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Intellectual Property and Vaccine Manufacturing: Utilizing Existing TRIPS Agreement Flexibilities for COVID-19 and Other Public Health Crises*

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Equitable access to COVID-19 vaccines is essential to alleviating the coronavirus pandemic's grave social and economic impact. Despite the rapid development and global increase in the production of vaccines, gross inequities are likely to continue. An effective pandemic response requires mapping current and projected future needs for vaccines and other essential health products, and diversifying their production and distribution accordingly. Some suggest that intellectual property (IP) rights protections are a significant barrier to such diversification. This article focuses on existing IP flexibilities and identifies practical options for utilizing them in increasing and diversifying the manufacture and distribution of COVID-19 vaccines. To provide inclusive, timely and pragmatic policy and legal recommendations, the article provides guidance on the full scope of flexibilities currently available across several categories of IP rights by

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contrasting the international principles established under the TRIPS Agreement with actual practice in a range of domestic jurisdictions.

I. INTRODUCTION

For most COVID-19 and other vaccine technologies, the manufacturing capacity remains highly concentrated in a handful of countries. Many attribute this inequitable and delayed distribution of vaccines, at least partly, to unevenly distributed production.[1] 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 forty-two COVID-19 vaccines subject to the World Health Organization's (WHO) emergency use listing and prequalification evaluation process include entirely novel messenger ribonucleic acid (mRNA) technologies, as well as viral vector and recombinant protein vaccines.[2] In turn, the creation of such technologies entails access to various inventions, knowhow, and regulatory data as part of a broader technology transfer process. Much of this subject matter is protected by intellectual property (IP) rights across

1. *See, e.g.*, Press Release, Economic and Social Council, Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting, U.N. Press Release ECOSOC/7039 (Apr. 16, 2021).

2. *Status of COVID-19 Vaccines Within WHO EUL/PQ Evaluation Process*, *World Health Organization* [WHO], (Oct. 21, 2022), https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_07July2022.pdf [https://perma.cc/7E3R-5SAE].

multiple jurisdictions.[3] IP content protected by copyright and industrial design rights may also be implicated. Therefore, an effective response to the COVID-19 pandemic and future potential health crises requires closely mapping the current and projected future needs of various jurisdictions, diversifying production and distribution centers accordingly, and overcoming any IP barriers to such diversification.

Governments and intergovernmental organizations have partly directed their pandemic response toward strategies for leveraging access to critical IP through a range of mechanisms, including the promotion of voluntary licensing, the creation of technology sharing platforms such as the WHO's COVID-19 technology access pool (C-TAP),[4] the implementation of humanitarian licensing programs such as the medicines patent pool (MPP),[5] targeted technology transfer initiatives, and various means to curb or remove the exclusive effect of applicable IP rights.

Two decades ago, World Trade Organization (WTO) members responded to related 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").[6] The Declaration identified several policy options or "flexibilities" open to WTO members to leverage access.[7] Faced with the current pandemic, acute concerns about potential IP obstacles have led several WTO member governments to press for a temporary waiver of certain

3. Ting-Wei Chiang & Xiaoping Wu, *Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytical Review of Medicines Patent Pool (MPP) COVID-19 Vaccines Patent Landscape (Vaxpal)*, World Trade Organization [WTO], Staff Working Paper ERSD-2022-01 (Feb. 10, 2022).

4. *WHO COVID-19 Technology Access Pool*, WHO, https://www.who.int/initiatives/covid-19-technology-access-pool (last visited Feb. 15, 2023) [https://perma.cc/HD4H-NVCS].

5. *MPP's Contribution to the Global Response to COVID-19*, MEDS. PAT. POOL, https://medicinespatentpool.org/covid-19 (last visited Feb. 13, 2023) [https://perma.cc/T9NU-9WZ8].

6. WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN (01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

7. These identified 'flexibilities' are only illustrative and not exhaustive of the potential TRIPS-compliant policy options that Members can take. WIPO has identified four clusters of TRIPS flexibilities relating to the method of implementing TRIPS obligations, substantive standards of protection, mechanisms of enforcement and areas not covered by the TRIPS Agreement. *Public Policy-Related Assistance – Flexibilities*, WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO], https://www.wipo.int/ip-development/en/policy/flexibilities.html (last visited Feb. 17, 2023) [https://perma.cc/WEK2-RKE9].

obligations under the TRIPS Agreement (TRIPS waiver).[8] 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.[9]

Importantly, many criticisms of the IP system and its implications for public health are concerned not with the principles of TRIPS itself, but rather with choices made in giving effect to those principles at the national level. Some claim that domestic procedures for implementing legitimate pro-access policy measures are overly restrictive, inefficient and bureaucratic.[10] Nevertheless, policy debate and scholarship have primarily concentrated on the international dimension. Therefore, this Article examines how real or purported IP barriers to regional COVID-19 vaccine production might be overcome using various options that address the critical shortfall in vaccine access for the current pandemic and future health needs. We use countries in the Asia-Pacific region as case studies to assess, clarify and illuminate existing IP flexibilities, while identifying practical options for utilizing these flexibilities at the domestic level, such as to increase and diversify production capacity. We attempt to provide some guidance on the full scope of flexibilities available across several categories of IP rights, by contrasting the TRIPS Agreement at the international level with actual practice in a range of domestic jurisdictions. Our analysis is intended to be comprehensive in scope and, therefore, less in-depth than if individual issues and provisions were treated in isolation. We adopt this approach to provide inclusive, timely, and pragmatic policy and legal recommendations to address the ongoing threat of current and future health crises.

8. Council for 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/669/Rev.1 (May 25, 2021); *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

9. Council for Trade-Related Aspects of Intellectual Property Rights, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic*, WTO Doc. IP/C/W/681 (June 18, 2021).

10. *See, e.g.*, Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID- 19 Pandemic* (LSE L., Soc'y & Econs., Working Papers No. 06/2021); James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, Free Trade Bulletin (Cato Institute), No. 78 (Dec. 16, 2020), https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf [https://perma.cc/QF7W-BCH8]; Poku Adusei, *Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa*, 14 J. WORLD INTELL. PROP. 1 (2011).

To ensure a concrete and pragmatic focus, we consider a representative sample of countries, including developing countries and least developed countries (LDCs): Bangladesh, Cambodia, Fiji, India, Indonesia, Malaysia, Mongolia, Nepal, Thailand, and Vietnam. We selected these countries to illustrate different economies' distinct potential roles 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.[11] Ultimately, diverse countries may have common interests in coordinated or pooled procurement and regulatory coordination or convergence to expedite and streamline regional access to vaccines.

II. TRIPS FLEXIBILITIES AND THEIR IMPLEMENTATION IN INTELLECTUAL PROPERTY LAW AND POLICY

The TRIPS Agreement, a multilateral trade agreement concluded as an annex to the Agreement Establishing the World Trade Organization, sets standards of IP protection for WTO members.[12] Unlike other WTO agreements, TRIPS primarily provides a "floor" of positive, minimum standards or general principles for how national systems protect IP.[13] These principles cover the eligible subject matter, the consequent rights, and the manner of their enforcement. In imposing these obligations, TRIPS, explicitly and implicitly, confers WTO members with some room for maneuver or flexibility, allowing them to go beyond the minimum standards imposed, while providing defined exceptions and limitations to these standards in certain circumstances.[14]

Importantly, TRIPS is not a self-executing treaty, meaning that members must give it effect by implementing the agreement through domestic laws and regulations.[15] This treaty implementation process allows members to adopt and adapt TRIPS standards to their national legal regimes and judicial and administrative systems, provided that these systems remain compliant and consistent with the treaty's more general

11. *See, e.g.*, *ASEAN Common Technical Dossier*, ASEAN (2016), https://asean.org/wp-content/uploads/2016/12/68.-December-2016-ACTD.pdf [https://perma.cc/NTG4-JLL4].
12. TRIPS Agreement, *supra* note 8, pmbl.
13. *Id.*
14. *Id.* art. 1.1.
15. *Id.* pmbl.

standards. TRIPS' inherent flexibilities are thus realized through WTO Members' national IP laws.[16]

This section examines and analyzes how the selected countries have implemented TRIPS provisions to date, so that recommendations can be made for broader use of the treaty's flexibilities to increase manufacturing capacity. 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.[17]

In adopting this interpretative framework, we employ a "practical jurisprudence" approach consistent with the VCLT's rules and principles. This approach has been developed and previously described 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."[18] As previously explained, this straightforward and objective reading of the TRIPS Agreement text enables greater legislative freedoms than an overly political or theoretical approach would otherwise allow.[19] We apply this approach in light of the practical demands created by the current global health situation.

A. 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-

16. WIPO, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, WIPO Doc. CDIP/5/4 (Mar. 1, 2010) [hereinafter *WIPO*, *Patent Related Flexibilities in the Multilateral Legal Framework*], https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-main1.pdf [https://perma.cc/X7FC-FCE5].

17. Vienna Convention on the Law of Treaties art. 26, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter Vienna Convention]; *see also id*. art. 31.3.

18. ANTONY TAUBMAN, *A Practical Guide to Working with TRIPS*, 43 (Oxford Univ. Press, 2011). The elaboration of this approach is the subject of the author's concurrent Ph.D. dissertation, which has been drawn on substantially for relevant passages of the present article: Antony Taubman, *Towards the 'Collective Management' of TRIPS* (due for conclusion in 2022 at the University of South Australia).

19. *See* TAUBMAN, A PRACTICAL GUIDE TO WORKING WITH TRIPS, *supra* note 18, at 43.

discrimination provisions) for ten years.[20] In 2015, that transition period was extended in respect of pharmaceutical products two times by the TRIPS Council before June 29, 2021,[21] when it was extended again until July 1, 2034.[22]

The LDCs in our survey and other LDCs in the Asia-Pacific—Bangladesh, Cambodia, Nepal, and Myanmar—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.[23] 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.[24] That said, manufacturing more recent vaccine technologies is considerably more complex than manufacturing 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 Articles 31 and 31*bis*, even where the imported vaccine was produced and exported under a compulsory license.

Bangladesh has diverged from TRIPS standards through its patent law, which provides patent protection for only sixteen years.[25] Bangladesh's law also allows the issue of compulsory licenses by non-government entities, and permits the cancellation of foreign patents after

20. TRIPS Agreement, *supra* note 8, art. 66.1.

21. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for the Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/73 (Nov. 6, 2015).

22. 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 (July 1, 2002).

23. Samoa and Vanuatu were LDCs on accession to the WTO but have since graduated from LDC status. *Boosting Trade Opportunities for Least Developed Countries*, WTO (2022) https://www.wto.org/english/res_e/booksp_e/boosting_trade_opportunities_for_ldcs_e_6.pdf [https://perma.cc/828K-974S].

24. *See* Mahmud-Al-Rafat et al., *COVID-19 Vaccine Inequity, Dependency, and Production Capability in Low-Income and Middle-Income Countries: The Case of Bangladesh*, 22(3) LANCET 310, 311 (2022); MUSTAFIZUR RAHMAN & SHERAJUM MONIRA FARIN, CTR. FOR POL'Y DIALOGUE, WTO DECISION ON TRIPS AND PUBLIC HEALTH: A WINDOW OF OPPORTUNITY FOR BANGLADESH'S PHARMACEUTICAL INDUSTRY 9 (2018).

25. RAHMAN & MONIRA FARIN, *supra* note 24, at 20.

four years if the product is not manufactured domestically.[26] Similarly, Nepal only grants patents with terms of seven years, and provides wider grounds for refusing to patent an invention.[27] Cambodia has availed itself of the decision to extend the transition period regarding pharmaceutical products.[28] 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.[29]

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).[30] Several acceding LDCs have entered into such "TRIPS-plus" accession commitments, creating some ambiguity as to their current obligations. However, subsequent TRIPS Council decisions have referred to extensions of the implementation period for all LDC members without qualification.[31]

B. Patents

A patent gives its owner the exclusive right to make, use or sell the invented product or process specified in the patent. Vaccines and vaccine manufacturing processes are often subject to the protection of one or more

26. Padmashree Gehl Sampath, P*harmaceutical Manufacturing in Bangladesh—A Success Story: What Can We Learn*?, 1 FEAPM ADVOCACY SERIES 22 (2019), https://strapi.eacgermany.org/uploads/5fda30fc68f07136175100_44e851ba12.pdf [https://perma.cc/U7T5-49WQ]. Some of these measures are arguably TRIPS compliant as nothing precludes patent revocation on particular grounds, including a failure to work an invention domestically.

27. 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, 1965, ch. 3, § 8 (Nepal) [hereinafter Nepalian PDTA].

28. Law on the Protection of Patents, Utility Model Certificates and Industrial Designs, 2003, art. 4 (Cambodia) [hereinafter Cambodian Patent and Designs Law].

29. *But see* Law on Compulsory Licensing for Public Health, 2018, art. 23 (Cambodia) [hereinafter Cambodian Compulsory Licensing Law].

30. Antony Taubman, *How Post-TRIPS Negotiations Reframe the 'Trade-Related Aspects' of Intellectual Property After TRIPS: The Lessons of WTO Accessions*, *in* TRADE MULTILATERALISM IN THE TWENTY-FIRST CENTURY: BUILDING THE UPPER FLOORS OF THE TRADING SYSTEM THROUGH WTO ACCESSIONS (Alexei Kireyev & Chiedu Osakwe eds., 2017).

31. *See, e.g.,* Extension of the Transition Period Under Article 66.1 for Least Developed Country Members, *supra* note 22 ("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.").

patents.[32] Thus, firms wishing to manufacture developed vaccines may encounter barriers to production where patents protect the vaccine and its production processes 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 production inputs where this occurs without the patent holder's authorization. Patents may also cover technologies and devices used to administer vaccines and technologies used for storage and delivery, so these also may need to be addressed to ensure effective vaccine access.[33]

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. This is a logical consequence of the strictly territorial scope of patents under national and regional systems.[34] Thus, most patented technology information becomes publicly available in most jurisdictions as soon as it is published, and early in the vaccine development process; generally, publication takes place eighteen months after the first filing data.[35] The key impediment to utilizing 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,[36] and a patent can be invalidated for insufficient disclosure.[37] Further knowhow is typically needed to effectively use patented technology. However, especially in the complex area of pharmaceutical technology, it may be difficult to replicate or reverse engineer detailed manufacturing know-how.

32. 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. *Patenting of Human Coronavirus Vaccines*, TABLEAU PUBLIC (last updated Nov. 26, 2022), https://public.tableau.com/app/profile/patent.analytics.hub/viz/Humancoronavirusvaccines/Vaccines [https://perma.cc/AX7F-S9TC]; *see also* Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546 (2021).

33. Hilde Stevens et al., *Vaccines: Accelerating Innovation and Access*, WIPO GLOB. CHALLENGES REP. 19 (2017), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_16.pdf [https://perma.cc/ZNQ5-6A8N].

34. *Id.*

35. 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 IP Statistics Data Center*, WIPO, https://www3.wipo.int/ipstats/ (last visited Dec. 15, 2021).

36. TRIPS Agreement, *supra* note 8, art. 29.1.

37. *Id.* art. 27.1.

In countries where a patent is in force, governments have considerable scope to override its exclusive effect in the public interest. These flexibilities are discussed in the following sections.

1. Patentability

a. 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."[38] 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.[39] 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 applying examination guidelines by patent authorities.

The threshold question is the definition of an "invention," and WTO members apply a variety of practices to ascertain what is an "invention." This includes numerous approaches to defining "invention" in inclusive terms and through exclusions of certain subject matter, including, among other things, the specific exclusions provided for expressly in Article 27 (see the following subsection).[40] A common, positive approach to defining "invention" is to refer to a solution to a problem in a technical field; by contrast, scientific principles and mere scientific discoveries are examples of common exclusions.

To some extent, the definition of "invention" is clarified further in many jurisdictions through judicial decisions. Similarly, WTO members determine specific criteria for patentable inventions through legislation and judicial decisions, by setting standards for novelty, inventive step and utility or industrial applicability.

The legislation and actual practice of countries show considerable diversity in defining and applying these terms, and in setting more general 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

38. *Id.*
39. *Id.* art. 27.1 n.5.
40. *Id.* art. 27.3.

and every new method of application of known processes and improvements in any known process."[41] Thailand includes under the definition of "invention": "any improvement of a known product or process."[42]

While often general in character, some definitions have specific applications in the pharmaceutical field, of which some have been formulated with the intention of raising the threshold for pharmaceutical patents. In particular, some definitions have been designed to curb a practice known as the '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: . . . new use of existing and/or known product; and/or . . . new forms from existing compound which does not generate significantly enhanced efficacy and contains different relevant known chemical structures to compound."[43] India's patent law excludes:

> [T]he 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.[44]

Another provision, commonly found in other countries' 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."[45] As noted elsewhere, this may provide the basis for refusing a patent over a mere vaccine composition.[46]

41. Patents Act, 1879 (Act No. 3/1879), § 2 (Fiji) [hereinafter Fijian Patent Law].

42. Patent Act B.E. 2522 [Patent Act 1979], as amended by Patent Act (No. 3) B.E. 2542 [Patent Act 1999] and Patent Act (No. 2) B.E. 2535 (1992), § 3 (Thai.) [hereinafter Thai Patent Law].

43. Law on Patents 2016, No. 13, art. 4f (Indon.) [hereinafter Indonesian Patent Law].

44. The Patents Act, 1970 (Act No. 39/1970), § 3(d) (India) [hereinafter Indian Patent Law].

45. *Id.* § 3(e).

46. *A Fair Shot for Vaccine Affordability: Understanding and Addressing the Effects of Patent on Access to Newer Vaccines*, MÉDECINS SANS FRONTIÈRES (Sept. 2017) [hereinafter *A Fair Shot for Vaccine Affordability*] https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf [https://perma.cc/Y5SX-72D9].

b. TRIPS Exclusions from Patentability

Along with general patentability criteria, Article 27 expressly sets out permissible exclusions from the scope of patentable subject matter, some of which may be relevant to pharmaceutical technologies.[47] These exclusions are optional for members and therefore provide scope for domestic policy choices.

Importantly, such exclusions do not provide for exceptional circumstances in which the rights of a patent-holder are suspended.[48] Instead, they operate as limitations on patentability *ex ante*, before a patent is granted, and hence effectively strip 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.[49]

Article 27.2 is unlikely to apply to vaccine technologies that governments and the public wish to be commercially exploited, although some jurisdictions may raise issues about the ethical basis of some biotechnologies.[50]

Article 27.3 allows members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."[51] Even if broadly construed, however, such methods 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 be limited to processes for the final administration of vaccines (should these be claimed as potentially patentable inventions).

Many members incorporate Article 27.2's terms directly into their patent legislation. For example, Cambodia's patent and industrial design

47. TRIPS Agreement, *supra* note 8, art. 27.3.

48. *Id.* art. 30.

49. *Id.* art. 27.2.

50. *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, 39, 1998 O.J. (L 213) 13 [hereinafter EU Directive 98/44/EC].

51. TRIPS Agreement, *supra* note 8, art. 27.3.

law provides that "inventions the commercial exploitation of which would be contrary to public order or morality shall not be patentable."[52] Some developing country members have incorporated the 27.3(a) exclusion of diagnostic, therapeutic and surgical methods directly into their domestic legislation.[53] India goes further by excluding from patentability "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings."[54] By excluding "prophylactic . . . treatment" from patentability, India's provision may possibly exclude methods for actual administration of vaccines, which are not expressly encompassed within the methods of treatment specified in Article 27.3.[55] 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 beings. Our survey revealed that this option of excluding treatment methods from patentability is not universally adopted by developing countries, which may reflect distinct IP policy choices around desired levels of technological innovation.

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 put the technology into effect. Patent disclosure is at the heart of the patent function: the *quid pro quo* that permits interested parties to use the patented technology in return for the patentee gaining a defined period of market exclusivity over the invention.[56] In principle, the protected technology must pass fully and effectively into the public domain. The ready availability of patent information online assists in making full use of the technology in those countries where the patent has not been applied for, typically the majority of developing countries. Thus, this mechanism can affect firms' ability to engage in technology transfer, including

52. Cambodian Patent and Designs Law, *supra* note 28, art. 9. *See also* Indian Patent Law, *supra* note 44, at § 3(b); Thai Patent Act 1979, *supra* note 42, § 9.

53. *See, e.g.*, Cambodian Patent and Designs Law, *supra* note 28, art. 4(iii); Patent Law 1993, art. 4.7.5 (Mong.) [hereinafter Mongolian Patent Law]; Patents Act, 1983 (Act. 291/1983), § 13(d) (Malay.) [hereinafter Malaysian Patent Law]; Thai Patent Law, *supra* note 42, § 9(4); Indonesian Patent Law, *supra* note 43, art. 9(b).

54. Indian Patent Law, *supra* note 44, § 3(i).

55. *See also* Thai Patent Law, *supra* note 42, § 9(4) n.36; Indonesian Patent Law, *supra* note 43, art. 4(f)(1).

56. Bingbin Lu, *Disclosure Requirements for Patent Application: Article 29 of the TRIPS Agreement and a Dimensional Exploration*, 35(4) EURS. INT'L PROP. REV. 336, 336 (2012).

enabling an early review of available technologies still undergoing development, even before exploring licensing possibilities.

Article 29 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."[57] 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."[58]

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."[59] Yet, there is evidence that, in some cases, disclosure does in practice fall short of technical disclosure, although in principle this leaves a patent vulnerable for revocation on the grounds of insufficient disclosure.[60] The word "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.[61] It is not strictly relevant for present purposes whether the words "a person skilled in the art" engenders a requirement for the disclosure to be technically or scientifically detailed, because members can go beyond the requirements in Article 29.1 by requiring more than merely a "clear and complete" disclosure.

Given the possibility of differing interpretations and applications of Article 29.1, governments can utilize 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," ensuring that the invention is properly disclosed, and when appropriate, can be properly worked.[62]

57. TRIPS Agreement, *supra* note 8, art. 29.1.

58. *Id.*

59. Siva Thambisetty et al., *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81(2) CAMBRIDGE L.J. 384, 397 (2022).

60. *A Fair Shot for Vaccine Affordability*, *supra* note 46, at 20.

61. This interpretation at the domestic level has been subject to widespread judicial and academic debate. *See generally* Lu, *supra* note 56.

62. Dale L. Carlson et al., *Patent Linchpin for the 21st Century – Best Mode Revisited*, 45 J.L. & TECH. 267, 270 (2005).

U.S. 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 . . . ."[63] 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."[64] 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."[65]

Our survey indicates that the laws of Cambodia,[66] India,[67] Malaysia,[68] Mongolia,[69] and Thailand[70] 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 is that it renders the patent invalid and open to attack and revocation, or alternatively, for the scope of the patented invention to be reduced.

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 making, using, offering for sale, selling, or importing patented products or products produced by a patented process, and from using a patented process.[71] However, these "exclusive rights" are not absolute. It is well established that they may be curtailed or overridden for the public interest or the legitimate interests of third parties, such as researchers and other firms. Articles 30, 31 and the related 31*bis*, dealt with in the following Section IIIB0, specify two broad classes of such exceptions and

63. Lu, *supra* note 56, at 337-38.

64. The Patents and Designs Act, 1911 (Act No. II of 1911) (Bangl.) § 26(h) [hereinafter Bangladesh Patent and Design Law] (the law includes insufficient specification as a ground for revocation). *See* Patent Regulations, 1986 (Act No. 327/1986) (Malay.) [hereinafter Malaysian Patent Regulations].

65. Nepalian PDTA, *supra* note 27, § 4.

66. Cambodian Patent and Designs Law, *supra* note 28, art. 18.

67. Indian Patent Law, *supra* note 44, § 10(4)(b).

68. Malaysian Patent Law, *supra* note 53, § 16.

69. Mongolian Patent Law, *supra* note 53, art. 7.3.1.

70. Thai Patent Law, *supra* note 42, § 17(3); Ministerial Regulations (No. 21) B.E. 2542 issued under Patent Act 1979 (2009) (Thai.), cl. 3(6) [hereinafter Thai Patent Regulation].

71. TRIPS Agreement, *supra* note 8, art. 28.

limitations to the rights provided for in Article 28.[72] Article 30 allows members to:

> [P]rovide 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.[73]

Similar exceptions apply for copyright-protected works, trademarks and industrial designs.[74] Article 30 has formed the basis of exceptions to patent rights in the laws of many WTO members. Some members have transposed the exact terms of TRIPS directly into their legislation. In practice, the range of specific exceptions implemented based on Article 30 has been limited to several specific categories. This subsection reviews only those most relevant to vaccine production and distribution.

a. Regulatory Review

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.[75] 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 that regulatory processes 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).[76] The Panel in *Canada—Patents* confirmed Canada's regulatory review exception was consistent with Article 30.[77] Since that finding, many WTO members have

72. *Id.*
73. *Id.* art. 30.
74. *Id.* arts. 13, 17 and 26; *see infra* Sections IIID-C.
75. TRIPS Agreement, *supra* note 8, art. 28.
76. *Id.* art. 30
77. *See generally* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (Mar. 17, 2000).

implemented this exception, including the EU, which had originally challenged its TRIPS-compliance.[78]

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. Particularly, 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. However, it only comes into play when a domestic regulatory authority is requesting data based on use of the patented technology during 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 that a domestic producer wishes to manufacture; and no other flexibilities have or will be utilized to provide the local producer with access to relevant IP in the invention before the patent term expires.

The *Bolar* exception is widely implemented across the WTO membership, but less so amongst the countries surveyed here.[79] 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 preferable for such an exception to be framed expressly in patent legislation.

b. Research and Other Exceptions

Other exceptions accepted as being generally permissible under Article 30 (depending on their scope and parameters) include private, non-commercial use; prior use (the continued use of an invention initiated or secreted before 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).[80]

However, the most significant for access to medicines are exceptions for research and analysis, and for pharmacists to make up prescribed medicines. It is generally accepted that researchers can use a patented invention for investigation, study, and experimentation, including for

78. *See generally id*.

79. *See, e.g*., Fijian Patent Law, *supra* note 41; Indian Patent Law, *supra* note 44; Malaysian Patents Act, *supra* note 53; Thai Patent Law, *supra* note 42.

80. A HANDBOOK ON THE WTO TRIPS AGREEMENT 47 (Antony Taubman et al., eds., 2020).

determining whether the invention actually produces the results claimed for it, provided this stops short of commercial exploitation.[81] 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, 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 does not apply to large-scale vaccine production and distribution.[82]

The research exception has been expressly implemented in the laws of several of the countries surveyed.[83] However, such an exception may be allowed by the courts based on the broader 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 provide clarity and confidence to those seeking to make use of this legitimate option and avoid the uncertainty and delay of litigation.

Thailand's patent law provides express exceptions for "any act for the purpose of study, exploration, experimentation or research, provided that it does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner" and "the compounding of a drug specifically to fill a doctor's prescription by a professional pharmacist or medical practitioner."[84]

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 to override or curtail the exclusive effect of legitimate patent rights in the public interest, and in particular to protect public health.[85] This includes an array of legal measures to authorize 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 licenses' (and are

81. *See, e.g.*, 35 U.S.C. § 271(e).

82. *See generally*, TRIPS Agreement, *supra* note 8, art. 31 (describing compulsory licenses).

83. *See, e.g.*, Mongolian Patent Law, *supra* note 53, art. 18.2.2; Indian Patent Law, *supra* note 44, § 47(3); Indonesian Patent Law, *supra* note 43, arts. 6(1)(b), 19(3); Thai Patent Law, *supra* note 42, § 36(1).

84. Thai Patent Law, *supra* note 42, § 36(2)-(3).

85. *See* TRIPS Agreement, *supra* note 8, art. 8.

referred to as such in the Doha Declaration).[86] In some contexts, however, this term has created the impression that governments' options are more limited than they are. Therefore, such interventions may be more broadly and descriptively termed 'non-voluntary use authorizations' (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."[87]

Compulsory licenses and other NVUAs can be issued on various grounds and for various policy reasons. 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 the 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.[88]

These mechanisms have been advocated where the pricing of 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,[89] an effect that has been extensively studied in relation to HIV/AIDS treatments since the time of the Doha Declaration.[90] Moreover, some have suggested that compulsory licenses can and should be used to incentivize (or pressure) patent owners to voluntarily license their inventions at reasonable prices.[91]

However, compulsory licensing may also be used to allow third parties to manufacture or import a product where the original patentee

86. *See* Doha Declaration, *supra* note 6, ¶ 5.

87. Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 932 (2008).

88. Doha Declaration, *supra* note 6, ¶ 5.

89. WIPO, *Draft Reference Document on the Exception Regarding Compulsory Licensing*, WIPO Doc. SCP/30/3 para. 220 (May 21, 2019) [hereinafter WIPO, *Draft Exception Regarding Compulsory Licensing*], https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf [https://perma.cc/9T7S-83GA].

90. Ellen 't Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14(1) J. INT'L AIDS SOC'Y 15, 5-6 (2011).

91. JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 328 (Kluwer Law Int'l, 2001); Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1, 1-2 (2020).

refuses to license it voluntarily, at least in those circumstances where refusal to license is viewed as anti-competitive in character, or where there are other grounds for overriding the exclusive effect of the patent, such as public health interests.[92] Compulsory licensing in such cases is an effective way of expanding manufacturing capacity beyond the originator firm's production chain—not necessarily to introduce competition and lower-priced medicines into the market, but to maximize 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)).

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

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

Thus, in some contexts, 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 license), or a more general authorization rather than a license as such. 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.

92. Wong, *supra* note 91, at 1-2.

a. Article 8 and the Doha Declaration in Context

The policy context for developing and actually implementing NVUAs in the public health domain is partly framed by TRIPS itself and the Doha Declaration. Negotiators were fully conscious of the need to safeguard domestic policy space, and, to that end, confirmed through Article 8 of TRIPS that, among other things, "[m]embers 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."[93]

The Doha Declaration further illuminated several aspects of this vital policy space and set it in a practical context. For instance, it confirmed that each member government "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[94] While the term "compulsory license" is not defined or clarified further in the Declaration—and is not expressly limited to patent rights as such—this clarification undoubtedly 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."[95] 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).[96] Rather, it is a procedural matter, concerning the situations in which governments can do away with a requirement for a potential user to first seek a voluntary license from the patent holder. The significance for streamlined domestic practice is further discussed below.

b. The Doha Declaration and Article 31*bis*

Paragraph 6 of the Doha Declaration recognizes the problem of members with insufficient or no manufacturing capacities in the pharmaceutical sector making effective use of compulsory licensing.[97] A

93. TRIPS Agreement, *supra* note 8, art. 8.1.
94. Doha Declaration, *supra* note 6, ¶ 5(b).
95. *Id.* ¶ 5(c).
96. *Id.* ¶ 5(b).
97. *Id.* ¶ 6.

country with the necessary domestic capacity could supply its needs through its own production under a compulsory license. But some countries are dependent on imports, and thus would need to import under a compulsory license. This was already possible to do under TRIPS, as NVUAs could be issued for importation as well as for domestic production.[98] However, if a country wished to *import* generic medicines produced under a compulsory license, that would require an additional 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 license be "predominantly for the supply of the domestic market," ruling out a compulsory license predominantly for export.[99]

The solution found was to create a new category of NVUA: a special compulsory license for production for export, to address needs identified by countries without their own production capacity. This ultimately led to the inclusion of a new Article 31*bis* and annex into TRIPS. This amendment entered into force in 2017, following formal legal acceptance by two-thirds of the membership.[100] It provides for a compulsory license to be issued expressly for export to respond to unmet needs identified by eligible countries.[101] The operation of this special compulsory licensing system and options for its more effective use are discussed below.

c. Political and Industry Pressure: Bolstering National Government Agency

In the course of debate over the pandemic response (including in the WTO TRIPS Council), some governments have raised concerns that, even when taking legitimate, TRIPS-compliant measures, they may be subject to political and economic pressure by major trading partners and the private sector. For instance, Pakistan has referred to "reports . . . [that] pharmaceutical companies are lobbying with their governments to impose sanctions to countries that adopt compulsory license[s]."[102] South Africa has maintained that the availability of TRIPS flexibilities "is not a reality

98. *Id.*
99. TRIPS Agreement, *supra* note 8, art. 31(f).
100. *Id.*
101. *Id.*
102. Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held on March 10-11 2021*, WTO Doc. IP/C/M/98/Add.1, (July 30, 2021), at 32.

for many developing countries, [since] whenever such flexibilities are invoked, political and other sanctions are used to counter such efforts."[103]

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

Dealing with such pressures is inherently a broader political matter beyond the formal scope of agreed international legal standards and the formal means for resolving differences.[104] Yet, this concern has been a consistent thread throughout both the recent debate about the pandemic response and the negotiation and implementation of the TRIPS Agreement:

> [T]he 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.[105]

This concern has arisen consistently about prospective or actual uses of NVUAs that override patent rights to leverage access to pharmaceuticals.[106] Therefore, it is no coincidence that this was one of the few specific flexibilities expressly addressed in the Doha Declaration, not least given misconceptions at the time that "compulsory licensing" was in

103. *Id.* at 37.

104. The analysis in this section is drawn from Antony Taubman, *A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policymakers*, 4 THE OPEN AIDS J. 4-24 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878976/pdf/TOAIDJ-4-4.pdf, and that author's current Ph.D. dissertation.

105. Antony Taubman, *Negotiating "Trade-Related Aspects" of Intellectual Property Rights*, *in* THE MAKING OF THE TRIPS AGREEMENT PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 15, 37 (WTO, 2015).

106. *See Analysis of Communications from the European Union to the Council for TRIPS, Médecins Sans Frontières* (June 24, 2021) [*hereinafter Analysis of Communication from the EU to the Council]*, https://msfaccess.org/sites/default/files/2021-06/COVID19_TechnicalBrief_MSF_EU-counterproposal-analysis_WTO-TRIPS-Waiver_update_20210624_ENG.pdf [https://perma.cc/GT7U-86EY]; Ellen 't Hoen & Pascale Boulet, *The EU Proposed Covid Waivers of Certain TRIPS Rules Are Mostly Meaningless*, MEDS. L. & POL'Y (Oct. 14, 2021), https://medicineslawandpolicy.org/2021/10/the-eu-proposed-covid-c-waivers-of-certain-trips-rules-are-mostly-meaningless/ [https://perma.cc/KJ9R-YHJG].

some sense illegitimate.[107] Thus our analysis of various options concerning Articles 31 and 31*bis* should also illuminate possibilities for guiding both domestic choices and coordinated regional responses that entail the robust and empowered use of existing options.

The critical need for strengthened agency by national governments in addressing the IP dimension of enhanced and sustainable vaccine production is a key element in this regard. National governments' agency in this sense can be analyzed 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);
- confidence to take choices that may attract criticism and political pushback; and
- administrative and legislative capacity to deploy choices in an effective and expeditious manner.

The critical aspect of reinforcing national government agency can be illustrated by practical examples, elaborated upon in more detail below, concerning the difficulties reported in making use of NVUAs under existing laws.[108] 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 authorized use of the patent subject matter in a timely manner; and severely limiting assumptions regarding scope and nature of actual authorizations, such as the assumption that authorizations must be in the form of single, "case-by-case" compulsory licensing of individually identified patents.[109]

None of these obstacles result from the TRIPS Agreement itself, and addressing them practically and objectively would shed light on mechanisms for making use of the greater scope for domestic agency that would be available under current TRIPS provisions.

107. *See generally* Doha Declaration, *supra* note 6.

108. *See also* Taubman, *Rethinking TRIPS*, *supra* note 87, at 932.

109. *See* WIPO, Draft Reference Document on the Exception Regarding Compulsory Licensing, SCP/30/3, 31 (May 21, 2019).

d. 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 authorization that is addressed by Articles 31 and 31*bis*.

Before 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 license, thus bypassing the requirement in Article 31(f) that the authorized use be predominantly for the supply of a member's domestic market.[110] That argument is now seen to rely on too broad an interpretation of Article 30, especially in view of *Canada—Patents*.[111]

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.[112] 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 the various forms of NVUA discussed above, which are of a kind that would not ordinarily satisfy the requirements of Article 30. This implicit recognition that these various forms of NVUAs would not ordinarily satisfy 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, because of the inherently prejudicial nature of compulsory licensing, TRIPS negotiators felt the need to introduce peculiarly adapted rules in Articles 31-31*bis* for utilizing this form of unauthorized use—rules that are accompanied by their own specific exceptions.[113] Thus the

110. 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?*, 7(1) J. INT'L ECON. L. 73 (2004); *see, e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, *Concept Paper Relating to Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health*, WTO Doc. IP/C/W/339 (Mar. 4, 2002); Council for Trade-Related Aspects of Intellectual Property Rights, *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/C/W/355 (June 24, 2002).

111. Matthews, *supra* note 110, at 90; *see also* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, *supra* note 77.

112. *See, e.g.*, TRIPS Agreement, *supra* note 8, art. 31 n.7.

113. *See, e.g.*, *id.* arts. 31(b), (k).

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.[114] However, they may—and ideally should—be viewed in a complementary way as part of a more systematic approach to TRIPS flexibilities to address public health needs.

The first avenue for pursuing large-scale production of medicines without the right holders' authorization, 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 procedures, aggregating demand to build economies of scale, and using complementary options to address regulatory processes. This is not to diminish the potential role and impact of waivers, future amendments or clarifications of TRIPS provisions. On the contrary, analyzing the full scope of application of Articles 31 and 31*bis* may directly illuminate the contours of the additional possibilities under these options, to more effectively diversify and build production capacity.

Given the widely expressed concerns that NVUA mechanisms are unduly cumbersome and thus unworkable,[115] 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 guidance from domestic practice across the Asia-Pacific region.

e. Making Full Use of NVUAs

The Doha Declaration has affirmed members' rights to determine the grounds for NVUAs, leaving their legitimacy as policy tools, especially during a public health crisis, beyond any reasonable challenge. As our survey demonstrates, members have specified a wide range of grounds in their domestic systems.[116] Hence, rather than a form of model law or prescribing a specific legal mechanism, TRIPS Agreement provisions on NVUAs can essentially be conceived as procedural

114. Andrew D. Mitchell & Tania Voon, *Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law*, 43(3) J. WORLD TRADE 571, 575 (2009).

115. *See, e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, *Responses to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671*, WTO Doc. IP/C/W/673 (Jan. 15, 2021), at 44-45. *See also* Behrang Kianzad & Jakob Wested, *No-One Is Safe Until Everyone Is Safe' – Patent Waiver, Compulsory Licensing and COVID-19*, 2 EUR. PHARM. L. REV. 71, 83-84 (2021).

116. *See, e.g.*, TRIPS Agreement, *supra* note 8, art. 31 n.7.

safeguards that are set out broadly and flexibly and aimed at ensuring due process and an equitable balance.

Compulsory licensing and government use authorizations in line with Article 31 have generally been used in the field of pharmaceuticals. However, their use in practice has been relatively infrequent even in this priority area.[117] Almost all jurisdictions provide in some way for compulsory licensing 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 nations, Thailand has used it seven times,[118] Malaysia twice,[119] Indonesia twice,[120] India once,[121] Mongolia once, Taiwan once, and Pakistan once. While some countries have amended their compulsory licensing laws since the pandemic began,[122] our survey reveals that some Asia-Pacific countries maintain compulsory licensing and procedures that are unnecessarily burdensome or limited in scope, in light of what is required by Article 31. Notably, Fiji and Nepal lack altogether a compulsory licensing regime, which means that these countries—despite offering patents in their jurisdiction—have no legal basis for issuing compulsory licenses or streamlined processes for utilizing Article 31*bis* as importers.[123] However, Fiji has before its Parliament a bill that would introduce both forms of NVUA: a compulsory license available upon application to a court (including for export in line with TRIPS Article 31*bis*), and a "state use" provision that

117. *See also Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic*, SOUTH CENTRE (2021), https://www.southcentre.int/wp-content/uploads/2021/03/Compulsory-licenses-table-Covid-19-2-March.pdf [https://perma.cc/2LPY-A6GL].

118. Siraprapha Rungpry & Edward J. Kelly, *Compulsory Licensing Developments in Thailand*, ASIA L. IP REV. 16, 2 (2008).

119. *A Comparison of Patent Law Developments*, ASIA BUS. L.J.: HEAD 2 HEAD (Oct. 4, 2021), https://law.asia/comparison-patent-law-developments/ [https://perma.cc/D3HA-WBYV].

120. The Indonesian government issued licenses in respect of seven HIV drugs in 2012. Chang-fa Lo, *Compulsory Licensing: Threats, Use and Recent Trends*, *in* CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS 144, 157 (Bryan Merucrio & Daria Kim, eds., 2017).

121. Raju KD, *Compulsory Licensing Provisions to Deal with Access to Patented Medicines in India*, 6 NUALS L.J. 8, 8 (2012), https://nualslawjournalcom.files.wordpress.com/2019/04/2592012_nuals_law_-journal-.pdf [https://perma.cc/G4E2-9DNL].

122. Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19-Responses to Questions*, WTO Doc. IP/C/W/672 (Jan. 15, 2021); *The European Union's Position on Compulsory Licensing and the TRIPS Waiver in the COVID-19 Pandemic*, MÉDECINS SANS FRONTIÈRES (May 2021) [hereinafter EU's Position on Compulsory Licensing and the TRIPS Waiver], https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF-AC_EU_CL_briefing-doc_ENG_May2021.pdf [https://perma.cc/Y5VF-7H4Q].

123. *See* Fijian Patent Law, *supra* note 41.

addresses the public interest and covers both patent applications and granted patents.[124]

Analysis of the practical use of NVUAs should take account of the practical reality that there are relatively few patents in force in any field of technology.[125] For such jurisdictions, a technology patented elsewhere is likely to enter the public domain upon publication (illustrates the relative rates of patent grants since 2000 in the general field of preparations for medical, dental, or toilet purposes, IPC A61K).

Figure 1. Word cloud of patents granted in the medical field (IPC A61K) since 2000. *Source:* lens.org

f. Grounds for Authorization

The substantive grounds for issuing a compulsory license are left open in the TRIPS Agreement, meaning that a government can provide any number of bases for the authorization of non-voluntary use.[126] Some of the countries surveyed here provide for only a few grounds.

The most common ground specified is a failure to work the invention in the relevant country's territory.[127] Another common ground is where

124. Patents Bill, 2020 (Act No. 46/2020) (Fiji) [hereinafter Fijian Patents Bill].

125. *See also* Taubman, *Rethinking Trips*, *supra* note 87, at 932.

126. Doha Declaration, *supra* note 6, ¶ 5(b); *see also* Taubman, *Rethinking Trips*, *supra* note 87, at 932; WTO Secretariat, *The TRIPS Agreement and COVID-19*, WTO 9 (Oct. 15, 2020) [hereinafter WTO Secretariat, The TRIPS Agreement and COVID19], https://www.wto.org/english/tratop_e/covid19_e/trips_report _e.pdf [https://perma.cc/5ELB-Q8NT].

127. *See, e.g.*, Malaysian Patent Law, *supra* note 53, art. 49(1)(a); Indian Patent Law, *supra* note 44, art. 84(1)(c); Cambodian Patent and Designs Law, *supra* note 28, art. 56.

demand is not being met, or not being met on reasonable terms.[128] Some countries adopt legal tests to determine such "reasonable terms."[129] For example, the UK Intellectual Property Office adopts a four-step test that takes account of: the nature of the invention; any licenses' terms under the patent; the patentee's expenditure and liabilities related to the patent; and the requirements of the purchasing public.[130] Such fact-dependent tests may reduce the likelihood or certainty that a compulsory license 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 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 other emergency circumstances are only present in the domestic patent laws of Cambodia, India, Indonesia, Malaysia, Mongolia, Thailand, and Vietnam.[131] Some countries, such as Malaysia and Thailand, include a public interest or national emergency ground in their laws by incorporating Article 31(b).[132] 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 license as a precondition to granting a compulsory license (other than in emergency or public use contexts).[133] Still, Correa maintains that a refusal "can [also] be . . . an *autonomous* ground for granting a compulsory license."[134]

128. Bangladesh Patent and Design Law, *supra* note 64, art. 22(1); Indian Patent Law, *supra* note 44, art. 84(7).

129. Johnathon Liddicoat & 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*, 4 INTELL. PROP. Q. 245, 249 (2021).

130. *Id.*

131. Cambodian Patent and Designs Law, *supra* note 28, 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"); Indian Patent Law, *supra* note 44, arts. 84(1)(a), 84(2); Indonesian Patent Law, *supra* note 43, art. 82(1); Malaysian Patent Law *supra* note 53, art. 84(1); Mongolian Patent Law, *supra* note 53, art. 20; Thai Patent Law, *supra* note 42, §§ 51, 52; Law on Intellectual Property, arts. 133, 145 (No. 50/2005/QH11) (Viet.) [hereinafter Vietnamese Intellectual Property Law].

132. Malaysian Patent Law, *supra* note 53, art. 84; Thai Patent Law, *supra* note 42, arts. 51, 52.

133. TRIPS Agreement, *supra* note 8, arts. 31(b), (k).

134. Carlos M. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 227, 243 (Keith E. Maskus & Jerome H. Reichman, eds., 2005).

Refusal to license on reasonable terms is expressly set out as a ground for compulsory licensing in the laws of a number of countries, and may also be the basis of a finding of anti-competitive practice that a compulsory license could remedy.[135]

Of the countries surveyed, only India's and Vietnam's laws expressly provide for this ground.[136] It is also identified as a potential ground of abuse within India's anti-competition provisions relating to abuse of dominant position.[137] It may also be said to appear in the form of some countries' ground of "demand not being met on reasonable terms."[138] In any case, including this ground explicitly is likely to furnish countries with greater options for implementing Article 31 at the domestic level. However, this approach should be tempered by the view that there is no fundamental or unconditional obligation on a patent holder to refuse a license, the legitimate exercise of exclusive rights being seen as central to the economic function of patent rights.[139]

g. Forms of Authorization

Article 31 is carefully framed to give scope for a diverse range of measures within domestic legal systems. Rather than prescribing any specific mechanism, 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 of the right holder, including use by the government or third parties authorized by the government."[140] 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 authorization to

135. *See, e.g.*, WIPO Secretariat, *Refusals to License IP Rights – A Comparative Note on Possible Approaches*, WIPO ¶ 18 (Aug. 2013), www.wipo.int/export/sites/www/ip-competition/en/studies/refusals_license_IPRs.pdf [https://perma.cc/QT9D-PS5R].

136. Indian Patent Law, *supra* note 44, art. 84(7)(a); Vietnamese Intellectual Property Law, *supra* note 131, art. 145(c) ("Where the person who wants to use the invention fails, in spite of efforts made after a reasonable time for negotiation on adequate price and commercial considerations, to reach an agreement with the holder of exclusive right to use invention upon the conclusion of a license contract for use of invention.").

137. 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* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY 517, 607 (Robert D. Anderson et al., eds., 2017).

138. *Id.*

139. *See* WIPO Secretariat, Refusals to License IP Rights, *supra* note 135.

140. TRIPS Agreement, *supra* note 8, art. 31.

infringe identified patent rights.[141] 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.[142]

Thus, it is plainly envisaged that a government may authorize 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 concerning 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 patent.

However, neither is the case. No 'compulsory license' application is required in such circumstances. The context in which an application may be required from a practical perspective is when a private firm wishes to use a patented technology in a *commercial* context and encounters a patent barrier. In that case, the firm concerned will naturally have clear information about the possibility of a patent barrier and will have investigated how to ensure it can exploit the invention freely. Should a private firm not seek a compulsory license, because it was unaware of applicable patents, allegations of patent infringement may arise (although, as discussed below, the TRIPS Agreement does not mandate that injunctive relief must be available in such circumstances).[143]

Our survey demonstrates that many governments have reserved the right to authorize the use of patented subject matter, separately from any distinct application by a third party.[144] 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."[145] Similarly, Indonesia's laws authorize "the government itself" to exploit a patent (including through

141. *Id.*

142. *Id.* art. 31(b).

143. Cambodian Patent and Designs Law, *supra* note 28, art. 47.

144. *See, e.g.*, Industrial Property Act, 13(5)(a), 1994 (Act No. 19/1994) (Tonga) [hereinafter Tongan Industrial Property Act].

145. Cambodian Patent and Designs Law, *supra* note 28, art. 47.52

authorization of a third party) "[i]n case that the government is in the opinion that a patent in Indonesia is very important for state defense and security" or "there is an urgent need for the public interest of a patent."[146] 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.[147] 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 owner of the patent . . . is anti-competitive."[148]

h. "Individual Merit": Article 31(a)

Article 31(a) requires that the "authorization of such use shall be considered on its individual merits . . ."[149] 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, thus posing a potential obstacle to the expeditious use of options under Articles 31-31*bis*.[150] However, Article 31(a) very clearly requires that each authorization to use "*the subject matter of a patent*" be considered on its individual merits, rather than each authorization to infringe a patent as such.[151] Any alternative reading would be inconsistent with the general nature of government-authorized use discussed immediately above. Thus subparagraph 31(a) leaves scope for approval relating to a package of technology (which may entail multiple patents held by distinct owners) and for multiple authorized users. A government body issuing a compulsory license or use order need only authorize 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 a particular subject matter or industry.[152] Still, it

146. Regarding the Procedure of Exploitation of Patent by the Government (Indon.) arts. 2(1)-(3) [hereinafter Indonesian Patent Regulation].

147. Malaysian Patent Regulations, *supra* note 64, art. 33b(5).

148. Malaysian Patent Law, *supra* note 53, § 84(1)(a)-(b).

149. TRIPS Agreement, *supra* note 8, art. 31(a).

150. *See, e.g.*, Council for Trade-Related Aspects of Intellectual Property Rights, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19-Responses to Questions, WTO Doc. IP/C/W/672 (Jan. 15, 2021), at 3; Lo, *Compulsory Licensing: Threats, Use and Recent Trends*, *in* CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS, *supra* note 120, at 151.

151. TRIPS Agreement, *supra* note 8, art. 31(a) (emphasis added).

152. A HANDBOOK ON THE WTO TRIPS AGREEMENT, *supra* note 80, at 112.

nevertheless entitles a government directly to authorize the production of a specified vaccine in a single step, regardless of the potential complexity of the patent landscape. This is presumably the most important kind of authority for governments seeking to increase the availability of vaccines or other identified COVID-related technologies.

We adopt this interpretation for several reasons, beginning with the text of TRIPS itself. When considered together, the opening of Article 31 and subparagraph 31(a) reads: "Where the law of a Member allows for other use . . . authorization of such use shall be considered on its individual merits."[153] 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 authorize a particular person or persons to use an invention.[154] Thus, subparagraph 31(g) refers to "*persons* so authorized."[155]

Secondly, as explained above, Article 31 does not formally frame a specific form of "compulsory license" *per se.* Instead, it sets out principles that govern any NVUA of patented subject matter, beyond the exceptions covered by Article 30.[156] Thus, nothing in TRIPS precludes a government from allowing a particular patented invention to be used generally, without authorization of the patent holder, provided those principles are followed. Equally, it is clear that authorizations 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 powers and functions.[157]

The reference to "proposed user" in Article 31(b) does not stop multiple proposed users from each making efforts to obtain authorization.[158] 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 based on economic value of the authorization, even where that authorization applies to multiple uses.[159]

This interpretation has implications for the way that Article 31*bis* might be utilized 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

153. TRIPS Agreement, *supra* note 8, art. 31(a).
154. *Id.*
155. *Id.* art. 31(g) (emphasis added).
156. *Id.* arts. 30-31.
157. *Id.*
158. *Id.* art. 31(b).
159. *See id*. art. 31(e)-(h).

of a compulsory license permitting exportation to more than one market in certain circumstances, a group of importing members can coordinate to issue compulsory licenses covering their distinct national jurisdictions for patented technology to be imported and used by any number of third parties or government bodies.[160]

i. Prior Efforts to Obtain Authorization: Article 31(b)

i. Limitation to Use in a Commercial Context

Under Article 31, TRIPS sets requirements for a proposed user of patented technology to first seek authorization from the right holder "on reasonable commercial terms and conditions," and those efforts must "have not been successful within a reasonable period of time."[161] 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 authorization "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[162] The global pandemic is unquestionably a national emergency and circumstance of extreme urgency. In any event, the Doha Declaration clarifies that "[e]ach 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."[163] In the context of a pandemic response, there is no requirement to seek prior approval from a patent holder to produce vaccines without their authorization. This requirement in domestic laws could be relaxed while remaining TRIPS-consistent.

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.[164] This is hardly a complex procedural step, however, compared with the complexity of

160. In this regard, art. 31*bis*.3 clarifies that the regional mechanism provided for in arts 31*bis*.2 and .5 of the TRIPS Annex does "not prejudice the territorial nature of the patent rights in question."

161. TRIPS Agreement, *supra* note 8, art 31(b).

162. *Id.*

163. Doha Declaration, *supra* note 6, ¶ 5(c).

164. TRIPS Agreement, *supra* note 8, art. 31(b).

establishing a new production line and clearing regulatory and good manufacturing standards for a new production of vaccines.

ii. 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 where a country has not waived the requirement to seek the patent holder's authorization. The terms "reasonable terms and conditions" and "reasonable period of time" have naturally become subject to differing interpretations.[165] However, this general principle provides members with sufficient flexibility to implement their own standards and mechanisms for determining what those standards might be in particular cases.[166] Countries can designate a shorter time period than an *ad hoc* or case-by-case application of "reasonable period of time" may allow.[167]

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 authorization have been unsuccessful has been defined variably.[168] Cambodia specifies twenty-one working days.[169] India specifies six months, but merely includes the requirement of unsuccessful efforts within a "reasonable period time" as a factor to be considered in determining whether a license should be granted.[170] At the highest end of the spectrum, Indonesia specifies twelve months.[171] It would increase certainty over the grant of a compulsory license to make unsuccessful efforts a standalone requirement but reduce the relevant time period (e.g. in terms of days, rather than months).

The terms "as soon as reasonably practicable" may be contrasted with the term "promptly," the latter imposing a slightly less stringent and

165. Lo, *Compulsory Licensing: Threats, Use and Recent Trends*, *in* CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS, *supra* note 120, at 151.

166. Mitchell & Voon, *supra* note 114, at 576.

167. *Id.*

168. Roger Kampf, *Special Compulsory Licenses for Export of Medicines: Key Features of WTO Members' Implementing Legislation* at [10] (WTO: Econ. Rsch. & Stats. Div., Staff Working Paper ERSD-2015-07, 2015).

169. Cambodian Patent and Designs Law, *supra* note 28, art. 9. 29

170. Indian Patent Law, *supra* note 44, § 84(6)(iv)-(v).

171. Indonesian Patent Regulation, *supra* note 146, art. 84(1).

longer time period.[172] 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 license. This notice may also be given concurrently with the notice required by importing members under Article 31*bis*/TRIPS Annex System (discussed below).[173]

Even after the Doha Declaration and the insertion of Article 31*bis*,[174] 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.[175] 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 neighboring country.[176] 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.[177] Although this does not itself clarify the territorial scope of "national emergency" for 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.[178]

Significantly, some countries (including developed nations) have omitted the exception to Article 31(b) from their domestic legislation

172. Lo, *Compulsory Licensing: Threats, Use and Recent Trends*, *in* CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS, *supra* note 120, at 149.

173. TRIPS Agreement, *supra* note 8, Annex.

174. *See* General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (Aug. 30, 2003), ¶ 9 (stating that the decision does not prejudice the interpretation of TRIPS, except for Articles 31(f) and (h)).

175. Mitchell & Voon, *supra* note 114, at 582.

176. TRIPS Agreement, *supra* note 8, at Annex, ¶ 1(b).

177. *See also* World Trade Organization, Ministerial Decision of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2 (2001).

178. Mitchell & Voon, *supra* note 114, at 582-83.

altogether.[179] However, all the countries surveyed with a compulsory license 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 authorization. These countries should maintain these carve-outs in their laws to ensure they can effectively use the flexibilities in Article 31(b).

j. Minimum Time Period From Patent Grant

Some domestic laws require the expiration of a particular time period before a compulsory license can be sought.[180] This feature in domestic legislation results from a requirement in the Paris Convention that a compulsory license 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.[181] However, some countries have superimposed this requirement on all compulsory licenses, regardless of the ground relied upon.[182]

Some laws impose this requirement, but appropriately limit it to compulsory licenses sought on the basis of a failure to work.[183] In such cases, a government use or emergency use authorization can be issued at any time after the patent grant.

k. 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 impose a general time limit on the compulsory license term.[184] 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

179. Liddicoat & Parish, *supra* note 129, at 254.

180. *See, e.g.*, Cambodian Patent and Designs Law, *supra* note 28, art. 56; Indian Patent Law, *supra* note 44, at § 84.

181. Paris Convention for the Protection of Industrial Property art. 5A(4), Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S 305 [hereinafter Paris Convention].

182. *See, e.g.*, Tongan Industrial Property Act, *supra* note 144, at § 13(5)(a).

183. *See* Indonesian Patent Law, *supra* note 43, art. 83(2) (clarifying that a request for a license on grounds of harm to the public interest "may be submitted at any time after a Patent is granted"); *see also* Malaysian Patent Law, *supra* note 53, §§ 49(1), 84; Mongolian Patent Law, *supra* note 53, art 20; Thai Patent Law, *supra* note 42, §§ 46, 51, 52.

184. Emily Ng & Jillian Clare Kohler, *Finding Flaws: The Limitations of Compulsory Licensing for Improving Access to Medicines – An International Comparison*, 16(1) HEALTH L. J. 143, 159 (2008).

particular predetermined timeline.[185] Doing so may jeopardies the possibility of such purpose being fulfilled. For example, a compulsory license issued to address critical public health needs may be less effective where its term is limited but the circumstances giving rise to the need for the license remain uncertain, such as a pandemic. Thus, members should ensure that the scope and duration of any relevant authorization is tied at least to the exigencies of the pandemic, and not a predetermined time limit.[186]

However, it should be noted that members are not limited to authorizing use specifically to address a 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 authorization is limited to addressing a particular health crisis because the member has, in seeking to conform with the parameters of Article 31(b), issued the compulsory license 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 authorization.

One issue relevant to laws authorizing the issue of a compulsory license, rather than the scope of individual licenses, is that some developing countries only authorize compulsory licenses for manufacture, not importation.[187] This could create a barrier to effective use of the Article 31*bis* system because it could preclude an importing member from issuing a compulsory license for importation under the system.

l. Predominantly for the Supply of the Domestic Market: Article 31(f)

The requirement that the use be authorized predominantly for the supply of the domestic market of the member authorizing the use previously meant that a country with little or no manufacturing capacity could not receive pharmaceuticals produced and imported under a

185. TRIPS Agreement, *supra* note 8, art. 31(c).

186. *See* Kampf, *supra* note 168, at 8 (examining key features in select WTO members' implementing measures).

187. Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 3 INT. J. HUM. RTS. 25, 32 (2005).

compulsory license in another country that did have such capacity.[188] Article 31*bis*, discussed in section III.B.5 below, now addresses this issue.

For certain key pharmaceutical-producing countries, Article 31(f) is less restrictive than it may appear, especially concerning a public health crisis affecting many countries rather than a single jurisdiction. A government would rarely prioritize servicing the vaccine needs of foreign nationals over their nationals; the practical experience of the pandemic supports this, where it is generally perceived as imperative that production be reserved primarily for domestic needs. Hence, government-led or government-authorized efforts to ramp up domestic vaccine production are 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 authorize production of a vaccine or other pharmaceutical predominantly for its domestic needs, and for that production also to be authorized for distribution to all other South Asian nations (with a combined population of 470 million) and all ASEAN nations (with a combined population of 660 million). There would be no need to consider alternatives to Article 31(f) because the non-predominant proportion of India's production would be for the supply of foreign markets.

m. Continued Existence of Circumstances Which Led to Authorization: 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."[189]

This provision does not require that the authorization 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" and the proviso

188. This would be the case where a "predominant" proportion of the demand for the product was from other Members rather than the domestic market.

189. TRIPS Agreement, *supra* note 8, art. 31(g).

that a review of the continued existence of the relevant circumstances be brought at the instigation of some party.[190] This provision's application to the pandemic is difficult to estimate, but the pandemic circumstances are likely to continue for some time. It is also noteworthy that members need not provide persons with the ability to petition a *variation* of the authorization whenever circumstances have changed.[191] Some domestic laws give the relevant authorities the power to review an authorization after a certain period, regardless of whether the circumstances leading to the authorization has ceased.[192]

n. 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, makes it clear that claims for remuneration—and their judicial review—may be entirely *ex post*, so this question need not delay or impede the actual authorized 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 from 1% to 2% of the value of production.[193] There is also a strong expectation that remuneration should be adjusted in cases of production for humanitarian purposes.

Remuneration guidelines commissioned by the United Nations Development Program 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 medicine" on the basis that "[r]emuneration policies should assist rather than defeat" the goal of enhancing access and lowering costs.[194]

190. *Id.*

191. *See, e.g.*, Cambodian Patent and Designs Law, *supra* note 28, art. 48 ("Upon request of the owner of the patent . . . the Minister may . . . vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.").

192. Cambodian Compulsory Licensing Law, *supra* note 29, art. 16.

193. *See* TRIPS Agreement, *supra* note 8, arts. 31(h)-(j).

194. James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, 62 (UNDP-WHO Health Econs. & Drugs, TCM Series No. 18, 2005).

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".[195] Cambodia's compulsory license law states that "[t]he production, importation or exportation of the Pharmaceutical Products under a compulsory license 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 amount, leaving it to the relevant ministers to determine the relevant "method" and "criteria" for the rate of remuneration.[196] Indonesia's law requires the annual patent fee to be paid by the government or the third-party authorized under the license.[197]

Article 31(j) provides some guidance regarding the meaning of "adequate" and the margin of deference left to members in applying that standard.[198] Article 31(j) requires that decisions relating to remuneration for use shall be subject to judicial review, which reveals that what is "adequate," and disputes about that question, are to be left entirely with the authorizing member. Importantly, this right to review need not prevent use, and may only relate to remuneration for use.

o. 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."[199] The words "any decision relating to the authorization of [ ] use" appear to cast a wide scope, probably meaning that judicial review be available for every decision that has some connection with a given authorization.[200] 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'.

Concerning both Article 31(i) and 31(j), there is no requirement to suspend the effect of a compulsory license before a final determination is made; only the requirement that judicial review be available. Therefore,

195. Indian Patent Law, *supra* note 44, § 90(1). 44

196. Cambodian Patent and Designs Law, *supra* note 28, art. 11; *c.f.* Thai Patent Law, *supra* note 42, at § 50(5).

197. Indonesian Patent Regulation, *supra* note 146, art. 11.

198. *See* TRIPS Agreement, *supra* note 8, art. 31(j).

199. *Id.* art. 31(i).

200. *Id.*

countries need not suspend a compulsory license by interlocutory injunction before a final determination is made that the license was granted illegally.[201] Cambodia's compulsory license law recognizes this by providing that a "competent court shall not issue any provisional measure until a final decision on the case is made."[202]

There is also no requirement to give a hearing to potentially interested parties, such as the patentee. However, some laws require that the patentee be given a hearing if requested, even in a national emergency or other urgent situations.[203] These provisions may be appropriate for non-emergency use situations, but should be removed from provisions that implement Article 31(b) so that they do not undermine governments' capacity to urgently authorize the use of medical and other emergency technologies.

5. Production for Export, Without the Right Holder's Authorization: Article 31*bis*

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."[204] 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.

The solution found by the TRIPS Council—a new form of compulsory license tailored for export of production to meet the needs of eligible countries—was implemented first as a waiver and then as a formal amendment to the TRIPS Agreement (the inclusion of Article 31*bis* with annex and Appendix). The procedure under Article 31*bis* (commonly referred to as the "Paragraph 6 System" or "System") 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 license without falling foul of Article 31(f).[205] The procedure applies only to "pharmaceutical products," which means:

201. Correa, *TRIPS Agreement and Access to Drugs*, *supra* note 187, at 33.
202. Cambodian Compulsory Licensing Law, *supra* note 29, art. 16.
203. *See, e.g.*, Malaysian Patent Law, *supra* note 53, § 84(4).
204. Doha Declaration, *supra* note 6, ¶ 6.
205. *See* TRIPS Agreement, *supra* note 8, art. 31*bis*.1-.5.

> 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.[206]

a. Export Compulsory Licenses in Context

Export compulsory licenses are not a stand-alone procurement tool; they correspond 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 must import it because they cannot produce it themselves; and
- affordable 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 license in a country that is at the same time serving a relatively larger population.

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

(i) 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) (i.e., the product is not patented in the relevant jurisdiction);

(ii) prices for the originator product can be negotiated to an affordable level without recourse to a compulsory license, or where products are appropriately priced and effectively and equitably available;

(iii) the originator company agrees to grant a voluntary license to a generic producer, or the patent holder has made non-assertion undertakings;

(iv) "regular" NVUAs under Article 31 are available, because, for example:

206. *Id.* at Annex, ¶ 1(a).

- a patent in the exporting Member does not protect the desired product, or a voluntary license is in place in that country;
- the exporting Member can satisfy the demand of the importing Member (either alone or together with other Members) under an ordinary Article 31 compulsory license "by exporting the[ir] *non-predominant* share of the production" (i.e., the medicine can be produced under a compulsory license primarily for the domestic market but a smaller proportion can be exported);[207] and
- 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 a NVUA for export only creates a legal pathway for production and export of the needed medicine, it does not by itself address any regulatory requirements in the importing or exporting country or create economies of scale sufficient to support fresh production. Equally, as we discuss below, there is no constraint against combining such authorizations with authorizations for domestic production and 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 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.[208]

b. Making Use of Export Compulsory Licenses

The Article 31*bis*/Paragraph 6 System has been utilized very rarely, and less often 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 "a pandemic or some other health security events."[209] However, as at the

207. Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review of the Special Compulsory Licensing, WTO Doc IP/C/86 (Nov. 11, 2020) at Appendix I, ¶ 5 (emphasis added). *See also* Ng & Kohler, *Finding Flaws*, *supra* note 184, at 150 ("If the product is only patented in the exporting country then only the exporting country must issue a compulsory licence").

208. WIPO, Draft Exception Regarding Compulsory Licensing, *supra* note 89, at 47, ¶ 180.

209. *Id.* at 47, ¶ 179.

time of writing, the System is yet to be used for COVID-19 purposes.[210] This is despite Bolivia notifying of its need for COVID-19 vaccines under the System, and Antigua and Barbuda notifying their intention to use it.[211]

This has led to considerable critical commentary from WTO members, public health advocates, and scholars. Much of this criticism, which has intensified during the pandemic, is levelled at its procedural requirements. It has been called, amongst other things, a "maze of rules and procedure,"[212] "unworkable" and "unnecessarily complex."[213] The annual review of the System by the TRIPS Council has not led to any specific proposals for its reform or adaptation, including in 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 a close and objective analysis of the relevant provisions under the general guidance of the Doha Declaration can facilitate the practical use of the existing system, including by maximizing flexibilities and strengthening coordination and mutual support among countries, and also help illuminate specific issues and questions that could be addressed in a review and reform process.

We address this task firstly by categorizing 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 effective use and practical operation.

Actual and potential problems with the use of the System can be classed into four broad categories:

(i) Constraints specifically embedded within the System itself (e.g., the need for prior notification and the requirement for special labelling).

(ii) Constraints resulting from specific choices made at the domestic level in implementing the System, which are more restrictive than is required under TRIPS (e.g., a requirement for eligible medicines

210. WTO Doc IP/C/86, *supra* note 207, at Annex 1, ¶¶ 5-10.

211. Council for Trade-Related Aspects of Intellectual Property Rights, Notification Under the Amended TRIPS Agreement, Notification of Intention to Use the Special Compulsory Licensing System as an Importing Member Bolivia, WTO Doc. IP/N/8/BOL/1 (Feb. 19, 2021); Council for Trade-Related Aspects of Intellectual Property Rights, Notification Under the Amended TRIPS Agreement, Notification of Intention to Use the Special Compulsory Licensing System as an Importing Member Antigua and Barbuda, WTO Doc. IP/N/8/ATG/1 (May 17, 2021).

212. Raadhika Gupta, *Compulsory Licensing under TRIPS: How Far It Addresses Public Health Concerns in Developing Countries*, 15 J. INTELL. PROP. RTS. 357, 359 (2010).

213. WTO Doc IP/C/W/673, *supra* note 115, at 3, ¶¶ 44-45.

to be specifically scheduled under domestic legislation before an application for a license can be made).

(iii) Constraints inherent in the use of compulsory licensing more generally (e.g., the need for specific authorization for use, as opposed to an entitlement to produce generic medicines without government authorization).

(iv) Constraints directly related to other aspects of production and supply, rather than the IP system or patent rights as such (e.g., regulatory approval in exporting or importing countries; the viability of small-scale production; and procurement policies and procedures).

While the literature is extensive, the evidence 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.

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.[214] In some cases, conditions and requirements within the TRIPS Annex give rise to procedural steps that must be undertaken by implementing members.[215] In other cases, certain steps must be undertaken by other relevant parties in the supply chain (e.g. licensees producing and supplying medicines).[216] 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 the safety and efficacy of pharmaceuticals.

Below, we list and differentiate between: (i) the procedural steps required to be fulfilled by exporting and importing Members utilizing the System; (ii) steps required to be undertaken by other parties; and (iii) general requirements that condition the use of Articles 31-31*bis*.

214. *See, e.g.*, Kianzad & Wested, *No-one Is Safe Until Everyone Is Safe*, *supra* note 115, at 83-85.

215. *Id.* at 84.

216. *Id.* at 83-84.

i. 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.[217] LDCs need not establish this as they are deemed to lack sufficient manufacturing capacity.[218]

The appendix to the TRIPS Annex 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."[219] Available practice suggests that a very general reference to the national situation is sufficient.[220] In the case of COVID-19 vaccines, the serious shortfalls of production capacity in regions of greatest need are very well documented and could hardly be questioned. There is ample documentation of the extensive disparities in production capacity in the developing world, especially for end-to-end production and more novel vaccine platforms.[221]

ii. No Requirement to Establish a Health Emergency

A common misconception is that an importing member must establish something akin to a national health emergency before it can avail itself of the System.[222] However, 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 how an importing member *may* wish to use

217. 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. TRIPS Agreement, *supra* note 8, at Annex, ¶ 1.2(a)(ii).

218. *Id*. at Appendix to the Annex.

219. *Id*. at (i) and (ii).

220. *Id*.

221. *See e.g*., Jodie Rogers, *Vaccine Production Efforts Across Key Regions Mapped in First-of-Its-Kind StudyX to Prepare for Future Pandemics*, CEPI (Oct. 27, 2021), https://cepi.net/news_cepi/vaccine-production-efforts-across-key-regions-mapped-in-first-of-its-kind-study-to-prepare-for-future-pandemics/ [https://perma.cc/2DBG-XLFJ]; *COVID-19 Vaccine Market Dashboard*, UNICEF, www.unicef.org/supply/covid-19-vaccine-market-dashboard (last visited Mar. 4, 2023).

222. Kianzad & Wested, *supra* note 115, at 83-84 (citing Jenny Wakely, *Compulsory Licensing under TRIPS: An Effective Tool to Increase Access to Medicines in Developing and Least Developed Countries*, 33(5) EUR. INTELL. PROP. REV. 299, 304 (2011).

the System "in a limited way."[223] Setting aside this distracting question is imperative for streamlining the use of options under Articles 31 and 31*bis*.

iii. 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 license (if the product is patented in its territory).[224]

The means of notification can be a brief email to the WTO secretariat. The notification indicates the scale of unmet needs for a particular medicine or medicines, and does not create an obligation to use the System. Importing members thus may choose to notify their needs concerning a large number of vaccines to "open up the widest possible range of potential suppliers, including through the System."[225] Members need not identify the relevant supplier.[226] The e-TRIPS submission system provides a streamlined platform for filing such notifications.[227]

There is a strong practical case for groups of members facing similar circumstances to lodge joint or coordinated notifications. It is long established practice in the WTO for groups of members to file such joint submissions.[228] An apposite example is the practice of all LDC members requesting extensions of time, under Article 66.1, for the suspension of TRIPS obligations.[229] Since this example concerns fundamental rights and obligations under TRIPS, 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 1 and Box 2).

223. TRIPS Agreement, *supra* note 8, at Annex, ¶ 1(b) (emphasis added).
224. *Id.* ¶ 2(c).
225. WTO Secretariat, The TRIPS Agreement and COVID-19, *supra* note 126, at 10.
226. WTO Doc IP/C/86, *supra* note 207, at Appendix I, ¶ 11.
227. *Id.* at 2, ¶ 7.
228. *Id.* at Appendix I, ¶ 11
229. *WTO Members Agree To Extend TRIPS Transition Period for LDCs Until 1 July 2034*, WTO (June 29, 2021), https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm (last visited Feb. 3, 2023) [https://perma.cc/NM2N-ESNX].

Box 1. 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 31*bis* System

Arcadia needs to import 18 million doses of Panaceavir.

Box 2. 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 31*bis* System and the need to import pharmaceutical products under the System

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

iv. Grant of License by Exporting Member

The exporting member must grant a compulsory license containing certain conditions, including that "only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the [importing] Member(s) which has notified its needs to the Council for TRIPS."[230] This license 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 is *not* required to issue a compulsory license since the technology is, by definition, completely unencumbered by patent rights in that country.[231]

There is no obstacle to an exporting member issuing compulsory licenses for export to several, or numerous, countries if 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 authorized 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.

v. Packaging and Labelling

Suppliers must use specific labelling or marking to make the finished vaccine clearly identifiable as being produced under the System. Furthermore, suppliers *should* use special packaging and/or special coloring/shaping to distinguish products, 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.[232]

The purpose of this provision, in the context of the pandemic response, must be understood as a measure to address vaccine inequity by

230. Other conditions are indicated throughout this section. *See, e.g.*, SHAYERAH I. AKHTAR, CONG. RSCH. SERV., R47231, WORLD TRADE ORGANIZATION: "TRIPS WAIVER" FOR COVID-19 VACCINES 4 (2022).

231. Even where there is no relevant patent protection in the importing Member, the System must be complied with to enable the exporting Member to supply the importing Member without falling foul of Article 31(f). TRIPS Agreement, *supra* note 8, art. 31(f).

232. AKTAR, *supra* 230, at 4.

providing a safeguard against diversion of shipments away from the priority communities that have been comparatively neglected. Thus, there is 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, the Vaccine Alliance (GAVI) and United Nations Children's Fund (UNICEF).[233] 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 from these provisions' text and the policy context that the distinguishing features required need not be complex and should be easily integrated into the production process. Special packaging or coloring is plainly not required if this has any impact on feasibility or cost.

In view of the attention paid to traceability and supply chain tracking of vaccine distribution, including through barcoding and similar methods, this specific data element 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, without affecting the cost or viability of distribution.[234]

Box 3: Example of labelling of a vaccine consignment

Sample label:
Vaccine export
under WTO TRIPS Agreement 31*bis*
Not for diversion

233. *See e.g.*, *GAVI Announcement: Vaccine Manufacturer GS1 Compliance*, UNICEF (Sept. 10, 2019), https://www.unicef.org/supply/stories/gavi-announcement-vaccine-manufacturer-gs1-compliance [https://perma.cc/2M8C-3Y5K].

234. Robert H. Vander Stichele et al., *How to Ensure We Can Track and Trace Global Use of COVID-19 Vaccines?*, 39(2) VACCINE 176 (2021); *QR Codes and Vaccine Vial Monitors in the Context of COVID-19 Vaccines*, WORLD HEALTH ORGANIZATION [WHO], at 3-6 (working Version 2.1, Oct. 30, 2020) https://www.who.int/publications/m/item/bar-codes-qr-codes-and-vaccine-vial-monitors-in-the-context-of-covid-19-vaccines [https://perma.cc/5HD8-NRMV].

Figure 2. 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 (ii) the distinguishing features of the product(s) used to avoid trade diversion.[235] This requirement must be inserted as a condition of the compulsory license.

- *Notification to the TRIPS Council*. The exporting Member must notify the TRIPS Council of the license, including "the conditions attached to it," "the name and address of the licensee," "the product(s) . . . [and] quantity[ies] for which the license has been granted," "the country(ies) to which the product(s) is (are) to be supplied," "the duration of the license," "the address of the website [describing the supplied quantities]," and "distinguishing features of the product(s)[‘] [packaging, coloring or shaping]."[236]

One concern raised about the Paragraph 6 System is that this procedure must be repeated for every compulsory license granted.[237] However, a pragmatic, needs-driven approach should provide ways of streamlining use of the System.

235. This requirement must be inserted as a condition to the compulsory license. *See* WTO, Draft Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/W/15/Rev.2 (2022) [hereinafter Ministerial Conference Twelfth Session Geneva], at 2, n.5.

236. TRIPS Agreement, *supra* note 8, at Annex, ¶ 2(c).

237. Correa, *TRIPS Agreement and Access to Drugs*, *supra* note 187, at 33-34.

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,[238] as made clear by the words "the country(ies) to which the product(s) is (are) to be supplied" in subparagraph 2(c).[239] 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 license for each new license that the System is used for.[240]

Third, Article 31*bis* refers to "pharmaceutical product(s)" in the plural, indicating that an export compulsory license can be granted in respect of more than one product.[241] 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 license."[242]

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).[243] 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 license (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, 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.[244] 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.

238. WTO Doc IP/C/W/681, *supra* note 9, at 3.
239. TRIPS Agreement, *supra* note 8, at Annex ¶ 2(c).
240. WTO Doc IP/C/86, *supra* note 207, at Appendix I, ¶ 18.
241. *See* TRIPS Agreement, *supra* note 8, art. 31*bis*(3).
242. *Id.* at Annex, ¶ 2(b)(ii).
243. *Id.* art. 31*bis*(3).
244. WTO Doc IP/C/W/672, *supra* note 150, at 18, ¶ 112.

vi. 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:

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

Procurement under a compulsory license 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.[245] Lower-cost combinations of the required medicines were already readily available from alternative generic suppliers in India.[246] Given a need for procurement procedures to ensure value for money, the fact that the System was used as one potential source for procurement led to significant savings and thus a better application of available resources (even though this made the supply less feasible for an inherently higher-cost manufacturer).[247]

Whatever method is used to procure medicines, several factors typically determine whether a supply is viable, including cost, regulatory

245. PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE, WTO, WHO & WIPO (2d ed. 2010) [hereinafter PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION], 243, available at https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf [https://perma.cc/WCK4-VSH8].

246. Ng & Kohler, *supra* note 184, at 166-67.

247. *See* PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION, *supra* note 245, at 243.

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, tool up for production, and actually produce and export medicines. This is so regardless of whether or not the option of a compulsory license for export is pursued, as 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.

It could be helpful, therefore, for countries or procurement programs—especially in the same region or subregion—to coordinate their notifications under the System. Several parallel notifications could make it feasible for a low-cost generic producer to undertake production and export that could serve all the countries in need. Scenarios 3 and 4 in Box 4 and

Box 5 below demonstrate the kind of joint notification that could be made. This coordinated approach to pooled procurement would have the additional benefit of easing concerns about potential political pressure in response to using the System. It would demonstrate how, as argued above, the agency of individual governments can be reinforced through collective action and what one of us has termed "solidarity as a practical craft."[248] At a practical level, a collaborative approach would open up a wider range of potential suppliers without necessitating repetitive use of the System.

Further, a more routine practice of early notification of unmet demand at the preliminary stages of procurement would also assist potential producers in tracking evolving demand for vaccines, a limiting factor that has emerged in the pandemic response.

248. Webster Uni. Geneva, Antony Taubman, *Solidarity as a Practical Craft: Vaccine Equity and International Economic Law*, YouTube (Nov. 9, 2021) [hereinafter Vaccine Equity and International Economic Law], https://www.youtube.com/watch?v=B3oIxOlYCXQ.

Box 4. 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 organization 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 31*bis* 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 license on patents covering Elixivir in its territory.

Box 5. Example of notification required

Scenario 4: Following further coordination led by the regional organization 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 31*bis* System and of need to import pharmaceutical products under the System

Dolopia and Euboea intend to use the System set out in Article 31*bis* and the TRIPS Annex, and 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.

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 31*bis*.

c. Requirements

In general, the System can be utilized by WTO members to import medicines without any specific steps to implement it domestically, since importation under a compulsory license 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. In any case, it may be reasonable to assess "adequate remuneration" to be zero, if remuneration is already provided for in the exporting country.[249] By contrast, countries wishing to facilitate supply through the System would generally need to make the necessary technical amendment to their laws to permit production for export, since it introduces a novel form of compulsory license in the exporting country. By 2015, 51 WTO members had adopted specific implementing measures, comprising the bulk of global export capacity, meaning that the system provides for a wide range of potential suppliers should it be used as a procurement tool.[250] Japan has explained that its guideline for administering award system and Article 93 of its Patent Act (providing for the grant of non-exclusive licenses for reasons of public interest) serves as the legal basis for the grant of compulsory licenses in accordance with international obligations and thus for export under the System.[251]

Of the countries surveyed, only India, Indonesia, and Cambodia have provisions expressly implementing some aspect of the Paragraph 6 System.[252] It may be desirable or constitutionally necessary for other members to adapt their domestic systems to facilitate use of the System. 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 licenses generally).[253]

For example, legislation may:

- oblige a licensee to 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 license be packaged or produced following certain

249. *See* TRIPS Agreement, *supra* note 8, art. 31(g)-(h).

250. Kampf, *supra* note 168, at Annex 1-IV.

251. *Id.* at 7.

252. A full list of WTO Members who have notified such legislation to the TRIPS Council or introduced such legislation but not notified it is available at: *Members Laws Implementing the "Paragraph 6" System*, WTO, https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm (last visited Feb. 17, 2023) [https://perma.cc/8G9N-6ZAX].

253. *See, e.g.*, Cambodian Compulsory Licensing Law, *supra* note 29, art. 15.

> prescribed requirements, to ensure compliance with indent 2(b)(ii).[254]

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 compulsory licensing law provides a suitable example of how developed countries and LDCs might approach this task.[255]

There are other requirements in the TRIPS Annex that members must comply with but 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."[256] 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.[257] 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.[258] 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 TRIPS, meaning that governments can use judicial and administrative processes already implemented in fulfilment of the treaty's requirements.[259]

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

254. *Id.* art. 15(b).

255. *Id.* art. 15.

256. TRIPS Agreement, *supra* note 9, at Annex ¶ 3.

257. 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. *Id*.

258. *Id.* at Annex, ¶ 4.

259. *Id.*

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.[260]

There is no requirement to seek the permission of an importing member's government before an exporting member issues a compulsory license to supply that country. However, some countries have introduced this requirement.[261] Cambodia does not require the importing member's permission. Still, it does require the application for an export compulsory license 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.[262] This may unnecessarily increase the administrative burden of utilizing the System.

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 partly by ensuring that additional requirements are not imposed as part of the compulsory license 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, particularly where a license is issued in circumstances of urgency.[263] 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.

d. Political and Industry Pressure

Pharmaceutical industry and political pressure, sometimes in the form of threatened or actual litigation, has often been cited as a deterrent to utilizing the System and compulsory licenses.[264] Several suits were instigated in India regarding *Nexavar*,[265] while Thailand was subject to

260. Kampf, *supra* note 168, at 9. India's law does not include this clarification whereas Cambodia's law does. *See* Cambodian Compulsory Licensing Law, *supra* note 29, art 11(2).

261. Ng & Kohler, *supra* note 184, at 153-54.

262. Cambodian Compulsory Licensing Law, *supra* note 29, art 14.

263. WIPO, *Draft Exception Regarding Compulsory Licensing*, *supra* note 89, at 47, 49.

264. *Id.*

265. Ng & Kohler, *supra* note 184, at 169.

international government criticism for authorizing the use of the antiretroviral medicine *Efavirenz*.[266]

Developing countries are unlikely to be met with litigious threats for issuing compulsory licenses to deal with a global pandemic. To the contrary, developing countries are likely to receive support from the international community.[267] 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.[268]

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."[269] Under Article 48, judicial authorities have the authority "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."[270]

Some suggest—appropriately, in our view—that countries should "create or clarify declaratory-judgment procedures that enable local firms to initiate civil suits against patentees and obtain authoritative rulings in advance regarding their rights to manufacture specific drugs."[271] Members should also be aware of the possibility of using domestic measures against anti-competitive enforcement of intellectual property rights, including sham litigation.[272] Developing countries are unlikely to

266. Rep.of the U.N. Secretary-General's High-Level Panel on Access to Medicines (Sept. 2016) [hereinafter Promoting Innovation and Access to Health Technologies], *Promoting Innovation and Access to Health Technologies* at 24-25.

267. Thailand, for example, received domestic and international support in its use of IP flexibilities to combat the HIV/AIDS epidemic. *See* Wong, *supra* note 91, at 2.

268. Adusei, *supra* note 10, at 13.

269. Robert D. Anderson et al., *The WTO TRIPS Agreement As a Platform for Application of Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY, IN TODAY'S GLOBAL ECONOMY, *supra* note 137.

270. TRIPS Agreement, *supra* note 8, art. 48(1).

271. William Fisher et al., *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 MICH. J. INT'L L. 1, 29 (2022).

272. *See generally* Inst. Applied Econ. Rsch. [IPEA], *Study on the Anti-Competitive Enforcement of Intellectual Property (IP) Rights: Sham Litigation*, WIPO Doc. CDIP/9/INF/6 REV (July 30, 2012) [hereinafter IPEA, *Study on the Ant-Competitive Enforcement of IP Rights*], https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_9/cdip_9_inf_6_rev.pdf [https://perma.cc/P8BZ-7AWR].

implement such measures, however, and existing measures in developed countries tend to employ high thresholds.[273] That said, 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.[274] This area has rarely been covered in the reports of technical assistance delivered.[275] Article 40 marks out members' entitlement to take anti-competitive measures to address actions such as "an abuse of intellectual property rights having an adverse effect on competition in the relevant market," whereby the patent holder pays an alleged infringer in return for the alleged infringer halting unauthorized production of generics and the patentee suspending litigation.[276] Such action may be deemed unreasonable or as amounting to an abuse of dominant position under domestic anti-competition law, a topic discussed in more detail below.[277]

e. The Regulatory Dimension

NVUAs, such as compulsory licensing, create a legal pathway to use patented technologies without the right holders' consent. However, they cannot ensure that it is feasible and effective to deploy the technology. A key potential barrier to the full and effective use of Articles 31 and 31*bis* is the need for regulatory requirements 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 for pharmaceuticals.[278] In some cases, regulatory approval requirements have been attached specifically

273. *Cf* Chile's Law No. 20169, Regula La Competencia Desleal, Febrero 7, 1997, DIARIO OFICIAL [D.O.] (Chile) [hereinafter Chilean Law on Unfair Competition]; Mark D. Janis, *"Minimal" Standards for Patent-Related Antitrust Law under TRIPS*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 134, at 774, 789-790.

274. Reports on Technical Cooperation Activities Under TRIPS art. 67, WTO (Aug. 26, 2022), https://etrips.wto.org/En/Search/TechnicalCooperationActivities [https://perma.cc/4JBX-CZMS].

275. *Id.*

276. 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* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 517, 608.

277. *Id.*

278. Interestingly, Mongolia incorporates a regulatory approval requirement into its patent law. *See* Mongolian Patent Law, *supra* note 53, art. 7.8.

to the compulsory license process so that approval is required before a license 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 for a compulsory license in Canada to permit vaccine production for export. Bolivia has concluded an agreement with Biolyse for the supply of vaccines and has notified its needs for vaccines to the TRIPS Council as required under the System.[280] However, a compulsory license has not been issued. While details of the matter are unclear, and have been the subject of some controversy, one reported obstacle has been the need for Canadian government authorities to establish that vaccines produced by Biolyse would be safe and effective.[281] This is essentially a regulatory matter and is not ultimately an IP issue, even though the ostensible obstacle to production appears to be the lack of a license.

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 licenses do not ordinarily require the disclosure of such information.[283]

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."[284] 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.[285]

Revocation is primarily permitted on the ground of a 'failure to work' within the laws of the countries surveyed.[286] India's law allows the

279. *See* Kampf, *supra* note 168, at 14.

280. *See* WTO Doc IP/N/9/BOL/1, *supra* note 211.

281. *See e.g.*, Muhammad Zaheer Abbas, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case* (South Centre Rsch. Paper No. 136, 2021).

282. Karen Walsh et al., *Intellectual Property Rights and Access in Crisis*, 52 INT'L REV. INTELL. PROP. & COMP. L. 379, 405 (2021).

283. These issues are addressed separately in Sections III.F and III.G.

284. Hans Morten Haugen, *Does TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) Prevent COVID 19 Vaccines as a Global Public Good?*, 24 J. WORLD INTELL. PROP. 195, 203 (2021).

285. *Id.*

286. Bangladesh Patent and Design Law, *supra* note 64, § 23(1); Indian Patent Law, *supra* note 44, § 85; Thai Patent Law, *supra* note 42, § 55(1).

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," subject to the patentee's right to be heard.[287]

Members may consider it too dissonant with their IP policy to revoke a patent when the option of a NVUA is available, an option that largely preserves a patent's originally intended function, while addressing public needs. However, revocation may be considered appropriate in particular circumstances.. For example, a member government may consider revocation preferable to the procedure under Articles 31-31*bis* because the invention is widely needed and revocation is the more administratively efficient option.

C. Copyright

Copyright issues in respect of written material on product information documents, product labelling and inserts, and software and data compilations utilized in the vaccine manufacturing and distribution process have been highlighted as distinct possibilities in the pandemic context.[288] Article 10(2) of TRIPS requires that "[c]ompilations of data or other material . . . which by reason of the selection or arrangement of their contents constitute intellectual creations" be protected.[289] As clarified by Article 9(2), copyright protects expressions, and not ideas.[290] It would not normally protect individual data items, such as raw statistics.

1. Article 13

Article 13 of TRIPS makes implicit the availability of exceptions to copyright protection. However, according to Article 13, "Members shall confine limitations or exceptions 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."[291] Article 13 is characterized by the same general structure found in exceptions for patents, trademarks and designs in the TRIPS Agreement, each providing

287. Indian Patent Law, *supra* note 44, § 66.

288. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/684 (Sept. 30, 2021), at 6, ¶ 40. *See also* Doris Estelle Long, *The Overlooked Role of Copyright in Securing Vaccine Distribution Equity*, INFOJUSTICE (Sept. 6, 2011), https://infojustice.org/archives/43621 [https://perma.cc/J5Q3-8EAM].

289. TRIPS Agreement, *supra* note 8, art. 10(2).

290. *Id*. art. 9(2).

291. *Id*. art 13.

for a "three-step test."[292] Although each of these provisions, starting with Article 13, can be traced to the *Berne Convention* and feature common concepts, their text, syntax and policy context differ fundamentally.[293] Giving primacy to the ordinary meaning of the terms in their context, we adopt the view arrived at by others that there are four unique tests in TRIPS.[294] Therefore, we approach these tests separately, except where the meaning and interpretation of the words used, and their application to specific cases, can be reconciled. 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."[295]

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.[296] While domestic exceptions and limitations may function as defenses in domestic litigation, their legal basis in TRIPS is part of the original balance of rights and obligations granted to WTO members. Therefore, any potential complainant at the WTO should bear the burden of demonstrating that a domestic exception does not satisfy the test.[297]

2. Copyright Exceptions Relevant to Vaccine Production and Distribution

Some have expressed doubt that Article 13 and its equivalents extend to public interest purposes,[298] and thus the pandemic context.[299]

292. *See* Christopher Geiger et al., *Towards a Balanced Interpretation of the "Three-step Test" in Copyright Law*, 30(12) EURO. INTELL. PROP. REV. 489 (2008).

293. TAUBMAN, A PRACTICAL GUIDE TO WORKING WITH TRIPS, *supra* note 18 at 91; Annette Kur, *Limitations and Exceptions Under the Three-Step Test – How Much Room to Walk the Middle Ground?*, *in* INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM: PROPOSALS FOR REFORM OF TRIPS 222 (Annette Kur, ed., 2011).

294. Andrew F. Christie & Robin Wright, *A Comparative Analysis of the Three-Step Tests in International Treaties*, 45 INT'L REV. INTELL. PROP. & COMP. L. 409 (2014). *See also* Panel Report, European Communities — Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, WTO Doc. WT/DS290/R (Mar. 15, 2005).

295. TAUBMAN, A PRACTICAL GUIDE TO WORKING WITH TRIPS, *supra* note 18 at 91.

296. Matthew Kennedy, *The "Three-Step Test" and the Burden of Proof in Disputes under the TRIPS Agreement*, 45 INT'L REV. INTELL. PROP. & COMP. L. 161 (2014). *See also* Caroline Henckels, *Permission to Act: The Legal Character of General and Security Exceptions*, 69 INT'L & COMPAR. L.Q. 557 (2020).

297. Kennedy, *supra* note 296 at 161.

298. *See generally* Geiger et al., *supra* note 292 at 489; Henning Grosse Ruse-Khan, *Assessing the Need for a General Public Interest Exception in the TRIPS Agreement*, *in* INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM: PROPOSALS FOR REFORM OF TRIPS, *supra* note 293, at 183.

299. WTO Doc. IP/C/673, *supra* note 115, at 1.

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, recognized and developed a notion of 'fair use' as a general law exception to copyright infringement.[300] The fair use doctrine is now codified in many of these jurisdictions' statutes, which set out the factors that judicial bodies must consider in adjudicating fair use defenses.[301]

a. Fair Use of Ancillary Works

Prima facie copyright infringements may arise where there is unauthorized use of a copyrighted work that subsists in the written material featured in product information documents and on product labelling and inserts.[302] Infringements may also occur where copyrighted software and data compilations are utilized 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 producing and distributing vaccines and other health products and not generally for any immediate commercial purpose.

300. Taubman, *Negotiating "Trade-Related Aspects" of Intellectual Property Rights*, *supra* note 105, at 47.

301. *See e.g.*, Copyright Act of 1976 § 101, 17 U.S.C. § 107 (2012) ("(i) the purpose and character of the use, including whether it is of a commercial nature or 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.").

302. Panels Report, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (June 28, 2018).

Members may wish to rely on Article 13 in creating a specific exception for such ancillary use, when it is necessary to produce or distribute 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 utilize a framework of judicially or administratively-applied exceptions. Notwithstanding the view that the frequently encountered "fair use" factors are cognizant with the three-step test,[303] we discuss whether a specific exception or fair use exception for these types of use is likely to satisfy Article 13. We assume that the first step ("certain special cases") is satisfied for these purposes.[304] 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."[305]

i. Normal Exploitation

The *Copyright* panel described "normal exploitation" 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."[306] As de Borja summarized, 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."[307] The *Patents* panel adopted a similar approach.[308]

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 usually be exploited by the originator commercially. Simply put, 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.

303. *See generally id*.

304. Panel Report, *United States – Section 110(5) of the US Copyright Act*, WTO Doc. WT/DS160/R (June 15, 2000), at 14.

305. *Id.* at 33.

306. *Id.* at 48.

307. Ana Gerdau de Borja, *Exceptions to Design Rights: The Potential Impact of Article 26(2) TRIPS*, 30(12) EURO. INTELL. PROP. REV. 500, 502-503 (2008) (internal citations omitted).

308. *See* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, *supra* note 77, at 59.

Thus, adopting the words of the United States fair use provision, the effect of the use upon the potential market for or value of the copyrighted work would be minimal if not wholly illusory.[309]

Although the second step focuses attention on the economic use of a copyrighted work, and has been interpreted in a way that limits it purely to economic considerations,[310] the words of the second step do not altogether exclude 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 economic competition with the ways that a rights holder typically extracts, and thus would generally expect to extract, economic value from the right. This interpretation conforms with both an empirical and value-judgment-based analysis.[311] Ricketson has suggested that any "normal 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."[312] As Lucas notes, panels applying the second step have perhaps so far been limited to the empirical approach only because of the economic nature of the exceptions with which they were concerned.[313]

This normative approach also aligns with that of the *Patents* panel, which 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".[314] That question is necessarily concerned with

309. *See* 17 U.S.C. § 107.

310. *See e.g.*, André Lucas, *For a Reasonable Interpretation of the Three-Step Test*, 32(6) EUR. INTELL. PROP. REV. 277, 279 (2010).

311. 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.'" Robin Wright, *The "Three-Step Test" and the Wider Public Interest: Towards a More Inclusive Interpretation*, 12(6) J. WORLD INTELL. PROP. 600, 612 (2021) (internal citations omitted).

312. Kur, *Limitations and Exceptions Under the Three-Step Test – How Much Room to Walk the Middle Ground?*, *in* INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM: PROPOSALS FOR REFORM OF TRIPS, *supra* note 293, at 231 (*citing* WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment, WIPO Doc. SCCR/9/7 (Apr. 5, 2003), at 25)).

313. Lucas, *supra* note 310, at 279. *See also* J C Ginsburg, *Toward Supranational Copyright Law? The WTO Panel Decision and the "Three-Step Test" for Copyright Exceptions*, 187 REVUE INTERNATIONALE DU DROIT D'AUTEUR 3, 14 (2001).

314. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, *supra* note 308, at 7.58.

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.[315] The *Copyright* panel's reference to "significant or tangible commercial gains" may be 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.[316] However, very little commercial value is likely to attach to the way in which merely ancillary product information is presented.

ii. Legitimate Public Interest

The third step requires that the relevant exception does not unreasonably prejudice the right holder's legitimate interests. In *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."[317] Similarly, the *Copyright* panel stated that legitimate interests "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."[318] That panel confirmed that its analysis of economic data to determine the unreasonableness of any prejudice caused did not mean that "legitimate interests are necessarily limited to . . . economic value."[319]

The two panels' shared focus on justifiability would seem to require something akin to the proportionality analysis or the weighing and balancing exercise undertaken by the panel in *Australia—Tobacco Plain Packaging*.[320] However, the term "justifiable" does not appear in either

315. TRIPS Agreement, *supra* note 8, art. 8.1.

316. Panel Report, *Section 110(5) of the US Copyright Act*, *supra* note 304, at ¶ 6.183.

317. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, *supra* note 308, ¶ 7.69; *see also* Panel Report, *Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, *supra* note 294, ¶ 7.663.

318. Panel Report, *Section 110(5) of the US Copyright Act*, *supra* note 304, ¶ 6.224.

319. *Id.* ¶ 6.227.

320. *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*, 37(4) INT'L INTELL. PROP. & COMP. L. 401, 434 (2006); *see also* Andrew Mitchell & Theodore Samlidis, *The Implications of the WTO Tobacco*

TRIPS Articles 13 or Article 30 and was only employed by the panels in giving meaning to the term "legitimate interests."[321] 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 each require a determination of what is legitimate by referring to public policies and social norms, matters in which members are given a significant margin of deference. Thus, the *Berne Convention* study group endeavored 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."[322]

For most, if not all, members, there is a strong public interest rationale for relevant product information being made available. Furthermore, since such product information is not being commercialised in itself, the originator arguably has no legitimate interest in exercising copyright over it commercially. In terms of the unreasonableness of the 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."[323] 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.

b. Government Use

Compulsory licenses for copyrighted works are well established under domestic and international law.[324] 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.[325]

Plain Packaging Disputes for Public Health Measures, 70 INT'L & COMPAR. L. Q. 1011, 1024 (2021).

321. *See* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, *supra* note 308, ¶ 7.69; Panel Report, *Section 110(5) of the US Copyright Act*, *supra* note 304, ¶¶ 6.224, 6.227; Panel Report, *Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, *supra* note 294, ¶ 7.663.

322. Wright, *supra* note 311, at 603 (citing BERNE CONVENTION FOR THE PROTECTION OF LITERARY AND ARTISTIC WORKS: PROPOSALS FOR REVISING THE SUBSTANTIVE COPYRIGHT PROVISIONS (ARTICLES 1 TO 20), *reprinted in* RECORDS OF THE INTELLECTUAL PROPERTY CONFERENCE OF STOCKHOLM at 113 (WIPO, 1971)).

323. Lucas, *supra* note 310, at 278.

324. *See* Long, *supra* note 288.

325. Berne Convention for the Protection of Literary and Artistic Works art 17.(1), Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221, arts 11*bis*, 13 [hereinafter Berne Convention]. Under

It may be argued that Articles 13, 17 and 26 do not permit compulsory licenses because the presence of Article 31, relating to patents, indicates that the TRIPS drafters felt the need for an explicit provision to that effect. However, as concluded above, Article 31 presupposes the right of members to authorize "other use" and merely imposes further restrictions on compulsory licensing for patents.[326] The result is that only compulsory licenses compliant with the requirements of Articles 31-31*bis* are permitted with respect to patents. However, an exception under Articles 13, 17 and 26 allows members to issue compulsory licenses provided no equivalent 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* (incorporated by reference into the TRIPS text) specify certain conditions for the grant of a compulsory license for particular copyrighted works.[327]

A powerful option available to members is a NVUA that could be used, for instance, to allow the use of copyrighted works for a public non-commercial purpose.

c. Narrow Scope of Exception

The fair use and non-voluntary use exceptions described above have a narrow scope of operation, applying only to the distribution of medicines approved by the relevant regulator. This distinct and circumscribed scope of use would further support an argument that the first and second steps of the test were satisfied. More specifically, this form of reproduction, potentially qualifying as "certain special case," would not intrude on a right holder's legitimate interest in the work, especially if the work is not reproduced, distributed, or sold separately, but forms only an ancillary element of a medicine that is the principal subject of production and distribution.

None of the surveyed countries' laws feature a specific exception covering the use of copyrighted work ancillary to the production or distribution of health products. However, Fiji's copyright law contains an

art 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," *id.* Appendix, art IV.

326. *Id.* at Section III.B.00.

327. Indonesia's law appears to contain a compulsory licensing provision for broadcasting on "national interests" grounds, and for translation/reproduction. Law on Copyrights 2014, No. 28, Arts 51, 84 [hereinafter Indonesian Copyright Law]; *see also* The Copyright Act, 2002 (Act No. 8/2002) § 5(1) (Nepal) [hereinafter Nepalian Copyright Act].

explicit public health exception,[328] and Indonesia's copyright law contains an exception to infringement for use for "security and governance, legislative, and judiciary."[329]

However, some countries surveyed maintain fair use or fair use-type exceptions that are framed wide enough 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.[330] 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; and (iii) the value of the work and the effect of the used part on the market.[331] Mongolia's law could be amended to include circumstances in which the use of copyrighted work is necessary for the distribution of vaccines or other essential health products.

D. Industrial Designs

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.[332] Industrial designs are overall 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, or personal protective equipment (PPE).[333]

Moreover, vaccines are primarily delivered through diluent containers, single and multidose vials and pre-filled syringes, and

328. Copyright Act, 1999 (Act No. 11/1999) §§ 58(1)-(2) (Fiji) [hereinafter Fijian Copyright Act] ("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," subject to the payment of "reasonable remuneration.").

329. Indonesian Copyright Law, *supra* note 327, art. 44(1)(b).

330. Law of Mongolia on Copyright and Related Rights, arts 24.2.1-24.2.3 (2006) (Mong.) [hereinafter Mongolian Copyright Law].

331. *Id.*

332. EDSON BEAS RODRIGUES JR., THE GENERAL EXCEPTION CLAUSES OF THE TRIPS AGREEMENT: PROMOTING SUSTAINABLE DEVELOPMENT 266 (Cambridge Univ. Press, 2012).

333. *See e.g.*, WTO Doc. IP/C/W/672, *supra* note 150, §§ 89, 91; WTO Secretariat, *The TRIPS Agreement and COVID-19*, *supra* note 126, at 11.

transported using refrigerators, freezers, and cold boxes.[334] Some jurisdictions have registered industrial designs for items such as vaccine transportation containers, freezers, syringes and other delivery items. These may be procured at several points throughout vaccine distribution and delivery by both private and public entities. However, no specific IP obstacles for access to such devices have come to light (in contrast with supply chain scarcity for vaccine inputs generally).[335]

Industrial design protection—if ever 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, PPE, 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, such as those mentioned above, may also be subject to industrial designs protection.

1. Scope of Industrial Design Protection

Industrial design protection generally applies to an article's visual appearance, presentation, or features.[336] It does not cover the way it 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.[337] However, as with patentability under Article 27, they are pre-grant options that can only be used to restrict which industrial designs 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."[338] Hence, attention to the

334. *See generally*, WHO, *How to Calculate Vaccine Volumes and Cold Chain Capacity Requirements*, WHO Vaccine Management Handbook (Mar. 2017).

335. WTO Secretariat, *Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19*, *WTO* (Oct. 8, 2021) [hereinafter WTO Secretariat's Information Note on Trade-Related Bottlenecks for Products to Combat COVID-19], https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf [https://perma.cc/RLN2-ZRKZ].

336. *Frequently Asked Questions: Industrial Designs*, WIPO, https://www.wipo.int/designs/en/faq_industrialdesigns.html (last visited Feb. 15, 2023) [https://perma.cc/9WJN-5TRD].

337. TRIPS Agreement, *supra* note 8, art. 25.

338. *Id.* art. 25.1.

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," thus limiting protection under design law to visual appearance and not how a product functions.[339]

Cambodia's law deems a design to be new "if it has not been disclosed to the public, anywhere in the world," unless within twelve months of the filing date.[340] Malaysia applies the same deeming provision but with a six-month filing exception.[341]

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.[342] 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."[343] Cambodia's law adopts a stricter approach to excluding designs dictated by technical or functional considerations, as it excludes only those designs that serve *solely* a technical function.[344] 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. Article 25.1 allows for some latitude in this respect, permitting members to exclude from protection all designs dictated "essentially" and not exclusively or even primarily by technical or functional considerations.[345] 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 end-users to its physical and aesthetic appearance.[346] Likewise, it could be said that packaging items serve a purely informational function.

339. *Id*. art. 25; TAUBMAN, A PRACTICAL GUIDE TO WORKING WITH TRIPS, *supra* note 18, at 102.

340. Cambodian Patent and Designs Law, *supra* note 28, art. 92; *see also* Thai Patent Law, *supra* note 42, § 57.

341. Industrial Designs Act, 1996 (Act No. 552/1996) § 12 (Malay.) [hereinafter Malaysian Industrial Designs Act].

342. TRIPS Agreement, *supra* note 8, art. 25.1.

343. Cambodian Patent and Designs Law, *supra* note 28, art. 90.

344. *Id*.

345. TRIPS Agreement, *supra* note 8, art. 25.1.

346. 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

Where laws have limited the exclusion to designs dictated "solely" to technical and functional considerations, this has led to divergent judicial interpretations. A decision given by the Court of Justice of the European Union (CJEU) diverged from previous interpretations in EU domestic courts when it held that Article 8 of the EU's Community Designs Regulation[347] 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."[348]

The CJEU rejected an approach where the design was dictated solely by functional considerations and, therefore, was 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.[349] 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. However, they 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.

2. Scope of Industrial Design Rights

Similar 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 that is a copy, or substantially a copy, of the

automobile industry). NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF TRADEMARKS AND DESIGNS 437 n.1111 (4th ed. 2019).

347. Council Regulation 6/2002 of 12 December 2001, Community Designs, 2002 O.J.(L3) 1, art. 8.1 [hereinafter Council Regulation 6/2002].

348. Case C-395/16, DOCERAM GmbH v. CeramTec GmbH, ECLI:EU:C:2018:172 § 31 (Mar. 8, 2018).

349. Under the CJEU's approach, this would be determined by taking into account "all the objective circumstances relevant to each individual case," *id.* at § 36.

protected design.[350] 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."[351] 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.[352]

Unlike its equivalents (Articles 13, 26 and 30), Article 26.2 has never been interpreted by a WTO dispute settlement panel. Even so, it is likely to be construed with some guidance from more extensively analyzed provisions, particularly Article 13, which has a closer conceptual linkage to industrial design protection.[353] 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. NVUAs are one example of a potential public health exception to the exclusive rights conferred by Article 26.1 that is 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."[354] A plain reading of these terms in isolation could expand the scope of permissible exceptions under Article 26.2 so that they affect not 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

350. *Compare* TRIPS Agreement, *supra* note 8, art. 26.1 *with* art. 28.

351. *See id*.

352. *Id*. art. 26.2.

353. This is so notwithstanding that art 26.2 is more textually similar to art 30. *See generally id*.

354. TRIPS Agreement, *supra* note 8, art. 26 (Allowing for "the *right* to prevent third parties . . . from making, selling or importing" articles incorporating protected designs) (emphasis added).

(e.g., "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).[355]

Nevertheless, the term "protection of industrial designs"—in contrast to the focus on *per se* rights—appears to simply reflect the wide scope that implementing members have in determining the particular mode of protection for designs.[356] For example, a country may choose to protect 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 recognizes 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. These two differences between Article 26.2 and analogous TRIPS provisions have no 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 their opening words, which define their operation and subject matter (i.e., "shall confine limitations or exceptions . . . to certain special cases" and "may provide limited exceptions").[357] 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 for 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. In contrast, Article 13 does not require such third-party interests to be considered. The 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.[358]

There are circumstances in which a NVUA exception would be needed in addition to the exclusion of industrial designs not dictated by

355. Christie & Wright, *supra* note 294, at 424-25.

356. *Compare* TRIPS Agreement, *supra* note 8, art. 26.2 *with* art. 13.

357. *See id*.

358. See Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, *supra* note 308, ¶ 7.68; Panel Report, *Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, *supra* note 294, ¶¶ 7.675-77 (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.)

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 are essential for the pandemic response. Examples of such articles include diagnostic tools such as RATs and PCRs.

No country in our survey has used 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."[359] Cambodia's, Malaysia's, and Thailand's laws only exclude designs contrary to public order or morality.[360] Cambodia's law also excludes the right holder's rights from cases where the design is used for experimentation and education.[361] It is unclear how such provisions might be applied for public health purposes.

Only Malaysia has introduced an explicit NVUA exception, which allows a compulsory license 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."[362] This "failure to work" authorization 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 IIC2, we conclude that a similar provision drafted to account for non-voluntary use in the public interest would be TRIPS-compliant, provided the license would not unreasonably conflict with normal exploitation of industrial designs and not unreasonably prejudice the legitimate interests of the design owner.

359. Law Regarding Industrial Designs 2000, No. 31, art. 4 (Idon.) [hereinafter Indonesian Industrial Designs Law].

360. Cambodian Patent and Designs Law, *supra* note 28, art. 93; Malaysian Industrial Designs Act, *supra* note 341, § 13; Thai Patent Law, *supra* note 42, § 58.

361. Indonesian Copyright Law, *supra* note 327, art. 9.

362. Malaysian Industrial Designs Act, *supra* note 341, § 27(c).

E. 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.[363]

Such information and know-how 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 in the context of newer technology platforms, such as mRNA vaccines.[364] Vaccine technologies are best understood as a package of various inputs comprising patented inventions and/or know-how, some of which may be confidential.[365] Hence, even if there is no patent in force in a particular jurisdiction, or a NVUA is granted under a patent, access to confidential information and related know-how 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.

1. Eligible Subject Matter

Article 39.2 calls for the protection of undisclosed information which: (a) 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; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.[366]

We do not examine in detail the terms in Article 39.2. Rather, we assume that some of the relevant know-how and other information about

363. Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets*, 16(11) J. INTELL. PROP. L. & PRACTICE 1242, 1246 (2021).

364. *Id.*

365. Geertrui Van Overwalle, *Uncorking Trade Secrets: Sparking the Interaction Between Trade Secrecy and Open Biotechnology*, *in* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 246, 250 (Rochelle Dreyfuss & Katherine Strandberg eds., 2011).

366. TRIPS Agreement, *supra* note 8, art. 39.2.

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 in the 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."[367] 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.[368] This third element would likely make it more difficult to prove that information claimed to be secret is not, in fact, secret.

2. The Nature of Protection

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."[369]

More generally, the protection is framed to give effect to the general requirement under the Paris Convention to suppress unfair competition.[370] Thus, a pivotal question in establishing infringement 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 require a claimant to discharge a burden of proof, for example, by showing that the information was obtained in this way through an identifiable chain of provenance, and not from either a legitimate source or through independent development.

Equally, protection is against unauthorized disclosure of the protected information *as such*. Suspension of, or exceptions to, such protection may in principle limit the scope of confidentiality or override contractual obligations, but it does not in itself force the holder of such

367. Sharon K. 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* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH, *supra* note 365, at 555.

368. *Id.* at 556.

369. TRIPS Agreement, *supra* note 8, art. 39.2.

370. Antony Taubman, *Fair Enough? Reconciling Unfair Competition with Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 121-61.

information to disclose that information where it is not otherwise accessible. Given that at least some critical vaccine 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 on how the relaxation of or exceptions to protection could lead positively to non-voluntary transfer of such technology. These limitations are beyond the scope of this Article.

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 willful/malicious disclosure.[371] 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.

4. Public Health Exceptions

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

Article 39.2 leaves flexibility to craft domestic protections for confidential information that exclude disclosure, use, or acquisition for public interest purposes. First, the reference to acts "contrary to honest commercial practices" removes government use in pursuit of fundamental public policy objectives from Article 39.2's scope. This is because the function of Article 39 as a whole is to build upon protection against acts of unfair competition under the *Paris Convention*, by providing explicit protections for undisclosed information (trade secrets and test data).[372]

371. *See generally* UNIF. TRADE SECRETS ACT (amended 1979), 14 U.L.A. 628 (2021).
372. *See* TRIPS Agreement, *supra* note 8; Paris Convention, *supra* note 181, art. 10(2).

The *Australia – Tobacco Plain Packaging* Panels clarified that "an act of unfair competition" under Article 10*bis*(2) of the *Paris Convention*, as incorporated by TRIPS Article 2.1, means "something . . . 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."[373] Thus, acts contrary to honest commercial practices would exclude acts by governments for non-commercial public use. This interpretation is reinforced by widespread practice amongst implementing Members.[374]

Second, Article 39.2's focus is on dishonest commercial practices, a species of unfair competition and a standard implemented variably by Members. The *Australia – Tobacco Plain Packaging* Panels 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."[375] Footnote 10 to Article 39.2 indicates the scope of "honest commercial practices," which "shall mean at least practices such as breach of contract, breach of confidence and inducement to breach."[376] The phrase "at least" indicates that Members are free to expand its scope 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.[377] Therefore, Sharon 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."[378]

373. Panels Report, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements*, *supra* note 302, ¶ 7.2671.

374. Directive 2016/943, of the European Parliament and of the Council of June 8 2016 on the Protection of Undisclosed Know-How and Business Information (Trade Secrets) Against Their Unlawful Acquisition, Use, and Disclosure, 2016 O.J. (L 157) 1, 8-9 [hereinafter EU Directive 2016/943].

375. Panels Report, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements*, *supra* note 302, ¶ 7.2671; G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property*, WIPO Pub. Doc. 611 (1996), https://tind.wipo.int/record/28637 [https://perma.cc/TRZ6-F8KA].

376. TRIPS Agreement, *supra* note 8, art. 39.2 n.10.

377. Bodenhausen, *supra* note 375, at 144. 375

378. Sharon K. 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* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH, *supra* note 365, at 561.

Thus, Members wishing to implement specific exceptions to protections against confidentiality breaches that are contrary to honest commercial practices may be better informed and guided by choices made at the domestic level than by attempts to discern an absolute meaning from Article 39.2's terms.

Indonesia's trade secret law clarifies there is no infringement of rights where the disclosure or use is "based on the interest for the security and defense, health, or safety of the public."[379] Similarly, Thailand's trade secret law excludes disclosure or use when necessary "for the protection of public health or safety," or when necessary "for the benefit of other public interests with no commercial purpose," as well as exclusions for reverse engineering.[380] Presuming that Thailand's provision was intended to be TRIPS-compliant, then it implicitly includes the notion that disclosure based on public interest considerations is not inherently contrary to honest commercial practices. Thailand's law, in particular, distinguishes between disclosure necessary for the protection of public health or safety (regardless of whether it is for a commercial purpose) and disclosure for the benefit of other public interests, which must be for a non-commercial purpose. Other Asia-Pacific countries may wish to include similar negative exceptions. The alternative approach is to explicitly and positively enumerate the practices that may be considered dishonest commercial practices, although even acts done for a public health purpose might fall within the scope of a country's enumerated practices.[381]

5. Implementing Exceptions

A significant practical consideration is that removing or limiting legal protection over confidential information does not automatically guarantee effective access to that information by those seeking to put it to work. Even where a firm with exclusive control over knowhow does not

379. Law Regarding Trade Secret 2000, No. 30, art. 15(a) (Idon.) [hereinafter Indonesian Trade Secret Law].

380. Trade Secrets Act B.E. 2545 (2002), as amended by Trade Secret Act (No. 2) B.E. 2558 (2015) § 7.2 (Thai.) [hereinafter Thailand's Trade Secret Law].

381. *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 Directives 84/450/EEC, European Parliament Directives 97/7/EC, 98/27/EC, and 2002/65/EC, and Regulation (EC) No. 2006/2004, 2005 O.J. (L 149) 22, 23 [hereinafter EU Directive 2005/29/EC]; *See generally*, WIPO, MODEL PROVISIONS ON PROTECTION AGAINST UNFAIR COMPETITION, WIPO Pub. No. 832(E) (1996), https://tind.wipo.int/record/28768?ln=en [https://perma.cc/CL5T-PZMQ].

have the negative right to prevent the disclosure, use, or acquisition of their information by third parties in certain circumstances, nothing compels that firm to disclose such information itself, and in most cases the firm will remain unwilling or unable to do so.[382] Further, knowhow such as detailed knowledge of vaccine production is not necessarily discretely packaged and easily transferred, regardless of the legal context. This means 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 two issues: (i) incentivizing full disclosure of the relevant knowhow; or (ii) forcing disclosure of such information.

Incentivizing full disclosure of relevant knowhow does not always prove successful and requires a careful calibration of fiscal and other policy measures. While removing legal protections over confidential information involves removing legally protected negative rights, forcing disclosure involves compelling positive action by private persons. As Olga Gurgula and John 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.[383] While more practically than legally significant, forced disclosure may have legal implications even where it involves a limited transfer of information from one firm to another. Under some systems, it may constitute a taking of property that must be compensated pursuant to a country's constitution. For example, a country's legal system may recognize confidential information as a legitimate type or property. Likewise, a country's definition of a 'taking' or an 'acquisition' may play a role.

Nothing in Article 39.2 precludes a government from forcing the disclosure of confidential information, particularly given 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. For example, the US Defense Production Act authorizes the forced disclosure of information (as well the acquisition of property) for public interest purposes.[384]

Despite the flexibility within Article 39.2, many countries' legal systems may make it difficult to adjust or adapt well-established legal principles to the exigencies of the pandemic. One option is to override

382. Unlike the licensing a patent, the very act of publicly disclosing a trade secret denudes it of its commercial value. *See* TRIPS Agreement, *supra* note 8, art. 39.2(b).

383. Gurgula & Hull, *supra* note 363, at 1250.

384. *Id.* at 1252.

trade secret protections using legislation, subject to each country's constitutional requirements. That task would be more straightforward for countries whose trade secrets law is wholly codified, or in civil law jurisdictions where governments could enact provisions that shield certain parties from liability for disclosure of certain confidential information. Indonesia and Thailand have a wholly statutory trade secret law.[385]

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 demanding for countries whose trade secret protections are sourced in multiple bodies of law and actionable through various legal claims. In India, for example, rights holders may seek both contractual remedies and remedies under an equitable doctrine of breach of confidence.[386] Countries wishing to remove or limit legal protection in a way that guarantees effective access to information may be required to not only effect the forced disclosure of such information, but also make wholesale amendments to trade secret protections, which may be embodied across distinct legislative and 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, constitutional arrangements and the independence of common law and statutory principles would require each State to legislate exceptions independently.[387]

F. Clinical Trial Data

Clinical trial or test data that demonstrates the safety and efficacy of new pharmaceuticals is, in some countries, required to be submitted to regulatory authorities as a condition of approval for new products and applications. Such data may also include sensitive information regarding the manufacturing process, formulation, dosage, delivery method, indicated uses and general safety information.[388] These regulatory procedures are distinct from the protection of IP as such, and many

385. Indonesian Trade Secret Law, *supra* note 379, art. 1.2; Thailand's Trade Secret Law, *supra* note 380, at 12.

386. Saltman Eng'g Co. v. Campbell Eng'g Co. Ltd. [1948] 3 All ER 413; John Richard Brady v. Chem. Process Equips. Priv. Ltd., AIR 1987 Del 372.

387. *Judicial Independence and Judicial Accountability at The Coalface of the Australian Judiciary* (July 2016), https://localcourt.nt.gov.au/sites/default/files/judicial_independence_and_judicial_accountability_at_the_coalface_of_the_australian_judiciary_.pdf [https://perma.cc/C4CB-49U4].

388. WTO Doc. IP/C/W/684, *supra* note 288, ¶ 87.

countries do not maintain entirely independent approval processes that call for data submission. Many base domestic approvals on approval in other countries or WHO emergency use or prequalification procedures, particularly in the context of urgent pandemic responses.

However, in 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 firms from producing follow-on COVID-19 vaccines. The relevant TRIPS standards apply when the domestic authorities undertake a distinct review of clinical trial data as a condition of regulatory approval.[389] Some bilateral and regional agreements provide for more extensive protection, which may expressly set a term of exclusivity over the originator's data, apply to reliance on data submitted for approval in other jurisdictions, or set limits over reliance on the originator's earlier regulatory approval.[390] Regulatory systems and processes in the Asia-Pacific have previously slowed or blocked the introduction of externally developed novel vaccines.[391] Due to relatively low costs and growing technical expertise, there has been an increasing trend in recent years for clinical trials to be conducted in the region, including COVID-19 vaccines.[392]

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 required to gain marketing approval for pharmaceutical and chemical products.[393] Only data the origination of which involves "considerable effort" is captured. Members must also protect the data against disclosure unless disclosure is necessary to protect the public, or steps are taken to ensure that the data is protected against unfair commercial use.

389. TRIPS Agreement, *supra* note 8, art. 8.1.

390. Comprehensive and Progressive Agreement for Trans-Pacific Partnership (Mar. 8, 2018) [hereinafter CPTPP], https://www.dfat.gov.au/sites/default/files/tpp-11-treaty-text.pdf [https://perma.cc/NMN9-ZWVX].

391. Theodore F. Tsai et al., *Immunization in the Asia-Pacific Region*, PLOTKIN'S VACCINES 1466, 1478 (2018).

392. Sheraz Ali et al., *Clinical Trials in Asia: A World Health Organization Database Study*, 10(3) PERSPS. CLINICAL RSCH 121 (2019); Chiranjib Chakraborty et al., *Asian-Origin Approved COVID-19 Vaccines and Current Status of COVID-19 Vaccination Program in Asia: A Critical Analysis*, 9 VACCINES 600, 609 (2021).

393. TRIPS Agreement, supra note 8, art. 39.3.

Article 39.3 remains one of the most debated TRIPS provisions and interpretations generally fall into two categories. One argues that Article 39.3 demands a *sui generis* IP regime requiring a minimum data exclusivity period.[394] The other argues that Article 39.3 only protects against dishonest or unlawful conduct such as theft or espionage of clinical trial data.[395] Under the latter interpretation, "[u]ndisclosed data are to be protected from unauthorized disclosure, but the protection against unfair commercial use of data is limited to data acquired by dishonest means."[396] In addition to these two interpretations, we add a third potential application of Article 39.3 that one of us has extracted previously: action need not be taken to prevent others from using or relying on the originator's data, even when 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.[397]

We believe that a detailed interpretation of Article 39.3 is unnecessary here,[398] largely because, as stated by one of us 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."[399] For one, the social norms and principles that give meaning to the term "unfair" reinforce that its interpretation and application should be determined by implementing Members within the context of their own social, legal and economic environment.[400] Ultimately, this allows governments to interpret and apply "unfair commercial practices" to exclude government use for public or philanthropic purposes, or use in

394. Gabriele Spina Ali, *The 13th Round: Article 39(3) TRIPS and the Struggle over "Unfair Commercial Use,"* 21 J. WORLD INTELL. PROP. 201, 202 (2018).

395. *Id*. at 202-03.

396. Antony Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods: The Problem of Test Data Protection*, 3 J. INT'L PROP. L. & PRAC. 591, 595 (2008).

397. *Id*.

398. Such interpretation has been undertaken elsewhere. *See, e.g*., Spina Ali, *supra* note 394; Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods*, *supra* note 396; Antony Taubman, *Fair Enough? Reconciling Unfair Competition with Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137.

399. Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods*, *supra* note 396, at 602; Daria Kim, *Enabling Access to Clinical Trial Data: When Is Unfair Use Fair*, 14(2) CHI.-KENT J. INTELL. PROP. 521, 538 (2015).

400. Spina Ali, *supra* note 394, at 210; CARLOS CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT (South Centre, 2002).

public health emergencies.[401] Indeed, the EU (a strong exporter of pharmaceuticals) suspends its data exclusivity period in cases where the pharmaceutical is manufactured under a compulsory license for export (but not the supply of the domestic market).[402] This is clearly intended to facilitate effective use of the Paragraph 6 System. Other countries may implement more expansive exceptions to protect public health.

Countries in the Asia-Pacific region maintain a diverse range of approaches to both regulatory approval of vaccines (including reliance on approval in other jurisdictions or by the WHO), and the protection of clinical trial data. Divergent regulatory mechanisms and cumbersome regulatory procedures have been identified as an obstacle to the timely production and distribution of vaccines.[403]

Malaysia imposes a data exclusivity requirement, but it excludes situations where compulsory licenses have been issued and any other measures consistent with the need to protect public health. The provision 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.[404] Many of the countries in our sample do not utilize explicit data exclusivity requirements. They may continue to omit this requirement provided 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 the practice of omitting the requirement to submit test data as a condition for the market approval of pharmaceutical products. Cambodia, for example, does not impose requirements to submit such data as a condition for pharmaceuticals to be imported, produced or exported under a compulsory license.[405] In such cases, Members may opt to permit their

401. *EU's Position on Compulsory Licensing and the TRIPS Waiver*, *supra* note 124, at 2-3.

402. 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?*, 42(9) EURO. INTELL. PROP. REV. 539, 544 (2020).

403. *Regulatory Responses to the COVID-19 Pandemic in Southeast Asia*, OECD (Oct. 11, 2021), https://read.oecd-ilibrary.org/view/?ref=1112_1112857-ojsehuakia&title=Regulatory-responses-to-the-COVID-19-pandemic-in-Southeast-Asia [https://perma.cc/7STC-YXYB].

404. Malaysia 2011 Directive of Data Exclusivity, § 5; *see generally*, Ellen F.M. 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10(19) J. PHARM. POL'Y PRAC. 1, 4 (2017).

405. Cambodian Compulsory Licensing Law, *supra* note 29, art. 18.29

regulatory approval bodies to rely on foreign test data or regulatory approval where no submission to the relevant authority is required.[406] This may also be achieved through regional approval mechanisms or WHO pre-qualification and emergency listing procedures.

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 just discussed). For 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 firms' ability to engage in effective technology transfer. Such compensation may account for numerous factors to ensure that use is not seen as competitively "unfair."[407] This "intermediary" approach is well-accepted within the literature,[408] and appears consistent with the likely purpose of Article 39.3, which is to provide an opportunity for investment amortization, and thus an incentive to produce such data for the public good.[409]

2. Test Data and Patents

Clinical trial data and patents are at the center of two distinct and independent regulatory regimes with their own purposes and incentive mechanisms.[410] However, overlap and complementarity between the two regimes is evident.[411] Therefore, countries can take steps to ensure that one regime does not impede utilizing flexibilities in another.

As already noted, *Bolar* exceptions can ensure that regulatory approval does not delay market entry once the patent term has expired.[412] Countries may also avoid "patent linkage" provisions, which prevent

406. Some note that this does not apply where the relevant pharmaceutical is registered locally. Spina Ali, *supra* note 394, at 219.

407. *See* Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods*, *supra* note 396, at 605.

408. *See generally* Kim, *supra* note 399, at 538.

409. *Id.* at 548-549; *see* Antony Taubman, *Fair Enough? Reconciling Unfair Competition with Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 152; Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods*, *supra* note 396.

410. Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods*, *supra* note 396, at 595.

411. *Id.*; Prabuddha Ganguli, *Complying with Article 39 of TRIPS . . . A Myth or Evolving Reality?*, 25 WORLD PAT. INFO. 329, 329 (2003).

412. *See above* Section III.B.3.

regulatory approval of a drug because it is already patented within the relevant territory.[413] The Indian Supreme Court has already held, for its own domestic legislation, that Article 39 does not require patent linkage.[414] Thus, the definition of "new drug" in India's regulatory approval legislation has no linkage with patent status.[415]

A key concern is the extent to which data exclusivity requirements may impede the use of compulsory licenses, including those issued to give effect to the Paragraph 6 System.[416] One option is to include a carve-out for compulsory licenses in those regimes where data exclusivity is enforced.[417] As stated above, Malaysia incorporates this clarification into its law,[418] 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 license."[419]

G. Restrictive Licensing and Anti-Competition

Often overlooked amongst the tools available to Members wishing to provide greater protection for public health, and in place of more IP-focused mechanisms, are measures aimed at addressing anti-competitive practices.[420] The two regimes of IP protection and anti-competition are far from inherently inconsistent. They may function as two practical policy levers for achieving a balance of incentives and technology transfer promotion.[421] Indeed, anti-competitive principles need not emerge solely as independent rules and provisions, but may also inform the development

413. Srividhya Ragavan, *The (Re)Newed Barrier to Access to Medication: Data Exclusivity*, 51(4) AKRON L. REV. 1163, 1191 (2017).

414. *Id*. at 1193-94. While the Indian Supreme Court is not the proper forum for the interpretation of TRIPS, 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.

415. *Id*. at 1191.

416. *See* Meitinger, *supra* note 405, at 132.406

417. *See* 't Hoen et al., *supra* note 404, at 4.

418. *See* Malaysia 2011 Directive of Data Exclusivity, *supra* note 404.

419. Cambodian Compulsory Licensing Law, *supra* note 29, art. 17.

420. Robert D. Anderson et al., *The WTO TRIPS Agreement As a Platform for Application of Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 73.

421. *See* Robert D. Anderson et al., *Time to Look Afresh at the International Dimension of Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 850; *see* 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* 3 INTELLECTUAL PROPERTY: TRADE, COMPETITION, AND SUSTAINABLE DEVELOPMENT THE WORLD TRADE FORUM 242 (Thomas Cottier et al., eds., 2010).

of balanced domestic IP law.[422] Competition 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.[423]

A common manifestation of anti-competitive practices in the IP context are restrictive voluntary licensing terms.[424] Anti-competition or "antitrust" law is comparatively less advanced in developing countries compared to certain developed countries like the United States, where it has been divided into three broad areas: anti-competitive licensing practices; regulation of anticompetitive unilateral conduct; and regulation of patent misuse.[425] Our analysis and recommendations focus on the first and third areas.

1. TRIPS and Anti-Competition

Article 8.2 of TRIPS recognizes the possibility of tempering IP protection with measures to address IP abuse by acknowledging that Members may need to prevent practices "which unreasonably restrain trade or adversely affect the international transfer of technology."[426] More practical and precise recognition of this balance between IP protection and anti-competition can be found in Article 31(k), which creates an exception to certain requirements for the issue of compulsory licenses under Article 31. It provides in part:

> 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

422. 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* 3 INTELLECTUAL PROPERTY: TRADE, COMPETITION, AND SUSTAINABLE DEVELOPMENT THE WORLD TRADE FORUM, *supra* note 421, at 243.

423. *Id*. at 244.

424. Josef Drexl, *The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, supra note 134, at 709, 717.

425. Janis, *"Minimal" Standards for Patent-Related Antitrust Law under TRIPS*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 134, at 784; *see also* Promoting Access to Medical Technologies and Innovation, *supra* note 245, at 23; *see also Voluntary Licenses and Access to Medicines*, MÉDECINS SANS FRONTIÈRES 15 (Oct. 2020), https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_summary-brief_Oct2020_ENG.pdf [https://perma.cc/X6J4-AC8N].

426. TRIPS Agreement, *supra* note 8, art. 8.2.

> anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.[427]

Apart from confirming the well-established principle that anti-competitive practices may form the basis of a compulsory license, 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).[428] As Morgan notes:

> it would be sufficient if a small group of potential exporters implemented remedies for anti-competitive pricing and issued broad compulsory licenses 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.[429]

The reference in Article 31(k) to judicial and administrative process suggests that an executive decision may be sufficient—a potentially efficient means of invoking the provision. However, the requirement for a "process" suggests a requirement for some substantive procedure in making that decision, as well as a normative framework at the domestic level that could act as the basis for a *bona fide* determination of anti-competitive practices. Therefore, Article 31(k), while a useful avenue for governments to take in circumventing the ordinary requirements of Articles 31(b) and (f), is not necessarily a less-burdensome alternative to Article 31*bis*, which, as we argue above, need not be as procedurally complex as claimed.

Notably, 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.[430] 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 behavior) to a "rule of reason" or case-by-case approach.[431] Some ambiguity in this regard is left by Article 40.2, which allows Members to specify in their legislation "licensing practices or conditions that *may in particular cases* constitute an abuse of [IP] rights having an adverse effect on competition

427. *Id.* art. 31.

428. Maxwell R. Morgan, *Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment*, 64(1) UNI. TORONTO FACULTY L. REV. 44, 85 (2006).

429. *Id.* at 86.

430. Anderson et al., *The WTO TRIPS Agreement As a Platform for Application of Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 68.

431. *Id.* at 71.

in the relevant market."[432] The words "may in particular cases" point toward a case-by-case approach rather than a *per se* approach. Developed countries are more favorably disposed to the case-by-case approach than developing countries, as developing countries tend to be concerned that curial determination will reduce the likelihood of practices being deemed anti-competitive.[433] Nevertheless, Article 40.2 must be read separately from Article 31(k); the former concerns voluntary licensing terms while the latter concerns requirements conditioning the use of and remuneration for compulsory licenses.[434] Despite its narrow application, the scope of anti-competitive practices under Article 31(k) is cast in much wider terms. Moreover, 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.[435]

Our survey reveals that very few countries include anti-competitive practices as grounds for compulsory licensing, and fewer still exclude the Article 31(b) requirements in such cases. India's law includes the "reasonable requirements of the public" not being satisfied as one ground for the issue of a compulsory license.[436] It deems this to be the case where a patentee imposes one of the conditions listed in Article 42.2.[437] Mongolia's law provides cases where "the patent owner sets unacceptable terms for the exploitation of the invention," as a ground for compulsory licensing,[438] while Vietnam's law provides cases where the patent holder "is considered [to have] performed anticompetition practices banned by competition law."[439]

432. TRIPS Agreement, *supra* note 8, art. 42.2 (emphasis added).

433. F.M. Scherer & Jayashree Watal, *Competition Policy and Intellectual Property: Insights from Developed Country Experience*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 397.

434. *Id.*

435. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 137, at 236-37.

436. Indian Patent Law, *supra* note 44, § 84(1)(a).

437. *Id.* at § 84(7); *see also id*. § 84(1).

438. Mongolian Patent Law, *supra* note 53, art. 20.

439. Vietnamese Intellectual Property Law, *supra* note 131, art. 145(d).

Most of the countries surveyed—Bangladesh,[440] Cambodia,[441] Fiji,[442] India,[443] Indonesia,[444] Malaysia,[445] Mongolia,[446] and Thailand[447]—maintain independent competition laws covering various practices.[448] Some of these provisions may capture anti-competitive IP licensing terms.. However, much would depend on their precise scope and whether the jurisdiction has a sufficiently developed anti-competition law framework. Implementing a new general anti-competition regime requires awareness of technical expertise and capacity restraints, considering their potential complexity.[449] Janis recommends that governments adopt what Reichman has termed a "'jurisprudence of licensing's' approach that draws selectively from practice in developed countries."[450]

Many countries surveyed prohibit restrictive license 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: "(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."[451] Among the

440. The Competition Act, 2012 (Act No. 23 of 2012) (Bangl.) [hereinafter Bangladesh Competition Act].

441. Law Concerning Marks, Trade Names and Acts Of Unfair Competition, 2002 (Cambodia) [hereinafter Cambodian Competition Law].

442. Fijian Competition and Consumer Commission Act, 2010 (Act No. 49/2010) (Fiji) [hereinafter Fijian Competition and Consumer Commission Act].

443. The Competition Act, 2002 (Act No. 12/2003) (India) [hereinafter Indian Competition Act].

444. Law Concerning the Prohibition on Monopolistic Practices and Unfair Business Competition 1999, No. 5 (Indon.) [hereinafter Indonesian Competition Law].

445. Malaysian Patent Law, *supra* note 53.

446. Law on Competition 2010 (Mong.) [hereinafter Mongolian Competition Law].

447. Trade Competition Act B.E. 2560 (2017) (Thai.) [hereinafter Thai Trade Competition Act].

448. *See, e.g.*, Bangladesh Competition Act, *supra* note 440, § 2(g).

449. Anderson et al., *The WTO TRIPS Agreement As a Platform for Application of Competition Policy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY, *supra* note 137, at 75; Janis, *"Minimal" Standards for Patent-Related Antitrust Law under TRIPS*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIMe, *supra* note 134, at 780.

450. Janis, *"Minimal" Standards for Patent-Related Antitrust Law under TRIPS*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 134, at 781 (citing J.H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 57 (1996)).

451. Indian Patent Law, *supra* note 44, § 140(1)(i).

prohibited conditions are those listed under Article 40.2 (e.g., exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing), and various exclusive dealing conditions.[452] 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."[453] Malaysia's patent law imposes 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."[454] Other conditions that that have been the focus of attention 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.[455]

H. Remedies

Laws on remedies for IP infringement can be crafted to manage abusive IP practices, for public interest purposes such as public health protection. The minimum TRIPS requirements for remedies are set out in Part III, Section 2. Article 44.1 requires each Member's judicial authorities to have the authority to order an injunction against the infringement of IP rights "immediately after customs clearance of such goods."[456] However, Article 44.2 clarifies Members' rights to limit remedies to remuneration for unauthorized use, pursuant to subparagraph 31(h). Thus, the remedy in the United States for unauthorized government use is limited to "reasonable and entire compensation for such use and manufacture."[457] The words "may limit the remedies available" in Article 44.2 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. Therefore, a Member's authorities need not award an injunction in all

452. *Id.* § 140(1).

453. Indonesian Patent Law, *supra* note 43, art. 78; *see also* Indonesian Copyright Law, *supra* note 327, art. 82; Indonesian Industrial Designs Law, *supra* note 359, art. 36.

454. Malaysian Patent Law, *supra* note 53, § 45.

455. *A Fair Shot for Vaccine Affordability*, *supra* note 46, at 19, 25-27.

456. TRIPS Agreement, *supra* note 8, art. 44.1.

457. 28 U.S.C. § 1498.

cases. The same is true with respect to *ex post* compensation or damages for "injury . . . suffered because of an infringement," which is distinct from the remuneration paid for IP use.[458] In each case, public interest considerations may be weighed against the right holder's legitimate interests in determining the amount of remuneration and/or compensation to be paid.[459] The reference to IP "infringement" suggests that no injunctive relief is required unless such infringement is established, thus ruling out interlocutory relief as a requirement and enabling vaccine production to continue in the public interest. Of course, interlocutory action for imminent or ongoing infringement is a legitimate means of preventing the unauthorized 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.

Some of the laws surveyed do not distinguish between the remedies available. They merely state, for example, that "[t]he owner of the patent shall . . . have the right . . . to institute court proceedings against any person who infringes the patent."[460] Others only provide that compensation is available for infringement.[461]

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.[462] Therefore, Cambodia's law patent provides interlocutory relief, as does Malaysia's patent law,[463] Thailand's patent law,[464] and Indonesia's law on copyright.[465]

Fiji's copyright law contains a provision on "unjustified proceedings" that confers on a court the power to declare that the bringing of proceedings for copyright infringement was "unjustified" and to make

458. TRIPS Agreement, *supra* note 8, art. 45.

459. *A Timeline of U.S. Attacks on India's Patent Law & Generic Competition*, MÉDECINS SANS FRONTIÈRES 1 (Jan. 2015) [hereinafter *A Timeline of U.S. Attacks on India's Patent Law*], https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf [https://perma.cc/J7Q8-E59U].

460. Cambodian Patent and Designs Law, *supra* note 28, art. 43; *see also*, Mongolian Patent Law, *supra* note 53, art. 29.

461. *See, e.g.*, Nepalian PDTA, *supra* note 27, § 24.

462. Cambodian Patent and Designs Law, *supra* note 28, art. 126.

463. Malaysian Patent Law, *supra* note 53, § 59; Malaysian Industrial Designs Act, *supra* note 341, §§ 33, 35.

464. Thai Patent Law, *supra* note 42, § 77*bis*.

465. Indonesian Copyright Law, *supra* note 327, art. 106.

an order for compensatory damages accordingly.[466] India's law contains similar provisions in respect of patents.[467]

III. LEGAL AND POLICY OPTIONS

The above sections reveal the broad spectrum of potential IP-related avenues available to WTO Members in both their individual and collective response to the pandemic, as well as more systemic preparation and capacity building for any future public health or other crises that might arise.

This section draws on the above analysis and discussion to provide broader practical recommendations in addition to the more discrete recommendations made throughout this article. We hope to thereby reinforce the role of the IP system within and beyond the TRIPS framework to leverage access to vaccines and other health products. This leveraged access may be achieved through dispersed production capacity or wider access to potential imports, including through regional coordination and cooperation. These recommendations are grouped according to three broad policy areas, relating to both independent national action and regional coordination.

A. Policy Area 1: Strengthening the Factual Basis for Decisions on IP Law and Policy

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 should consider whether a country or group of countries is likely to remain largely reliant on imported vaccines, or if it has actual or potential production capacity. An equally 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. This would be better suited to individual countries' specific needs and circumstances, while also strengthening the basis for regional cooperation.

Members should therefore assess IP legal and policy framework based on immediate and longer-term options for vaccine access, develop

466. Fijian Copyright Act, *supra* note 328, § 120.
467. Indian Patent Law, *supra* note 44, § 106.

IP management policies for publicly funded R&D, and strengthen planning and strategic partnerships with regional countries and institutions, with a view to collaborative access and development programs.

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 is likely to vary significantly within and across regions. This entails preparing landscape studies that would illuminate: (i) the extent to which background and foreground IP, especially patents, have been protected in jurisdictions across the region; and (ii) considering whether, and to what extent, test data protection applies to regulatory approval outcomes in jurisdictions across the region.

Clearer mapping of the IP landscape may reveal that IP-related barriers to vaccine access in certain jurisdictions or regions 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.

Therefore, Members should strengthen analytical capacity and seek technical assistance in tracking patent and other registration activity, assessing the impact of clinical trial data protection, and map requirements for the submission of such data. They should also work with regional partners and institutions to develop a coordinated approach to such technology tracking and IP mapping exercises.

B. Policy Area 2: Legal and Legislative Framework for the IP System

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, policymakers have a positive opportunity to assess the adequacy and appropriate balance of IP laws for health innovation and access given 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);

- suitable exceptions to patents and other IP rights have been included in legislation, to ensure scope for pre-commercialization activities such as experimentation, research and regulatory approval; and

- 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, either 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 prioritize options, and the political will to implement necessary reforms and legislative development. Members can take two key steps in particular: (i) undertaking a 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; and (ii) coordinating review process with regional partners and regional and international institutions, to promote synergies, mutual learning, and best practices. We discuss these review processes below, in the context of each category of IP discussed.

Where countries lack a mechanism for authorization of use of patented subject matter, they should either confirm a streamlined process for authorization of such use (without prior negotiation) in the event of a health emergency or, for non-commercial public use, introduce an independent scheme for government use without the need to seek prior authorization. Members should also consider clarifying that the substantive grounds for government or government-authorized use (such as public non-commercial use) are not limited to an emergency, in line with a clearer understanding of Article 31(b) of TRIPS.

It is also imperative that Members introduce and, where already in place, streamline domestic procedures for implementing both Articles 31 and 31*bis* 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 31*bis* 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.

Equally as important is clarifying or amending laws to ensure that compulsory licensing and government use authorizations, including those under domestic mechanisms to implement Article 31*bis*, 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: (i) an express *Bolar* exception; and (ii) an express research exception. Finally, where Members desire a policy environment conducive to technology transfer, they may 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.

Members can ease any copyright or design-related obstacles to vaccine distribution and access by assessing and potentially reviewing 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. It may also be prudent to review the scope for non-voluntary government or public non-commercial use of such materials. Likewise, Members can 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 based on public health needs.

Concerning undisclosed or confidential information, a first step available to Members is assessing and potentially reviewing domestic law on undisclosed information (confidential information, know-how or trade secrets), to clarify its application in a public health context. This would include review of how the disclosure, use or acquisition by government for public interest purposes might be accommodated or better accommodated by domestic laws; and how liability for disclosure necessary for the transfer of essential medical technologies affects such transfer. Such assessments may need to be made having regard to the implications for constitutional rules on "taking" property.

Concerning clinical trial data, Members should, where necessary, review the role of clinical trial data in domestic regulatory processes, and consider possibilities for regional cooperation on, and mutual recognition

of, regulatory approval. This may involve assessing and potentially reviewing domestic law on the protection of clinical trial data, including concerning:

- 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 license for export
- trial data for pharmaceuticals produced under a compulsory license 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.

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, rather than at the international level (except under regional mechanisms, where applicable). Hence, achieving a beneficial balance of rights and interests under the IP system in a practical sense is determined almost exclusively 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 essential resources to ensure greater transparency of granted IP rights and applications in process, and their compliance with domestic and international standards.

To ensure these elements are in place, Members may wish to clarify and streamline procedures for the timely grant of IP rights and the availability of opposition procedures and applications for compulsory licensing and other interventions, as well as integrate such procedures with international systems to facilitate and support administration and transparency. Increased transparency can be achieved through timely publication of applications, decisions on grant and grant of IP rights.

C. *Policy Area 3: Coordinated and Collaborative Access Mechanisms*

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, Members must address multiple countries' demand for vaccines to enhance leverage and create economies of scale, link IP options and TRIPS flexibilities to pooled or coordinated procurement, and use 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. However, concrete avenues include notifying, at an early stage of procurement, unmet needs for vaccines (and other medicines) under Article 31*bis* of TRIPS, and coordinating 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).

IV. CONCLUSION

TRIPS waiver proposals and decisions have focused on introducing, expanding, or recasting existing TRIPS flexibilities in response to the COVID-19 pandemic. In contrast, little attention has been paid to how these flexibilities in their current form might be more effectively and widely implemented. When leveraged at the domestic level, such options present powerful tools for increasing local production of vaccines and other essential medicines, and improving their availability within developed nations. When utilized and deployed by groups of countries in cooperation, they open up avenues for reinforcing government agency, aggregating demand, creating economies of scale, and developing resistance against potential political and industrial pressure. In particular, greater use of coordinated and collaborative access mechanisms would offer opportunities for more efficient and streamlined use of the System for export under Article 31*bis* (and now the 2022 Ministerial Decision).

A diverse survey of IP laws within the Asia-Pacific region demonstrates that many existing TRIPS flexibilities, despite being clearly available, are not widely or consistently implemented by Members. For example, a legislative framework for use of the Article *31bis* System, while not strictly necessary, is absent in a majority of countries in the region, potentially increasing administrative inefficiencies and undermining the System's potential. Thus, our survey, although partially

representative of the full WTO Membership, reveals a disjunct between the international principles established under the TRIPS Agreement and the actual practice in domestic jurisdictions. Similarly, the pandemic experience has shown that regional cooperation has been effective in developing technology sharing platforms, vaccine donation facilities and other programs, but utilized relatively sparingly in bypassing or overcoming perceived IP barriers to increasing production capacity and improving regional and global distribution of essential health products.

Against this background, we have sought to show that discrete legislative and other legal options do remain available for individual countries to achieve public health objectives in times of emergency, and that groups of countries can act collectively to address the more practical barriers to implementation during times of public health crisis.