji, Patents Bill 2020 (Bill no 46 of 2020).

Figure 8: Word cloud of patents granted in the medical field (IPC A61K) since 2000



Source: lens.org

3.2.4.6 Grounds for authorisation

The substantive grounds for issuing a compulsory licence are left open in the TRIPS Agreement,[179] meaning that a government can provide any number of bases for the authorisation of non-voluntary use. Some of the countries surveyed here provide for only a limited number of grounds.

3.2.4.6.1 Implementation in the Asia-Pacific region

The most common ground specified is a failure to work the invention in relevant country's territory.[180] Another common ground is where demand is not being met, or not being met on reasonable terms.[181] Some countries adopt legal tests to determine such 'reasonable terms'. For example, the UK Intellectual Property Office adopts a four-step test that takes account of: (i) the nature of the invention; (ii) any licences' terms under the patent; (iii) the patentee's expenditure and liabilities related to the patent; and (iv) the requirements of the purchasing public.[182] Such fact-dependent tests may reduce the likelihood or certainty that a compulsory licence will be granted in a public health emergency context, and should be accompanied (but not necessarily replaced) by other grounds better suited to serving public health interests.

Grounds for invocation that are lacking in some domestic regimes that may be useful in the pandemic context include: (i) public health or public interest; (ii) refusal to deal; and (iii) general government use. Grounds based on public interest, public health or

[179] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, adopted 14 November 2001, para 5(b) ('Doha Declaration'). See also Antony Taubman, 'Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing' (2008) 11(4) Journal of International Economic Law 927, 932; WTO Secretariat, the TRIPS Agreement and COVID-19, Information Note (15 October 2020) 9.
[180] See e.g. Patents Act No. 291 of 1983 (Malaysia) s 49(1)(a); Patent Acts, 1970 (India) ss 84(1)(c); Law on Patents, Utility Models and Industrial Designs (Cambodia) art 56.
[181] The Patents and Designs Act (Act No. II of 1911) (2003) (Bangladesh) s 22(1); Patents Act, 1970 (India) s 84(7).
[182] Johnathon Liddicoat and James Parish, 'Ironing Out the Wrinkles: Reforms to Crown Use and Compulsory Licensing to Help Prepare the Patents Act 1977 for the Next Health Crises' (2021) Issue 4 Intellectual Property Quarterly 245, 249.

other emergency circumstances are only present in the domestic patent law of Cambodia, India, Indonesia, Malaysia, Mongolia, Thailand, and Vietnam.[183] Some countries, such as Malaysia and Thailand, include a public interest or national emergency ground in their laws by incorporating Article 31(b).[184] Including such provisions could streamline the application process significantly in circumstances of a public health crisis.

Article 31(b) sets a refusal to issue a voluntary licence as a precondition to granting a compulsory licence (other than in emergency or public use contexts), but Correa maintains that a refusal 'can [also] be … an *autonomous* ground for granting a compulsory licence'.[185] Refusal to licence on reasonable terms is expressly set out as a ground for compulsory licencing in the laws of a number of countries,[186] and may also be the basis of a finding of anti-competitive practice that could be remedied by a compulsory licence.

Of the countries surveyed, only India's and Vietnam's law expressly provide for this ground.[187] It is also identified as a potential ground of abuse within India's anti-competition provisions relating to abuse of dominant position.[188] It may also be said to appear in the form of some countries' ground of 'demand not being met on reasonable terms'. In any case, including this ground explicitly is likely to furnish countries with greater options for implementing Article 31 at the domestic level. This approach should be tempered, however, by the view that there is no fundamental or unconditional obligation on a patent holder to refuse a licence, the legitimate exercise of exclusive rights being seen as central to the economic function of patent rights.[189]

3.2.4.7 Forms of authorisation

Article 31 is carefully framed to give scope for a diverse range of measures within domestic legal systems. Rather than prescribing any specific mechanism for authorisation, it applies, as we have noted, to the general context '[w]here the law of a Member allows for other use of the subject matter of a patent without the authorization

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[183] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 47(i): 'the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires'; Patent Acts, 1970 (India) ss 84(1)(a), 84(2); Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 82(1); Patents Act No. 291 of 1983 (Malaysia) s 84(1); Patent Law of 25/06/1993 (Mongolia) art 20; Patent Act B.E. 2522 of 11/03/1979 (Thailand) ss 51, 52; Law on Intellectual Property (No. 50/2005/QH11) (Vietnam) arts 133, 145.

[184] Patents Act No. 291 of 1983 (Malaysia) s 84; Patent Act B.E. 2522 of 11/03/1979 (Thailand) ss 51, 52.

[185] Carlos M Correa, 'Can the TRIPS Agreement foster technology transfer to developing countries?' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 227, 243 (original emphasis).

[186] See e.g. the laws of Egypt and Vietnam, discussed in WIPO Secretariat, 'Refusals to License IP Rights – A Comparative Note on Possible Approaches' (August 2013), 9 <www.wipo.int/export/sites/www/ip-competition/en/studies/refusals_license_IPRs.pdf>

[187] Patent Acts, 1970 (India) s 84(7)(a); Law on Intellectual Property (No. 50/2005/QH11) (Vietnam) art 145(c), establishing as such a ground 'failure to reach agreement on a licence in spite of efforts made within a reasonable time for negotiation on satisfactory commercial price and conditions' (WIPO translation).

[188] Unlike other provisions in India's competition law, these provisions are not subject to an IP exemption: see Robert D Anderson et al, 'Competition Agency Guidelines and Policy Initiatives Regarding Intellectual Property in the BRICS and Other Major Jurisdictions: A Comparative Analysis' in Robert D Anderson, Nuno Pires de Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 517, 607.

[189] WIPO Secretariat (n 186).

of the right holder, including use by the government or third parties authorized by the government.' Accordingly, it includes direct use of a technology by or on behalf of a government agency, for public policy purposes, and in that instance without even direct reference to a patent or patents — given that it relates to use of a patent's subject matter, rather than express authorisation to infringe identified patent rights. This point is reinforced in Article 31(b), which clarifies that for public non-commercial use, a government or contractor permitted to use a technology is not expected to carry out a patent search, but is obliged simply to inform a patent holder if there is knowledge or demonstrable grounds to know that a valid patent is involved.

Thus it is plainly envisaged that a government may authorise the use of a technology for public use — and *a fortiori* in an emergency or situation of urgency — without seeking to identify relevant patents in advance. This understanding is critical to addressing two major concerns that have been voiced in relation to the use of NVUAs to overcome exclusive rights in the pandemic: (i) that a burdensome process of searching for and identifying relevant patents must be undertaken prior to any NVUA being issued; and (ii) that a multitude of distinct NVUAs must be ordered one by one for each individual patent. Neither is the case.

No application for a 'compulsory licence' is therefore required in such circumstances. The practical context in which an application, as such, may be required is when a private firm wishes to make use of a patented technology effectively in a commercial context, and in seeking to do so encounters a patent barrier. In that case, the firm concerned will by definition have clear information about the possibility of a patent barrier and will have investigated how to ensure freedom to operate. Equally, should a private firm not seek a compulsory licence, on the basis that it was not aware of applicable patents, the matter falls to considering available remedies for alleged infringement of a patent in the event of a firm producing vaccines potentially covered by a vaccine. However, as discussed below, the TRIPS Agreement does not mandate that injunctive relief must be available in such circumstances. As reflected in domestic practice among WTO members, it is possible for remedies to be limited to payment of adequate remuneration, enabling vaccine production to continue in the public interest.

3.2.4.7.1 Implementation in the Asia-Pacific region

Our survey demonstrates that many governments have reserved the right directly to authorise the use of patented subject matter, separately from any distinct application by a third party.[190] For instance, under Cambodia's patent law, 'the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention'.[191] Similarly, Indonesia's laws authorise 'the government itself' to exploit a patent (including through authorisation of a third party) '[i]n the case that the government is in the opinion that a patent in Indonesia very important for state defense and security' or 'there is an urgent

[190] See e.g. Industrial Property Act No. 19 of 1994 (Tonga) s 13(5)(a).
[191] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 47.

need for the public interest of a patent'.[192] In Malaysia, the Minister may decide that, even without the agreement of the patent owner, a Government agency or a third person designated by the Minister may exploit a patented invention. The Minister's decision-making power is enlivened where there is 'national emergency or where the public interest … so requires' or 'where a judicial or relevant authority has determined that the manner of exploitation by the [patent owner] … is anti-competitive'.[193]

3.2.4.8 'individual merits': Article 31(a)

Article 31(a) requires that the 'authorization of such use shall be considered on its individual merits'. This refers to authorisation of the use of patented subject matter, rather than authorisation to infringe a patent as such. Any alternative reading would be inconsistent with the general nature of government authorised use discussed immediately above. There are concerns that subparagraph 31(a) requires each *license* to be considered and granted on its individual merits; that is, on a case-by-case basis,[194] thus posing a potential obstacle to the expeditious use of options under Articles 31-31*bis*. However, this is clearly not the case. Subparagraph 31(a) very clearly requires that each *authorization* be considered on its individual merits, leaving scope for approval relating to a package of technology (which may entail multiple patents held by distinct owners) and for multiple authorised users. This means that a government body issuing a compulsory licence or use order need only authorise the use of a given vaccine and its manufacturing process once. Article 31(a) may preclude governments from compulsorily licensing a whole category of multiple patents relating to particular subject matter or industry.[195] But there can be no doubt, for current purposes, that it entitles a government directly to authorise the production of a specified vaccine in a single step, regardless of the potential complexity of the patent landscape. This, presumably, is the kind of authority that is most important for governments seeking to make available vaccines or other identified COVID-related technologies.

There are several reasons why we adopt this interpretation, beginning with the text of TRIPS itself. When considered together, the opening of Article 31 and subparagraph 31(a) reads: '[w]here the law of a Member allows for other use … authorization of such use shall be considered on its individual merits'. It is clear that the 'authorization' in subparagraph 31(a) refers to a Member *allowing* 'other use' of a particular invention, not the decision to authorise a particular person or persons to use an invention. Thus Article 31 refers to 'third *parties*' and '*persons* so authorized.[196]

Secondly, Article 31 does not formally frame a specific form of 'compulsory licence' *per se,* but rather sets out principles that govern any authorisation of non-voluntary use of patented subject matter, beyond the exceptions covered by Article 30. Thus, nothing

[192] Government Regulation of the Republic of Indonesia Number 27 Year 2004 Regarding the Procedure of Exploitation of Patent by the Government (Indonesia) arts 2(1)-(3).
[193] Patents Act No. 291 of 1983 (Malaysia) s 84(1).
[194] See e.g. WTO Doc IP/C/W/672 (n 21) [3]; Chang-fa Lo, 'Compulsory Licensing: Threats, Use and Recent Trends' in Bryan Mercurio and Daria Kim (eds), Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options (Routledge, 2017) 144, 151.
[195] Taubman, Wager and Watal (n 151) 112.
[196] TRIPS Articles 31, 31(g) (emphases added).

in TRIPS precludes a government from allowing a particular patented invention to be used generally, without authorisation of the patent holder, provided those principles are followed. Equally, it is clear that authorisations may be upon the request of a third party (typically, in this context, a generic pharmaceutical producer), or directly, *ex officio*, by a government authority in the exercise of its functions.

The reference to 'proposed user' in Article 31(b) does not stop multiple proposed users from each making efforts to obtain authorization. Moreover, the fact that Article 31(e) requires that use shall be non-assignable is not inconsistent with more than one user having authority to use an invention; and remuneration under Article 31(h) can be calculated on the basis of the economic value of the authorization, even where that authorization applies to multiple uses.

This interpretation has implications for the way that Article 31*bis* might be utilised by a group of Members operating at a regional scale to gain the benefit of the System. As Article 31*bis*.3 contemplates the issue of a compulsory licence permitting exportation to more than one market in certain circumstances, a group of importing Members can coordinate to issue compulsory licences covering their distinct national jurisdictions[197] with respect to patented technology to be imported and used by any number of third parties or government bodies.

3.2.4.9 Prior efforts to obtain authorisation: Article 31(b)

3.2.4.9.1 Limitation to use in a commercial context

Under Article 31, TRIPS sets requirements for a proposed user of patented technology first to seek authorization from the right holder 'on reasonable commercial terms and conditions'[198], and such efforts must not be successful within a reasonable period of time. However, this requirement does not apply in the case of most practical scenarios related to the COVID-19 response: there is no requirement to seek prior authorisation 'in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. The global pandemic is unquestionably such a national emergency and circumstance of extreme urgency. In any event, the Doha Declaration clarifies that 'each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other *epidemics*, can represent a national emergency or other circumstances of extreme urgency'.[199] In the context of responding to a pandemic, there is clearly no requirement to seek prior approval from a patent holder to produce vaccines without their authorisation; where this has been identified as an obstacle in domestic laws, it is unquestionably not a TRIPS requirement and could be relaxed in domestic laws while remaining TRIPS-consistent.

[197] In this regard, Article 31bis.3 clarifies that the regional mechanism provided for in Article 31bis.2 and Article 5 of the TRIPS Annex does not 'prejudice the territorial nature of the patent rights in question'.
[198] TRIPS art 31(b).
[199] Doha Declaration para 5(c).

Patent holders do need to be informed, once the potential application of their patent rights comes to light — 'as soon as reasonably practicable' in circumstances of national emergency or extreme urgency, and 'promptly' in the case of public non-commercial use. However, this is hardly a complex procedural step, compared with the complexity of establishing a fresh production line and clearing regulatory and good manufacturing standards for a new production of vaccines.

3.2.4.9.2 Where licensing negotiations are required

Although a prior request for licensing terms is not required in most realistic pandemic response scenarios, it may be helpful to consider the TRIPS principles that may apply if, for any reason, a country chooses not to waive the requirement to seek the patent holder's authorisation. The terms 'reasonable terms and conditions' and 'reasonable period of time' have naturally become subject to differing interpretations. This general principle, however, provides Members with sufficient flexibility to implement their own standards, as well as mechanisms for determining what those standards might be in particular cases.[200] Countries have the option of designating a shorter time period than an *ad hoc* or case-by-case application of 'reasonable period of time' may allow.

Where explicitly specified by implementing Members, the 'reasonable period of time' that must pass before it can be said that efforts to obtain the patentee's authorisation have been unsuccessful has been defined variably. The reasonable period of time ranges anywhere from 21 days and 12 months.[201] Cambodia specifies a period of 21 working days.[202] India specifies a period of 6 months, but merely includes the requirement of unsuccessful efforts within a 'reasonable period time' as a factor to be considered by the Controller in determining whether a licence should be granted.[203] It would increase certainty over the grant of a compulsory licence to introduce unsuccessful efforts as a standalone requirement but reduce the relevant time period (e.g. in terms of days, rather than months). At the highest end of the spectrum, Indonesia specifies a period of 12 months.[204]

Although often seen as a barrier to implementing time-sensitive compulsory licensing, the requirements of Article 31(b) can be dispensed with by implementing Members in circumstances such as those brought about by the COVID-19 pandemic. The terms 'as soon as reasonably practicable' may be contrasted with the term 'promptly', the latter imposing a slightly less stringent and longer time period. This *ex-post* notification requirement is, in either case, unlikely to present significant issues for the authority responsible. Nevertheless, implementing Members may wish to reduce the number of procedural steps involved by giving notice to the rights holder at the same time as issuing the licence. This notice may also be given concurrently with the notice required

[200] Mitchell and Voon (n 166) 576.
[201] Roger Kampf, 'Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation' (Staff Working Paper ERSD-2015-07, World Trade Organization, Economic Research and Statistics Division, 31 July 2015) 10.
[202] Law On Compulsory Licensing for Public Health (Cambodia) art 9.
[203] Patent Acts, 1970 (India) ss 84(6)(iv), (v).
[204] Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 84(1).

to be given by importing Members under Article 31*bis*/TRIPS Annex system (discussed below).

Even after the Doha Declaration and the insertion of Article 31*bis*,[205] it remains unclear whether the exception to Article 31(b) can be invoked in cases where the 'national emergency' is occurring in an importing Member.[206] This may be of particular significance where a compulsory license is used to supply another WTO Member with no manufacturing capacity under the Article 31*bis* mechanism. Nevertheless, COVID-19 is likely to constitute a national emergency in both exporting and importing countries for the foreseeable future, and 'other circumstances of extreme urgency' may in any case be interpreted to encompass the urgent public health needs of a neighbouring country. The Doha Declaration itself may provide some flexibility in this regard, as it confirms the right of Members to determine what constitutes such circumstances, and relays a common understanding that health crises are encompassed within them. Although this does not itself clarify the territorial scope of 'national emergency' for the purposes of Article 31(b), it reinforces the margin of deference that countries retain in determining the existence and scope of such emergencies. Moreover, the terms of Article 31(b) appear sufficiently imprecise to permit a wider interpretation of 'national emergency' that extends to emergencies occurring in other countries.[207]

Significantly, some countries (including developed nations)[208] have omitted the exception to Article 31(b) from their domestic legislation altogether. However, all the countries surveyed with a compulsory licence regime either include this carve-out or provide for an independent scheme of government use in cases of national emergency, other circumstances of urgency or public non-commercial use without the need to seek prior authorisation. These countries should maintain these carve-outs in their laws to ensure they are able to make effective use of the flexibilities in Article 31(b).

3.2.4.10 Minimum time period from patent grant

Some domestic laws require the expiration of a particular time period before a compulsory licence can be sought.[209] This feature in domestic legislation is the result of a requirement in the *Paris Convention* that a compulsory licence not be issued on the ground of a failure to work until at least four or three years from the time of patent application or grant respectively.[210] However, some countries have superimposed this requirement on all compulsory licences, regardless of the ground relied upon.[211]

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[205] Paragraph 9 of the Decision implementing the Doha Declaration states that the decision does not prejudice the interpretation of TRIPS, except for Articles 31(f) and (h): WTO General Council, implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003, WT/L/540 (1 September 2003) paragraph 9.
[206] Mitchell and Voon (n 166) 582.
[207] Mitchell and Voon (n 166) 583.
[208] Liddicoat and Parish (n 182) 254.
[209] See e.g. Law on Patents, Utility Models and Industrial Designs (Cambodia) art 56. Patents Act, 1970 (India) s 84.
[210] Paris Convention for the Protection of Industrial Property of March 20, 1883, art 5A(4).
[211] See e.g. Industrial Property Act No. 19 of 1994 (Tonga) s 13(5)(a). See also Liddicoat and Parish (n 182) 253.

Some laws impose this requirement, but appropriately limit it to compulsory licences sought on the basis of a failure to work.[212] In such cases, a government use or emergency use authorization can be issued at any time after the patent grant.

3.2.4.11 Scope and duration limited: Article 31(c)

Article 31(c) limits the scope and duration of use to the purpose for which such use was authorized. Some Members implement a general time limit on the term of compulsory licences.[213] The words 'limited to the purpose for which it was authorized' in Article 31(c) indicate clearly that the *purpose* of the use is operative, and that Members need not limit use to a particular predetermined timeline where that would jeopardise the possibility of such purpose being fulfilled (i.e. where the circumstances that go toward fulfilling such a purpose remain uncertain, such as a pandemic). Thus, Members relying on compulsory licensing should ensure that the scope and duration of any relevant authorisation is tied at least to the exigencies of the pandemic, and not a predetermined time limit.[214]

It should be noted, however, that Members are not limited to authorising use specifically for the purposes of addressing the pandemic or particular health crisis, and may instead do so to provide for greater domestic resilience and more diverse supply and procurement possibilities. In such a case, both the permissible scope and duration of the use may be wider. However, it may be that the purpose of an authorisation is limited to addressing the pandemic because the Member has, in seeking to conform with the parameters of Article 31(b), issued the compulsory licence in the case of a national emergency. In such cases, the exigencies of the pandemic are likely to guide the scope and duration of the authorisation.

One issue relevant to laws authorising the issue of a compulsory licence, rather than the scope of individual licences, is that some developing countries only authorise compulsory licences for the purposes of manufacture, not importation.[215] This is likely to create a barrier to effective use of the Article 31*bis* System, because it could preclude an importing Member from issuing a compulsory licence for the purposes of importation under the System.

3.2.4.12 Use non-exclusive and non-assignable: Article 31(d)-(e).

The authorised use must be non-exclusive and non-assignable, meaning that the patent holder retains their rights over the invention, and the licensee/authorised user is not permitted to assign their rights under the licence/authority. As these requirements

[212] See e.g. Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 83(2), clarifying that a request for a licence on grounds of harm to the public interest 'may be submitted at any time after a Patent is granted'; Patents Act No. 291 of 1983 (Malaysia) ss 49(1), 84; Patent Law of 25/06/1993 (Mongolia) art 20; Patent Act B.E. 2522 of 11/03/1979 (Thailand) ss 46. 51, 52.
[213] Emily Ng and Jillian Clare Kohler, 'Finding Flaws: The Limitations of Compulsory Licensing for Improving Access to Medicines – An International Comparison' (2008) 16(1) Health Law Journal 143, 159.
[214] See Kampf (n 201) 8.
[215] Carlos M Correa, 'TRIPS Agreement and Access to Drugs in Developing Countries' (2005) 3 International Journal on Human Rights 25, 32.

are proscriptive in nature, they do not necessarily require any positive action on the part of Members.

3.2.4.13 Predominantly for the supply of the domestic market: Article 31(f)

The requirement that use be authorised predominantly for the supply of the domestic market of the Member authorising the use previously meant that a country with little or no manufacturing capacity could not receive pharmaceuticals produced and imported under a compulsory licence in another country that did have such capacity.[216] However, Article 31*bis*, discussed below, now addresses this issue.

At the same time, for certain key pharmaceutical producing countries, this provision is less restrictive than it may appear, especially in relation to a public health crisis affecting many countries and not one single jurisdiction. It would rarely be the case that a government prioritised servicing the vaccine needs of foreign nationals over their own nationals; the practical experience of the pandemic suggests the opposite — a generally perceived imperative for production to be in part reserved for domestic needs. Hence, government-led or government-authorised efforts to ramp up domestic vaccine production are on the whole likely to seek to service domestic needs as well as those of foreign countries. This is practically important, in considering the options available under this provision.

Hypothetically, it would be open to India, for instance, with a domestic population of 1.37 billion, to authorise production of a vaccine or other pharmaceutical predominantly for its domestic needs, and for that production also to be authorised for distribution to all other South Asian nations (with a combined population of 470 million) and all ASEAN nations (population 660 million). In such a case, there would be no need to consider alternatives to this provision because the non-predominant proportion of India's production would be for the supply of foreign markets, with the predominant proportion of its use being for the supply of its domestic market.

3.2.4.14 Continued existence of circumstances which led to authorisation: Article 31(g)

Article 31(g) provides that the authorization 'shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur' and that the 'competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances'.[217]

This provision does not require that the authorisation be terminated if and when the relevant circumstances have ceased to exist and are unlikely to recur, but rather requires that persons within a Member's jurisdiction have the opportunity to petition its termination on such grounds. This is made clear by the words 'shall be liable' as well as the proviso that any review of the continued existence of the relevant circumstances

[216] This would be the case where a 'predominant' proportion of the demand for the product was from other Members rather than the domestic market.
[217] TRIPS art 31(g).

shall be brought at the instigation of some party. This provision's application to the pandemic is difficult to estimate, but it is likely that these circumstances are likely to continue for some time.

Members need not provide persons with the ability to petition a *variation* of the authorisation whenever circumstances have changed.[218] Article 31(g) only requires the possibility of having the authorisation terminated when the circumstances that led to it have ceased to exist.

Some laws give the relevant authorities the power to review authorisation after a certain period, regardless of whether the circumstances leading to the authorisation has ceased.[219]

3.2.4.15 Adequate Remuneration: Article 31(h), (j)

The residual requirement for remuneration should not in itself be an obstacle to NVUAs issued in response to the COVID pandemic. Procedurally, Article 31, read in parallel with Article 42 of TRIPS, makes it clear that claims for remuneration — and their judicial review — may be entirely ex post, so that this question need not delay or impede the actual authorised use. While practice varies considerably as to the exact level of remuneration (bearing in mind, also, that several patents may be relevant to a particular vaccine, and there is no expectation of a one-to-one mapping between individual patents and vaccines), common figures run to 1 to 2% of the value of production, and there is a strong expectation that in cases of production for humanitarian purposes, remuneration should be adjusted accordingly.

Remuneration guidelines commissioned by UNDP and WHO recommend that systems for remuneration 'should not be overly complex or difficult to administer' and 'should anticipate and address the need to divide royalty payments among various patent holders when the product is subject to multiple patents', and that 'amount of the royalty should not present a barrier for access to medicines', on the basis that '[r]emuneration policies should assist rather than defeat' the goal of enhancing access and lowering costs.[220]

3.2.4.15.1 Implementation in the Asia-Pacific region

India's patent law requires that remuneration be 'reasonable', having regard to 'the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors'.[221] Cambodia's Compulsory Licence Law states that 'the production, importation or exportation of the Pharmaceutical Products under a compulsory licence shall be subject to payment of remuneration to the patent holder', but does not specify the considerations to be taken into account in determining an adequate or equitable

[218] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 48.
[219] Law On Compulsory Licensing for Public Health (Cambodia) art 16.
[220] James Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, UNDP-WHO (Health Economics and Drugs TCM Series No. 18, 2005) WHO/TCM/2005.1, 82.
[221] Patents Act, 1970 (India) s 90(1).

amount, leaving it to the relevant Ministers to determine the relevant 'method' and 'criteria' for the rate of remuneration.[222]

Indonesia's law requires the annual patent fee to be paid by the government or the third-party authorised under the licence.[223] Article 31(j) provides some guidance as to the meaning of 'adequate' and the margin of defence left to Members in applying that standard. Article 31(j) requires that decisions relating to remuneration for use shall be subject to judicial review. The mandated availability of judicial review over such decisions reveals that what is 'adequate', and disputes about whether a given amount of remuneration is 'adequate', is to be left entirely with the Member authorising the use. Members should also be mindful that this right to review need not prevent use, and may only relate to remuneration for use.

3.2.4.16 Judicial Review: Article 31(i)

Article 31(i) provides that 'the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member'. The words 'any decision relating to the authorisation of … use' appear to cast a wide scope, which probably means that judicial review be available for every decision that has some connection with a given authorisation. In this sense, there is a curious cross-over with Article 31(j), except for the additional words 'other independent review by a distinct higher authority'.

With respect to both Article 31(i) and 31(j), there is no requirement to suspend the effect of a compulsory licence before a final determination is made — only that judicial review be available. Therefore countries need not suspend a compulsory licence by way of interlocutory injunction until a final determination is made that it was granted illegally. [224] Cambodia's Compulsory Licence recognises this by providing that a 'competent court shall not issue any provisional measure until a final decision on the case is made'.[225]

There is also no requirement to give potentially interested parties, such as the patentee, a hearing. However, some laws require that the patentee be given a hearing if requested, even in circumstances of national emergency or other urgent situations.[226] These provisions may be appropriate for non-emergency use situations but should be removed from provisions that implement Article 31(b).

3.2.4.17 Anti-Competitive Practice: Article 31(k)

Article 31(k) creates an exception to the requirements in the other subparagraphs of Article 31 relating to anti-competitive practices, and is therefore examined in detail

[222] Law On Compulsory Licensing for Public Health (Cambodia) art 11. Cf Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 50(5).
[223] Government Regulation Of The Republic Of Indonesia Number 27 Year 2004 Regarding The Procedure Of Exploitation Of Patent By The Government (Indonesia) art 11.
[224] Carlos M Correa, 'TRIPS Agreement and Access to Drugs in Developing Countries' (2005) 3 International Journal on Human Rights 25, 33.
[225] Law On Compulsory Licensing for Public Health (Cambodia) art 16.
[226] See e.g. Patents Act No. 291 of 1983 (Malaysia) s 84(4).

below as part of a broader exploration of the options available relating to anti-competition.

3.2.5 Production for export, without the right holder's authorization: Article 31bis

The Doha Declaration acknowledged that countries with no or limited pharmaceutical production capacity 'could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.'[227] Despite the use of the term 'compulsory licensing' — which, as discussed above, has been framed in limited terms in some discussion concerning the pandemic response — we understand this phrase to refer to the full array of legitimate NVUAs, including government use orders and executive decrees.

But what is the nature of the potential difficulties to be addressed? A country with available production capacity can authorise medicines production for domestic use, and for export (provided production is not predominantly directed to overseas destinations), which is the most immediate and most effective form of using NVUAs. Such a country can also credibly threaten the use of NVUAs as a means of gaining leverage in negotiations with the patent holder, since the NUVA may be a realistic alternative to gaining access. But a country which lacks significant production capacity may also lack the capacity to make either form of 'effective use' of NVUAs. It is entitled to override any applicable patent rights in its jurisdiction to provide for import of medicines without the right holders' authorisation — and this may enable import of generic medicines from countries where patents are not in force. This was an option, for example, for access to HIV AIDS treatments which were produced abundantly and cheaply off-patent in India in particular. In such cases, importation would be possible into a jurisdiction where a patent was in force, as a legitimate option for use of NVUAs under Article 31.

The solution found by the TRIPS Council, was to create a new form of compulsory licence — a special compulsory licence tailored for export of production to meet the needs of eligible countries. This was implemented first as a waiver and then as a formal amendment to the TRIPS Agreement (the inclusion of Article 31bis with Annex and Appendix), The procedure under Article 31*bis* (commonly referred to as the 'Paragraph 6 System' or 'special compulsory license for export') addresses the constraint outlined above: where a Member seeks to import a pharmaceutical product that it cannot produce locally and an exporting Member cannot export the desired product under a compulsory licence without falling foul of Article 31(f).[228] The procedure applies only to 'pharmaceutical products', which means:

> any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha Declaration], [including] active ingredients necessary for its manufacture and diagnostic kits needed for its use.[229]

[227] Doha Declaration para 6.
[228] See TRIPS art 31bis.1.
[229] Annex to the TRIPS Agreement, paragraph 1(a).

3.2.5.1 Export compulsory licences in context

This form of NVUA is not a stand-alone procurement tool; it corresponds to a specific set of practical circumstances, which are inherently atypical:

- An unmet need for medicines has been identified, the country or countries in need lack the capacity to produce it themselves, and thus must import it.
- Affordable and otherwise acceptable medicines are not available:
  - from or with the consent of the right holder;
  - for import from a country where a relevant patent is not in force; nor
  - from production under a compulsory licence in a country which is at the same time serving a relatively larger population.

It follows that the System does not apply to most procurement scenarios, for example:

- affordable supplies are already available from countries where no patent is in force (the experience with older ARV treatments for HIV/AIDS, which were mostly imported at highly competitive prices by countries from generic producers in India);
- prices for the originator product can be reduced through negotiation to an affordable level without recourse to a compulsory licence;
- the originator company agrees to grant a voluntary licence to a generic producer; or
- the medicine is already produced under a compulsory licence primarily for the domestic market but a smaller proportion can be exported.

Accordingly, 'regular' NVUAs under Article 31 are available:

- where the desired product is not protected by a patent in the exporting Member, or where a voluntary licence is in place in that country;
- where the exporting Member can satisfy the demand of the importing Member (either alone or together with other Members) under an ordinary Article 31 compulsory licence 'by exporting [their] *non-predominant* share of the production'[230]; and
- where anti-competitive practices are found through judicial or administrative processes, thus allowing the Member to bypass subparagraphs 31(b) and (f) under subparagraph 31(k).

Since the compulsory licence or NVUA for export only creates a legal pathway for production and export of the needed medicine, it does not, in itself, address any regulatory requirements in either the importing or exporting country or create economies of scale sufficient to support a fresh production. Equally, there is no constraint, as we discuss below, against combining such authorisations with authorisations for domestic production and for export to other countries in need. One principal constraint with this mechanism is that it is designed to respond to identified needs, and thus is demand-driven in character; alternative models to resolving this issue (as discussed below) have framed the solution in terms of creating a legal

[230] Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review of the Special Compulsory Licensing System Report to the General Council, WTO Doc IP/C/86 (11 November 2020) Appendix I [5] (emphasis added). See also Ng and Kohler (n 213) 150.

pathway to enable a generic firm to produce medicines solely for export, building up supply capacity, which can then be exported to meet subsequently identified needs.

3.2.5.2 Making use of export compulsory licenses

The Article 31*bis*/Paragraph 6 System has been utilised very rarely, and less than compulsory licensing under Article 31. Shortly before the pandemic, in 2019, the WIPO Standing Committee on the Law of the Patents anticipated that the System may be more widely used in the event of a pandemic or some other health security event.[231] However, the system is yet to be used for COVID-19 purposes.[232] This is despite Bolivia notifying its need for COVID-19 vaccines under the system, and Antigua and Barbuda notifying its intention to use it.

This lack of use has led to considerable critical commentary including from WTO Members and from public health advocates and scholars, a critical view which has understandably intensified in the course of the pandemic. Much of this criticism is levelled at its procedural requirements: it has been called, amongst other things, a 'maze of rules and procedure',[233] 'unworkable' and 'unnecessarily complex'.[234] The annual review of the system by the TRIPS Council since its establishment has not led to any specific proposals for its reform or adaptation, including at the brief reviews undertaken in the first two years of the pandemic.

While we agree that the System could be simplified and streamlined, we believe that it is also imperative to analyse the relevant provisions closely and objectively, under the general guidance of the Doha Declaration which encourages a reading of TRIPS provisions which is favourable to the promotion of public health. This will not only facilitate the practical use of the existing system where it has practical potential, including by maximising flexibilities and strengthening coordination and mutual support among countries, but will also help illuminate specific issues and questions that could be addressed in a review and reform process.

We therefore address this question firstly by categorising the obstacles and difficulties attributed to the system, then by working through the specific requirements of the system, and finally by developing recommendations for its practical operation and for clearing away obstacles to its effective use.

Actual and potential problems with the use of the system can be classed in four broad categories:

1. Constraints specifically embedded within the system itself: examples commonly cited include the need for prior notification and the requirement for special labelling.

[231] World Intellectual Property Organization, Standing Committee on the Law of Patents Thirtieth Session Geneva, June 24 to 27, 2019, Draft Reference Document on the Exception Regarding Compulsory Licensing, SCP/30/3 (21 May 2019) 47.
[232] Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review Of The Special Compulsory Licensing System Report To The General Council, WTO Doc IP/C/86 (11 November 2020) [5]-[6].
[233] Raadhika Gupta, 'Compulsory Licensing under TRIPS, How far it addresses Public Health Concerns in Developing Countries' (2010) 15 Journal of Intellectual Property Rights 359.
[234] IP/C/W/673 (n 72) [44-45].

2. Constraints resulting from specific choices made at the domestic level in implementing the system, which are more restrictive than is required under TRIPS: a commonly cited example is a requirement for eligible medicines to be specifically scheduled under domestic legislation before an application for a license can be made.
3. Constraints that are inherent in the use of compulsory licensing more generally: examples include the need for specific authorisation for use, as opposed to an entitlement to produce generic medicines without government authorisation, and some concerns addressed in the section on Article 31 above.
4. Constraints that are not directly related to the IP system or patent rights as such, but rather relate to other aspects of production and supply: these include regulatory approval in either exporting or importing countries or both, the viability of production of small runs of medicines, and procurement policies and procedures.

While the literature on these issues is very extensive, the evidence available clearly indicates that the main practical constraints concern (i) choices made at the domestic level in the implementation of the system, especially on the part of potential exporting countries and (ii) regulatory requirements and procurement practices. It is clear that the number and nature of the combined procedural steps in Articles 31-31*bis* have sometimes been made to appear more expansive and burdensome than necessary. This is partly due to combining specific procedural steps with more general principles that condition the use of these provisions.[235] In some cases, conditions and requirements within the TRIPS Annex give rise to procedural steps that must be undertaken by implementing Members. In other cases, certain steps must be undertaken by other relevant parties in the supply chain, in particular the licensees producing and supplying medicines. These exporting Member requirements are more detailed, being linked to actual production of medicines, but such parties are likely to have more legal, technical and economic capacity than importing Members in satisfying them. In any event, these requirements are not on the scale of the regulatory procedures normally in place to ensure safety and efficacy, and good manufacturing practice where relevant.

Below we set out a list of the procedural steps required to be fulfilled by exporting and importing Members utilising the System, and differentiate them from general requirements that condition the use of Articles 31-31*bis* and steps required to be undertaken by other parties.

- *Establishment of insufficient or no manufacturing capacity.*

The **importing** Member must have established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question.[236]

[235] See e.g. Behrang Kianzad and Jakob Wested, ‘‘No-one is Safe Until Everyone is Safe’ – Patent Waiver, Compulsory Licensing and COVID-19’ (2021) 5(2) European Pharmaceutical Law Review 71, 83-84.
[236] Paragraph 1.2(a)(ii) of the TRIPS Annex requires that the TRIPS Council notification ‘confirms’ that the importing Member has established insufficient manufacturing capacity, indicating that this exercise must have been completed prior to the notification being made.

LDCs need not establish this as they are deemed to lack sufficient manufacturing capacity.[237]

The Appendix to the Annex to TRIPS offers Members a considerable degree of deference in this regard. Rather than imposing burdensome procedures, the Appendix clarifies that Members can establish insufficient capacity by simply *establishing* 'no manufacturing capacity in the pharmaceutical sector', or existing capacity in the pharmaceutical sector that is 'insufficient for the purposes of meeting its needs.'[238] Such practice as is available suggests that very general reference to the national situation is sufficient; in the case of COVID-19 vaccines, the serious shortfalls of production capacity in regions of greatest need are very well documented in any case, and could hardly be questioned. Considering vaccine production in the context of the current pandemic, there is ample documentation of the very extensive disparities in production capacity in the developing world, especially for end-to-end production and for more novel vaccine platforms.[239]

- *No requirement to establish a health emergency*

A common misconception is that an importing Member establish something akin to a national health emergency before it can avail itself of the System.[240] This is plainly not the case, just as it is not the case for other use of NVUAs. Paragraph 1(b) of the TRIPS Annex clarifies that an importing Member can make a notification 'at any time', and provides national emergency or other circumstances of extreme urgency as an 'example' of the way in which an importing Member *may* wish to use the system 'in a limited way'. It is imperative that this distracting question be set aside in the interests of focussing on streamlined use of options under both Articles 31 and 31bis.

- *Notification to the TRIPS Council*. The **importing** Member must inform the TRIPS Council:
  - of its intention to use the Paragraph 6 System (unless it is an LDC);
  - of the name of the product and the quantities needed; and
  - that it has granted or intends to grant a compulsory licence (if the product is patented in its territory).

The means of notification can be a brief email to the WTO Secretariat. The notification does not create an obligation to use the system, and is essentially an indication of the scale of unmet needs for a particular medicine or medicines. Thus importing Members may choose to notify their needs in relation to a large number of vaccines to 'open up the widest possible range of potential suppliers, including through the System'.[241]

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[237] Appendix to the Annex to the TRIPS Agreement.
[238] Appendix to the Annex to the TRIPS Agreement, indents (i) and (ii).
[239] See e.g. Jodie Rogers, 'Vaccine production efforts across key regions mapped in first-of-its-kind study to prepare for future pandemics' (CEPI, 27 October 2021) <https://cepi.net/news_cepi/vaccine-production-efforts-across-key-regions-mapped-in-first-of-its-kind-study-to-prepare-for-future-pandemics/>; UNICEF COVID-19 Vaccine Market Dashboard <www.unicef.org/supply/covid-19-vaccine-market-dashboard>
[240] Behrang Kianzad and Jakob Wested, ''No-one is Safe Until Everyone is Safe' – Patent Waiver, Compulsory Licensing and COVID-19' (2021) 5(2) European Pharmaceutical Law Review 71, 83-84 citing Jenny Wakely, 'Compulsory licensing under TRIPS: an effective tool to increase access to medicines in developing and least developed countries' (2011) European Intellectual Property Review, 304.
[241] WTO Secretariat, the TRIPS Agreement and COVID-19, Information Note (15 October 2020) 10.

Members need not identify the relevant supplier.[242] The e-TRIPS Submission System provides a streamlined platform for filing such notifications.[243]

There is a strong practical case for groups of members facing similar circumstances to lodge a joint notification, or coordinated notifications. It is long established practice in the WTO for groups of members to file such joint submissions — an apposite example is the practice of all LDC members to request extensions of time for the application of TRIPS obligations in general, under Article 66.1. Since this example concerns fundamental rights and obligations under the Agreement, it is clearly acceptable and appropriate for groups of members to lodge a joint submission that combines their national needs for vaccines or other medicines (see **Box 2** and **Box 3**).

Box 2: Example of notification required

Scenario 1: Arcadia is an LDC. Its Ministry of Health, in cooperation with an international procurement programme, determines it needs 18 million doses of the medicine panaceavir; it has exercised its rights not to protect pharmaceutical patents until at least 2033. The following notification would be sufficient:

Notification of need to import pharmaceutical products under the TRIPS Article 31bis system

Arcadia needs to import 18 million doses of Panaceavir.

Box 3: Example of notification required

Scenario 2: Sanatos is a middle-income developing country with a limited pharmaceutical industry; a Ministry of Health procurement programme determines it needs 30 million doses of the medicine elixivir. It elects to notify its needs and its intention to use the system together. The following notification would be sufficient:

Notification of intention to use the Article 31bis system and the need to import pharmaceutical products under the system

Sanatos intends to use the System set out in Article 31bis and the Annex of the TRIPS Agreement.

Sanatos needs to import 30 million doses of elixivir.

Sanatos has found that its manufacturing capacity in the pharmaceutical sector is insufficient to meet its needs for this product(s), on the basis of 'Pharma Sanatos 2018', the most recent report on the pharmaceutical sector prepared by the Sanatos Ministry of Industry.

If no patent is in force in Sanatos, it may wish to add (optionally):

Elixivir is not protected by a patent in the territory of Sanatos.

If a patent is in force:

Sanatos intends to authorize use of the subject matter of the patent or patents in force for Elixivir without the consent of the patent owner in accordance with the provisions of Articles 31 and 31bis of the TRIPS Agreement.

- *Grant of licence by exporting Member*. The **exporting** Member must grant a compulsory licence containing certain conditions,[244] including that 'only the amount

[242] IP/C/86, Appendix 1 [11].
[243] Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review of the Special Compulsory Licensing System Report to the General Council, WTO Doc IP/C/86 (11 November 2020) [7].
[244] Other required conditions are indicated throughout this section.

necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the importing Member(s) which has notified its needs to the TRIPS Council'. This licence must comply with the remaining requirements in Article 31 not affected by Article 31*bis*.

Where the relevant pharmaceutical product is not patented in the territory of the importing Member, the *importing* Member clearly is *not* required to issue a compulsory licence since the technology is by definition completely unencumbered by patent rights in that country.[245]

There is no obstacle to an exporting member issuing compulsory licenses for export to several, or numerous, countries in the event that they have notified their needs for the medicine. Equally, it would be possible to issue parallel compulsory licenses or NVUAs to provide for domestic needs and to meet needs identified by importing countries. In practical terms, the same facility may be authorised to produce in parallel for domestic needs alongside servicing one or more other countries' needs as notified through the system, thereby creating opportunities for economies of scale and regulatory convergence.

- *Packaging and labelling.* **Suppliers** must use specific labelling or marking to make the finished vaccine clearly identifiable as being produced under the system. Further, suppliers *should* use special packaging and/or special colouring/shaping of the products to distinguish them, but this further stipulation does not apply if such distinction is not feasible or has a significant impact on price. This requirement has been identified as a potential source of unnecessary burdens including in the context of the COVID-19 pandemic.

The purpose of this provision, in the context of the pandemic response, must be understood as a measure to address vaccine inequity by providing a safeguard against diversion of shipments away from the priority communities that have been comparatively neglected. There is, therefore, a strong vaccine equity component to the balanced and effective implementation of this provision. Throughout the pandemic, it has been conventional for vaccine shipments to be labelled according to their source and destination, and in particular with reference to certain humanitarian access programs such as those managed by GAVI and UNICEF. There is no evidence that such labelling has created an obstacle or additional expense, while at the same time there has been extensive concern that vaccines are diverted to wealthy countries for use as boosters when equity would demand they should be directed to lesser developed countries.

It is evident both from the text and the policy context of these provisions that the distinguishing features required need not be complex and should be easily integrated into the production process. Indeed there is arguably a moral and legal obligation to take measures to ensure that shipments intended for neglected communities do

[245] Even where there is no relevant patent protection in the importing Member, the Paragraph 6 System must be complied with to enable the exporting Member to supply the importing Member without falling foul of Article 31(f).

actually reach those communities. Special packaging or colouring is plainly not required if this has any impact on feasibility or cost.

In view of the attention paid more generally to traceability and supply chain tracking of vaccine distribution, including through barcoding and similar methods,[246] this specific data element relating to shipments under this system may be incorporated with other tracking information and presented in an efficient manner that complements wider traceability and monitoring mechanisms aimed at supporting low- and middle-income countries,[247] without affecting the cost or viability of distribution.

Box 4: Example of labelling of a vaccine consignment

Sample label:

Vaccine export

under WTO TRIPS Agreement 31bis

Not for diversion

Figure 9: Example of labelling of a vaccine consignment

Source: unicef.org

- *Online publication of certain information*. The **licensee** must post on a website the following information before shipment begins: (i) the quantities being supplied to each destination; and the distinguishing features of the product(s) used to avoid trade diversion.[248] This requirement must be inserted as a condition of the compulsory licence.
- *Notification to the TRIPS Council*. The **exporting** Member must notify the Council for TRIPS of the grant of the licence, including the conditions attached to it, the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence, and the address of the website describing the supplied quantities and distinguishing features of the product's packaging, colouring or shaping.

[246] Robert H Vander Stichele, Christian Hay, Malin Fladvad, Miriam C J M Sturkenboom, and Robert T Chen 'How to ensure we can track and trace global use of COVID-19 vaccines?' (2021) 39(2) Vaccine 176.
[247] World Health Organisation, 'Bar-codes, QR codes and Vaccine Vial Monitors in the context of COVID-19 vaccines' (October 2020) <https://www.who.int/publications/m/item/bar-codes-qr-codes-and-vaccine-vial-monitors-in-the-context-of-covid-19-vaccines>
[248] This requirement must be inserted as a condition to the compulsory licence.

One concern raised about the Paragraph 6 System is that this procedure must be repeated for every compulsory licence granted.[249] However, a pragmatic, needs-driven approach should provide ways of streamlining use of the system.

First, as already indicated, an importing Member's Council notification can be made in respect of more than one product and can therefore be expansive in its scope, meaning that the Member need not repeat a notification for every product it needs.

Second, an exporting Member's notification may cover multiple importing Members,[250] as made clear by the words 'the country(ies) to which the product(s) is (are) to be supplied' in subparagraph 2(c). Even where an exporting Member's notification does not cover more than one importing Member, that exporting Member may adopt and submit a *pro forma* notification and simply replace the appended licence for each new licence that the System is used for.[251]

Third, Article 31*bis* refers to 'pharmaceutical product(s)' in the plural, indicating that a compulsory licence issued under Article 31*bis* can be granted in respect of more than one product. Pharmaceutical products in plural form are also referred to under subparagraphs 1.2(a) and (b) of the TRIPS Annex. Subparagraph (b)(ii) refers specifically to 'products produced under the licence'.

Fourth, a regional mechanism can be adopted both under Article 31*bis*.3 and outside the scope of that provision through the coordinated use of notifications when pooling procurement (discussed below). As noted in the discussion of Article 31(a) above, a group of importing Members could issue a joint notification under the TRIPS Annex and issue a joint compulsory licence (which would have separate legal force in each of the jurisdictions concerned).

Fifth, in the light of concerns that an importing Member may need to be supplied by more than one exporting Member, each of whom must engage with the System,[252] the steps involved in notifying details of these distinct exports are scarcely on the scale of the administrative, regulatory and logistical steps required for actual production and delivery. An importing Member need not specify in its Council notification the exporting Member(s) from which it seeks to import the relevant product or products.

Integrating notification into vaccine procurement

Routine, early notification of needs for vaccines can and ideally should be notified at an early stage of vaccine procurement, as soon as a clear target for the vaccine type and estimated doses required becomes available. This could precede any of the regular steps in procurement, such as:

[249] Carlos M Correa, 'TRIPS Agreement and Access to Drugs in Developing Countries' (2005) 3 International Journal on Human Rights 25, 34.
[250] Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication From The European Union to the Council for TRIPS, WTO Doc IP/C/W/681 (18 June 2021).
[251] Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review of the Special Compulsory Licensing System, WTO Doc IP/C/86 (11 November 2020), Appendix 1 [18].
[252] WTO Doc IP/C/W/672 (n 21) [112].

- surveying potential suppliers;
- considering regulatory and quality aspects;
- reviewing the patent landscape where relevant;
- issuing requests for tender or similar processes;
- following any applicable rules for transparency and competitiveness in procurement.

Procurement under a compulsory licence for export can then proceed if the best option for supply is from a generic producer in a country where a relevant patent is in force. If an alternative pathway would produce a preferable procurement outcome, then there would be nothing to prevent taking that option. The best price is often obtained in a competitive environment — so the Paragraph 6 System can be used to increase the range of potential suppliers bidding for a procurement contract. The experience of Rwanda's imports under the System demonstrates this effect. Lower-cost combinations of the required medicines were already readily available from alternative generic suppliers in India, and given the need for procurement procedures to ensure value for money (among other things), the fact that the System was used as one, but not the exclusive, potential source for procurement led to a significant savings and consequently a better application of available resources (even though this made the supply less feasible for an inherently higher-cost manufacturer).[253] At the time of the Rwanda example, Canada was one of the first potential exporting countries to provide for compulsory licences of medicines expressly for export; since that time, the number and scope of countries introducing such legislation has grown very considerably, to the extent that they now comprise roughly 80% of existing pharmaceutical export capacity.[254] While the System has not been used for export since then, its potential contribution is now accordingly very much greater, making urgent the consideration of factors constraining its use and how to overcome them.

Since the system is intended exactly to enable export under a compulsory licence from the country of production, it is plainly necessary to take the necessary steps in that country for the supply to go ahead.

Whatever method is used to procure medicines, several factors typically determine whether a supply is viable. Cost is a major factor, especially for developing countries. Other factors include regulatory approval, quality, and sustainability of supply. The level of demand and economies of scale may also determine potential suppliers.

If only a relatively small supply is required, it may not be feasible or economic to go through necessary regulatory approval and quality certification, to tool up for production, and actually to produce and export medicines — whether or not the option of a compulsory licence for export is pursued. Legal entitlement to produce and export the medicine does not in itself make it viable actually to produce it. This may be an issue for countries or procurement programs servicing relatively small populations.

[253] See outline of the Canada – Rwanda case in WHO, WIPO, WTO (n 47) 243.
[254] Kampf (n 201) Annex III.

It could be helpful, therefore, for countries or procurement programs — especially in the same region or subregion — to coordinate their notifications of needed pharmaceuticals under the System. Several parallel notifications taken together could tip the scale, in effect, and make it feasible for a low-cost generic producer to undertake the production and export so as to serve all the countries in need. Scenarios 3 and 4 demonstrate the kind of joint notification that could be made in this manner, aggregating demand from relatively small quantities for individual countries to a more viable production target approaching 100 million doses. This coordinated approach to pooled procurement would have the additional benefit of easing concerns, voiced in debate about use of the System, about potential political pressure (see following section). Such a step, taken in the spirit of solidarity, would demonstrate how, as argued above, the agency of individual governments can be reinforced through collective action and act as an instance of what one of us has termed 'solidarity as a practical craft'.[255] Again, at a practical level, this approach would open up a wider range of potential suppliers for this pooled procurement, without necessitating use of the System should more advantageous supplies be available.

Further, tracking evolving demand for vaccines has emerged as one limiting factor in the effective response of manufacturing and distributing vaccines, and a more routine practice of early notification of unmet demand at the preliminary stages of procurement would also assist potential producers to plan and adjust accordingly.

Box 5: Example of notification required

Scenario 3. Achaea, Boeotia, and Corcyra are LDCs located in the same region. Only one provides for patenting of pharmaceuticals. In coordination with a regional organisation and an international procurement program, they elect to combine their needs for the medicine Elixivir in a single joint notification.

Notification of need to import pharmaceutical products under the TRIPS Article 31bis system

Achaea, Boeotia, and Corcyra, intend to import the following number of doses of Elixivir

Achaea – 16 million doses

Boeotia – 28 million doses

Corcyra – 1.4 million doses

Boeotia intends to issue a compulsory licence on patents covering Elixivir in its territory.

[255] Antony Taubman, 'Solidarity as a Practical Craft: Vaccine Equity and International Economic Law', 26th International Humanitarian & Security Conference, November 9, 2021 <www.youtube.com/watch?v=B3oIxOlYCXQ from 1.19.20>

Box 6: Example of notification required

Scenario 4. Following further coordination led by the same regional organisation and international procurement program, two developing countries in the region decide to pool procurement with the three countries in Scenario 3.

Notification of intention to use the TRIPS Article 31bis system and of need to import pharmaceutical products under the system

Dolopia and Euboea intend to use the System set out in Article 31bis and the Annex of the TRIPS Agreement, and to import the following number of doses of Elixivir

Dolopia – 34 million doses

Euboea – 22 million doses

The lack of sufficient pharmaceutical production capacity in Dolopia and Euboea is documented in the report, Global Status and Outlook: Pharmaceutical Production in 2022, available at.

Elixivir is not protected by a patent in the territory of Dolopia.

Euboea intends to authorize use of the subject matter of the patent or patents in force for Elixivir without the consent of the patent owner in accordance with the provisions of Articles 31 and 31bis of the TRIPS Agreement

3.2.5.3 Requirements

In general, the System can be utilised by WTO Members to import medicines without any specific steps to implement it domestically, since importation under a compulsory licence is already an option in most countries, and in many potential importers there will be no patent in force in any case. In some instances, only the rules on remuneration may need to be adjusted, since remuneration is not expected in both exporting and importing countries, although arguably it is reasonable to assess 'adequate remuneration' (as required by Article 31 of TRIPS) to be zero, if remuneration is already provided for in the exporting country. By contrast, for export under the System, since it introduces a novel form of compulsory licence in the exporting country, countries wishing to facilitate supply through this mechanism would generally need to make the necessary technical amendment to their laws to permit production for export. By 2015, 51 WTO Members had adopted specific implementing measures, comprising the bulk of global export capacity,[256] meaning that the System provides for a wide range of potential suppliers, should it be effectively used as a procurement tool. Japan, also, has explained that its Guideline for Administering Award System and Article 93 of its Patent Act (providing for the grant of non-exclusive licences for reasons of public interest) serve as the legal basis for the grant of compulsory licences in accordance with international obligations and thus for export under the System.

[256] Kampf (n 201) Annex III.

Of the countries surveyed, only India, Indonesia and Cambodia have provisions expressly implementing some aspect of the Paragraph 6 System.[257] It may be desirable or constitutionally necessary for other Members to adapt their domestic systems to facilitate use of the System. In particular, exporting Members may deem it appropriate to incorporate the requirements of TRIPS Annex paragraph 2(b) into their domestic compulsory licensing laws to ensure that the conditions referred to in that paragraph are inserted into compulsory licenses issued under the System (but not compulsory licences generally).[258]

For example, legislation may require that a licensee post the information required to be posted online by indent 2(b)(iii), or require that any products produced and exported under a System compulsory licence be packaged or produced in accordance with certain prescribed requirements, to ensure compliance with indent 2(b)(ii).[259] While not always strictly necessary, these provisions may ensure that the Article 31*bis* procedure is being properly complied with by all government and non-government parties involved. Cambodia's *Law on Compulsory Licensing for Public Health* provides a suitable example of how developed countries and LDCs might approach this task.

There are other requirements in the TRIPS Annex that Members must comply with but that are auxiliary to the System procedure itself. Paragraph 3 requires that 'eligible importing Members … take reasonable measures … to prevent re-exportation of the products that have actually been imported into their territories under the system.' This requirement is to ensure that the products imported are used for the public health purposes in the importing Member, and are not re-exported elsewhere *following importation*. Only 'reasonable' measures proportionate to the Member's administrative capacities and to the risk of trade diversion need to be adopted, and only if such measures are within the Member's means.[260] While this provision has been identified as a potential burden, its potential use to safeguard vaccine equity in the course of the pandemic — limiting the prospect of vaccines being diverted from those in most need to wealthier, better supplied, communities — suggests that it may be applied in a balanced and equitable manner.

Paragraph 4 requires Members make available 'effective legal means' to prevent the products produced under the System from being imported into and sold in their territories in a manner inconsistent with the System. This provision is intended to prevent importation that does not comply with the System's requirements. Paragraph 4 clarifies that these means must be those already required to be available under

[257] As of January 2022, WTO Members notifying such legislation to the TRIPS Council included Albania. Australia, Botswana, Canada, China, Croatia, Cuba, European Union, Hong Kong, China, India, Jordan, Kazakhstan, New Zealand, Norway, Oman, Philippines, Republic of Korea, Russian Federation, Singapore, Switzerland, and Chinese Taipei. Others had introduced such legislation but not notified it. <www.wto.org/english/tratop_e/trips_e/par6laws_e.htm>

[258] See e.g. Law On Compulsory Licensing for Public Health (Cambodia) art 15.

[259] See e.g. Law On Compulsory Licensing for Public Health (Cambodia) art 15.

[260] If developing or least-developed importing Members request technical and financial cooperation from developed Members that is on mutually agreed terms and conditions, those developed Members must provide such cooperation.

TRIPS, meaning that governments can use judicial and administrative processes already implemented in fulfilment of the treaty's requirements.

Article 31*bis*.2 waives the requirement for adequate remuneration to be paid by the importing Member under Article 31(h) in cases where the patentee has already been paid remuneration in the exporting Member's territory. Some countries that have implemented the System into their domestic law have not incorporated this clarification, giving rise to the possibility that the patentee will be paid twice.[261] There is also no requirement to seek the permission of importing Member's government before an exporting Member issues a compulsory licence for the purposes of supplying that country. However, some countries have introduced this requirement.[262] Cambodia does not require the importing Member's permission but does require the application for an export compulsory licence to include letters from the importing Member indicating its intention to import, a copy of the importing Member's notification to General Council, and a commitment to comply with the conditions set out in the Annex.[263] This may unnecessarily increase the administrative burden of utilising the System.

Finally, Members should ensure that the domestic procedures adopted for implementing both Articles 31 and 31*bis* are as simple, efficient and transparent as possible. This can be achieved in part by ensuring that additional requirements are not imposed as part of the compulsory licence process. Members should also reduce the number of administrative, legislative and judicial authorities involved in the compulsory licensing process, clearly defining their respective roles and ensuring they pursue policy goals harmoniously,[264] particularly where a licence is issued in circumstances of urgency. Judicial bodies should be reserved for the role designated to them by Articles 31(i) and (j) and other applicable TRIPS provisions, subject to the requirements of an individual Member's system of government.

3.2.5.4 Political and Industry Pressure

Pharmaceutical industry and political pressure, sometimes in the form of threatened or actual litigation, has been oft cited as a deterrent to utilising the System and compulsory licenses generally.[265] Two countries from our sample have been previously subject to such pressure. Several suits were instigated in India regarding *Nexavar*,[266]

[261] Kampf (n 201) 9. India's law does not include this clarification whereas Cambodia's law does: Law On Compulsory Licensing for Public Health (Cambodia) art 11(2).
[262] Ng and Kohler (n 213) 153-154.
[263] Law On Compulsory Licensing for Public Health (Cambodia) art 14.
[264] World Intellectual Property Organization, Standing Committee on the Law of Patents Thirtieth Session Geneva, June 24 to 27, 2019, Draft Reference Document on the Exception Regarding Compulsory Licensing, SCP/30/3 (21 May 2019) 47, 49.
[265] World Intellectual Property Organization, Standing Committee on the Law of Patents Thirtieth Session Geneva, June 24 to 27, 2019, Draft Reference Document on the Exception Regarding Compulsory Licensing, SCP/30/3 (21 May 2019) 47, 49.
[266] Ng and Kohler (n 213) 169.

while Thailand was subject to international government criticisms for authorising use of the antiretroviral medicine *Efavirenz*.[267]

Developing countries are unlikely to be met with litigious threats for issuing compulsory licences to specifically deal with a global pandemic. To the contrary, developing countries are likely to receive support from the international community.[268] Domestic-level IP enforcement in developing countries may also be unattractive to patent holders due to the physical, procedural and legal complexities associated with such processes.[269]

TRIPS provides direct and indirect mechanisms for addressing abusive or vexatious litigation. For example, Article 41.1. provides that enforcement procedures must be applied in a manner that avoids 'the creation of barriers to legitimate trade and to provide for safeguards against their use'.[270] Under Article 48, judicial authorities have the authority to 'to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse' and 'to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.'[271]

Some suggest — appropriately, in our view — that countries should 'create (or clarify) declaratory-judgment procedures that enable local firms … to obtain, in advance, authoritative rulings concerning their rights to manufacture specific drugs.'[272] Members should also be aware of the possibility of using domestic measures against anti-competitive enforcement of intellectual property rights, including sham litigation.[273] However, developing countries are unlikely to have such measures implemented,[274] and existing measures in developed countries tend to employ high thresholds.[275] That said, TRIPS Article 67 expressly provides that technical and financial assistance made available to developing country Members must include assistance in dealing with the abuse of IP rights, an area that has rarely been covered in the reports of technical assistance actually delivered.[276] Article 40 of TRIPS marks out the entitlement of

[267] United Nations, Report of the United Nations Secretary-General's High-Level Panel On Access To Medicines: Promoting Innovation and Access to Health Technologies (September 2016) 24-25.
[268] Thailand, for example, received domestic and international support in its use of IP flexibilities to combat the HIV/AIDS epidemic: 'Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10(1):010358 Journal of Global Health 1, 2.
[269] Poku Adusei, 'Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa' (2011) 14(1) Journal of World Intellectual Property 1, 13.
[270] TRIPS art 41.1 cited in Robert D Anderson, Anna Caroline Müller and Antony Scott Taubman, 'The WTO TRIPS Agreement as a Platform for Application of Competition Policy to the Contemporary Knowledge Economy' in Robert D Anderson, Nuno Pires de Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 62, 82.
[271] TRIPS art 41.1 cited in Anderson, Müller and Taubman (n 270) 82.
[272] Fisher, Okediji and Sampath (n 32) 29.
[273] See generally, Institute for Applied Economic Research (IPEA), 'Study on the Anti-Competitive Enforcement of Intellectual Property (IP) Rights: Sham Litigation', WIPO Document CDIP/9/INF/6 REV (30 July 2012).
[274] Cf Chile's Law No. 20.169.
[275] Mark D Janis, '"Minimal" standards for patent-related antitrust law under TRIPS' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 774, 789-790.
[276] See Reports by Developed Country Members on Technical Cooperation Activities under TRIPS Art. 67, at <e-trips.wto.org>

Members to take action against Members may also seek to use anti-competitive measures to address actions such as 'reverse payment patent settlements', whereby the patent holder pays an alleged infringer in return for the alleged infringer halting unauthorised production of generics and the patentee suspending litigation. Such action may be deemed unreasonable or as amounting to an abuse of dominant position under domestic anti-competition law,[277] a topic discussed in more detail below.

3.2.5.5 The regulatory dimension

NVUAs, such as compulsory licensing, create a legal pathway for the use of patented technologies without the right holders' consent. However, they do not, and cannot, ensure in themselves that it is feasible and effective to actually deploy the technology. A key factor, potentially posing a barrier to the full and effective use of Articles 31 and 31*bis*, is the need for regulatory required to demonstrate the safety and efficacy of a vaccine or other health-related subject matter. Many countries' compulsory licensing regimes operate independently of requirements to gain regulatory approval of pharmaceuticals.[278] In some cases, regulatory approval requirements have been attached specifically to the compulsory licence process so that approval is required before a licence can be granted.[279]

A striking example of the need to clarify the regulatory dimension is that of the current controversy over the application by the firm Biolyse under Canada's CAMR for a compulsory licence to permit vaccine production for export. Bolivia has concluded an agreement with Biolyse for the supply of vaccines, to be produced under compulsory licence in Canada, and has notified its needs for vaccines to the TRIPS Council as required under the Article 31bis system.[280] However, a compulsory licence has not been issued, and the matter reportedly remains with the domestic agencies concerned in Canada. While details of the current status of this matter are unclear, and have been the subject of some controversy,[281] one specific obstacle has reportedly been the need for Canadian government authorities to assure themselves that vaccines produced by Biolyse would be safe and effective. This is in essence a regulatory matter, and not a requirement of TRIPS nor ultimately an intellectual property issue, even though the ostensible obstacle to production appears to be the lack of a licence.

[277] Robert D Anderson et al, 'Competition Agency Guidelines and Policy Initiatives Regarding Intellectual Property in the BRICS and Other Major Jurisdictions: A Comparative Analysis' in Robert D Anderson, Nuno Pires de Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 517, 608.
[278] Interestingly, Mongolia incorporates a regulatory approval requirement into its patent law: Patent Law of 25/06/1993 (Mongolia) art 7.8.
[279] Kampf (n 201) 14.
[280] Notification of Need to Import Pharmaceutical Products Under the Special Compulsory Licensing System, WTO Doc IP/N/9/BOL/1 (11 May 2021).
[281] e.g. Muhammad Zaheer Abbas, Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case, South Centre Research Paper 136, 2021.

Another barrier to effective use of patents is the disclosure of otherwise secret or confidential information pertaining to the use of the patent.[282] Compulsory licences do not ordinarily require the disclosure of such information.[283]

3.2.6 Revocation

Article 32 of TRIPS provides that '[a]n opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.' As noted by Haugen:

> [b]ecause TRIPS Article 32 specifies no requirements for when revocation or forfeiture can be decided, specifying only the availability of judicial review, TRIPS does not prohibit states from authorizing patent revocation or forfeiture to protect prevailing public interests.[284]

Revocation is primarily permitted on the ground of a failure to work within the laws of the countries surveyed.[285] India's law allows the Government to revoke a patent where it is 'of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public'. The power is subject to the patentee's right to be heard.[286]

Members may consider it too dissonant with their IP regime to opt for revocation when the option of non-voluntary authorised use is available — an option that largely preserves a patent's originally intended function (subject to a limited blunting of the patent holder's exclusivity rights), while addressing the public needs. However, revocation may be considered appropriate where a Member's particular circumstances make the procedure under Articles 31-31*bis* overly burdensome.

3.3 Copyright

3.3.1 Article 13

Article 13 of TRIPS provides: 'Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.'[287] Article 13 provides for a 'three-step test', with a general structure similar to exceptions for patents, trademarks and designs in the TRIPS Agreement. Although each of these provisions, starting with Article 13, can be traced to the *Berne Convention* and feature common concepts,[288] their text, syntax and policy context differ fundamentally. Giving primacy to the ordinary meaning of the terms in their context, we adopt the view that there are four such tests in TRIPS, 'each of which is uniquely

[282] Karen Walsh, Andrea Wallace, Mathilde Pavis, Natalie Olszowy, James Griffin and Naomi Hawkins, 'Intellectual Property Rights and Access in Crisis' (2021) 52 International Review of Intellectual Property and Competition 379, 405.
[283] These issues are addressed separately in Sections 3.6 and 3.7.
[284] Haugen (n 85) 203.
[285] The Patents And Designs Act, 1911 (Bangladesh) s 23(1); Patent Acts, 1970 (India) s 85; Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 55(1).
[286] Patents Act, 1970 (India) s 66.
[287] TRIPS art 13.
[288] Antony Taubman, A Practical Guide to Working with TRIPS (Oxford University Press, 2011) 91; Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur (ed), Intellectual Property Rights in a Fair World Trade System Proposals for Reform of TRIPS (Edgar Elgar, 2011) 222.

different'.[289] We therefore approach these tests separately, except where the meaning of words used and their interpretation by WTO panels can be reconciled and the same conclusions can be drawn about their application to specific cases. Therefore, we seek to 'ensure general consistency in the way these terms are interpreted, while recognizing the distinct policy contexts of different forms of IP'.[290]

We also adopt the view that the three-step test provisions 'form part of standards on the scope of protection' at the domestic level of implementation.[291] Thus, while the exceptions and limitations at the domestic level may function as defences, their legal basis in TRIPS functions as part of the original balance of rights and obligations. It should therefore be on any potential complainant to bear the burden of demonstrating that a domestic exception does not satisfy the test.[292]

3.3.2 Copyright exceptions relevant to vaccine production and distribution

Some have expressed doubt that Article 13 and its equivalents extend to public interest purposes,[293] and thus the pandemic context.[294] However, we identify two types of exceptions potentially permissible under Article 13 relevant to vaccine production and distribution: (i) exceptions for use by commercial entities of copyrighted materials necessary but ancillary to vaccine production and distribution (e.g. product inserts and software); and (ii) non-voluntary government or public non-commercial use (i.e. compulsory licensing of copyrighted material).

These two pandemic-specific exceptions fit within two broader, existing categories of exception that have been introduced or have evolved within domestic IP systems under the pretext of Article 13: fair use and non-voluntary use. While many exceptions, such as specific free uses, may be directly legislated into a country's IP system, many common law jurisdictions have, over time, recognised and developed a notion of 'fair use' as a general law exception to copyright infringement.[295] The fair use doctrine is

[289] Andrew F Christie and Robin Wright, 'A Comparative Analysis of the Three-Step Tests in International Treaties' (2014) 45 International Review of Intellectual Property and Competition Law 409, 409. The Panel in EC – Trademarks said: 'whilst it is instructive to refer to the interpretation by two previous panels of certain shared elements found in Arts. 13 and 30, it is important to interpret Art. 17 according to its own terms': Panel Report, European Communities — Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, WTO Doc WT/DS290/R (15 March 2005) [7.694] ('EC – Trademarks').

[290] Antony Taubman, A Practical Guide to Working with TRIPS (Oxford University Press, 2011) 91.

[291] Matthew Kennedy, 'The ''Three-Step Test'' and the Burden of Proof in Disputes Under the TRIPS Agreement' (2014) 45 International Review of Intellectual Property and Competition Law 161, 161. See further Caroline Henckels, 'Permission to Act: The Legal Character Of General And Security Exceptions In International Trade And Investment Law' (2020) 69(3) International & Comparative Law Quarterly 557.

[292] Kennedy (n 289) 161. See also Caroline Henckels, 'Permission to Act: The Legal Character Of General And Security Exceptions in International Trade And Investment Law' (2020) 69(3) International & Comparative Law Quarterly 557.

[293] See generally, Christopher Geiger, Jonathan Griffiths and Reto M Hilty, 'Towards a Balanced Interpretation of the ''Three-step Test'' in Copyright Law' (2008) 31(12) European Intellectual Property Review 489; Henning Grosse Ruse-Khan, 'Assessing the need for a general public interest exception in the TRIPS Agreement' in in Annette Kur (ed), Intellectual Property Rights in a Fair World Trade System (Edward Elgar Publishing, 2011) 167, 183.

[294] IP/C/W/673 (n 72) [60]-[61].

[295] Taubman, Wager and Watal (n 151) 47.

now codified in many of these jurisdictions' statutes, which set out the factors that judicial bodies must consider in adjudicating a fair use defence.[296]

3.3.2.1 Fair use of ancillary works

Prima facie copyright infringements may arise where there is an unauthorised use of a copyrighted work that subsists in the written material featured in product information documents and on product labelling and inserts. Infringements may also occur where copyrighted software and data compilations are utilised in the vaccine manufacturing and distribution process. Such items generally contain information about product distribution, clinical dose and delivery recommendations or guidelines, and warnings about side-effects. The use of such written material by commercial entities would ordinarily be ancillary to the production and distribution of vaccines and other health products and not generally for any immediate commercial purpose.

Members may wish to rely on Article 13 in creating a specific exception for such ancillary use, when it is necessary for the production or distribution of essential COVID-19 or pandemic-related health products. Alternatively, such use could fall within the scope of the 'fair use' systems maintained in those jurisdictions that utilise a framework of judicially or administratively applied exceptions. Notwithstanding the common view that the frequently encountered 'fair use' factors are cognisant with the three-step test,[297] we discuss whether either a specific exception or fair use exception for these types of use is likely to satisfy Article 13. We assume for these purposes that the first step ('certain special cases') is satisfied. Relevantly to both legislated and judicially applied exceptions, the *Copyright* Panel clarified that 'there is no need to identify explicitly each and every possible situation to which the exception could apply, provided that the scope of the exception is known and particularised.'[298]

3.3.2.1.1 Normal exploitation

In *Copyright*, 'normal exploitation' was described as 'uses, that … enter into economic competition with the ways that the right holders normally extract economic value from that right to the work and thereby deprive them of significant or tangible commercial gains'.[299] As summarised by de Borja, an 'exception conflicts with the "normal exploitation" of rights where it deprives the right-owner of the actual and potential economic gains that could normally be anticipated both in empirical and in legal terms.'[300] The *Patents* Panel adopted a similar approach.[301]

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[296] See e.g. Copyright Act 1976 (US) § 107: (i) the purpose and character of the use, including whether such use is of a commercial nature or is for non-profit educational purposes; (ii) the nature of the copyrighted work; (iii) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (iv) the effect of the use upon the potential market for or value of the copyrighted work.

[297] See generally, Australian Law Reform Commission, 'Copyright and the Digital Economy' (ALRC Report 122, 2012) 116-122.

[298] Panel Report, United States – Section 110(5) of US Copyright Act, WTO Doc WT/DS160/R (15 June 2000) [6.108] ('US – Section 110(5) of the US Copyright Act').

[299] Panel Report, US – Section 110(5) of the US Copyright Act (n 298) [6.183].

[300] Ana Gerdau de Borja, 'Exceptions to Design Rights: The Potential Impact of Article 26(2) TRIPS' (2008) 31(12) European Intellectual Property Review 500, 502-503.

[301] See Panel Report, Canada – Patents (n 169) [7.54]-[7.57].

Assuming that the second step must be interpreted strictly in economic terms, there is a strong argument that any copyrighted work subsisting in health product inserts, packaging, labelling and similar materials would not normally be exploited by the originator in a commercial manner. To put it simply, the manufacturers of such products do not ordinarily extract economic value from the presentation of such information, which is usually included as a matter of practical, legal or regulatory necessity. Thus, adopting the words of the United States fair use provision,[302] the effect of the use upon the potential market for or value of the copyrighted work would be minimal if not completely illusory.

Although the second step focuses attention to the economic use of a copyrighted work, and has been interpreted in a way that limits it purely to economic considerations,[303] the words of the second step do not altogether exclude incorporation of non-economic, practical considerations into even an empirical examination of whether such economic value is being normally extracted. Thus it may be said that the mere ancillary use of copyrighted works for extraordinary public health purposes is not a use that enters into economic competition with the ways that a rights holder normally extracts, and thus would normally expect to extract, economic value from the right. This interpretation conforms with both an empirical and value-judgment based analysis.[304] As Lucas notes, panels applying this step have so far been limited to the empirical approach perhaps only because of the economic nature of the exceptions with which they were concerned.[305] Along similar lines, Ricketson has suggested that 'any interpretation of the second step … should be viewed against the wider context of the [*Berne Convention*] and include an investigation of non-economic normative considerations including "whether this particular kind of use is one that the copyright owner should control".'[306]

This normative approach also aligns with that of the *Patent* Panel; it considered that what is 'normal' might be determined by asking what is 'normal in the sense of being essential to the achievement of the goals of patent policy'.[307] That question is necessarily concerned with more than just economic concerns. The economic concerns of any IP policy guided by the TRIPS framework are ultimately directed to the achievement of higher goals, such as the transfer of technology, growth in innovation and in turn the promotion of various socio-economic interests.[308]

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[302] See above n 296.
[303] See e.g. Lucas (n 315) 279.
[304] Wright notes that the Copyright Panel contemplated a definition of 'normal exploitation' that 'could have both the empirical connotation of "regular, usual, typical or ordinary" and a more normative definition such as "conforming to a type or standard"': Wright (n 314) 612 citing US – Copyright [6.166].
[305] Lucas (n 315) 279. See also J C Ginsburg, ''Toward Supranational Copyright Law? The WTO Panel Decision and the ''Three-Step Test'' for Copyright Exceptions' (2001) 187 Revue Internationale du Droit d'Auteur 3, 14.
[306] Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur (ed), Intellectual Property Rights in a Fair World Trade System Proposals for Reform of TRIPS (Edgar Elgar, 2011) 231 citing Ricketson, The Three-Step Test, Deemed Quantities, Libraries and Closed Exceptions (Centre for Copyright Studies, 2002) 35 cited in Wright (n 314) 614.
[307] Panel Report, Canada – Patents (n 169) [7.58].
[308] TRIPS art 8.1.

The *Copyright* Panel's reference to 'significant or tangible commercial gains' may be highly relevant where the exception proposed has a significant quantitative effect on economic extraction, regardless of the qualitative or normative context in which the exception is applied. However, very little commercial value is likely to attach to the way in which merely ancillary product information is presented.

3.3.2.1.2 Legitimate public interest

The second step requires that the relevant exception does not unreasonably prejudice the legitimate interests of the right holder. In *Canada – Patents*, the Panel stated that the term 'legitimate interests … must be defined in the way that it is often used in legal discourse — as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms.'[309] Similarly, the Panel in *Copyright* stated that it 'relates to lawfulness from a legal positivist perspective, but it has also the connotation of legitimacy from a more normative perspective, in the context of calling for the protection of interests that are justifiable in the light of the objectives that underlie the protection of exclusive rights.'[310] The *Copyright* Panel confirmed that its analysis of economic data to determine whether any prejudice caused was unreasonable did not mean that 'legitimate interests are necessarily limited to … economic value'.[311]

The two Panel's shared focus on justifiability[312] would seem to require something akin to the proportionality analysis or weighing and balancing exercise undertaken by the Panel in *Australia – Tobacco Plain Packaging*.[313] However, the term 'justifiable' does not feature in the provisions and was only employed by the two panels in giving meaning to the term 'legitimate interests'. Therefore, rather than requiring a Member to establish that the prejudice to legitimate interests is justifiable in the sense required by Article 20 of TRIPS, the panels' reports establish that what is legitimate is to be determined by reference to public policies and social norms, matters about which Members are given a significant margin of deference. Thus the *Berne Convention* Study Group endeavoured for '... a formula capable of safeguarding the legitimate interests of the author while leaving a sufficient margin of freedom to the national legislation to satisfy important social or cultural needs'.[314]

In most if not all Members, there is a strong public interest rationale for relevant product information being made available, and since such product information is not being commercialised in itself, the originator arguably has no legitimate interest in exercising copyright over it in a commercial manner. In terms of the unreasonableness of the

[309] Panel Report, Canada – Patents (n 169) [7.69]. See also Panel Report, EC – Trademarks (n 289) [7.663].
[310] Panel Report, US – Section 110(5) of the US Copyright Act (n 298) [6.224], [6.227].
[311] Panel Report, US – Section 110(5) of the US Copyright Act (n 298) [6.224], [6.227].
[312] See Martin Senftleben, 'Towards a Horizontal Standard for Limiting Intellectual Property Rights? WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law' (2006) 37(4) International Review of Intellectual Property and Competition Law 401, 434.
[313] See Andrew Mitchell and Theodore Samlidis, 'The Implications of the WTO Tobacco Plain Packaging Disputes for Public Health Measures' (2021) 70 International & Comparative Law Quarterly 1011, 1024.
[314] Robin Wright, 'The ''Three-Step Test'' and the Wider Public Interest: Towards a More Inclusive Interpretation' (2009) 12(6) The Journal of World Intellectual Property 600, 603 citing Document. S/1, Records 1967, p. 113.

prejudice incurred, this is likely to depend 'not only … on the intensity of the prejudice suffered by the right owner, but also on considerations of general interest that may command the maintenance of an exception'.[315] Assuming that the originator does not maintain a legitimate interest in protecting its copyright over the material, then the unreasonableness of any prejudice to such interests is a moot point.

3.3.2.2 Government use

Compulsory licences for copyrighted works are well established under domestic and international law.[316] The *Berne Convention* establishes the right of countries to determine the conditions under which the economic rights of certain authors can be exercised, subject to the payment of equitable remuneration.[317]

It may be argued that Articles 13, 17 and 26 do not permit compulsory licences because the presence of Article 31 indicates that the TRIPS drafters felt the need for an explicit provision to that effect. However, Article 31 presupposes the right of Members to authorise 'other use' and merely imposes further restrictions on compulsory licencing for patents.[318] The result is that only compulsory licences compliant with the requirements of Articles 31-31*bis* are permitted in respect of patents, but that an exception under Articles 13, 17 and 26 allows Members to issue compulsory licences, provided no relevant restrictions apply. Significantly in this regard, Article 21 of TRIPS explicitly clarifies that 'compulsory licensing of trademarks shall not be permitted', while Articles 11*bis* and 13 of the *Berne Convention* specify certain conditions for the grant of a compulsory licence for particular copyrighted works.[319]

It follows that a powerful option available to Members is a non-voluntary use authorisation that could be used, for instance, to allow the use of copyrighted works for a public non-commercial purpose.

3.3.2.3 Narrow scope of exception

In both cases, the fair use and non-voluntary use exceptions described above would have a narrow scope of operation, applying only to the distribution of medicines approved by the relevant regulator. This narrow scope of operation — a very distinct and circumscribed scope of use of the copyright work — would further support an argument that the first and second steps of the test were satisfied: this form of reproduction potentially qualifying as 'certain special case', and not intruding on a right holder's legitimate interest in the work, given especially that the work is not reproduced,

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[315] André Lucas, 'For a Reasonable Interpretation of the Three-Step Test' (2010) 32(6) European Intellectual Property Review 277, 278.
[316] Long (n 56).
[317] Berne Convention Article 11bis, Article 13. Under Article IV of the Convention Appendix, such compensation must be 'consistent with standards of royalties normally operating on licenses freely negotiated between persons in the two countries concerned': Appendix, Article IV.
[318] See above Section 3.2.4.4.
[319] Indonesia's law appears to contain a compulsory licensing provision for broadcasting on 'national interests' grounds, and a translation/reproduction compulsory licensing provision: Law of Republic of Indonesia Number 28 of 2014 on Copyrights (Indonesia) arts, 51, 84. See also The Copyright Act 2002 (Nepal) s 20.

distributed or sold separately, but forms only an ancillary element of a medicine that is the principal subject of production and distribution.

3.3.2.3.1 Implementation in the Asia-Pacific region

None of the surveyed countries' laws feature a specific exception that covers the use of copyrighted work ancillary to the production or distribution of health products, although Fiji's copyright law contains an explicit public health exception,[320] and Indonesia's copyright law contains an exception to infringement for use for the purposes of 'security and governance, legislative, and judiciary'.[321]

However, some of the countries surveyed maintain fair use or fair use-type exceptions that are framed sufficiently widely to account for the circumstances discussed above. For example, Mongolia's law lists circumstances in which use is deemed not to constitute copyright infringement, provided such use does not contradict with the normal exploitation of published works or affect the legal interests of the right holder. The following conditions must be considered: (i) whether the use has a non-profit purpose; (ii) the extent of use and the importance of the used parts; (iii) the value of the work and the effect of the used part on the market. Mongolia's law could be amended to include circumstances in which use of the copyrighted work is necessary for the distribution of vaccines or other essential health products.

3.4 Industrial Designs

Industrial design protection — if at all likely to become a barrier to accessing essential health products used in the pandemic response — is more likely to limit the distribution and use of ventilators, personal protective equipment, and diagnostic tools such as rapid antigen tests ('RATs') and polymerase chain reaction tests ('PCRs'), than inputs for vaccine production. However, certain articles essential to the transportation and delivery of vaccines may also be subject to industrial designs protection, including diluent containers, single- and multidose vials and pre-filled syringes, refrigerators, freezers and cold boxes.

3.4.1 Scope of Industrial Design Protection

Industrial design protection generally applies to the visual appearance and presentation of an article, or features of an article, and does not cover the way an article works, let alone its underlying technology or composition. Article 25 of TRIPS leaves Members with considerable latitude to define the scope of subject matter eligible for industrial design protection, with several potential exceptions that may be relevant to some medical products and their inputs. However, as with patentability under Article 27, these are pre-grant options that can only be used to restrict which industrial designs

[320] Fiji Copyright Act 1999 states: Copyright in a work is not infringed by anything done in relation to the work, by or on behalf of the State or by any person authorised in writing by a government department … (a) for the purpose of national security or during a period of emergency; or (b) in the interests of the safety or health of the public or any member of the public': s 58. Use under s 58 is subject to the payment of 'reasonable remuneration': s 58(2).
[321] Law of Republic of Indonesia Number 28 of 2014 on Copyrights (Indonesia) art 44.

become protected in the Member's territory; they cannot be used to restrain the rights of persons already entitled to such protection.

Article 25.1 states that protection must be provided to 'new or original' designs but that 'Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features'.[322] Hence, attention to the threshold of 'significant difference' in the medical field may limit the range of designs protected. Members may also make use of their entitlement to exclude from protection 'designs dictated essentially by technical or functional considerations,'[323] thus limiting protection under design law to visual appearance and not the way in which a product functions.[324]

3.4.1.1 Implementation in the Asia-Pacific region

Cambodia's law deems a design to be new 'if it has not been disclosed to the public, anywhere in the world', unless within 12 months of the filing date.[325] Malaysia applies the same deeming provision but with a 6-month filing exception.[326]

Only one of the countries surveyed make use of their entitlement to exclude from protection 'designs dictated essentially by technical or functional considerations', which is likely to cover certain medical technologies. Cambodia's law clarifies that protection does not extend to anything in an industrial design 'which serves solely to obtain a technical result and to the extent that it leaves no freedom as regards arbitrary features of appearance.'[327] Cambodia's law adopts a stricter approach to the exclusion of designs dictated by technical or functional considerations, as it excludes only those designs that serve *solely* a technical function. The relevant aspect of the industrial design must be so essential to its technical function that no choice could be made about arbitrary visual features. The wording of Article 25.1 in this respect allows for some latitude in its application, permitting Members to exclude from protection all designs dictated 'essentially' and not exclusively or even primarily by technical or functional considerations. This reinforces the aesthetic focus of industrial design protection on a product's visual appearance. Thus, it could be said that a ventilator valve primarily serves a technical and functional purpose, with little regard paid by its designer or its end-users to its physical and aesthetic appearance.[328] Likewise, it could be said that packaging items serve a purely informational function.

Where laws have limited the exclusion to designs dictated 'solely' to technical and functional considerations, this has led to divergent judicial interpretations of these

[322] TRIPS art 25.1.
[323] TRIPS art 25.1.
[324] Antony Taubman, A Practical Guide to Working with TRIPS (Oxford University Press, 2011) 102.
[325] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 92. See also Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 57.
[326] Industrial Designs Act 1996 (Malaysia) s 12.
[327] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 90.
[328] Arguments based on a 'matter of concern' – that aesthetic considerations do not enter into the buyer's decision to buy a product – have been rejected in some jurisdictions, although the outcomes in these cases may be dictated by the relevant industry under consideration (e.g. the automobile industry): Nuno Pires de Carvalho, The TRIPS Regime of Trademarks and Designs (Kluwer Law International B.V., 4th ed, 2019) [1111].

terms. A decision given by the Court of Justice of the European Union ('CJEU') went contrary to previous interpretations in the domestic courts of EU countries when it held that Article 8 of the EU's Community Designs Regulation[329] excludes protection:

> where considerations other than the need for [the] product to fulfil its technical function, in particular those related to the visual aspect, have not played any role in the choice of those features, even if other designs fulfilling the same function exist.[330]

In so doing, the CJEU rejected an approach whereby a design was only dictated solely by functional considerations, and thus excluded from protection, where the article could not take any alternative physical form and still be capable of performing the same technical function. The more capacious interpretation adopted by the CJEU could exclude certain medical technologies from protection where no regard whatsoever is paid to the article's aesthetic appearance.[331] However, a law that permitted the exclusion of articles not dictated 'essentially' by technical considerations, and that was given a similarly capacious interpretation, could exclude medical devices that were designed and developed primarily with their technical function in mind, even if aesthetic considerations also played a subsidiary role.

Asia-Pacific countries may wish to include such provisions, but should make full use of the flexibility offered by Article 25.1 by keeping the threshold at articles that are dictated 'essentially' by technical or functional considerations.

3.4.2 Scope of Industrial Design Rights

Similarly to the analogous patent provision, Article 28, Article 26.1 of TRIPS requires that owners of protected industrial designs are given rights to prevent third parties from 'making, selling or importing' articles that bear or embody a design which is a copy, or substantially a copy, of the protected design. However, Article 26.1 leaves greater latitude to Members to define the scope of rights conferred by industrial designs protection, as it states that rights need only be protected 'when such acts are undertaken for commercial purposes'. A Member may wish to clarify that persons with protected rights cannot enforce those rights against persons engaging in purely public or philanthropic use of industrial designs, including for public health emergency purposes, a situation that clearly comprises the pandemic response.

Article 26.2 provides that:

> Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

Unlike equivalent provisions applying to copyright, trademarks and patents, which employ similar concepts, Article 26.2 has never been interpreted by a WTO dispute

[329] Council Regulation (EC) No. 6/2002 of 12 December 2001 on Community Designs, Article 8(1).
[330] DOCERAM GmbH v CeramTec GmbH (Court of Justice of the European Union, C-395/16, ECLI:EU:C:2018:172, 8 March 2018) [30]-[31].
[331] Under the CJEU's approach, this would be determined by taking into account 'all the objective circumstances relevant to each individual case': DOCERAM GmbH v CeramTec GmbH (Court of Justice of the European Union, C-395/16, ECLI:EU:C:2018:172, 8 March 2018) [36].

settlement panel. Even so, it is likely to be construed with some guidance from those more extensively analysed provisions, particularly Article 13 concerning copyright, which has a closer conceptual linkage with industrial design protection.[332] Aside from the differences addressed below, the concepts used in Article 26.2 appear to be borrowed directly from Article 13, indicating that any conclusions about a public health exception for copyright would apply equally to industrial designs. NVUA is a potential public health exception to the exclusive rights conferred by industrial designs protection relevant to increasing vaccine production and access.

Article 26.2 uses the term 'protection of industrial designs', in contrast to words akin to 'rights conferred by a patent' or 'exclusive rights'.[333] A plain reading of these terms in isolation could have the effect of expanding the scope of permissible exceptions under Article 26.2 so that they do not affect only the rights conferred by protection, but also the scope of design protection itself. A further difference lies in Article 26.2's reference to 'the' normal exploitation of 'industrial designs' (in the plural), in contrast to 'a' normal exploitation of the relevant singular subject matter (e.g. 'a patent', 'a trademark'). This difference has given rise to the view that the relevant assessment when considering 'normal exploitation' is as to the *general* exploitation of all designs (not individual designs).[334]

Nevertheless, the term 'protection of industrial designs' — in contrast to the focus on *per se* rights — appears to merely reflect the wide scope that implementing Members have in determining the particular mode of protection for protected designs. For example, a country may choose to protect industrial designs solely through unfair competition rules (i.e. without the formal grant or recognition of *per se* rights), through a distinct system of registrable industrial designs that recognises exclusive rights explicitly, or even as copyrighted works. The reference to the normal exploitation of 'industrial designs' further reflects the heterogeneous nature of potential industrial designs protection amongst implementing countries. Neither of these two differences between Article 26.2 and analogous TRIPS provisions have any practical bearing on the possibility of introducing an exception under Article 26.2 for non-voluntary use in the public interest.

Further differences between Articles 13 and 26.2 lie in the opening words of these provisions, which define their operation and subject matter (i.e. 'shall confine limitations or exceptions … to certain special cases' and 'may provide limited exceptions'). While Article 13 requires that exceptions do not conflict with a normal exploitation of a work, Article 26.2 requires that exceptions do not *unreasonably* do so in respect of industrial designs. Finally, Article 26.2 requires that the legitimate interests of third parties be considered in determining whether an exception unreasonably prejudices the legitimate interests of the design owner, whereas Article 13 does not require such interests to be taken into account in respect of the legitimate interests of the right

[332] This is so notwithstanding that Article 26.2 is more textually similar to Article 30, providing for patent exceptions.
[333] TRIPS art 26 provides for 'the right to prevent third parties … from making, selling or importing' articles incorporating protected designs' (emphasis added).
[334] Christie and Wright (n 289) 424.

holder. This latter distinction has particular significance for a NVUA exception based on overriding public interest concerns, because WTO adjudicators have clarified that 'third parties' include consumers and competitors of the relevant rights holder.[335]

There are circumstances in which a NVUA exception would be needed in addition to an exclusion of industrial designs not dictated by aesthetic considerations (Article 25.1), and an exception to exclusive rights for industrial designs not made, sold or imported for commercial purposes (Article 26.1). The former exclusion applies only where an industrial design is not already subject to protection, while the latter exception only applies in the case of non-commercial use. Regarding the latter, it may be expedient, in the pandemic context, to permit third parties to use or sell articles incorporating protected designs that are subject to wholesale production for commercial purposes, but that are essential for the pandemic response. Examples of such articles include diagnostic tools such as RATs and PCRs.

3.4.2.1 Implementation in the Asia-Pacific region

No country in our survey has made use of their entitlement to limited protected design rights in cases of non-commercial use. The use of general exception-type provisions in some industrial designs law is more variable. Indonesia's law excludes designs from protection that are 'contrary to the prevailing laws and regulation, public order, religion or morality';[336] Cambodia, Malaysia and Thailand's laws only exclude designs that are contrary to public order or morality.[337] Cambodia's law also excludes the right holder's rights from cases where the use of the design is for the purposes of experimentation and education.[338] It is unclear how such provisions might be applied for public health purposes.

Only one country in our survey has introduced an explicit NVUA exception. Malaysia's law allows a compulsory licence to be granted for the use of protection industrial designs, but only 'on the ground that the industrial design is not applied in Malaysia by any industrial process or means to the article in respect of which it is registered to such an extent as is reasonable in the circumstances of the case'.[339] This is a 'failure to work' authorisation that is likely to have limited application in a public health context, where the industrial design is being applied in the country. Based on our analysis above at Section 3.3.2, we conclude that a similar provision drafted to account for non-voluntary use in the public interest would be TRIPS-compliant, provided the licence would not unreasonably conflict with normal exploitation of industrial designs and not unreasonably prejudice the legitimate interests of the design owner.

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[335] See Panel Report, Canada – Patents (n 169) [7.68]; Panel Report, EC – Trademarks (n 289) [7.675]-[6.677], noting that the Panel in EC – Trademarks based this conclusion on the particular function of trademarks as distinguishing, for both owners and consumers, goods and services of one undertaking from those other undertakings.

[336] Law of the Republic of Indonesia Number 31 Year 2000 Regarding Industrial Designs (Indonesia) art 4.

[337] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 93; Industrial Designs Act 1996 (Malaysia) s 13; Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 58.

[338] Law of the Republic of Indonesia Number 31 Year 2000 Regarding Industrial Designs (Indonesia) art 9.

[339] Industrial Designs Act 1996 (Malaysia) s 27(c).

3.5 Confidential Information

3.5.1 Eligible Subject Matter

The undisclosed information to be protected in accordance with Article 39.2 is defined as that which: (i) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (ii) has commercial value because it is secret; and (iii) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

We do not undertake a detailed examination of the terms in Article 39.2. Rather, we assume that some of the relevant knowhow and other information pertaining to the COVID-19 vaccine manufacturing process would fall within the scope of this provision because it is secret and has commercial value because it is secret. The words 'as a body or precise configuration and assembly of its components' were inserted to 'preclude the argument that information is not a trade secret if its component parts are publicly available.'[340] Moreover, the requirement that the information has been subject to reasonable steps to keep it secret is intended to remove the need for a court to verify the confidentiality of the information without interfering with the secrecy of such information.[341] This third element is likely to make it more difficult to prove that information claimed to be secret is not in fact secret.

3.5.2 The nature of protection

Article 39.2 provides that eligible subject matter is to be prevented from being 'disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices'; this latter concept is defined to include 'at least practices such as breach of contract, breach of confidence and inducement to breach' and 'the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.'[342]

More generally, the protection is framed as a means of giving effect to the general requirement under the Paris Convention to suppress unfair competition.[343] Thus a pivotal question in establishing infringement of this protection is how and in what circumstances the information was obtained, and whether this falls foul of a test for unfair competition or unfair commercial practices. This can impose on a claimant the requirement to discharge a burden of proof, in particular to show that the information

[340] Sandeen, 'The limits of trade secret law: Article 39 of the TRIPS Agreement and the Uniform Trade Secrets Act on which it is based' in Rochelle C Dreyfuss and Katherine J Strandburg (eds), The Law and Theory of Trade Secrecy (Edward Elgar Publishing, 2011) 537, 555.
[341] Sandeen (n 340) 566.
[342] TRIPS art 39.2, footnote 10.
[343] Antony Taubman, 'Fair Enough? Reconciling Unfair Competition with Competition Policy' in Robert D Anderson, Nuno Pires De Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 121-161.

was obtained in this way through an identifiable chain of provenance, and not obtained either from a legitimate source or through independent development.

Equally, protection is against unauthorised disclosure of the protected information, as such. Suspension of or exceptions to such protection may, in principle, enable the scope of confidentiality to be limited or even contractual obligations to be overridden. But it does not in itself force a holder of such information to disclose it, if it is not otherwise accessible. Given that at least some critical vaccine production knowhow is likely to be practically available only through direct transmission from experts, and may not be recorded or available in tangible or easily accessible form, there are limitations, beyond the scope of this paper, on how the relaxation of or exceptions to protection could lead positively to non-voluntary transfer of such technology.

3.5.3 Remedies

Although the underlying basis for a cause of action and subsequent remedies differs according to the practice of implementing Members, the ordinary remedy for the misappropriation of trade secrets generally includes injunctive relief prohibiting the further dissemination of protected information, and potentially compensatory or exemplary (punitive) damages for any combination of loss, unjust enrichment or wilful/malicious disclosure.[344] In those common law countries where equitable remedies may be awarded, an account of profits may be available, as an alternative to restitutionary damages, to disgorge the defendant of any profits improperly made.

3.5.4 Public Health Exceptions

An effective public health exception to the protections provided for by Article 39.2, in the pandemic context, should enable a potential follow-on manufacturer to gain access to and use of confidential knowhow necessary for the production of COVID-19 vaccines. A public health exception that achieves this result could expressly permit the acquisition, disclosure or use of confidential information by government bodies. However, in most situations, such information would also need to be disclosed to and used by third parties involved in the production of vaccines.

Article 39.2 leaves Members with flexibility to craft domestic protections for confidential information in a way that excludes disclosure, use or acquisition for public interest purposes. First, the reference to acts that are ‘contrary to honest commercial practices’ removes from the scope of Article 39.2 government use in pursuit of fundamental public policy objectives. This is because the function of Article 39 as a whole is to build upon the protection against acts of unfair competition under the *Paris Convention*, by

[344] For a general but by no means comprehensive illustration, see the model trade secrets law adopted by 48 US jurisdictions: Uniform Trade Secrets Act (Uniform Law Commission, 1979) <https://www.uniformlaws.org/committees/community-home?CommunityKey=3a2538fb-e030-4e2d-a9e2-90373dc05792>

providing explicit protections for undisclosed information (trade secrets and test data).[345]

The Panels in *Australia – Tobacco Plain Packaging* clarified that 'an act of unfair competition' under Article 10bis(2) of the *Paris Convention*, as incorporated into TRIPS by Article 2.1, means 'something that is done by a market actor to compete against other actors in the market, in a manner that is contrary to what would usually or customarily be regarded as truthful, fair and free from deceit within a certain market'.[346] Thus acts contrary to honest commercial practices would not encompass acts by governments for non-commercial public use. This interpretation of Article 39.2 is reinforced by widespread practice amongst implementing Members.[347]

Second, the focus of Article 39.2 is on dishonest commercial practices, a species of unfair competition and a standard that has been implemented variably by Members. The Panels in *Australia – Tobacco Plain Packaging* observed that '[h]ow industrial and commercial matters are usually or customarily carried out differs from market to market, as do the perceptions of and the standards for determining what constitutes "honest" commercial practices'.[348] Footnote 10 to TRIPS Article 39.2 gives some indication of the scope of 'honest commercial practices', which 'shall mean at least practices such as breach of contract, breach of confidence and inducement to breach'.[349] The word 'at least' indicates that Members are free to expand the scope of dishonest commercial practices beyond those specifically listed. This follows the logic of the *Paris Convention*, which leaves it to each country define what constitutes 'unfair competition' according to its own concepts, but gives a list of illustrative examples that countries must follow.[350] Therefore, Sandeen observes that 'in the same way that WTO member countries are generally free to define what constitutes acts contrary to honest business practices, they can also define proper means to include reverse engineering and independent invention.'[351]

Thus, Members wishing to implement specific exceptions to protections against breaches of confidentiality that are contrary to honest commercial practices may be

[345] Thus, Article 39.1 of TRIPS reads: 'In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3'. Moreover, Article 10bis(2) of the Paris Convention specifies that '[a]ny act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition'

[346] Panel Report, Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WTO Doc WT/DS457/R (adopted 28 June 2018) [7.2671] ('Australia – Plain Packaging').

[347] See e.g. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure ('EU Directive'), Preamble, art 1.2(b).

[348] Panel Report, Australia – Plain Packaging (n 346) [7.2671]. See Georg HC Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property (World Intellectual Property Organization, 1969) 144.

[349] TRIPS art 39.2, footnote 10.

[350] Georg HC Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property (World Intellectual Property Organization, 1969) 144.

[351] Sandeen (n 340) 561.

more helpfully informed and guided by choices made at the domestic level than by attempts to discern an absolute meaning from the terms in Article 39.2.

3.5.4.1 Implementation in the Asia-Pacific region

Indonesia's trade secret law provides that there is no infringement of a trade secret owner's rights where the disclosure or use is 'based on the interest for the security and defense, health, or safety of the public'.[352] Similarly, Thailand's trade secret law excludes disclosure or use '[w]hen it is necessary for the protection of public health or safety' or 'when it is necessary for the benefit of other public interests with no commercial purpose', as well as exclusions for reverse engineering.[353] Presuming that Thailand's provision was intended to be TRIPS-compliant, then implicit in Thailand's provision is the normative idea that disclosure based on public interest considerations is inherently not contrary to honest commercial practices. Thailand's law in particular distinguishes between disclosure that is necessary for the protection of public health or safety, regardless of whether it is for a commercial purpose, and disclosure of information that is for the benefit of other public interests, which must be for a non-commercial purpose. Other Asia-Pacific countries may wish to include negative exceptions along the same lines. The alternative approach is to explicitly and positively enumerate the practices that may be considered dishonest commercial practices,[354] although it is possible that even acts done for a public health purpose might fall within the scope of a country's enumerated practices.

3.5.5 Implementing Exceptions

A significant practical issue is that removing or limiting legal protection over confidential information does not, in itself, guarantee effective access to that information on the part of those seeking to put it to work. Where a firm with exclusive control over their knowhow does not have the negative right to prevent the disclosure, use or acquisition of their information by third parties in certain circumstances, there is nothing that compels the firm to disclose such information itself, and in most cases the firm will remain unwilling or unable to do so.[355] Further, knowhow such as detailed knowledge of vaccine production is not necessarily discretely packaged and easily transferred, regardless of the legal context, meaning that effective access and absorption may entail direct and sustained contact between skilled personnel. There are two options to address at least the first of these issues: (i) incentivising full disclosure of the relevant knowhow; or (ii) forcing disclosure of such information.

Incentivising full disclosure of relevant knowhow does not always prove successful, and requires a careful calibration of fiscal and other policy measures. While removing

[352] Law Of The Republic Of Indonesia Number 30 Year 2000 Regarding Trade Secret (Indonesia) art 15.
[353] Trade Secrets Act B.E. 2545 (2002) (Thailand) s 7.
[354] See e.g. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No. 2006/2004 of the European Parliament and of the Council. See generally, WIPO, Model Provisions on Protection Against Unfair Competition (WIPO, 1996).
[355] Unlike the licensing a patent, the very act of publicly disclosing a trade secret denudes it of its commercial value, as is recognised explicitly by TRIPS Article 39.2(b).

legal protections over confidential information is a question of removing negative rights in the form of legal protections, forcing disclosure is a matter of compelling positive action by private persons. As Gurgula and Hull note, forced disclosure need not amount to 'public disclosure', but may involve transferring the information to an appropriate manufacturer who would keep it confidential.[356] While more a practical than legal issue, forced disclosure may have legal implications within the context of a given country's legal system even where it involves a limited transfer of information from one firm to another. For instance, it may constitute a taking of property that must be compensated under a country's constitution, depending amongst other things on: (i) whether that country's legal system recognises confidential information as a legitimate type of property; and (ii) how the country defines 'taking' or other similar terms such as 'acquisition'.

Nothing in Article 39.2 itself precludes a government from forcing the disclosure of confidential information, particularly in view of the *negative* rights that Article 39.2 confers, but also because government-compelled disclosure itself could very well be excluded from the scope of acts considered contrary to honest commercial practices. The US Defence Production Act is an example of a law that authorises the forced disclosure of information (as well the acquisition of property) for public interest purposes.

Despite the flexibility within Article 39.2, the nature of many countries' legal systems may make it difficult to adjust or adapt well-established legal principles to the exigencies of the pandemic. One option in such cases is to override trade secret protections using legislation, subject to each country's individual constitutional requirements. That task would be simpler for countries whose trade secrets law is codified exclusively in statute or in civil law jurisdictions, where one option would be to insert provisions shielding certain parties from liability for the disclosure of certain confidential information. Indonesia and Thailand have a wholly statutory trade secret law.[357] However, even in countries with a codified trade secrets law, it would likely be necessary to shield parties from liability for other general law claims, such as breach of contract. The task is still more significant for those countries whose trade secret protections are sourced in multiple bodies of law and are actionable through a variety of legal claims. In India, for example, contractual remedies may be sought for the unauthorised disclosure of confidential information, but remedies may also be sought under an equitable doctrine of breach of confidence.[358] Therefore, countries wishing to remove or limit legal protection over confidential information in a way that guarantees effective access to such information may be required to not only force the disclosure of such information, but also make wholesale amendments to laws that give rise to trade secret protections, which may be embodied across distinct legislative and

[356] Gurgula and Hull (n 60) 1250.
[357] Law Of The Republic Of Indonesia Number 30 Year 2000 Regarding Trade Secret (Indonesia) art 1.2; Trade Secrets Act B.E. 2545 (2002) (Thailand).
[358] India's breach of confidence doctrine has its genesis in the English common law tradition starting with Saltman Engineering Co. v. Campbell Engineering Co. Limited, (1948) 65 RPC 203: John Richard Brady v. Chemical Process Equipments Private Limited, AIR 1987 Delhi 372 (Delhi High Court).

general law regimes. It is not inconceivable that such legal reforms could be enacted through single pieces of legislation, although this would depend on each country's constitutional arrangements. For example, in Australia, both constitutional arrangements and the independence of common law and statutory principles would require each State to independently legislate exceptions to such principles.

3.6 Clinical Trial Data

3.6.1 Exclusivity and Compensation

In short, Article 39.3 of TRIPS requires that Members protect against unfair commercial use any undisclosed test or other data that is required as a condition for gaining marketing approval for pharmaceutical and chemical products. Only data the origination of which involves 'considerable effort' is captured. Members must also protect the data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.[359]

Article 39.3 remains one of the most debated TRIPS provisions. Interpretations of Article 39.3 generally fall into two categories. One argues that Article 39.3 demands a *sui generis* IP regime requiring a minimum period of data exclusivity. The other argues that Article 39.3 only protects against dishonest or unlawful conduct such as theft or espionage of clinical trial data.[360] Under the latter interpretation, 'undisclosed data must be protected from unauthorized disclosure, but the protection against unfair commercial use of data is limited to data acquired by dishonest means'.[361] In addition to these two interpretations, we add a third potential application of Article 39.3 that one of us has extracted previously: no action can be taken to prevent others from using or relying on the originator's data, even where subject to unfair commercial use, but the originator may be entitled to a share of the costs of the data's production, which would remedy the unfairness of the use or reliance.[362]

We believe that a detailed interpretation of Article 39.3 is unnecessary here,[363] largely because — as one us has stated elsewhere — '[t]he diversity of norm-setting at national and bilateral levels suggests … that the details of protection standards (scope of subject matter, duration of protection, and nature of exclusive rights) are settled — as is much domestic legislation — at a pragmatic rather than abstract level'.[364] For one, the social norms and principles that give meaning to the term 'unfair' reinforce that its

[359] TRIPS Article 39.3 reads: Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.
[360] Gabriele Spina Alì, 'The 13th Round: Article 39(3) TRIPS and the struggle over "Unfair Commercial Use"' (2018) 21 Journal of World Intellectual Property 201, 202-203.
[361] Antony Taubman, 'Unfair competition and the financing of public-knowledge goods: the problem of test data protection' (2008) 3(9) Journal of International Property Law & Practice 591, 595.
[362] Taubman (n 361) 595.
[363] Such interpretation has been undertaken elsewhere: see e.g. Alì (n 360); Taubman (n 361); Taubman (n 343).
[364] Taubman (n 361) 602. See also, Daria Kim, 'Enabling Access to Clinical Trial Data: When Is Unfair Use Fair' (2015) 14(2) Chicago-Kent Journal of Intellectual Property 521, 538.

interpretation and application should be determined by implementing Members within the context of their own social, legal and economic environment.[365] This would allow governments to interpret and apply unfair commercial practices so that it excludes from its scope government use for public or philanthropic purposes, or use in cases of public health emergencies.[366] Indeed, the EU (a strong exporter of pharmaceuticals) suspends its data exclusivity period in cases where the pharmaceutical is manufactured under a compulsory licence for the purposes of export (but not supply of the domestic market).[367] This is clearly intended to facilitate effective use of the Paragraph 6 System (an issue discussed below), but other countries may implement more expansive exceptions in the interests of protecting public health.

3.6.1.1 Implementation in the Asia-Pacific region

Malaysia imposes a data exclusivity requirement, but excludes from the law situations where compulsory licences have been issued or any other measures consistent with the need to protect public health, and clarifies that the government may take necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis or other extremely urgent circumstances declared by the Government.[368] Many of the countries in our sample do not utilise explicit data exclusivity requirements,[369] and may continue to omit this requirement provided that they provide some level of protection against what they consider to be 'unfair commercial use' of test data.

As Article 39.3 has no applicability where no test or other data is required to be submitted, other countries may continue their practice of omitting the requirement to have test data submitted as a condition for the market approval of pharmaceutical products. Cambodia does not impose requirements to submit such data as a condition for pharmaceutical products to be imported, produced or exported under a compulsory licence.[370] Indonesia prevents the exportation of clinical samples from study subjects which requires validated laboratories and procedures to be established locally.[371] In such cases, Members may opt to permit their regulatory approval bodies to rely on foreign test data or regulatory approval, in which case no submission to the relevant authority is required.[372] This may also be achieved through regional approval

[365] Alì (n 360) 210; Carlos Correa, 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement' (South Centre, June 2002) 27.
[366] Medecins Sans Frontieres, 'The European Union's position on compulsory licensing and the TRIPS waiver in the COVID-19 pandemic' (May 2021) 5.
[367] Dhanay Cadillo Chandler, 'Uh-Oh We are in Trouble! Compulsory Licenses v Data Exclusivity in the EU: One More Challenge to Overcome in the Race to Find a COVID-19 Vaccine?' (2020) 42(9) European Intellectual Property Review 539, 544.
[368] Malaysia 2011 Directive of Data Exclusivity, section 5. See generally, Ellen F M 't Hoen, Pascale Boulet and Brook K Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation' (2017) 10(19) Journal of Pharmaceutical Policy and Practice 1, 4.
[369] This may be contrasted with data exclusivity regimes in the EU and US, which include an eight-year and [] protection period respectively: Regulation (EC) No 726/2004
[370] Law On Compulsory Licensing for Public Health (Cambodia) art 18.
[371] Tsai, Rao and Xu (n 65) 1478.
[372] Alì (n 360) 219. Some note that this does not apply where the relevant pharmaceutical is registered locally: Ingo Meitinger, 'Implementation of Test Data Protection According to Article 39.3 TRIPS: The Search for a Fair Interpretation of the Term Unfair Commercial Use' (2005) 8(2) Journal of World Intellectual Property 123, 136-137.

mechanisms or WHO pre-qualification and emergency listing procedures. Countries in the Asia-Pacific lack a centralised regulatory approval process such as that utilised by the EU.[373] One option for Asia-Pacific countries would be to adopt such a process through an existing regional economic or other cooperative union, such as the Association of South East Asian Nations ('ASEAN'), and in particular the ASEAN-Network for Drug, Diagnostics and Vaccines Innovation and South Asian Association for Regional Cooperation.[374] The Pharmaceutical Product Working Group could also be involved.

Concerns about the safety and efficacy of new vaccines means that Members may not wish to dispense with regulatory approval requirements (although, these concerns can be addressed through the regional mechanism outlined above). Importantly, for the countries that do maintain explicit exclusivity requirements, the possibility of a compensatory regime, as outlined above, may be the most efficient and effective means of ensuring protection against unfair commercial use while maintaining the ability of firms to engage in effective technology transfer. Such compensation may take account of a number of factors to ensure that use is not seen as competitively 'unfair'.[375] This 'intermediary' approach is well-accepted within the literature,[376] and appears consistent with the likely purpose of Article 39.3, which is to provide an opportunity for investment amortization,[377] and thus an incentive to produce such data for the public good.[378]

3.6.2 Test Data and Patents

Clinical trial data and patents are at the centre of two distinct and independent regulatory regimes with their own purposes and incentive mechanisms.[379] However, overlap and complementarity between the two regimes is evident,[380] and therefore countries can take steps to ensure that one regime does not act as an impediment to utilising flexibilities in another.

As already noted, *Bolar* exceptions may be utilised to ensure that regulatory approval does not delay market entry once the patent term has expired.[381] Countries may wish to ensure that their legislation does not feature 'patent linkage' provisions that prevent regulatory approval of a drug because it is already patented within the relevant territory.[382] The Indian Supreme Court has already held, for the purposes of its own

[373] Tsai, Rao and Xu (n 65) 1473.
[374] Tsai, Rao and Xu (n 65) 1479.
[375] For more detailed discussion, see Taubman (n 361) 605.
[376] See generally, Kim (n 364) 538.
[377] Kim (n 364) 548-549.
[378] Kim (n 364) 548-549; Antony Scott Taubman, 'Fair Enough? Reconciling Unfair Competition with Competition Policy' in Robert D Anderson, Nuno Pires de Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 121, 152. See also Taubman (n 361) 605.
[379] Taubman (n 361) 595.
[380] Taubman (n 361) 595; Prabuddha Ganguli, 'Complying with article 39 of TRIPS . . . a myth or evolving reality?' (2003) 25 World Patent Information 329, 329.
[381] See above Section 3.2.3.
[382] Srividhya Ragavan, 'The (Re)Newed Barrier to Access to Medication: Data Exclusivity' (2017) 51(4) Akron Law Review 1163, 1191.

domestic legislation, that Article 39 does not require patent linkage.[383] Thus India's definition of 'new drug' in its regulatory approval legislation has no linkage with patent status.[384]

A key issue of concern is the extent to which data exclusivity requirements may act as an impediment to the use of compulsory licences, including those issued for the purpose of utilising the Paragraph 6 System.[385] As indicated above, one option is to include a carve-out for compulsory licenses in those regimes where data exclusivity is enforced.[386] As stated above, Malaysia incorporates this clarification into its law,[387] as does Cambodia whose law provides that '[t]he protection conferred to test data and other undisclosed information shall not be invoked to prevent, impede or delay the execution of a compulsory licence'.[388]

3.7 Exhaustion and Parallel Importing

Article 6 of the TRIPS Agreement removes the issue of exhaustion from the scope of TRIPS. Exhaustion refers to the total exhaustion of an IP owner's rights in a product once such rights have been sold or licensed to a third party. Article 6 allows Members to adopt whatever system of exhaustion they wish, including exhaustion that operates at the domestic, regional or international level.[389] Where a country adopts a system of national exhaustion, the IP owner exhausts their rights only in the country where the first sale of the product is authorised, but can still enforce their rights in other countries where their IP rights in that product subsist.[390] International exhaustion provides greater latitude for the importation of patented products like vaccines because, once an IP owner's rights are sold or licensed in a given jurisdiction, the IP owner's rights are exhausted in that and every other jurisdiction in the world. International exhaustion means that countries and their enterprises can engage in one of two kinds of parallel importation: (i) importing domestically produced products back into the country once they have been sold to international markets; and (ii) importing goods produced in a foreign market with the authorisation of the right-holder under a licence into a market where no such authorisation has been granted.[391]

Parallel importation has long been advocated as a way of obtaining lower priced medicines, and is one potential option available to developing countries to obtain greater access to vaccines. However, parallel importation is primarily a solution for

[383] Ragavan (n 382) 113-1194. The Indian Supreme Court is, of course, not the proper forum for the interpretation of the WTO Agreement, but the judgment demonstrates the ability of Members to interpret TRIPS provisions in a way that fulfils practical needs while maintaining reverence to the treaty text.
[384] Ragavan (n 382) 113-1188.
[385] Ingo Meitinger, 'Implementation of Test Data Protection According to Article 39.3 TRIPS: The Search for a Fair Interpretation of the Term Unfair Commercial Use' (2005) 8(2) Journal of World Intellectual Property 123, 132.
[386] Ellen F M 't Hoen, Pascale Boulet and Brook K Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation' (2017) 10(19) Journal of Pharmaceutical Policy and Practice 1, 4.
[387] See above n 368.
[388] On Compulsory Licensing for Public Health (Cambodia) art 17.
[389] Unless in conflict with Most-Favoured-Nation Treatment.
[390] Mitchell and Voon (n 166) 577.
[391] Rajnish Kumar Rai and Srinath Jagannathan, 'Parallel imports and unparallel laws: an examination of the exhaustion doctrine through the lens of pharmaceutical products' (2012) 21(1) Information & Communications Technology Law 53, 58.

avoiding the high prices of finished products; it is not necessarily an avenue for increasing local or regional vaccine manufacture, save to the extent that it provides manufacturing countries with greater access to lower-cost vaccine ingredients and inputs. Moreover, parallel importation has been criticised — often by developed nations — on numerous grounds.[392] One issue that warrants consideration is whether an IP owner's rights are exhausted by the sale of a product made under a compulsory licence in an exporting country.[393]

3.7.1 Implementation in the Asia-Pacific region

Countries may wish to implement systems of international exhaustion to open up the full scope of options available for increasing access to medicines generally. Our survey of select domestic laws in the Asia-Pacific region reveals that a majority of the countries in our survey utilise a system of national exhaustion.

Table 5: Exhaustion in the Asia-Pacific

International Exhaustion	Regional Exhaustion	National Exhaustion	N/A
India	N/A	Cambodia	Fiji
Vietnam		Indonesia	
		Malaysia	
		Thailand	
		Bangladesh	

Source: Authors' compilation

3.8 Restrictive Licensing and Anti-Competition

Often overlooked amongst the tools available to Members wishing to provide greater protection for public health, and in lieu of more IP-focused mechanisms,[394] are measures aimed at addressing anti-competitive practices. Contrary to a popular view, these two regimes of IP protection and anti-competition are far from inherently inconsistent and may function as two practical policy levers for achieving a balance of proper incentive structures and technology transfer promotion.[395] Indeed, anti-competitive principles need not emerge solely as independent rules and provisions, but may also inform the development of a balanced domestic IP law.[396] Competition

[392] Rajnish Kumar Rai and Srinath Jagannathan, 'Parallel imports and unparallel laws: an examination of the exhaustion doctrine through the lens of pharmaceutical products' (2012) 21(1) Information & Communications Technology Law 53, 60-62. See also Robert D Anderson, 'Intellectual Property Rights, Competition Policy and International Trade: Reflections on the Work of the WTO Working Group on the Interaction between Trade and Competition Policy (1996-1999)' in Thomas Cottier, Petros C Mavroidis, Marion Panizzon and Simon Lacey (eds), Intellectual Property: Trade, Competition, and Sustainable Development The World Trade Forum, Volume 3 (University of Michigan Press, 2003) 235, 250-253.
[393] Frederick Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO (2002) 5(2) Journal of International Economic Law 469, 472.
[394] Anderson, Müller and Taubman (n 270) 73.
[395] Robert D Anderson, Antony Scott Taubman and Nuno Pires de Carvalho, 'Time to Look Afresh at the International Dimension of Competition Policy and Intellectual Property? Some Concluding Observations' in Robert D Anderson, Nuno Pires de Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 836, 850; Anderson (n 392) 242.
[396] Anderson (n 392) 243.

law may play a remedial role, especially where an IP regime is seen as being ill-suited for addressing the peculiarities of a significant health crisis.[397]

A common manifestation of anti-competitive practices in the IP context are restrictive voluntary licensing terms. [398] Anti-competition or 'antitrust' law is seen as being comparatively well-advanced in certain developed countries like the United States, but much less so in developing countries. In the United States, this body of law has been divided into three broad area of 'anti-competitive licensing practices; … regulation of anticompetitive unilateral conduct; and … regulation of patent misuse'.[399] Our analysis and recommendations here focus on the first and third areas.

3.8.1 TRIPS and Anti-Competition

The possibility of tempering IP protection with measures to address abuses of IP rights is recognised at the outset of TRIPS, with Article 8.2 acknowledging that Members may need to prevent practices 'which unreasonably restrain trade or adversely affect the international transfer of technology'. More practical and precise recognition of this balance between IP protection and anti-competition can be found in Article 31(k) of TRIPS, which creates an exception to certain requirements for the issue of compulsory licences under Article 31. It provides:

> Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

Apart from confirming what is already well-established — that anti-competitive practices may form the basis of a compulsory licence — Article 31(k) has also been posited as a means to avoid the so-called 'procedural nightmare' under Article 31*bis*, which was specifically implemented to address subparagraph (f).[400] As Morgan notes:

> it would be sufficient if a small group of potential exporters implemented remedies for anti-competitive pricing and issued broad compulsory licences in response to violations. A limitation of this approach is that any potential exporter would also have to experience a substantial domestic competition problem (to ground jurisdiction of its competition authorities) before it could participate as an exporter.[401]

The reference to a judicial and administrative process suggests that an executive decision may be sufficient, which could be a more efficient means of invoking the provision. However, the requirement for a 'process' indicates some substantive

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[397] Anderson (n 392) 244.
[398] Josef Drexl, 'The critical role of competition law in preserving public goods in conflict with intellectual property rights' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 709, 717.
[399] Janis (n 275) 784. See also United Nations, Report of the United Nations Secretary-General's High-Level Panel On Access To Medicines: Promoting Innovation and Access to Health Technologies (September 2016) 23; Voluntary Licences and Access to Medicines (Médecins Sans Frontières Technical Briefing Document, October 2020) 15.
[400] Maxwell R Morgan, 'Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment' (2006) 64(1) University of Toronto Faculty of Law Review 44, 85.
[401] Morgan (n 400) 86.

procedure would be required in the making of that decision, as well as some normative framework in place at the domestic level that could act as the basis for a *bona fide* determination that practices were anti-competitive. Therefore, Article 31(k), while a useful avenue for governments to take in avoiding the requirements of Articles 31(b) and (f), is not necessarily a less-burdensome alternative to Article 31*bis*, which as we outline in Section 3.2.5 above, need not be as procedurally complex as some have claimed.

Importantly, the TRIPS drafters left open the types of practices that may be determined anti-competitive, as well as the legal standards to be used in making such a determination.[402] However, the negotiating history of TRIPS demonstrates a movement from *per se* determinations (e.g. based on pre-defined categories or instances of anti-competitive behaviour) to a 'rule of reason' or case-by-case approach.[403] Some ambiguity in this regard is left by Article 40.2, which allows Members to specify in their legislation 'licencing practices or conditions that *may in particular cases* constitute an abuse of [IP] rights having an adverse effect on competition in the relevant market.[404] The words 'may in particular cases' and the two qualifying conditions 'abuse of [IP] rights' and 'adverse effect on competition in the relevant market' point toward a case-by-case approach rather than a *per se* approach. Developed countries are more favourably disposed to the former approach than developing countries, the latter being concerned that curial determination will reduce the likelihood of practices being deemed anti-competitive.[405] Nevertheless, Article 40.2 must be read separately from Article 31(k), as the former concerns voluntary licencing terms and the latter concerns requirements conditioning the use of and remuneration for compulsory licences. The scope of anti-competitive practices under Article 31(k), despite its narrower application, are cast in much wider terms. Moreover, the phrasing of Article 40.2 suggests the adoption of a rule of reason approach, but by no means demands it; its terms are sufficiently vague to leave Members with flexibility in adopting whatever approach they deem appropriate.[406]

As Janis notes, an overly restrictive interpretation of Article 40.2 would 'run counter to practice in some developed countries'.[407] Article 40.2. allows Members 'to adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.'[408] The

[402] Anderson, Müller and Taubman (n 270) 68.
[403] Anderson, Müller and Taubman (n 270) 71.
[404] TRIPS art 42.2 (emphasis added).
[405] F M Scherer and Jayashree Watal, 'Competition Policy and Intellectual Property: Insights from Developed Country Experience' in Robert D Anderson, Nuno Pires de Carvalho and Antony Taubman (eds), Competition Policy and Intellectual Property in Today's Global Economy (Cambridge University Press, 2021) 396, 397.
[406] Cf Carlos M Correa, 'Can the TRIPS Agreement foster technology transfer to developing countries?' in Keith E Maskus, and Jerome H Reichman (eds), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Cambridge University Press, 2005) 227, 236-237.
[407] Janis (n 275) 779.
[408] TRIPS art 42.2.

reference to particular licensing conditions further supports an interpretation not bound to a rule of reason approach.

3.8.1.1 Implementation in the Asia-Pacific region

Our survey reveals that very few countries include anti-competitive practices as a ground for compulsory licensing, and fewer still exclude the Article 31(b) requirements in such cases. India's law includes the 'reasonable requirements of public' not being satisfied as one ground for the issue of a compulsory licence, and deems this to be the case where a patentee imposes one of the conditions listed in Article 42.2.[409] Mongolia's law provides cases where 'the patent owner sets unacceptable terms for the exploitation of the invention' as a ground for compulsory licencing,[410] while Vietnam provides cases where the patent holder 'is considered [to have] performed anticompetition practices banned by competition law'.[411]

Most of the countries surveyed — Bangladesh,[412] Cambodia,[413] Fiji,[414] India,[415] Indonesia,[416] Malaysia,[417] Mongolia,[418] and Thailand[419] — maintain independent competition laws that cover a range of practices, including anti-competitive horizontal and vertical agreements, abuse of dominant position or misuse of market power, and price-fixing. Bangladesh's law, for example, covers a range of anti-competitive contracts such as tie-in-arrangements, exclusive supply agreements; exclusive distribution agreements, refusal to transact agreements, and resale price maintenance agreements.[420] Anti-competitive IP licensing terms may be captured by some of these provisions. However, much would depend on these provisions' precise scope and parameters and whether the jurisdiction in question has a sufficiently developed anti-competition law framework. The implementation of anti-competition regime for those without one requires an awareness of technical expertise and capacity restraints, especially in view of their potential complexity.[421] Janis recommends adopting what Reichman has termed a '"jurisprudence of licencing" approach that draws selectively from practice in developed countries'.[422]

Many of the countries surveyed also prohibit restrictive licence terms through their patent or other IP laws, rather than a standalone anti-competition law. For example, India's *Patents Act* prohibits the insertion of certain sui generis anti-competitive terms into:

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[409] Patents Act, 1970 (India) s 84(7). See s 84(1).
[410] Patent Law of 25/06/1993 (Mongolia) art 20.
[411] Law on Intellectual Property (No. 50/2005/QH11) (Vietnam) art 145(d).
[412] Competition Act 2012 (Bangladesh).
[413] Cambodia's Law on Competition only came into force on 5 October 2021.
[414] Fijian Competition and Consumer Commission Act 2010 (Fiji).
[415] Competition Act 2002 (India).
[416] Monopolistic Practices and Unfair Business Competition 1999 (Indonesia)
[417] Competition Act 2010 (Malaysia).
[418] Law of Mongolia on Competition 2010 (Mongolia).
[419] Thailand Trade Competition Act 2017 (Thailand).
[420] Competition Act 2012 (Bangladesh) s 2(g).
[421] Anderson, Müller and Taubman (n 270) 75; Janis (n 275) 780.
[422] Janis (n 275) 781 citing J H Reichman, 'From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement' (1996) 29 New York University Journal of International Law and Politics 11, 57.

(i) any contract for or in relation to the sale or lease of a patented article or an article made by a patented process; or
(ii) licence to manufacture or use a patented article; or
(iii) a licence to work any process protected by a patent.

Among the conditions prohibited are those listed under Article 40.2 (exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing), as well as various exclusive dealing conditions.[423] Indonesia's patents law simply states:

> A Licensing Agreement is prohibited from containing provisions that may damage the Indonesian national interest or to contain restrictions which obstruct the abilities of Indonesian people to transfer, master and develop technology.[424]

Malaysia's patent law prohibits 'restrictions not derived from the rights conferred by [the Act] on the owner of the patent, or unnecessary for the safeguarding of such rights', but allows restrictions 'concerning the scope, extent or duration of exploitation of the patented invention, or the geographical area in, or the quality or quantity of the products in connection with, which the patented invention may be exploited'.[425] Other conditions that that have been the focus of attention by commentators include: the removal of tiered royalty payments, the inclusion of 'non-suit' or 'non-assertion' clauses, the removal of restrictions on research or clinical experimentation, and the removal of confidentiality clauses.[426] India's patent law requires that the provisions of voluntary licences remain confidential if requested by the patent holder, subject to the order of the court.[427] While a court order may be utilised in cases of public emergency to ensure the transparency of potential overly restrictive and anti-competitive licence terms, this is largely dependent on the court's initiative and the grounds proposed for an order.

3.9 Remedies

Laws on remedies for IP right infringement can be crafted to manage the abuse of IP rights for public interest purposes, such as public health protection. The minimum requirements for remedies are set out in Part III, Section 2 of TRIPS. Article 44.1 requires that Members' judicial authorities have the authority to order an injunction against the infringement of IP rights 'immediately after the customs clearance of such goods'. However, Article 44.2 clarifies the right of Members to limit remedies to remuneration for unauthorised use in accordance with subparagraph 31(h). Thus the remedy in the United States for unauthorised government use is limited to 'reasonable and entire compensation for such use and manufacture'.[428] The words in Article 44.2

[423] Patents Act, 1970 (India) s 140(1).
[424] Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indonesia) art 78. See also Law Of The Republic Of Indonesia Number 30 Year 2000 Regarding Trade Secret (Indonesia) art 9; Law of the Republic of Indonesia Number 28 of 2014 on Copyrights (Indonesia) art 82; Law of the Republic of Indonesia Number 31 Year 2000 Regarding Industrial Designs (Indonesia) art 36.
[425] Patents Act 2006 (Malaysia) s 45.
[426] Médecins Sans Frontières, 'A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines' (Medicines Sans Frontiers, September 2017) 19. See also Voluntary Licences and Access to Medicines (Médecins Sans Frontières Technical Briefing Document, October 2020) 25-27.
[427] Patents Act, 1970 (India), s 69.
[428] Government Patent Use 28 U.S.C. § 1498.

'may limit the remedies available' means that the availability of remuneration is a minimum requirement from which Members must not derogate.

Even in cases other than compulsory use, a Member's judicial authorities must merely 'have the authority' to issue an injunction, meaning that a Member's authorities are not mandated to award an injunction in all cases. The same is true with respect to *ex post* compensation or damages for 'injury … suffered because of an infringement',[429] which is distinct from the remuneration paid for IP use. In each case, public interest considerations may be weighed against the legitimate interests of the right holder in determining the amount of remuneration and/or compensation to be paid.[430] The reference to IP 'infringement' suggests that no injunctive relief is required unless such infringement is actually established, thus giving Members the option of removing the availability of interlocutory relief before a final determination is reached. Of course, interlocutory action for imminent or ongoing infringement is a legitimate means of preventing unauthorised use of protected IP subject matter. Therefore, removing the availability of provisional relief may be reserved for IP subject matter that is essential to the pandemic response.

3.9.1 Implementation in the Asia-Pacific region

Some of the countries surveyed do not distinguish between the remedies available and merely state, for example, that 'the owner of the patent shall have the right … to institute court proceedings against any person who infringes the patent.[431] Others only provide that compensation is available for infringement.[432]

Cambodia's patent law permits a competent Court to 'grant an injunction to prevent infringement or an imminent infringement, award damages and grant any other remedy provided for in the general law' where the patent owner has so requested (or where a licensee has requested the patentee to institute proceedings and they have not done so).[433] Cambodia's law patent therefore provides for interlocutory relief, as does Malaysia's patent law,[434] Thailand's patent law,[435] and Indonesia's law on copyright.[436]

Fiji's copyright law contains a provision on 'unjustified proceedings' that confers on a court the power to declare that the brining of proceedings for copyright infringement was 'unjustified' and to make an order for compensatory damages accordingly.[437] India's law contains similar provisions in respect of patents.[438]

[429] TRIPS art 45.
[430] Medecins Sans Frontieres, 'A Timeline of U.S. Attacks on India's Patent Law & Generic Competition' (January 2015) 1.
[431] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 43. See also, Patent Law of 25/06/1993 (Mongolia) art 29.
[432] See e.g. The Patent, Design and Trade Mark Act, 2022 (1965) (Nepal) s 24.
[433] Law on Patents, Utility Models and Industrial Designs (Cambodia) art 126.
[434] Patent Act 2006 (Malaysia) s 59. See also Industrial Designs Act 1996 (Malaysia) ss 33, 35.
[435] Patent Act B.E. 2522 of 11/03/1979 (Thailand) s 77bis.
[436] Law on Copyright 2014 (Indonesia) art 106.
[437] Copyright Act 1999 (Fiji) s 120.
[438] Patent Act, 1970 (India) s 106.

4. TRIPS Waiver

At the time of writing, WTO Members are yet to reach consensus on a TRIPS waiver, with discussions reportedly characterised by considerable differences.[439] The matter is highly dynamic and the specific outcome uncertain, despite more general convergence on the objective of overcoming vaccine inequities. In parallel with the more general TRIPS waiver proposal, the EU and some other Members have signalled willingness to consider specific waivers of some TRIPS provisions, especially to streamline and facilitate the use of compulsory licences and other NVUAs, alongside the EU's proposal for a declaration clarifying Members' rights.[440]

The original waiver proposal itself can be broken down into three complementary elements, with distinct legal and practical characteristics:

(i) suspension of the obligations to provide IP rights *as such* at a certain standard and to ensure exceptions and limitations to rights comply with certain broad principles (Part II of TRIPS); and
(ii) suspension of the obligation to provide for the effective enforceability of covered IP rights, including through the availability of effective civil and criminal remedies, and the enforcement of rights at the border (Part III of TRIPS).
(iii) a 'peace clause' or agreement that precludes Members from enforcing and seeking compliance with TRIPS obligations through the WTO dispute settlement mechanism.

An extensive debate between governments,[441] and amongst analysts and scholars,[442] on the need for, and likely effectiveness of, a general waiver of core TRIPS provisions continues. By contrast, relatively little attention has been paid to specific measures that Members may take in the event that a waiver of some kind is agreed upon, and the practical and legal procedures that may be required to give effect to the greater scope of agency afforded to governments under a waiver. These practical questions are distinct from those that concern the validity, necessity or propriety of a waiver and are of major systemic significance both in the immediate term and in the future. There is no question about the general legitimacy of the waiver mechanism as an option for WTO Members to seek, given that it is expressly provided for in the WTO Agreement. It may well be an avenue considered by individual countries, country groupings, or the

[439] World Trade Organization, 'Members continue discussions on IP COVID-19 response as high-level engagement intensifies' (World Trade Organization, 16 December 2021) <https://www.wto.org/english/news_e/news21_e/trip_16dec21_e.htm>
[440] Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from The European Union to the Council for TRIPS, WTO Doc IP/C/W/681 (18 June 2021). For criticisms, see Médecins Sans Frontières (MSF), Analysis of Communications from the European Union to the Council for TRIPS (24 June 2021); Ellen 't Hoen and Pascale Boulet, 'The EU proposed Covid waivers of certain TRIPS rules meaningless' (Medicines Law & Policy, 14 October 2021).
[441] In particular, TRIPS Council minutes passim in WTO Docs IP/C/M/97 Add 1., IP/C/M/98 Add 1., IP/C/M/99 Add 1., IP/C/M/100 Add 1., and IP/C/M/101 Add 1.
[442] This ongoing debate has been widely contributed to: Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal, July 2021; Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 18); Bacchus (n 18); Bryan Mercurio, 'The IP waiver for COVID-19: bad policy, bad precedent' (2021) 52(8) International Review of Intellectual Property and Competition Law 983. See generally, Congressional Research Service, 'Potential WTO TRIPS Waiver and COVID-19' (CRS Insight, IN11662 , 4 June 2021).

WTO Membership as a whole to address specific obstacles that are identified in the current pandemic or in future public health crises. Therefore, this analysis seeks to set out, objectively, what additional options may be open to Members in the event of a waiver of TRIPS provisions, without taking a position on the desirability of any particular waiver proposal nor seeking to advocate any specific outcome at the intergovernmental level. This is with a view to illuminating both current and future possibilities for a potentially powerful, but still not clearly elaborated, tool for access to priority medical technologies.

4.1 The overall implications of a waiver

Agreement on a waiver that suspends a range of obligations under TRIPS would, by definition, open up options for measures at the domestic level that would not otherwise be available to Members with TRIPS-compliant laws and legal systems. Options canvassed in the debate have included suspension of IP right protection over COVID-19-related material, designs and inventions, halting the processing of applications for protection, such as new COVID-19 technologies, and creating wider exceptions to IP rights than are understood to be available under the TRIPS Agreement.[443] The waiver proposal as revised in June 2021 would, on the face of it, provide for a range of measures at the domestic level that would otherwise conflict with TRIPS obligations:

- the grant or recognition of otherwise eligible IP rights in the first place;
- processing otherwise legitimate applications for patents or industrial designs on relevant subject matter;
- refusing to grant protections and patents over designs and inventions, or suspending existing ones;
- discrimination in the enjoyment of patent rights on the grounds of field of technology;
- exceptions to IP rights that are broader than Articles 13, 26 and 30 would otherwise allow;
- determining that normal remedies for infringement of legitimate IP rights are not available in respect of certain COVID-19-related acts (such as vaccine production);
- suspending certain procedural steps that would otherwise be required for the grant of compulsory licences and other NVUAs, such as:
    - *ex ante* blanket authorisations for all potentially relevant technologies (i.e. a whole class of medicines) (Article 31(a));
    - disregarding the need to subsequently notify the right holder in the event of commercial use (Article 31(b));
    - permitting production mainly for export and not domestic use without the requirements of 31bis being satisfied (31(f)); and
    - suspending the obligation to compensate the right holder even *ex post* (31)h)); and

[443] See, e.g. WTO Docs IP/C/M/98, IP/C/M/99, IP/C/M/100, IP/C/M/101, IP/C/M/102, IP/C/M/103. See generally, WTO Doc IP/C/W/673 (n 72) and the documents cited in the oral status report to the General Council which had been circulated in document JOB/IP/53, reproduced in Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, Held in the Centre William Rappard on 13-14 October; 5, 18 and 29 November; and 16 December 2021, WTO Doc IP/C/M/103 (6 January 2022) [92].

- permitting uses of undisclosed information and clinical trial data in ways that would otherwise respectively constitute dishonest commercial practices (Article 39.2) or unfair commercial use (Article 39.3).

While a waiver may entitle Members to reduce the terms of IP rights or revoke such rights altogether, the time-limited character of a waiver — and the possibility of domestic legal, procedural and other constraints (discussed below) — may complicate such steps. For example, there could be legal and procedural difficulties in reinstating rights or titles over IP subject matter such as patents and industrial designs that have been revoked.

There are some issues that a waiver could not address at all. For example, a waiver would not alleviate the challenges surrounding the forced disclosure of confidential information.[444] There would also be no or negligible benefit in waiving certain TRIPS provisions that already provide Members with latitude to impose higher standards than TRIPS requires. For example, Article 29 provides for a minimum standard of disclosure that Members may choose to go beyond in their domestic law.

A waiver, however implemented, would not in itself dispense with regulatory requirements nor procurement procedures. Thus, a waiver could not overcome any obstacles to vaccine production, distribution and export that relate to approval of medicines from the point of view of safety and efficacy. This suggests that regulatory questions would need to be addressed in conjunction with the implementation of a waiver. Thus, to take the controversy over the supply to Bolivia of vaccines by the Canadian firm Biolyse, if it is indeed the case that the Canadian government has not ascertained that the firm can produce vaccines that meet regulatory standards, this situation would remain the case under a waiver, even if Canada were to take steps to suspend IP rights under a TRIPS waiver, because these steps *in themselves* would not remove regulatory standards applied to medicines. It would be possible, of course, for governments to elect to permit vaccines to be produced expressly for export without complying with domestic regulatory standards, at least in principle, although governments may prove hesitant to permit production and export of vaccines which would not comply with their own domestic standards. In any event, the regulatory dimension would need to be considered and addressed in the context of practically implementing a waiver at the domestic level.

4.2 Implementing a Waiver

As TRIPS is not self-executing, and as IP rights are defined, administered and enforced under domestic law, any waiver of its provisions at the international level would not lead directly to any curtailment or suspension of IP rights or their enforcement. For governments to take advantage of a waiver would require implementation at the domestic level whether through a legislative amendment, or other executive or

[444] Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 18) 17; RM Hilty, PHD Batista, S Carls, D Kim, M Lamping and PR Slowinski, 'Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021' (7 May 2021).

administrative action by Members.[445] Some discussion of the waiver proposal seems to be predicated on the assumption that a waiver of TRIPS obligations amounts to an automatic waiver or suspension of IP rights as such, and that a waiver thus provides a fast-track approach to overcoming IP barriers to access that would be swifter and more immediate than domestic processes, notably NVUAs. However, even in jurisdictions with a strong tradition of direct effect of international treaty law, we are not aware of any legal mechanism that would lead directly from a waiver of TRIPS obligations to the effective absence or unenforceability of IP rights provided for under domestic laws.

Further systemic research may be needed to clarify this situation as it is a key aspect of understanding a TRIPS waiver as a practical tool, both for current and future scenarios. Further, current waiver proponents have emphasized the potential diversity of national mechanisms for implementing a waiver. As observed by waiver proponents, 'there is no size fits all approach to national implementation', given the distinct nature of each Member's legal and constitutional system.[446] At the same time, if a waiver is intended to promote greater coordination and cooperation between governments in the spirit of solidarity, then a highly heterogenous approach to implementation in different national systems may impede any potential benefits, while consuming considerable administrative or legislative bandwidth and, for that matter, domestic political capital.

Here, we provide a general overview of the potential mechanisms for implementing the waiver proposed. In order to highlight some of the practical considerations that Members may need to take into account in adopting any of these mechanisms, we outline what each of these options might mean for Australia, as an example of a Member with a highly developed IP system, a high level of engagement at the international level, and a complex constitutional system.

4.2.1 Peace Clause: Suspension of International Dispute Resolution

There are various forms of agreement to suspend or refrain from taking certain action in international dispute resolution, against an understanding that this may lead to greater domestic willingness to take actions that may be argued to infringe international obligations; these are known informally as 'peace clauses'. Past, somewhat diverse WTO practice has shown two broad categories of such measures: (i) agreement to exclude altogether certain disputes from the scope of multilateral dispute settlement; and (ii) agreement to exercise restraint in initiating dispute settlement proceedings. An example of the first category in the area of TRIPS is the exclusion of non-violation and situation complaints, initially under Article 63.2 and subsequently through successive Ministerial Conference decisions. The second form of peace clause is exemplified in Article 24.1 of the WTO Dispute Settlement Understanding ('DSU'), which provides that 'Members shall exercise due restraint in raising [dispute settlement] matters involving a least-developed country Member' and that 'complaining parties shall exercise due restraint' in seeking compensation or retaliation against an LDC. The

[445] Carlos M. Correa, 'TRIPS Agreement and Access to Drugs in Developing Countries' (2005) 3 International Journal on Human Rights 25, 31.
[446] WTO Doc IP/C/W/672 (n 21) [75]. See also IP/C/W/684 (n 56) [53].

waiver proposal initiated by India and South Africa would provide for agreement on a prohibition of dispute settlement as such, and not simply due restraint.

A peace clause of some kind would entail Members foregoing what would otherwise be a political choice to invoke their rights under the DSU to instigate dispute settlement procedures against another WTO Member; it would not require formal legal change at the domestic level. If, as one of us has explored,[447] practical agency of national governments and their willingness to pursue pragmatic options may be partly guided by a risk assessment as to the consequences of dispute settlement action, this mechanism may provide reinforcement for taking potentially difficult choices, while not in itself creating distinct options as such.

At a practical level, it should be noted that the extent of dispute settlement complaints taken in particular by developed countries against developing country Members has been minimal since around the year 2000. Further, the current absence of an operational Appellate Body does mean that any outcome from a dispute at the level of panel proceedings is potentially suspended through the possibility of 'appeal into the void'. However, the uncertainty over whether, when and how this state of affairs may be resolved would presumably lead to some reluctance to take significant domestic action, especially to build up vaccine production capacity, purely on this basis.

4.2.2 Suspension of Domestic Enforcement Action

Potential mechanisms for blunting Part III obligations include removing available remedies such as injunctive or interlocutory relief, and limiting other remedies by, for example, setting a cap on available compensation or remedies for infringements relating to COVID-19 subject matter. While the focus under this mechanism would be on waiving Part III of TRIPS, removing or limiting remedies may be achieved by defining exceptions to IP rights under Part II of TRIPS in terms of a lack of capacity to enforce such rights (e.g. regulatory review exceptions in Asia-Pacific jurisdictions).

The suspension or modification of enforcement action for COVID-19 subject matter would not be without practical limitations. In Australia, for example, it would require amongst other things an amendment to various enforcement mechanisms found in Australia's statutory IP law, but also various general law entitlements to bring enforcement action against the disclosure of confidential information that is protected by contract or equitable principles. As discussed in the next two sections, such mechanisms would also raise questions under domestic constitutional law and the possibility of violations under other international agreements.

4.2.3 Temporary Suspension of IP Legislation

Some advocates of the TRIPS waiver have contemplated the suspension of existing IP rights, or suspension of the processing of applications. This would entail removing the legal effect or even the registration or recognition of IP rights that would otherwise be legitimately made available. In some jurisdictions, executive action may be sufficient

[447] See generally, Taubman (n 89).

to implement this, while in others it would be necessary to pass some form of legislation. Proponents of a waiver have reinforced that legislative amendment 'need not be a time-consuming exercise'.[448]

However, practical difficulties remain with this approach. In the patent field, for instance, a number of the critical technologies are platform technologies, with much wider application than COVID-19 alone.[449] This gives rise to a related issue about the difficulty of managing these patents and patent applications. Would they be revoked or refused purely in respect of their application to COVID-19? Would examiners or judicial authorities have the capacity to determine the applicable scope of a platform technology to COVID-19 vis-à-vis other applications? Similar considerations for technologies such as vaccine storage, transportation and delivery apply. That said, 'use' patents (their claims defined in terms of use of a technology to address COVID-19 in particular) would be more easily addressed by this kind of mechanism, although they would not enable a full solution in many cases if other, broader technology platforms are part of the access equation.

4.3 Constitutional questions

Domestic IP systems and countries' wider constitutional frameworks interact with one other in diverse ways. Even where a TRIPS waiver would permit certain action under TRIPS, constitutional principles may limit the ability of governments to take that action lawfully at the domestic level. For example, the removal or modification of enforcement remedies for IP infringement may amount to a taking of property without just or reasonable compensation. It is conceivable that, depending on the constitutional provision or principle in question, the removal of a right to enforcement action could constitute a taking of property, or even that this removal means an infringement of IP rights constitutes a taking in respect of which there has not been made available any just compensation. Much would depend on the constitutional language used and the existing body of law that governs its meaning and interpretation.

The Australian case of *JT International v Commonwealth of Australia*[450] illustrates how specific constitutional language and interpretation is determinative of the outcome. In that case, it was held that restrictions on the use of trademarks brought about by the Australian government's tobacco plain packaging laws did not constitute an 'acquisition of property' for the purposes of s 51(xxxi) of Australia's constitution, because neither the Commonwealth of Australia nor any other party acquired any property. Rather than acquiring property, the Commonwealth placed limitations on relevant trademark owners' negative rights to prevent the unauthorised use of their trademarks by third parties.

The constitutions of the countries in our survey contain similar 'taking' provisions that utilise a range of formulations and that would be subject to differing interpretations (

[448] IP/C/W/684 (n 56) [54]-[56].
[449] See generally, Chiang and Wu (n 8).
[450] (2012) 250 CLR 1.

Table 6). For example, the terms ‘requisition’ and ‘use’ found in the constitutions of Bangladesh, Malaysia and Nepal are more likely to cover the non-voluntary use of IP rights than the term ‘acquisition’. Similarly, a regulation that interferes with IP rights in a manner akin to Australia’s plain packaging laws is more likely to be captured by a provision like India’s, which refers to the ‘deprivation’ of property. A deprivation does not necessarily require a corresponding acquisition of the same by another party. Similarly, the term ‘expropriation’ can be interpreted in different ways, and may include the deprivation of an economic benefit even where no ‘taking’ occurs.

Table 6: Acquisition provisions in Asia-Pacific constitutions

Country	Constitutional requirement
Bangladesh	Any acquisition, nationalisation or requisition of property must be compensated by an amount and in a manner specified by law, but the adequacy of that compensation cannot be questioned.[451]
Cambodia	‘Expropriation from ownership’ must be exercised in the public interest as provided by law and subject to the payment of fair and just *ex ante* compensation.[452]
India	Substantial deprivations of property must be done in accordance with law, for a public purpose, and be compensated.[453]
Malaysia	The compulsory use or acquisition of property must be accompanied by adequate compensation.[454]
Nepal	An acquisition or requisition of, or encumbrance created on, property must be in the public interest and be subject to compensation, the basis of which must be prescribed by law.[455]
Thailand	‘Expropriation’ of property must be for public interest purpose and subject to the payment of fair compensation.[456]
Vietnam	In cases made absolutely necessary by reason of national defence, security or national interest, in case of emergency and for protection against natural calamity, the State can make a forcible purchase of or can requisition pieces of property of individuals or organisations against compensation, taking into account current market prices.[457]

Source: Authors’ compilation

4.4 Broader international obligations

The TRIPS Agreement is not, of course, the sole source of individual Members’ international obligations relating to the protection of IP in their domestic systems, and so the temporary suspension of TRIPS obligations does not necessarily create full freedom of choice to wind back, limit or suspend IP rights in national systems. This section reviews some systemic considerations, noting that these may be both complex

[451] Bangladesh Constitution s 42.
[452] Cambodia Constitution art 44.
[453] India Constitution art 31; Dwarkadas Srinivas of Bombay v The Sholapur Spinning and Weaving Co 1954 AIR 119 (18 December 1953) (Supreme Court of India); The State of West Bengal vs Subodh Gopal Bose and Others 1954 AIR 92 (17 December 1953) (Supreme Court of India).
[454] Malaysia Constitution art 32.
[455] Nepal Constitution s 25(2)-(3).
[456] Thailand Constitution s 37.
[457] Vietnam Constitution art 32.

and diverse in character, so that this brief overview simply offers a taxonomy of issues for practical purposes, without seeking to provide a definitive analysis of the legal situation in each case.

4.4.1 Other multilateral conventions

The TRIPS Agreement itself refers to and applies several of the multilateral IP conventions administered by WIPO. For the purposes of the present paper, the most significant are the Berne and Paris Conventions, foundational elements of international IP law that are substantively incorporated into TRIPS.[458] but also separately and independently adhered to by almost all WTO Members. Article 2 provides that '[n]othing in Parts I to IV of this Agreement shall derogate from existing obligations' under, inter alia, the Paris and Berne Conventions.

On the face of it, a waiver proposal covering Part II, Section 1 of TRIPS (on substantive copyright protection) would address the obligation in Article 9 of TRIPS to comply with Articles 1 to 21 of the Berne Convention, provisions that provide the bulk of substantive TRIPS law on copyright. A waiver covering Parts II and III of TRIPS may also engage the obligation in Article 2 to comply with Articles 1 to through 12, and Article 19, of the Paris Convention, '[i]n respect of' Parts II, III and IV of TRIPS. This is potentially relevant, especially in relation to certain standards on compulsory licensing of patents (as discussed above) and the protection of undisclosed information and clinical trial data, framed in TRIPS as implementation of Article 10bis of the Paris Convention.

The implications of a waiver of TRIPS provisions for a country's separate and parallel obligations under the Paris and Berne Conventions have not been fully explored. However, many LDCs are parties to both these treaties while also benefiting from extensions of time for the implementation of TRIPS and from specific waivers under TRIPS. The closest analogy that has arisen in WTO practice has been the authorisation by the Dispute Settlement Body ('DSB'), in three dispute settlement cases, for some Members to suspend certain concessions under TRIPS to other Members as a remedy for their failure to implement dispute settlement findings. This has meant the DSB has given approval for such Members to suspend various elements of IP protection for nationals from the Members concerned. In turn, this has raised the issue of whether, and if so on what legal basis,[459] the DSB's authorisation should flow through to suspending relevant obligations separately under the Paris and Berne Conventions.

In the first of these cases, Ecuador's complaint against the then European Communities regarding the import and sale of bananas, the arbitration decision found that Ecuador may request obligations under the TRIPS Agreement, 'to the extent that suspension requested under the GATT and the GATS … is insufficient to reach the

[458] Antony Taubman, ""Trade-related" after all? Reframing the Paris and Berne Conventions as multilateral trade law", in Graeme W Austin , Andrew F Christie , Andrew T Kenyon , Megan Richardson (eds.), Across Intellectual Property (Cambridge University Press, 2020).
[459] For an extensive discussion, see Antony Taubman, 'Self-Help', Justified Disobedience and the Suspension of TRIPS Obligations, forthcoming (2022), drawn on for this section.

level of nullification and impairment indicated.'[460] This finding raised the question of the relation between the suspension of TRIPS obligations and the conventions administered by WIPO. The Arbitrators noted that the parties disagreed on whether the non-derogation provision of TRIPS Article 2.2 'prevents or permits the suspension of TRIPS obligations which have a relation to' the cited WIPO conventions: Paris Convention, Berne Convention, the Rome Convention or the IPIC Treaty.[461] However, they observed that Article 2.2 only refers to Parts I to IV, and not Part V of TRIPS, the provisions on 'Dispute Prevention and Settlement.' From their reading of Article 64 of TRIPS and Article 22.3 of the DSU46, the Arbitrators concluded that suspension of certain TRIPS obligations was consistent with all the requirements of Article 22 of the DSU and that 'no other provision of the WTO agreements indicate that an authorization by the DSB of that request would in theory be prohibited under WTO law.'[462]

The Arbitrators did not consider that their jurisdiction under the DSU extended to determining whether a Member's suspension of certain TRIPS obligations, on the DSB's authorisation, would be inconsistent with that Member's international obligations arising from treaties other than the agreements covered by the WTO (e.g. the Paris, Berne and Rome Conventions, which Ecuador had ratified). They concluded that it is 'if at all, entirely for Ecuador and the other parties to such treaties to consider whether a specific form chosen by Ecuador for implementing such suspension of certain TRIPS obligations gives rise to difficulties in legal or practical terms under such treaties.'[463]

This discussion represents, still, the most extensive analysis in WTO decisions concerning the implications of cross-retaliation for separate legal obligations under WIPO conventions. In the ensuing debate in the DSB, the EC expressed concerns about the Arbitrators' 'rather flexible interpretation of the procedural provisions of the DSU, in particular, with regard to due process considerations'[464] and 'the way the Arbitrators had addressed the possible use of cross-retaliation in general and its application to the TRIPS, in particular, when taking into account the specific nature of intellectual property rights.' The EC expected 'a stronger reasoned argument as a basis for authorizing retaliatory measures under one agreement when the violation occurred under another.' However, the consequence of non-compliance with WIPO conventions was not mentioned.

International treaty law — in particular the law on countermeasures — does, at least in principle, provide for certain avenues for reconciling a suspension of WIPO treaty obligations in the context of dispute settlement.[465] In the context of an agreed TRIPS waiver, the relevant legal issues include the character of a waiver decision as a subsequent agreement, the principle of estoppel, and the apparent consent of the

[460] Decision of the Arbitrators on European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Arbitration by the European Communities under Article 22.6 of the DSU, WTO Doc WT/DS27/ARB/ECU (24 March 2000) 36 [173] ('EC – Bananas – Recourse to Arbitration').
[461] EC – Bananas – Recourse to Arbitration (n 460) 31 [148].
[462] EC – Bananas – Recourse to Arbitration (n 460) 31 [150].
[463] EC – Bananas – Recourse to Arbitration (n 460) 31 [151].
[464] Dispute Settlement Body, Minutes of Meeting Held in the Centre William Rappard on 7 April 2000, WTO Doc WT/DSB/M/78 (12 May 2000) [38].
[465] Elaborated in Taubman (n 459).

parties to the consequences of such a waiver, as well as the expectation that the waiver decision should be effective in practice. However, these issues are simply identified for present purposes and not elaborated in this paper.

4.4.2 Bilateral and regional trade agreements

A TRIPS waiver may also raise similar questions relating to Members' obligations under the numerous bilateral and regional trade agreements that provide substantive obligations to protect IP, almost all of which have been concluded subsequently to TRIPS. An additional factor, not present in the Paris and Berne Conventions, is the availability of dispute settlement proceedings under most of these agreements. These bilateral and regional obligations regarding IP take diverse legal forms, including:

- direct, general reaffirmations of TRIPS obligations;
- separate bilateral obligations to protect and to enforce IP rights to a certain level, without express reference to TRIPS; and
- specific 'TRIPS-plus' obligations, which either elaborate on or extend certain TRIPS provisions (for instance in limiting grounds for compulsory licensing of patents).

In the event of a TRIPS waiver, Member governments seeking to implement the waiver in their domestic systems may be confronted with claims that there was a risk of breach of such separate trade agreements, and even the theoretical prospect of dispute settlement under them (although, in the context of a temporary measure to address a pandemic, and given the very low rate of dispute settlement in general under such agreements, the likelihood of actual disputes being brought may be considered slim).

Should the issue arise, there are several approaches to analysing the legal implications. These may address the substance of obligations of such agreements, or the possibility of dispute settlement to enforce such obligations. These possibilities may include the following, although we do not suggest that these are necessarily applicable in any particular case:

- in some bilateral and regional agreements, specific reference to public health exclusions under TRIPS, such as references to the Doha Declaration, and side letters concluded with this effect;
- the scope of consent that is implicit in a WTO agreement on a waiver, which could be argued to flow through to bilateral obligations on the basis that the waiver could not be effectively implemented if overlapping bilateral obligations supervened; and
- applying the principle of estoppel to dispute settlement claims under bilateral agreements that would, again, effectively target the implementation of an agreed TRIPS waiver.

Table 7: Examples of potentially relevant FTAs

Surveyed country	Relevant FTAs
India	India – Japan
Indonesia	Japan – Indonesia FTA (esp. arts 119, 121)
Malaysia	Japan – Malaysia (esp. art 127)
Mongolia	Japan – Mongolia
Thailand	Japan – Thailand EPA (esp. art 140)
Vietnam	EU – Vietnam

Surveyed country	Relevant FTAs
	Japan – Vietnam US – Vietnam (esp. arts 14-15)
Regional	CPTPP

4.4.3 Bilateral investment treaties

In addition to trade agreements, numerous BITs expressly include IP as a protected asset.[466] Depending on how it is implemented at the domestic level, the suspension or cancellation of IP rights could, in principle, lead to a claim that BIT obligations are infringed, either as an illegitimate expropriation of IP rights or on the basis of procedural fairness, even when taken as implementation of a TRIPS waiver.[467] Many BITs provide for dispute settlement, including the possibility of investor-state dispute settlement: one reported case concerned a company's claim (not upheld by the panel) that a trend of judicial decisions had thwarted legitimate expectations as to the availability of IP rights.[468]

BIT negotiators have foreseen the possibility of a claim that a compulsory licence amounts to an expropriation of assets under a BIT, and for that reason a number of BITs expressly clarify that compulsory licensing in compliance with TRIPS is permitted: for instance, a recent BIT provides this its provisions on expropriation do not apply 'to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with TRIPS Agreement.'[469] However, this suggests that issues may arise should NVUAs not be TRIPS-consistent. In an initial review, we have not been able to find a provision that expressly addresses the question of a separate waiver of TRIPS obligations.

Given the distinctive characteristic of a TRIPS waiver — a temporary measure at a time of a global health crisis — it may prove unlikely that actual cases would be pursued, whether by other governments or by companies affected. And BIT provisions concerning situations of national emergency may also be invoked: for instance, a recent BIT provides that '[n]on-discriminatory regulatory actions by a Party that are designed and applied to achieve legitimate public welfare objectives, such as the protection of public health, safety, and the environment, do not constitute expropriation…'[470] That said, the considerations discussed above in relation to bilateral trade agreements may also apply to the analysis of the impact of a TRIPS waiver on BIT obligations as well.

[466] The UNCTAD Investment Policy Hub identifies 2794 BITs, and 424 Treaties with Investment Provisions (TIPs), a majority of which have some coverage of IP rights, either expressly or implicitly: <investmentpolicy.unctad.org/international-investment-agreements> (accessed 16 April 2022).
[467] Prabhash Ranjan, 'A BIT of a Challenge for India' (The Wire, 22 May 2021) <thewire.in/trade/trips-waiver-a-bit-of-a-challenge-for-india>
[468] Eli Lilly and Company v. The Government of Canada, UNCITRAL (ICSID Case No. UNCT/14/2).
[469] ASEAN – Hong Kong, China SAR Investment Agreement (2017), entered into force 17/06/2019, art 10.5.
[470] ASEAN – Hong Kong, China SAR Investment Agreement (2017), entered into force 17/06/2019, Annex 2, para 4.

5. Technology transfer

The TRIPS Agreement as amended has several positive obligations relating to technology transfer, with direct relevance to the COVID-19 response. Under Article 66, developed country Members are obliged ('shall') to 'provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'. While there has been extensive debate about the nature of this obligation and the extent to which it has been effectively implemented, the technology transfer programs reported under this provision since 2001 have increasingly included medical technologies[471] The entry into force of the amended TRIPS Agreement in 2017 confirms the commitment of Members 'to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2.'[472] Recent work on their implementation has taken up COVID-19 and vaccine technologies expressly, with LDC Members identifying these as priority areas for technological development. More generally, technology transfer to LDCs has formed part of the wider pandemic response. The United Nations Technology Bank for Least Developed Countries has taken up COVID-19-related technologies in its implementation, and has coordinated with the WTO on implementation of Article 66.2.[473] Some LDCs have been identified as potential production hubs for vaccines, notably Bangladesh in the Asia-Pacific region.

The amended TRIPS Agreement confirms Members' recognition of 'the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector.' Operationalising this recognition is clearly a priority in the context of collaborative responses to the pandemic, potentially helping to frame a regional response for the Asia-Pacific. Little attention has been paid to this, however, whether in general terms or in responding to the TRIPS Agreement's encouragement to use compulsory licensing for export 'in a way which would promote this objective.'[474] The proposals, set out above (Section 3.2.5), for more effective and coordinated use of the Article 31bis mechanism within a regional context, offer a sound treaty-based framework for expanding vaccine production through technology transfer, while also recognising the inherently cooperative and collaborative nature of such a project.

[471] Jayashree Watal and Leticia Caminero, 'Least-developed countries, transfer of technology and the TRIPS Agreement' (WTO Staff Working Paper, No. ERSD-2018-01, World Trade Organization, 22 February 2018) 6.
[472] Annex to the TRIPS Agreement, art 6.
[473] World Trade Organization 'Workshop looks at incentives for technology transfer to LDCs under TRIPS Agreement' (10 March 2021) <https://www.wto.org/english/news_e/news21_e/tech_18mar21_e.htm>
[474] Annex to the TRIPS Agreement, art 6.

6. Security Exception

The security exception in Article 73(b) of TRIPS has been identified by some commentators as providing an avenue for introducing IP measures that are sensitive to public health requirements and that may be introduced to increase manufacturing capacity for vaccines.[475] Article 73 provides:

> Nothing in this Agreement shall be construed:
>
> …
>
> (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;
>
> …
>
> (iii) taken in time of war or other emergency in international relations …

Rather than a source of flexibility in the substantive rights and obligations enjoyed and imposed on Members, or a suspension of specific TRIPS standards, Article 73 operates as a defence in the event that a Member was to be challenged under WTO dispute settlement mechanisms. The exception has been analysed extensively, primarily outside but now also within the pandemic context. In past dispute settlement cases considering security exceptions in WTO Agreements,[476] panels have found that a Member may decide what constitutes its 'essential security interests' and whether a measure is 'necessary' to protect those interests,[477] subject to the Member interpreting and applying those terms in good faith.[478]

Derived from a general requirement of *bona fide* interpretation is a minimum requirement of plausibility that ensures the 'essential security interest' relied upon by the defendant Member has some plausible connection with any one of the circumstances or subject matters listed in the exception.[479] The existence of such circumstances (and whether the interest claimed has a plausible connection with them) is to be determined objectively, and therefore constitutes the exception's only truly justiciable element. We limit our brief analysis to the issue of what constitutes an 'emergency in international relations' — the only limb of Article 73 that has a potential *direct* plausible connection with a public health crisis.[480]

In *Russia – Measures Concerning Traffic in Transit*, the Panel defined 'international relations as 'generally to mean "world politics", or "global political interaction, primarily among sovereign states"', and determined that an 'emergency in international relations' refers 'generally to a situation of armed conflict, or of latent armed conflict, or

[475] It is noteworthy that Article 73(b) has not been formally identified by any WTO Member as a viable option in addressing IP barriers to the pandemic response.
[476] The GATT and TRIPS security exceptions are the only two WTO security exceptions to have been adjudicated.
[477] Panel Report, Russia – Measures Concerning Traffic in Transit, WTO Doc WT/DS512/R (5 April 2019) [7.146]-[7.147] ('Russia – Measures Concerning Traffic in Transit').
[478] The Panel in Russia – Measures Concerning Traffic in Transit took this from Article 26 of the Vienna Convention.
[479] Panel Report, Saudi Arabia – Measures concerning the Protection of Intellectual Property Rights, WTO Doc WT/DS567/R (16 June 2020) [7.242].
[480] TRIPS art 73(b).

of heightened tension or crisis, or of general instability engulfing or surrounding a state.'[481] The Panel considered that these are situations that 'give rise to particular types of interests … i.e. defence or military interests, or maintenance of law and public order interests.'[482]

The Panel reasoned that 'as the existence of an emergency in international relations is an objective state of affairs, the determination of whether the relevant action was "taken in time of" an "emergency in international relations"... is that of an objective fact, subject to objective determination.'[483] The Panel interpreted the term 'taken in time of' (in contrast to 'relating to' for the other subparagraphs) to describe a temporal connection between the action and the events of emergency in international relations. Therefore, for a measure to fall under the third limb, it must be a measure '*taken in time* of war or other emergency in international relations'.

Abbott, in analysing this issue relies primarily on the WHO's statement declaring the COVID-19 crisis a Public Health Emergency of International Concern, citing 'interaction between the States … the allocation of medicines (including vaccines) and medical devices among States' and ultimately framing 'emergency in international relations' as an issue of inequitable access to health care.[484] More plausible grounds posited by Abbott for classifying the pandemic as an international relations emergency is the 'sharp slowdown international trade and travel' and 'the threat of hostility'.[485] Without entering into the debate surrounding the security exception's general parameters under WTO disciplines, we find an objective characterisation of the pandemic and vaccine inequity as an 'emergency in international relations' to be somewhat strained.

While a pandemic or vaccine inequity are each certainly unlikely to constitute a situation of 'armed conflict' or 'heightened tension', it could be that they constitute a 'crisis' or even 'general instability engulfing or surrounding a state'. However, fitting a pandemic and vaccine inequity into a broad interpretation of these terms seems to ignore the context in which the Panel used them. In this regard, the Panel clarified that:

> the matters addressed by [the other] subparagraphs give rise to similar or convergent concerns, which can be formulated in terms of the specific security interests [which] … are all defence and military interests, as well as maintenance of law and public order interests. An 'emergency in international relations' must be understood as eliciting the same type of interests as those arising from the other matters addressed in the enumerated subparagraphs of Article XXI(b).[486]

The Panel also stated that 'the reference to "war" in conjunction with "or other emergency in international relations" … and the interests that generally arise during war … suggest that political or economic differences between Members are not sufficient, of themselves, to constitute an emergency in international relations …'[487]

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[481] Panel Report, Russia – Measures Concerning Traffic in Transit (n 477) [7.73], [7.76].
[482] Panel Report, Russia – Measures Concerning Traffic in Transit (n 477) [7.76].
[483] Panel Report, Russia – Measures Concerning Traffic in Transit (n 477) [7.77].
[484] Frederick Abbott, 'The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic' (South Centre, Research Paper 116, August 2020) 7.
[485] Frederick Abbott, 'The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic' (South Centre, Research Paper 116, August 2020) 7.
[486] Panel Report, Russia – Measures Concerning Traffic in Transit (n 477) [7.74].
[487] Panel Report, Russia – Measures Concerning Traffic in Transit (n 477) [7.75].

These clarifications by the Panel reveal that the words 'crisis' and 'general instability engulfing or surrounding a state' are to be understood in the context of threats arising out of a physical conflict, or the threat of a physical conflict, between nations. Even if an increase in hostility and violence could be linked to the pandemic as a whole, it is unlikely that measures implemented to increase IP access for the purposes of increasing the manufacture and distribution of COVID-19 vaccines could be justified on the basis of a security exception along these lines. The connection between increasing vaccine access and preventing violence or social unrest in response to the pandemic's various social and economic impacts would be far too weak to satisfy the minimum requirement of plausibility. Moreover, to our knowledge, such violence and social unrest has been observed in the pandemic context solely as a response to domestic policy choices, rather than as a product of conflict between nations.

Considering the practical domestic level, the limitations of this mechanism as an access tool are illustrated by the proposal to use the security exception to suspend the effect of Article 31(f), thus circumventing the need to rely on Article 31*bis* in enabling government authorisation of vaccine production mainly for export without a patent holder's consent.[488] This scenario would not, of course, arise if a Member authorised use partly to address a domestic emergency and partly for export. It would presumably entail establishing some form of understanding with each recipient Member that it had established that its essential security interests were at stake during a time of emergency in international relations, and somehow framing export as necessary to address these essential security interests. One commentator has suggested that is

> doubtful whether [a Member] can invoke Article 73(b)(iii) to justify the suspension of the enforcement of patent rights in its own territory in order to protect the essential security interests of [another Member] by exporting patented medicines or vaccines [to it].'[489]

Given the options available for streamlined and coordinated use of Article 31*bis* — and its present implementation in many exporting producers' laws — this option raises considerable practical questions, apart from the legal ones. Hence, leaving the interpretation and application of Article 73 aside, we query whether Article 73 would be practically effective in responding to public health issues. This is particularly so given political sensitives surrounding the exception, and the expansive array of options available to Members for these purposes elsewhere within the TRIPS Agreement. Given that the essential need is for greater solidarity and cooperation among Members, in the spirit of the Solidarity Call for Action, the signal that individual Members' national security interests should prevail over vaccine equity may also run counter to much needed political convergence on a more cooperative and collaborative pandemic response.

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[488] See Emmanuel Kolawole Oke, 'Is the National Security Exception in the TRIPS Agreement a Realistic Option in Confronting COVID-19?' (EJIL:Talk!, 6 August 2020) <https://www.ejiltalk.org/is-the-national-security-exception-in-the-trips-agreement-a-realistic-option-in-confronting-covid-19/>

[489] Emmanuel Kolawole Oke, 'Is the National Security Exception in the TRIPS Agreement a Realistic Option in Confronting COVID-19?' (EJIL:Talk!, 6 August 2020) <https://www.ejiltalk.org/is-the-national-security-exception-in-the-trips-agreement-a-realistic-option-in-confronting-covid-19/>

7. Legal And Policy Options: Practical Recommendations

This concluding section draws on the above analysis and discussion to provide practical recommendations for actions that may be taken to reinforce the role of the IP system within and beyond the TRIPS framework to leverage access to vaccines. This leveraged access may be achieved either through dispersed production capacity or a wider access to potential imports, including through regional coordination and cooperation. These recommendations are grouped according to five broad policy areas, relating both to individual national action and options for regionally based coordination. The recommendations have also been extracted in the form of a standalone checklist for national and regional policymakers and planners.

The timeframe for recommended actions ranges from action that can be taken immediately in response to the pandemic, to longer-term planning for future resilience and the systematic review and reform of relevant policies, legislation and administration. These more systemic reforms, by their character, are likely to take time extending beyond the current pandemic but may nonetheless be driven by the challenges faced since the pandemic was declared in March 2020. It would be impractical, burdensome and unrealistic to address the full range of recommendations in a single broad program. For this reason, we provide the following indicative timeline which also serves as a summary of the more detailed recommendations provided below.

Timeline of possible actions

Immediate

- National and coordinated regional action to identify, document and notify demand for vaccines, to aggregate demand, create economies of scale and leverage access.
- Step up pooled procurement making full use of existing TRIPS flexibilities
- Mapping the IP landscape as a basis for planning the establishment or repurposing of vaccine production facilities.
- Integrate IP dimension in policies for funding and material support for research and development.

Short-term

- Clarification and streamlining of procedures for making use of existing provisions for government use, public non-commercial use, and compulsory licensing.
- National and coordinated regional review of the implications of any WTO outcome on the pandemic, including:
  - options for national and coordinated regional action; and
  - consideration of domestic options for implementation.
- National and coordinated regional review of the practical state of play regarding facilitated regulatory approval, mutual recognition and other forms of convergence, and implications for access to protected clinical trial data.

Medium-term

- Review and possible revision of legislation and administration on the basis of the pandemic experience and wider issues regarding innovation and access to medical technologies.
- Domestic and regional workshops to promote sharing of best practice and potential areas for convergence and systematic cooperation, building on existing regional frameworks.

7.1 Policy Area 1: Strengthening the factual basis for decisions on IP law and policy

7.1.1 Short- and longer-term approach to sustained access to vaccines

In assessing options for both short- and longer-term approaches to sustained access to vaccines, policymakers need to consider whether a country or group of countries is likely to remain largely reliant on imported vaccines, or has actual or potential production capacity. Equally, a significant consideration is whether a country has, or plans to develop, substantial capacity for vaccine R&D.

An objective review of these questions would enable a more tailored, nuanced approach to integrating IP law and policy with innovation and access programs that is better suited to individual countries' specific needs and circumstances, while also strengthening the basis for cooperation within the region.

Recommended actions:

- Assess IP legal and policy framework based on immediate and longer term options for vaccine access.
- Develop IP management policies for publicly funded R&D.
- Strengthen planning and strategic partnerships with regional countries and regional institutions with a view to collaborative access and development programs.

7.1.2 Illuminating the intellectual property landscape

Immediate and longer-term action will be better informed and more effective if it is based on a clearer understanding of the actual state of play concerning IP coverage, keeping in mind that the situation will vary greatly across the region from countries with a large number of applicable IP rights to those with none. This entails preparing landscape studies that would illuminate:

- the extent to which background and foreground IP, especially patents, have been protected in jurisdictions across the region; and
- considering whether, and to what extent, test data protection apply to regulatory approval outcomes in jurisdictions across the region.

Clearer mapping of the IP landscape may reveal that, in certain jurisdictions or regions, IP-related barriers to vaccine access are more hypothetical than real. However, there are considerable challenges in maintaining an up-to-date and accurate analysis of a fast-evolving and complex technology landscape.

Recommended actions:

- Strengthen analytical capacity and seek technical assistance to:
  - track patenting and other registration activity;
  - assess the impact of clinical trial data protection on vaccine regulation and approval; and
  - map requirements for the submission of clinical trial data.
- Work with regional partners, and with regional and international institutions, to develop a coordinated approach to technology tracking and IP mapping.

7.2 Policy Area 2: Innovation and Product Development: the IP Dimension

7.2.1 Managing IP generated in research and development

For those countries currently undertaking or seeking to undertake significant R&D, especially if this involves the investment of public funds and resources, appropriate policies need to be updated or developed to ensure that the resultant IP is managed so as to meet the public's needs and expectations. This would entail considering:

- the extent to which each country is investing resources in vaccine R&D, or planning to; and then

- the degree to which leverage over ensuing IP should be maintained to safeguard the public interest.

To undertake this effectively entails meeting the challenge of ensuring capacity to monitor R&D programs and to manage resulting IP.

Recommended actions:

- Update or initiate, as appropriate, policies to ensure continuing leverage over or access to IP resulting from publicly funded or publicly supported R&D programs
- Coordinate such policies with regional partners and regional institutions, with the support of regional and multilateral organisations.

7.3 Policy Area 3: Legal and legislative framework for the IP system

7.3.1 Adequacy and appropriate balance of IP laws for health innovation and access

Despite the enormous challenges of the domestic and the international response to the pandemic, there is a positive opportunity for policymakers to assess the adequacy and appropriate balance of IP laws for health innovation and access, in view of the hard lessons learned during this public health crisis. The review process may include considering:

- whether the criteria for grant of patents and other IP rights are well adapted to domestic and regional needs and circumstances, while conforming with the principles laid down in international agreements (e.g. TRIPS);
- whether suitable exceptions to patents and other IP rights have been included in legislation, with a view to ensuring scope for pre-commercialisation activities such as experimentation, research and regulatory approval; and
- whether suitable, balanced rules and streamlined, clear procedures have been included in legislation providing for use in the public interest of patented subject matter without the right holder's consent:
    - on the initiative of government authorities; or
    - following the application of interested third parties.

Addressing this need is a complex task. It entails developing and drawing effectively on the necessary technical and legal capacity to review and prioritise options, and the political will to implement necessary reforms and legislative development.

Recommended actions:

- Multi-stakeholder public health review of IP laws in terms of both overall settings and specific measures, to enhance innovation and access in a way tailored to domestic needs and priorities.

Patents

- Where countries lack such a mechanism, either confirm a streamlined process for authorisation of use of patented subject matter (without prior negotiation) in the event of a health emergency or for non-commercial public use, or introduce an independent scheme for government use without the need to seek prior authorisation.
- Clarify that the substantive grounds for government use or government-authorised use (such as public non-commercial use) are not limited to an emergency as such, in line with a clearer understanding of Article 31(b) of TRIPS.
- Introduce, and where already in place, streamline domestic procedures for implementing both Articles 31 and 31bis, to ensure they are as simple, efficient and transparent as possible, including through:
  - creating streamlined domestic blueprint procedures for the implementation of Article 31 and 31bis requirements;
  - avoiding procedural requirements in addition to those required by TRIPS;
  - clearly defining the respective roles of distinct authorities; and
  - ensuring that judicial review is focused and appropriate.
- Confirm or amend laws to ensure that compulsory licencing and government use authorisations, including those under domestic mechanisms to implement Article 31bis, provide for both *manufacture* and *importation*.
- To ensure a clear, codified basis for principles that may aid in R&D, technology transfer and production processes, consider incorporating into domestic patent legislation, where not already present:
  - an express *Bolar* exception; and
  - an express research exception.
- Where Members desire a policy environment that is conducive to technology transfer, consider improving patent information services to health technologies, and clarifying or updating patent disclosure obligations, such as the optional ‘best known mode’ for implementing an invention.

Copyright

- Assess and potentially review the scope of copyright protection under domestic law for copyrighted material such as product inserts that only form an ancillary element of a product that is the principal subject of production and distribution.
- Review the scope for non-voluntary government or public non-commercial use of such materials.

Designs

- Assess and potentially review the applicable domestic law on designs, including:

- a potential exclusion of designs dictated essentially by technical or functional considerations;
- a requirement of significant difference from known designs or combinations of design features;
- a limitation of protection of designs in cases of 'non-commercial use'; and
- the possible scope for non-voluntary government use of protected industrial designs, including on the basis of public health needs.

Undisclosed Information

- Assess and potentially review domestic law on undisclosed information (confidential information, knowhow or trade secrets), with a view to clarifying its application in a public health context, including with respect to:
  - disclosure, use or acquisition by government for public interest purposes;
  - liability for disclosure necessary for the transfer of essential medical technologies; and
  - implications for constitutional rules on taking of property.

Clinical Trial Data

- Review the role of clinical trial data in domestic regulatory processes, and consider possibilities for regional cooperation on, and mutual recognition of, regulatory approval.
- Assess and potentially review domestic law on protection of clinical trial data, including with regard to:
  - the scope of data exclusivity, where present in the law;
  - the possibility of government use of trial data for public or philanthropic purposes, or use in cases of public health emergencies;
  - scope for production for export, including through a special compulsory licence for export
  - trial data for pharmaceuticals produced under a compulsory licence or other NVUA;
  - substituting a requirement for the submission of regulatory test data with reliance on foreign regulatory approval, regional approval mechanisms, or WHO pre-qualification and emergency listing procedures.
- Coordinate review process with regional partners and regional and international institutions, with a view to promoting synergies, mutual learning and best practices.

7.3.2 Enhancing the administration and transparency of the IP system

Applications for IP rights are assessed, examined, granted and administered under national systems of domestic law (apart from regional mechanisms, none of which are available in the Asia-Pacific region); they are not granted and administered at the international level. Hence, achieving a beneficial balance of rights and interests under the IP system in a practical sense is not determined at the international level, but rather through domestic action, reinforced as needed by enhanced agency of domestic institutions. Hence it is critical to ensure the necessary technical capacity and human capital required for effective administration, and the necessary resources to ensure

greater transparency of granted IP rights and applications in process, and their compliance with domestic and international standards.

Recommended actions:

- Clarify and streamline procedures where necessary, both for the timely grant of IP rights and the availability of opposition procedures and applications for compulsory licensing and other interventions.
- Integrate such procedures with international systems to facilitate and support administration and transparency.
- Strengthen transparency through timely publication of applications, decisions on grant and grant of /IP rights.

7.3.3 Engaging with regional and international institutions to enhance the operation of the IP system

Clarity, accuracy and effective functioning of the IP system assists in ensuring that it delivers its intended social and economic benefits. By contrast, lack of transparency and poorly based or inconsistent decisions on the legitimacy of applications for protection potentially impede these benefits. Without encroaching on domestic regulatory autonomy, there are considerable benefits to be derived from a more cooperative approach to managing IP systems, with the support of regional and international institutions. This can proceed for mutual benefit across the region, despite diverse domestic priorities and circumstances, differences in legal systems, unique bilateral commitments, and varied IP landscapes across the region, as well as a lack of clear 'best practice' models that would assist regional convergence.

Recommended actions:

- Promote 'best practice' exchanges through regional forums and institutions including through regional and sub-regional capacity building and policy dialogue initiatives.
- Cooperate on the development of and systematic access to technological, regulatory and IP information.

7.4 Policy Area 4: Coordinated and collaborative access mechanisms

7.4.1 Regional coordination and cooperation

In the spirit of solidarity, the effective agency of national governments in leveraging immediate and sustainable access to vaccines and other medicines is enhanced in practice through regional coordination and cooperation. To achieve this entails addressing how to:

- aggregate multiple countries' demand for vaccines in order to enhance leverage and create economies of scale;
- link the use of IP options and TRIPS flexibilities to pooled or coordinated procurement; and
- make use of regional and international mechanisms to coordinate a cooperative approach.

There are potential challenges in coordinating across groups of countries in the region, and the clarity of information about the available mechanisms.

Recommended actions:

- At an early stage of procurement, notify unmet needs for vaccines (and other medicines) under TRIPS 31bis.

Coordinate notifications of need with regional partners within a pooled or coordinated procurement process (see, e.g., Box 2, Box 3, Box 5 and

- Box 6).
- Work with regional and international partners (WHO, UNESCAP, WTO) to identify and aggregate unmet needs, including through a series of practical workshops.

7.5 Policy Area 5: Use of waiver mechanisms and exceptions

7.5.1 Making use of general waivers and exceptions under TRIPS

In the event of agreement by WTO Members on a TRIPS waiver or further clarification of public interest exceptions under TRIPS, governments may wish to consider how to make use of the additional options resulting from such an outcome. To mark out the potential options would entail considering:

- specific obstacles to access and diversifying production that may be addressed by agreed waivers and exceptions under TRIPS;
- specific options available for LDCs in particular;
- how countries in the region can best coordinate their use of these options to leverage access; and
- how to deal with bilateral and regional trade agreements, and potential constitutional questions.

Making effective use of these options entails addressing the challenges of establishing or clarifying the necessary legal mechanisms under domestic law, and coordinating their use across different countries to maximise leverage, the benefits of pooled and coordinated procurement, and economies of scale.

Recommended actions:

- Establish focused regional workshops on the practical use of existing and newly identified mechanisms, to map out their potential scope and to identify means of coordinated use.
- Consider the domestic practical and legal challenges likely to be encountered in implementing various waiver mechanisms.

7.5.2 Potential future targeted, technically focussed waiver requests to overcome specific obstacles

The option of a tailored, technically-focussed waiver of specific TRIPS obligations remains a potential future option to overcome identified obstacles, either for individual Asia-Pacific countries or for groups of them in cooperation. Should the need for a targeted waiver arise, the question arises as to how to coordinate a position and progress such a request, and what solutions may be necessary to address challenges for access to therapeutics and diagnostics, on the basis of experience with the vaccine issue. Although the right to request waivers of WTO obligations plainly remains available for any Member, there are likely to be perceived political obstacles to making a further waiver proposal, as well as challenges for coordinating and presenting a common position before the WTO.

Recommended actions:

- Monitor experience with existing flexibilities, waivers and exceptions.
- Establish regional or subregional dialogues on obstacles encountered with vaccines, therapeutics and diagnostics.
- Explore this topic at future regional and subregional workshops.

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