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TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO

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SOUTH CENTRE

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TRIPS FLEXIBILITIES AND ACCESS TO MEDICINES: AN EVALUATION OF BARRIERS TO EMPLOYING COMPULSORY LICENSES FOR PATENTED PHARMACEUTICALS AT THE WTO

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ABSTRACT

Under Articles 31 and 31bis of the TRIPS Agreement, WTO members may validly sanction the use of a patented invention without the patent owner's authorization by issuing a compulsory license (CL). In the pharmaceuticals space, governments have historically employed compulsory licenses to compel originator manufacturers to license their patents to generic manufacturers before patent expiry, increasing the supply and reducing the price of patented pharmaceuticals domestically.

This paper evaluates the three primary barriers to employing compulsory licenses for pharmaceuticals underscored by members during TRIPS waiver discussions at the WTO: (1) a lack of enabling domestic legislation, (2) a lack of domestic manufacturing capacity coupled with an unworkable Article 31bis importation system, and (3) consistent political pressure from other members to refrain from issuing compulsory licenses. A survey of members' domestic compulsory license legislation finds that virtually all members have enacted enabling legislation under Article 31 for the issuance of compulsory licenses to supply their local markets. However, implementation of Article 31bis is limited by a lack of enabling compulsory license export legislation, streamlined administrative processes, or both across all members, preventing members lacking domestic manufacturing capacity from importing pharmaceuticals. An analysis of USTR Special 301 Reports from 1994-2021 further reveals that countries have consistently been placed on the Special 301 Report Priority Watch List for issuing pharmaceutical compulsory licenses, with instances as recent as 2020. As such, general reluctance by members to issue compulsory licenses due to overt political pressure through the Special 301 Report is likely warranted. These results highlight a range of barriers preventing the full use of compulsory licenses for pharmaceuticals under the current Article 31 and 31bis framework, with the effects disproportionately borne by member states lacking domestic manufacturing capacity.

En virtud de los artículos 31 y 31bis del Acuerdo sobre los ADPIC, los miembros de la OMC pueden sancionar válidamente el uso de una invención patentada sin la autorización del titular de la patente mediante la concesión de una licencia obligatoria. En el ámbito de los productos farmacéuticos, los gobiernos han recurrido históricamente a las licencias obligatorias para lograr que los fabricantes originales concedan licencias de sus patentes a los fabricantes de genéricos antes de la expiración de las mismas, aumentando la oferta y reduciendo el precio de los productos farmacéuticos patentados a nivel nacional.

En este documento se evalúan los tres principales obstáculos al empleo de licencias obligatorias para los productos farmacéuticos que los miembros subrayaron durante las discusiones sobre la exención de los ADPIC en la OMC: (1) la falta de legislación nacional habilitante, (2) la falta de capacidad de fabricación nacional junto con un sistema de importación inviable en virtud del artículo 31bis, y (3) la presión política constante de otros miembros para que se abstengan de conceder licencias obligatorias. Un estudio de la legislación nacional sobre licencias obligatorias de los miembros revela que prácticamente todos los miembros han promulgado leyes de habilitación en virtud del artículo 31 para la emisión de licencias obligatorias para abastecer sus mercados locales. Sin embargo, la aplicación del artículo 31bis se ve limitada por la falta de legislación habilitadora de licencias obligatorias para la exportación, procesos administrativos simplificados, o ambos, en todos los miembros, lo que impide que los miembros que carecen de capacidad de fabricación nacional importen productos farmacéuticos. Un análisis de los informes especiales 301 de la USTR de 1994 a 2021 revela además que los países han sido incluidos constantemente en

la lista de vigilancia prioritaria del informe especial 301 por emitir licencias obligatorias para productos farmacéuticos, con casos tan recientes como el de 2020. Por lo tanto, es probable que se justifique la reticencia general de los miembros a emitir licencias obligatorias debido a la presión política manifiesta a través del Informe Especial 301. Estos resultados ponen de manifiesto la existencia de una serie de obstáculos que impiden el pleno uso de las licencias obligatorias para productos farmacéuticos en el marco actual del artículo 31 y 31bis, cuyos efectos recaen desproporcionadamente en los Estados miembros que carecen de capacidad de fabricación nacional.

Conformément aux articles 31 et 31bis de l'Accord sur les ADPIC, les membres de l'OMC peuvent valablement sanctionner l'utilisation d'une invention brevetée sans l'autorisation du titulaire du brevet en délivrant une licence obligatoire (CL). Dans le secteur pharmaceutique, les gouvernements ont toujours eu recours aux licences obligatoires pour inciter les fabricants de médicaments d'origine à concéder des licences pour leurs brevets à des fabricants de médicaments génériques avant l'expiration du brevet, ce qui a permis d'augmenter l'offre et de réduire le prix des médicaments brevetés sur le marché intérieur.

Ce document évalue les trois principaux obstacles à l'utilisation des licences obligatoires pour les produits pharmaceutiques soulignés par les membres lors des discussions sur la dérogation aux ADPIC à l'OMC : (1) l'absence de législation nationale habilitante, (2) le manque de capacité de fabrication nationale associé à un système d'importation de l'article 31bis inapplicable, et (3) la pression politique constante exercée par d'autres membres pour qu'ils s'abstiennent de délivrer des licences obligatoires. Une étude de la législation nationale sur les licences obligatoires des membres montre que pratiquement tous les membres ont adopté une législation d'habilitation au titre de l'article 31 pour l'émission de licences obligatoires afin d'approvisionner leurs marchés locaux. Cependant, la mise en œuvre de l'article 31bis est limitée par l'absence de législation d'exportation de licences obligatoires, de processus administratifs rationalisés, ou les deux, chez tous les membres, ce qui empêche les membres manquant de capacité de fabrication nationale d'importer des produits pharmaceutiques. Une analyse des rapports spéciaux 301 de la USTR de 1994 à 2021 révèle en outre que les pays ont toujours été placés sur la liste de surveillance prioritaire du rapport spécial 301 pour avoir délivré des licences obligatoires dans le domaine pharmaceutique, avec des exemples aussi récents qu'en 2020. En tant que tel, la réticence générale des membres à délivrer des licences obligatoires en raison de la pression politique manifeste exercée par le rapport spécial 301 est probablement justifiée. Ces résultats mettent en évidence une série d'obstacles empêchant la pleine utilisation des licences obligatoires pour les produits pharmaceutiques dans le cadre actuel de l'article 31 et 31bis, les effets étant supportés de manière disproportionnée par les États membres qui manquent de capacité de fabrication nationale.

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I. INTRODUCTION

Since the adoption of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement), the relationship between patents and access to affordable pharmaceuticals has emerged as a cornerstone public health debate. While some advance that patents are essential for the development of new and innovative pharmaceuticals, the exercise of the monopoly pricing power conferred by patents plays a central role in limiting access to pharmaceuticals for patients in low- and high-income populations alike.[1] Compulsory licensing is a mechanism through which governments may legitimately authorize the use of patented inventions by generic manufacturers before the date of patent expiry.[2] Compulsory licenses (CLs) have been issued by many governments as a means to increase access to patented pharmaceuticals, either by directly increasing the supply of a licensed pharmaceutical or as a bargaining tactic during price negotiations with the patent holder to secure reduced prices on the original patented product.[3]

Article 31 of the TRIPS Agreement provides World Trade Organization (WTO) member countries with the legal grounds to issue CLs without the risk of violating their international trade obligations under the agreement. Pursuant to Article 31, CLs applicants are procedurally required —with some exceptions— to attempt to negotiate a voluntary license from the target patent holder before issuing a CL. Once a CL is issued, members must ensure that the patent holder is paid adequate remuneration and that the CL is non-exclusive, non-assignable, and directed predominantly for supply to the issuing member's domestic market.[4] In 2001, the *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration) expressly identified the Article 31 "predominantly for the supply of the domestic market" requirement as a severe limitation to the WTO compulsory licensing system, since it precluded members without domestic manufacturing capacity from using compulsory licensing to secure access to needed medicines through importation from other members.[5] In 2003, a waiver later incorporated as Article 31*bis* was introduced to provide members lacking domestic manufacturing capacity with the means to import medicines under CL.[6] Since the Doha

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[1] World Health Organization, "Access to Medicines – Intellectual property protection: impact on public health", *WHO Drug Information*, vol. 19, No. 3 (2005). Recent experiences of high prices and restricted access in high-income populations include hepatitis C treatment Sofosbuvir (65,000 USD per course in the USA), gene therapy Zolgensma (2.1 million USD single treatment in the USA), and cancer drugs Sprycel (11,600 USD per month in the USA) and Gleevec (~10,000 USD per fill in the USA at its peak in 2015, before a generic competitor entered the market). See Barber, Melissa J et al, "Price of a hepatitis C cure: cost of production and current prices for direct-acting antivirals in 50 countries," *Journal of Virus Eradication*, vol. 6, No. 3 (2020); Nuijten, Mark, "Pricing Zolgensma – the world's most expensive drug," *Journal of Market Access & Health Policy*, vol. 10, No. 1 (2022); Goldstein, Daniel et al, "A global comparison of the cost of patented cancer drugs in relation to global differences in wealth," *Oncotarget*, vol. 8, No. 42 (2017); Cole, Ashley and Stacie Dusetzina, "Generic price competition for specialty drugs: too little, too late?" *Health Affairs*, vol. 37, No. 5 (2018).

[2] World Trade Organization, "Compulsory licensing of pharmaceuticals and TRIPS." Available from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

[3] Beall, Reed and Randall Kuhn, "Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis," *PLoS Medicine*, vol. 9, No. 1 (2012); Kohler, Jillian and Kristina Lybecker, "AIDS Policy and pharmaceutical patents: Brazil's strategy to safeguard public health" *The World Economy*, vol. 28, No. 2 (2005).

[4] *Agreement on Trade-Related Aspects of Intellectual Property Rights,* 15 April 1994, *Marrakesh Agreement Establishing the World Trade Organization,* Annex 1C, 1896 UNTS 299 (entered into force 1 January 1995), art 31.

[5] World Trade Organization, "Declaration on the TRIPS Agreement and Public Health", Document WT/MIN(01)/DEC/2 (2001). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/Min01/DEC2.pdf&Open=True.

[6] World Trade Organization, "Fact sheet: TRIPS and pharmaceutical patents – obligations and exceptions," September 2006. Available from https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

Declaration, members have issued CLs over 60 times using the Article 31 and 31*bis* pathways to secure expanded access to needed pharmaceuticals.[7]

During the COVID-19 pandemic, the relationship between the international intellectual property system and access to pharmaceuticals has gained prominence as a central global public health concern. In October 2020, a wholesale waiver of the patent, industrial design, undisclosed information, and copyright sections of the TRIPS Agreement in relation to the prevention, containment, and treatment of COVID-19 was proposed by India and South Africa at the WTO.[8] In May 2021, the waiver was clarified as intended to apply to all COVID-19-related health products and technologies, their materials or components, and their methods and means of manufacture.[9] The waiver has been met with polarizing reception from WTO members, industry stakeholders, and civil society groups: opponents contend that existing TRIPS flexibilities, including the issuance of CLs, are sufficient to address public health needs during the pandemic,[10] while proponents have emphasized the TRIPS Agreement's inadequacy in the context of a global crisis requiring a rapid and internationally coordinated response.[11] In particular, cited rationales for the support of a COVID-19 TRIPS waiver have focussed on the inefficiencies and challenges associated with employing the existing Article 31 and 31*bis* CL framework. These challenges are thought to undermine countries' abilities to readily employ CLs to secure access to urgently needed pharmaceuticals, including vaccines.[12]

This paper examines three barriers to employing CLs for pharmaceuticals identified during the TRIPS waiver discussions at the WTO. These are: (1) a lack of enabling domestic legislation, (2) a lack of domestic manufacturing capacity coupled with an unworkable Article 31*bis* importation system, and (3) consistent political pressure from other members to refrain from issuing CLs. It proposes that under non-pandemic circumstances, these legal, technical, administrative, and political factors undermine members' ability to issue CLs. Thus, when responding to emergency situations of urgent global health need, exclusive reliance on the CL system is likely to be an insufficient solution to ensuring rapid and widespread access to needed pharmaceuticals. While a COVID-19 TRIPS waiver may offer members a temporary avenue to circumvent these barriers, further work is required to systematically improve access to pharmaceuticals under the existing CL system.

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[7] South Centre, "Scope of compulsory license and government use of patented medicines in the context of the COVID-10 pandemic", (Geneva, 2021). Available from https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/.

[8] World Trade Organization, "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19", Document IP/C/W/669 (2020). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

[9] World Trade Organization, "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19", Document IP/C/W/669/Rev.1 (2021). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True.

[10] Notably, the EU and originator pharmaceutical manufacturers. See for example, World Trade Organization, "Urgent trade policy responses to the COVID-19 crisis: intellectual property", Document IP/C/W/680 (2021). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W680.pdf; Albert Bourla, Pfizer Chairman and CEO, "An open letter from Pfizer Chairman and CEO to colleagues," Press Statement. Available from https://www.pfizer.com/news/hot-topics/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines.

[11] See for example, World Trade Organization, "Council for Trade-Related Aspects of Intellectual Property: Minutes of meeting", Document IP/C/M/96/Add.1 (2020). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M96A1.pdf&Open=True. The TRIPS waiver was presented at the TRIPS Council by India and South Africa. There are now over 62 co-sponsors, including the African Group, Bolivia, Egypt, Eswatini, Fiji, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, Vanuatu, Venezuela, and Zimbabwe. A list of major civil society organizations in support of the waiver is available from https://www.policyalternatives.ca/newsroom/updates/civil-society-letter-supporting-indias-and-south-africas-proposal-trips-agreement.

[12] Médecins Sans Frontières, "Compulsory licenses, the TRIPS waiver, and access to COVID-19 medical technologies", (26 May 2021). Available from https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies.

II. METHODS

The limitations to the use of CLs raised by WTO members during initial TRIPS waiver discussions were reviewed, with the three most frequently cited identified for further exploration: (1) a lack of enabling domestic legislation, (2) a lack of domestic manufacturing capacity coupled with an unworkable Article 31*bis* importation system, and (3) consistent political pressure from other members to refrain from issuing CLs. To evaluate these barriers, datasets were constructed to identify (1) all members with enabling domestic CL legislation, (2) all members legally and technically capable of exporting pharmaceuticals under CL through the Article 31*bis* mechanism, and (3) the frequency of members being publicly discouraged from engaging in compulsory licensing by other members. The specific data sources and collection methods are discussed in further detail below.

II-A. Survey of CL Legislation

The World Intellectual Property Organization (WIPO) maintains a comprehensive and centralised database of all members' patent law flexibilities (WIPO Database on Flexibilities in the Intellectual Property System).[13] Throughout the COVID-19 pandemic, WIPO has also maintained a tracker of additional emergency intellectual property laws and regulations introduced by its members (WIPO COVID-19 IP Policy Tracker: Legislative and Regulatory Measures).[14] The presence or absence of enabling domestic CL legislation for each WTO member was recorded with reference to these two databases, since these were endorsed as the authoritative and most current account of WTO members' intellectual property legislation by the WTO.

Members were separately evaluated for the presence of legislation enabling the use of CLs for the domestic market under Article 31 and the presence of CL legislation enabling pharmaceutical export under Article 31*bis*. This dataset was verified by cross-referencing the results with a 2010 WIPO review of WTO member CL legislation, which specifically queried whether members had enacted legislation to implement Article 31*bis*, and the official WTO webpage dedicated to tracking member implementation of Article 31*bis* (last updated January 2016).[15] Further consultation upon South Centre review resulted in the inclusion of an additional Article 31*bis* CL law for Brazil.

II-B. Analysis of Domestic Manufacturing Capacity and Barriers to Using the Article 31bis System

WTO members' pharmaceutical manufacturing capacities were primarily determined in reference to a 2010-2014 series of World Health Organization (WHO) Pharmaceutical Country Profiles, which explicitly queried whether respondent countries maintained domestic

[13] World Intellectual Property Organization, "Database on flexibilities in the intellectual property system", Query: patents, compulsory licenses and government use. Available from https://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp?field_id=2343&type_id=2349&territory_id=.

[14] World Intellectual Property Organization, "COVID-19 IP Policy Tracker", Query: legislative and re. measures. Available from https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access; World Trade Organization, "COVID-19: measures regarding trade-related intellectual property rights". Available from https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

[15] World Intellectual Property Organization, "*Annex II: Categories of different provisions on specific flexibilities*", Document CDIP/5/4. Available from https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex2.pdf#page=1. World Trade Organization, "COVID-19: Measures regarding trade-related intellectual property rights." Available from https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

manufacturing capacity.[16] For members without WHO Country Profiles, manufacturing capacity was determined based on domestic pharmaceutical consumption, export, and import value data compiled in a 2017 survey by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).[17] Together, these sources informed estimates of nearly all WTO members' manufacturing capacities, either through direct inquiry or inferred from industry trade data. Data was unavailable for 16 United Nations classified least developed countries (LDCs), World Bank classified lower-middle income countries (LMICs), and World Bank classified high income country (HIC) microstates and Special Administrative Regions. These countries were all ascribed a classification of "no domestic manufacturing capacity" in consultation with working experts in the field.[18] The list of countries with domestic manufacturing capacity was then cross-referenced with the list of countries with domestic legislation enabling the export of pharmaceuticals under Article 31*bis,* to produce a final list of countries considered both legally and technically eligible to export pharmaceuticals under CL through the Article 31*bis* pathway.

To evaluate additional procedural and technical barriers associated with using the Article 31*bis* system, a targeted review of the literature was conducted to provide an overview of past members' experience engaging in Article 31*bis* compulsory licensing. Literature was limited to works published from 2003 (the year Article 31*bis* was introduced to the TRIPS Agreement) to 2021. Particular weight was ascribed to primary accounts published by Médecins Sans Frontières, a group involved in overseeing the only successful exercise of Article 31*bis*, of their experience using the Article 31*bis* pathway to facilitate the export of HIV/AIDS drugs from Canada to Rwanda in 2008 and 2009.[19]

II-C. Survey of Political Pressure

In TRIPS Council discussions regarding a possible COVID-19 TRIPS waiver, members expressly identified the United States Trade Representative (USTR) Special 301 Report and European Commission IP Watchlist as sources of political pressure that actively discourage members from issuing CLs.[20] Each report series was catalogued from 1994 (the year the TRIPS Agreement was signed) to 2021. The identities and offender classifications of members placed on the USTR Special 301 Report due to "inadequate" pharmaceutical patent provisions were recorded, with entries flagged if members were expressly included due to the use of

[16] See World Health Organization, "Development of country profiles and monitoring of the pharmaceutical situation in countries". Available from https://www.who.int/tools/monitoring-and-evaluation/pharmaceutical-sector-country-profile; World Health Organization, "Pharmaceutical country profile data collection tool", (2019). Available from https://www.who.int/publications/m/item/pharmaceutical-country-profile-data-collection-tool.

[17] International Federation of Pharmaceutical Manufacturers and Associations, *IFPMA Facts and Figures*, (Geneva, 2017). Available from https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf.

[18] One expert with extensive experience in global pharmaceutical manufacturing and several experts with experience working in access to pharmaceuticals in low- and middle-income countries.

[19] Médecins Sans Frontières, "Review of the Canadian Access to Medicines Regime: Submission to the Government of Canada", (Toronto, 2007). Available from https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_msf_11-eng.pdf.

[20] For example, highlighted by Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela, and Zimbabwe in World Trade Organization, "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 – Responses to questions", Document IP/C/W/672 (2021). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W672.pdf&Open=True.

pharmaceutical CLs.[21] The identities of members placed on the European Commission IP Watchlist due to "inadequate" pharmaceutical patent provisions were similarly recorded.[22]

III. RESULTS

The following section reports on the extent to which members face each of the three barriers to issuing pharmaceutical CLs, using the indicators described in section II.

III-A. Barrier 1: Lack of Enabling Domestic CL Legislation

While the TRIPS Agreement ensures that no member can be challenged at the WTO by another if it issues a CL pursuant to Articles 31 or 31*bis*, a member's actual ability to engage in compulsory licensing is defined by its national legislation. All members except LDC members (which are exempt from TRIPS compliance until 2034) are subject to the intellectual property standards provided by the TRIPS Agreement, and are thus required to provide inventions that are new, involve an inventive step, and are capable of industrial application with 20 years of patent protection from the date of filing.[23] Since compulsory licensing defines a legal exception to the exclusive rights otherwise held by patent owners, express legislation enabling the issuance of CLs is required for countries to engage in compulsory licensing. Without this legal pathway, members that completely lack enabling domestic legislation cannot issue CLs despite the permissibility of this flexibility under the TRIPS Agreement.

Upon review, 95 per cent (155 of 164) of WTO members have domestic legislation enabling the issuance of CLs under Article 31 of the TRIPS Agreement, either as directly codified law or through legislation enabling the domestic adoption of intellectual property provisions codified under regional agreements.[24] This means that nearly all members are legally capable of issuing CLs to produce pharmaceuticals primarily for the supply of their domestic markets. Of the nine countries that currently do not have enabling domestic CL legislation in place, five (Afghanistan, Haiti, Nepal, Solomon Islands, and Yemen) are LDCs exempt from TRIPS compliance and thus not yet affected by this lack of legislation. Furthermore, while Venezuela does not currently have enabling domestic CL legislation in place, the country's history of

[21] USTR Special 301 Reports from 1994-2009 are publicly available at Office of the United States Trade Representative, "Previous Special 301 Reports". Available from https://ustr.gov/issue-areas/intellectual-property/special-301/previous-special-301-reports. Reports from 2010-2021 are available at Office of the United States Trade Representative, "Special 301 Report". Available from https://ustr.gov/issue-areas/intellectual-property/special-301.

[22] European Commission, "Counterfeit and Piracy Watch List", 7 December 2018. Available from https://trade.ec.europa.eu/doclib/docs/2018/december/tradoc_157564.pdf; European Commission, "Counterfeit and Piracy Watch List", 14 December 2020. Available from https://trade.ec.europa.eu/doclib/docs/2020/december/tradoc_159183.pdf.

[23] *Agreement on Trade-Related Aspects of Intellectual Property Rights,* 15 April 1994, *Marrakesh Agreement Establishing the World Trade Organization,* Annex 1C, 1896 UNTS 299 (entered into force 1 January 1995), art 27(1).

[24] For example, CL legislation under Decision No. 486 of the *Andean Community Commission Establishing the Common Regime on Industrial Property* or the *Agreement Revising the Bangui Agreement on the Creation of an African Intellectual Property Organization*.

refusing to issue patents for pharmaceutical products likely reduces the importance of CLs for increasing its domestic access to pharmaceuticals.[25] By contrast, in Fiji, Maldives, and Suriname, the absence of enabling domestic CL legislation likely serves as a real barrier to employing compulsory licensing to expand domestic supplies of pharmaceuticals.

III-B. Barrier 2: Lack of Domestic Manufacturing Capacity and Challenges to Using Article 31bis

Countries that do not have domestic manufacturing capacity must rely on the importation of pharmaceuticals under Article 31*bis* if they wish to employ CLs to increase their population's local access to pharmaceuticals. During periods of international crisis, these cross-border trade flows are particularly vulnerable to disruption. Approximately 22 per cent (37 of 164) of WTO members lack the domestic capacity to manufacture basic small molecule pharmaceuticals. An additional 6 per cent (10 of 164) maintain only limited domestic manufacturing capacities, with most of these members unable to produce sufficient quantities to effectively support their local populations or to produce more complex pharmaceutical products. This suggests that approximately 28 per cent of all members are likely dependent on the Article 31*bis* pathway to issue CLs for pharmaceuticals. Of these countries, 46 per cent are UN classified LDCs and 16 per cent are World Bank classified LMICs.

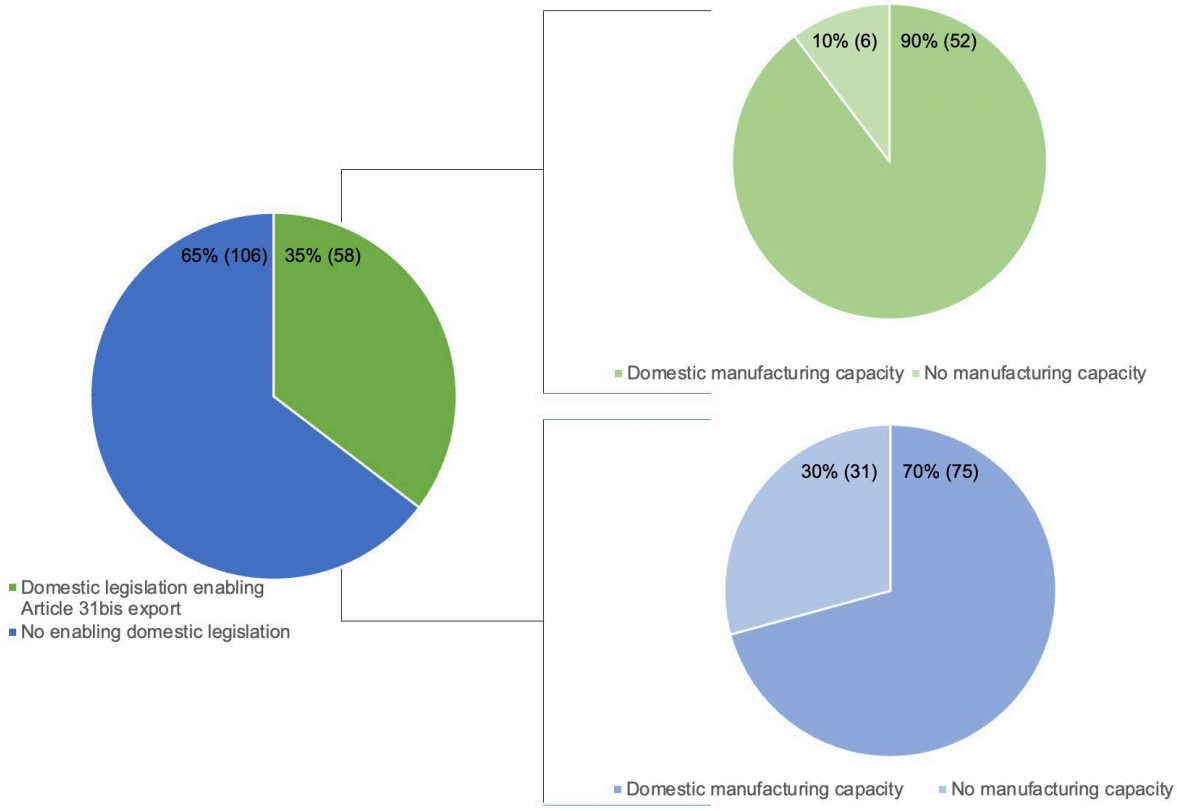
Two primary challenges involved with the use of Article 31*bis* are identified below: (1) constraints on the number of members eligible to serve as exporters under Article 31*bis*, and (2) the existence of onerous technical and procedural requirements faced by eligible members that discourage their participation as exporters.

i. Lack of eligible exporters

For a member to serve as an eligible Article 31*bis* exporter, it must have both the legal and technical capacity to produce pharmaceuticals under Article 31*bis* and export them to members lacking domestic manufacturing capacity. Upon review, only 32 per cent of all WTO members have such capacity. Four per cent (6 of 164) of all members have the necessary legislation but lack domestic manufacturing capacity, while 46 per cent (75 of 164) have domestic manufacturing capacity but do not have the necessary legislation (Figure 1). This lack of eligible exporters limits importing members' ability to use the Article 31*bis* CL pathway, since they are prevented from relying on 70 per cent of all technically capable members as a source of generic production.

[25] Jones, Casimir, "Venezuelan Patent and Trademark Office issues the first notice of allowances in pharmaceutical patent applications since 2004", *Lexology*, 21 May 2021. Available from https://www.lexology.com/library/detail.aspx?g=c8c1b377-bbea-46d1-bab2-ac817ca967eb.

Figure 1
WTO members with and without domestic manufacturing capacity, based on whether members have domestic legislation enabling the export of pharmaceuticals under Article 31*bis*



ii. Procedural and technical constraints faced by exporters

Significant administrative requirements impede members from serving as Article 31*bis* exporters. This includes the procedural requirement that members notify the TRIPS Council before exercising the pathway, which takes time and administrative effort, as well as the requirement that generic manufacturers first attempt to obtain separate voluntary licenses from target patent holders unique to each importing member country.[26] Supplementary procedural steps mandated by a particular exporting country's domestic CL legislation, including additional legislative or regulatory proceedings, must also be complied with, introducing further administrative delays. Administrative hurdles have a particularly pronounced deterrent effect when the market opportunity for generic manufacturers is limited. Given that 62 per cent of countries reliant on Article 31*bis* importation are LDCs, LICs or LMICs, it is likely that most countries attempting to import pharmaceuticals under CLs offer relatively small commercial opportunities to generic manufacturers and are thus more vulnerable to these administrative barriers.

The only successful case of compulsory licensing under Article 31*bis* occurred in 2008 and 2009, resulting in the export of a limited supply of antiretroviral HIV/AIDS medicines from Canada to Rwanda under the Canadian Access to Medicines Regime (CAMR). In 2004,

[26] Correa, Carlos M., "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", (Geneva, World Health Organization, 2004). Available from https://apps.who.int/iris/handle/10665/68743.

CAMR was enacted to provide Canada with a defined legal and administrative pathway to export pharmaceuticals under Article 31*bis*. However, CAMR has proved difficult to apply in practice. Under CAMR, generic manufacturers seeking to produce pharmaceuticals for export under Article 31*bis* must ensure that the products have received regulatory approval by Health Canada.[27] This can pose an administrative barrier if, for example, the manufacturer is seeking to export a product for which there is no Canadian domestic commercial market. Manufacturers must additionally ensure that the products they intend to manufacture are already included on the country's list of products eligible for Article 31*bis* export. If they are not, manufacturers must request that these target products be added to the list of eligible products via legislative amendment to the national Patent Act.[28] This process is particularly time consuming, historically requiring an average 7-8 months but having previously taken up to 15 months.[29] It has also been criticized for lacking transparency, since the criteria for determining whether a requested product will be added to the list is not publicly defined.[30]

There has been limited engagement by generic manufacturers with the Article 31*bis* compulsory licensing pathway. Since 2004, there have been five attempts by generic manufacturers to use Canada's Article 31*bis* system. Of these, three CL applications were abandoned by manufacturers largely due to the long time horizon associated with amending the country's eligible product list.[31] One application, submitted in March 2021 to produce Johnson & Johnson's COVID-19 vaccine for export to Bolivia, is currently ongoing and has yet to secure the addition of the vaccine to the country's eligible product list.[32] The one successful use of CAMR required the exporting manufacturer to secure both an amendment to the country's Patent Act and regulatory approval from Health Canada, and took four years from the initial date of CL application to deliver the requested lamivudine-nevirapine-zidovudine triple combination therapy to Rwanda. Upon the license's termination, the generic manufacturer publicly stated that it would not export pharmaceuticals under CL again, citing both the specific CAMR requirements and the Article 31*bis* country-by-country prerequisite voluntary licensing negotiations as unduly burdensome procedural requirements preventing the scalable use of the system.[33]

While not all WTO member states have the same requirements as Canada to export pharmaceuticals under Article 31*bis*, no other country has successfully exported pharmaceuticals using the Article 31*bis* exception or developed an export procedure as well-defined as CAMR. This means that members lacking domestic manufacturing capacity and seeking to import pharmaceuticals under Article 31*bis* are faced with the choice of either using Canada's procedurally onerous but established system or attempting to use the Article 31*bis* export system of another eligible member without the benefit of a procedural precedent.

Finally, members seeking to produce pharmaceuticals for export under Article 31*bis* are also required by TRIPS to substantively implement anti-diversion measures when manufacturing any Article 31*bis* CL product. This includes expressly labelling all produced lots as specifically designated for export to the requesting member importer, as well as ensuring that the products are packaged, coloured, or shaped distinctively from those versions normally produced by the manufacturer for standard consumer purchase.[34] Any anti-diversion measure that requires additional manufacturing diversification or otherwise prevents generic manufacturers from

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[27] Médecins Sans Frontières, *supra* note 19.
[28] Ibid.
[29] Schouten, Arianna, "Canadian experience with compulsory licensing under the Canadian Access to Medicines Regime", KEI Briefing Note 2021:2 (31 March 2021). Available from https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2021-2-CAMR-Canadian-Compulsory-Licensing.pdf.
[30] Ibid.
[31] Ibid.
[32] Ibid.
[33] Ibid., Talaga, Tanya, "Hope for cheap HIV drugs dims", *The Star*, 19 September 2009. Available from https://www.thestar.com/life/health_wellness/2009/09/19/hope_for_cheap_hiv_drugs_dims.html.
[34] Correa, *supra* note 26.

employing standardized manufacturing processes risks undermining their ability to minimize costs and production timelines by taking advantage of normal economies of scale in production. This in turn stands as an additional barrier to the full use of the Article 31*bis* compulsory licensing pathway.

III-C. Barrier 3: Political Pressure Against Issuing CLs

Though Article 31 and 31*bis* serve to protect members that engage in compulsory licensing from challenge at the WTO, these Articles do not insulate them from political pressure by other members seeking to discourage the use of CLs. It is for this reason that members opposed to the use of CLs were able to successfully exert political pressure to prevent the issuance of any CLs for pharmaceuticals from 1994–2001.[35] Only after the Doha Declaration's affirmation of members' rights to use CLs in the pursuit of protective public health policies did members begin to regularly issue CLs for the production of needed pharmaceuticals.[36] However, political pressure seeking to dissuade the use of CLs continues to be exerted by members with strong domestic originator pharmaceutical industries and industry lobbyists. Since 1989, the United States has employed regularly published reports to actively "name and shame" and threaten with trade retaliations countries engaging in "unsatisfactory" intellectual property practices based on the US Special Section 301 of the Trade Act. More recently, a similar strategy has also been pursued by the European Union (EU) through its Intellectual Property Watch List. The relationship between both reports and member use of CLs is discussed in further detail below.

i. USTR Special 301 Report

The USTR Special 301 Report classifies target countries into three tiers of offenders:

- "Watch List" countries, with intellectual property policies warranting further review;
- "Priority Watch List" countries, with serious intellectual property deficiencies that the US government actively encourages countries to redress, and;
- "Priority Foreign Countries", defined as those wilfully engaged in "the most onerous and egregious [intellectual property] acts, policies, and practices" and against whom the United States can lawfully impose trade sanctions.[37]

Since the TRIPS Agreement entered into force, the number of WTO members placed on the Special 301 Report due to unsatisfactory intellectual property protection for pharmaceuticals has nearly quadrupled, rising from five countries in 1994 to 18 in 2021. While no country has been listed as a Priority Foreign Country due to their intellectual property practices in the pharmaceutical sector, several countries have been placed on the Watch List or Priority Watch List. Since 1996, an average of 20 countries have been placed on the Special 301 Report each year for this reason, with the exception of a brief decline during the height of the HIV/AIDS crisis and the period shortly following the Doha Declaration (2000-2003) (See Figure 2).

Though the Doha Declaration affirms members' rights to issue CLs for the protection of public health, countries including Brazil, India, Thailand, and Turkey have since been included on the Special 301 Report for their actual or contemplated use of compulsory licensing for pharmaceuticals. As recently as 2020, India was included as a Priority Watch List country, with its compulsory licensing system for pharmaceuticals specifically referenced in the Report.

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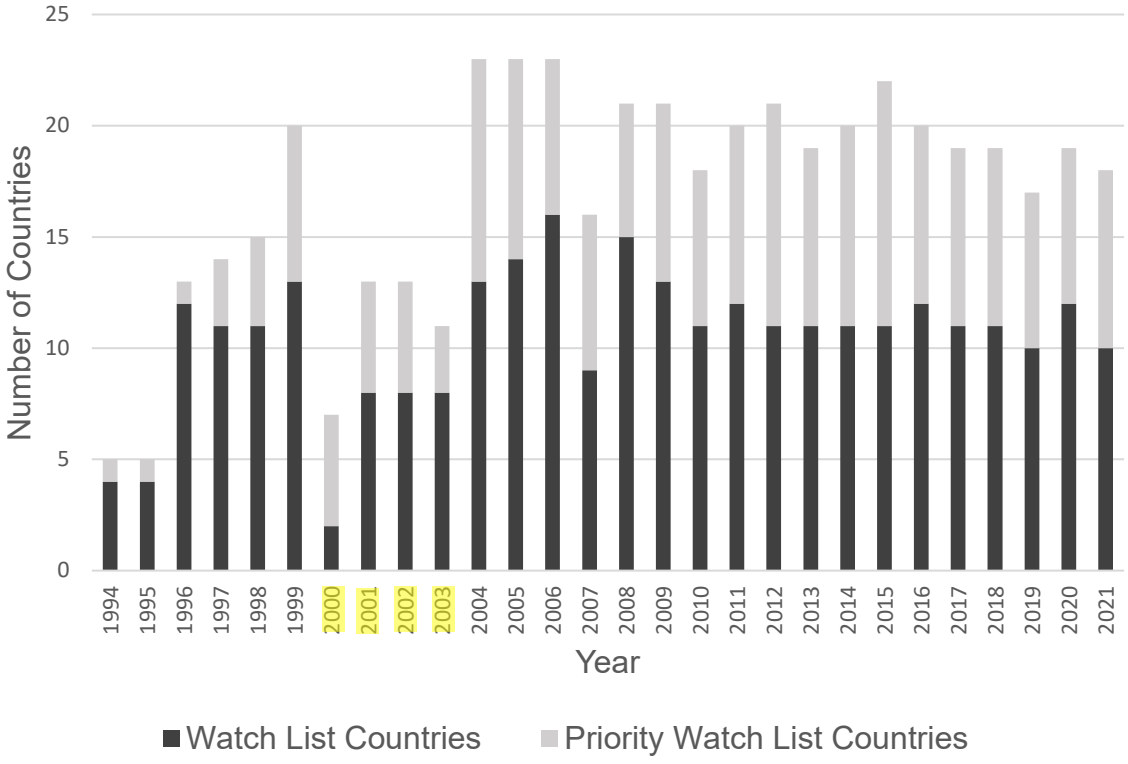
[35] Beall and Kuhn, *supra* note 3.
[36] Ibid., World Trade Organization *supra* note 5.
[37] Drahos, Peter, "Global property rights in information: the story of TRIPS at the GATT", *Prometheus Critical Studies in Innovation* vol. 6 (1995).

This suggests that members face consistent and overt public pressure from the United States to refrain from engaging in compulsory licensing for pharmaceuticals – either directly if named and placed on the Special 301 Report for the use of CLs, or indirectly if deterred from using CLs after witnessing other members be placed on the Special 301 Report. Notably, the 2021 Special 301 Report acknowledged members' legitimate ability to issue CLs to address "serious public health emergencies", such as the COVID-19 pandemic, "in a manner consistent with the provisions of the TRIPS Agreement and the Doha Declaration."[38] While the 2021 edition thus refrained from listing any countries due to their use of CLs, it remains unclear whether this marks a new policy shift or is instead an exceptional allowance unique to the COVID-19 pandemic.

ii. European Commission IP Watch List

The inaugural EU IP Watch List was published in 2018 for the purpose of monitoring and enforcing the protection of intellectual property abroad.[39] Since then, a second Watch List was published in 2020. Despite being cited by members during COVID-19 TRIPS waiver discussions as a source of political pressure interfering with the full exercise of TRIPS flexibilities, neither Watch List focuses on countries that fail to provide "adequate" patent protection in the pharmaceutical sector. Rather, intellectual property scrutiny for pharmaceuticals within the Watch List has been limited to the abuse of trademarks and the online sale of counterfeit products. As a result, there is no indication that members face overt and public pressure from the EU through its Watch List to refrain from issuing CLs on pharmaceutical products for the protection of public health.

Figure 2
Number of countries placed on the USTR Special 301 Report due to alleged inadequate intellectual property protection in the pharmaceutical sector (1994-2021)



[38] United States, Office of the United States Trade Representative (2021). *2021 Special 301 Report* (Washington DC, 2021). Available from https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf.
[39] European Commission, *supra* note 22.

Note in Figure 2 the decline in countries in 2000-2003, corresponding to the height of the HIV/AIDS crisis and the two-year period following the 2001 Doha Declaration (highlighted).

IV. Discussion

An analysis of WTO members' domestic CL legislation and pharmaceutical manufacturing capacities reveals that members likely face significant legal, procedural, and technical barriers to engaging in pharmaceutical compulsory licensing under the Article 31*bis* system. While only nine WTO members completely lack the legal ability to issue CLs, the majority of technologically capable members are legally precluded from producing pharmaceutical products for export to members lacking domestic manufacturing capacity. Additional procedural requirements and obligatory technical anti-diversion measures introduce further barriers to pharmaceutical production under CLs for export in countries otherwise eligible to serve as Article 31*bis* exporters, serving to disincentivize use of the Article 31*bis* system. Furthermore, trends among USTR Special 301 Report-listed countries indicate that members face consistent and overt political pressure from the United States to refrain from engaging in compulsory licensing for pharmaceuticals, irrespective of whether CLs are issued through the Article 31 or 31*bis* pathway. As the world's largest economy, such pressure is particularly influential when actively presented as a core policy on which other countries' positive trade relations with the US depend. It also likely underrepresents the total scope of political pressure faced by members seeking to exercise CLs for pharmaceuticals, since it does not capture additional forms of pressure exerted by members or pharmaceutical industry interest groups outside the USTR Special 301 Report. For example, the 2016 UN Secretary General High-Level Panel on Access to Medicines reported that members have also faced political critique from the European Trade Commissioner and have received manufacturer threats to stop registering new pharmaceutical products within their territories in response to issuing pharmaceutical CLs.[40]

Taken together, this suggests that the barriers to compulsory licensing are borne most heavily by members that lack domestic pharmaceutical manufacturing capacity, since these are the countries that face the barriers unique to the Article 31*bis* pathway and the twofold effects of political pressure – either as direct political targets or indirect collateral stakeholders when eligible exporters are targeted. Given that nearly 30 per cent of WTO members can only use the Article 31*bis* importation pathway if they wish to issue CLs, and that further members would likely need to use the Article 31*bis* importation pathway to issue CLs for pharmaceuticals with specific or particularly complex manufacturing requirements beyond their domestic capabilities, this reflects a marked limitation to the current compulsory licensing system under the TRIPS Agreement. It also highlights the compounding effects of inequitable access to medicines; over 60 per cent of the countries relegated to exclusively using the Article 31*bis*

[40] United Nations, "Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: promoting innovation and access to health technologies", September 2016. Available from https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

pathway are LDCs, LICs or LMICs, and thus the countries also most likely to face capacity issues when responding to urgent public health crises.

IV-A. Implications for a COVID-19 TRIPS Waiver

There have been few attempts to directly resolve the identified barriers to compulsory licensing. Although advocacy groups have emphasized the very real limitations to the widespread use of Article 31*bis*, members face limited incentives to ensure that they have the legislation in place to serve as exporters or to attempt to establish streamlined administrative processes to facilitate the production and export of pharmaceuticals under CL. Political priority is low since their domestic populations are not those that stand to directly benefit, while the risk of trade sanctions for issuing CLs is high. Instead, countries lacking domestic manufacturing capacity have primarily focussed on non-CL policy options to secure access to affordable patented pharmaceuticals, such as pooled procurement mechanisms or direct price negotiations.

During discussions regarding the adoption of a COVID-19 TRIPS waiver, proponent members have emphasized the need for a response system that is flexible, administratively simple, and timely. In its 2021 edition of the Special 301 Report, the USTR specifically identified the COVID-19 pandemic as a qualifying and non-challengeable public health emergency on which CLs for COVID-19 related pharmaceuticals, therapies, and medical devices can be legitimately issued.[41] The European Union has also been actively advocating for the use of compulsory licensing during the pandemic.[42] While this stands as a promising indication that overt inter-governmental political pressure to refrain from compulsory licensing has been largely restrained during the COVID-19 pandemic, barriers originating directly from patent owners remain. For example, Russia's decision to issue a CL for the production of Gilead's patented COVID-19 treatment candidate, remdesivir, was met by a lawsuit brought by Gilead over the validity of the order.[43]

Given the country-by-country and product-by-product nature of compulsory licensing, as well as the distinct likelihood that the members most in need are those obliged to using the Article 31*bis* pathway, it is likely implausible that compulsory licensing under the existing TRIPS system can rapidly and adequately meet member needs in the context of a global pandemic. Emergency CL legislation amendments introduced by several high-income countries at the beginning of the pandemic underscore an implicit acknowledgement of the baseline limitations present in the CL system.[44] The EU proposed emergency relaxation of the Article 31*bis* notification requirements lends further support to the position that the existing Article 31 and 31*bis* system is ill-equipped to serve as an effective public health tool during the pandemic. In May 2021, the United States expressed its support for a limited TRIPS waiver applicable to all COVID-19 vaccine-related technology. While decidedly narrower in scope than the original TRIPS waiver proposal, it stands as an unprecedented departure from the US' historically aggressive defence of intellectual property in the pharmaceuticals space. It also highlights a growing understanding of patents as a barrier to securing global access to affordable medicines.

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[41] United States, Office of the United States Trade Representative, *supra* note 38

[42] World Trade Organization, "Draft General Council Declaration on the TRIPS Agreement and Public Health in the circumstances of a pandemic", Document IP/C/W/681 (2021). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W681.pdf.

[43] "Russian court rejects US firm's lawsuit over COVID-19 drug remdesivir", *Reuters*, 28 May 2021. Available from https://www.reuters.com/business/healthcare-pharmaceuticals/russian-supreme-court-rejects-gilead-lawsuit-over-covid-19-drug-2021-05-27/.

[44] For example, Canada and Hungary, Médecins Sans Frontières, *supra* note 12.

A COVID-19 TRIPS waiver offers members a temporary mechanism to circumvent the identified barriers associated with the Article 31 and 31*bis* CL system. In particular, it enables countries with domestic manufacturing capacity to produce and export generic versions of needed pharmaceuticals regardless of their formal CL legislation status. It would also enable these countries to bypass onerous procedural and technical requirements otherwise prescribed by their domestic Article 31*bis* CL systems, if applicable. However, a waiver alone will be insufficient to ensure that all countries have rapid access to the COVID-19 pharmaceuticals they need. For example, as seen in cases of COVID-19 vaccine nationalism, it is unlikely that countries with manufacturing capacity will prioritise the export of pharmaceuticals during periods of global shortages before first securing supplies for their domestic populations. A waiver also struggles to guarantee country access to the technological know-how required to successfully produce many of these pharmaceutical products, regardless of whether members may permissibly render the underlying patents unenforceable. Nonetheless, the underlying premise that members urgently require administratively efficient pathways to increase pharmaceutical supplies remains widely unchallenged; by entering into voluntary licensing agreements for COVID-19 vaccines during the pandemic, even manufacturers have tacitly acknowledged this need.

IV-B. Recommendations

Beyond the emergency implementation of a TRIPS waiver, four recommendations are offered toward improving member use of the Article 31 and 31*bis* TRIPS compulsory licensing system. First, all members lacking enabling domestic CL legislation should actively work toward introducing such legislation to ensure that they have the legal option to engage in compulsory licensing under Articles 31 and 31*bis*. While LDC members in this category have until 2034 to implement such changes, non-LDC members stand to immediately benefit from the availability of compulsory licensing as a public health policy option. Technical assistance from organizations including WIPO, the UNDP, and the South Centre to implement these legislative changes may be helpful, however it is important to ensure that the resulting legislation is not administratively burdensome, unduly onerous, or otherwise restrictive in its practical application. This is particularly important since it has been observed that many members with existing CL legislation have found their regimes to be procedurally unworkable in practice.[45]

Second, members with robust domestic generic manufacturing capacity should make conscious efforts to amend their domestic patent legislations to expressly permit the production of pharmaceuticals under CL for export through the Article 31*bis* pathway. This is particularly true for countries that already have a history of issuing pharmaceutical CLs for domestic use, such as Ecuador and Thailand. Third, WTO members should consider reviewing the procedural requirements of their domestic Article 31*bis* CL systems to ensure that generic manufacturers seeking to produce pharmaceuticals under CL for export can expect commercially feasible timelines. Finally, consistent and vocal advocacy from members and civil society groups may help restrain countries in favour of stronger pharmaceutical patent protection from systematically discouraging the legitimate use of pharmaceutical CLs for the protection of public health. The current COVID-19 TRIPS waiver negotiations have placed a spotlight on intellectual property and access to medicines, while simultaneously eliciting unprecedented support for compulsory licensing by members that have historically sought to restrict the use of CLs. Fostering the post-pandemic continuation of these attitudes stands to directly reduce the political barriers to compulsory licensing normally faced by members.

[45] Halajian, Dina, “Inadequacy of TRIPS & the compulsory license: why broad compulsory licensing is not a viable solution to the access to medicines problem”, *Brooklyn Journal of International Law*, vol. 38, No. 3 (2013).

V. CONCLUSION

An analysis of the barriers to compulsory licensing underscored by WTO members during the COVID-19 TRIPS waiver discussions reveals that member use of CLs is undermined by a lack of enabling domestic CL legislation, a lack of members eligible to manufacture and export pharmaceuticals to those lacking domestic manufacturing capacity, onerous procedural and technical anti-diversion requirements, and political pressure among members. This indicates that there remain system-wide barriers preventing the full use of CLs to improve pharmaceutical access under the current Article 31 and 31*bis* framework. Further, the effects of these barriers appear to disproportionately affect member states lacking domestic manufacturing capacity, thus undermining the goal of equitable access underpinning both the Doha Declaration and Article 31*bis*. In the context of COVID-19, where the majority of these members are LDCs, LICs or LMICs with limited pandemic response capacities, an effort to provide members with a mechanism to legitimately circumvent these barriers emerges as a warranted public health response for ensuring access to urgently needed pharmaceuticals.

APPENDIX

Table 1: **WTO members with enabling CL legislation for the production of pharmaceuticals under Article 31*bis* of the TRIPS Agreement**

Albania	China	France	Kazakhstan	North Macedonia	South Korea
Antigua and Barbuda	Croatia	Germany	Latvia	Norway	Spain
Australia	Cuba	Greece	Liberia	Oman	Sweden
Austria	Cyprus	Hong Kong	Liechtenstein	Philippines	Switzerland
Belgium	Czech Republic	Hungary	Lithuania	Poland	Tajikistan
Botswana	Denmark	Iceland	Luxembourg	Portugal	Tanzania
Brazil	Djibouti	India	Malta	Romania	Uganda
Burundi	Estonia	Ireland	Montenegro	Singapore	UK
Bulgaria	EU	Italy	Netherlands	Slovakia	Zambia
Canada	Finland	Jordan	New Zealand	Slovenia	

Table 2: **WTO members without enabling CL legislation for the production of pharmaceuticals under Article 31*bis* of the TRIPS Agreement**

Afghanistan	Colombia	Guinea	Maldives	Paraguay	Thailand
Angola	Congo	Guinea-Bissau	Mali	Peru	Togo
Argentina	Costa Rica	Guyana	Mauritania	Qatar	Tonga
Armenia	Cote D'Ivoire	Haiti	Mauritius	Russia	Trinidad and Tobago
Bahrain	Dominica	Honduras	Mexico	Rwanda	Tunisia
Bangladesh	Dominican Republic	Indonesia	Moldova	St Kitts and Nevis	Turkey
Barbados	DRC	Israel	Mongolia	Saint Lucia	UAE
Belize	Ecuador	Jamaica	Morocco	St Vincent and the Grenadines	Ukraine
Benin	Egypt	Japan	Mozambique	Samoa	Uruguay
Bolivia	El Salvador	Kenya	Myanmar	Saudi Arabia	USA
Brunei Darussalam	Eswatini	Kuwait	Namibia	Senegal	Vanuatu
Burkina Faso	Fiji	Kyrgyzstan	Nepal	Seychelles	Venezuela
Cabo Verde	Gabon	Laos	Nicaragua	Sierra Leone	Vietnam
Cambodia	Gambia	Lesotho	Niger	Solomon Islands	Yemen
Cameroon	Georgia	Macao	Nigeria	South Africa	Zimbabwe
Central African Republic	Ghana	Madagascar	Pakistan	Sri Lanka	
Chad	Grenada	Malawi	Panama	Suriname	
Chile	Guatemala	Malaysia	Papua New Guinea	Taipei	

Table 3: **WTO members with domestic pharmaceutical manufacturing capacity. *Denotes limited manufacturing capacity**

Afghanistan*	Croatia	Honduras	Mali*	Peru	Tanzania
Albania	Cuba	Hong Kong	Malaysia	Philippines	Thailand
Argentina	Cyprus	Hungary	Mauritius*	Poland	Togo
Armenia	Czech Republic	Iceland	Mexico	Portugal	Trinidad and Tobago
Australia	Denmark	India	Moldova	Qatar	Tunisia
Austria	Dominican Republic	Indonesia	Mongolia	Romania	Turkey
Bahrain	DRC	Ireland	Montenegro*	Russia	UAE
Bangladesh	Ecuador	Italy	Morocco	Rwanda*	Uganda
Barbados	Egypt	Israel	Mozambique	Saudi Arabia	UK
Belgium	El Salvador	Jamaica	Myanmar	Senegal*	Ukraine
Bolivia	Estonia	Japan	Namibia	Singapore	Uruguay
Brazil	Eswatini	Jordan	Nepal	Slovakia	USA
Brunei Darussalam	Finland	Kazakhstan	Netherlands	Slovenia	Venezuela
Bulgaria	France	Kenya	New Zealand	South Africa	Vietnam
Cambodia	Gabon	Kuwait	Nicaragua*	South Korea	Yemen
Canada	Georgia	Kyrgyzstan	Nigeria	Spain	Zambia
Chile	Germany	Latvia	North Macedonia	Sri Lanka	Zimbabwe
China	Ghana	Liberia	Norway	Suriname*	
Colombia	Greece	Lithuania	Oman	Sweden	
Congo	Guatemala	Luxembourg	Pakistan	Switzerland	
Costa Rica	Guinea	Malta	Panama	Taipei	
Cote D'Ivoire	Guyana	Malawi*	Paraguay	Tajikistan	

Table 4: **WTO members without domestic pharmaceutical manufacturing capacity**

Angola	Burundi	Dominica	Laos	Mauritania	Samoa
Antigua and Barbuda	Cabo Verde	Fiji	Lesotho	Niger	Seychelles
Belize	Cameroon	Gambia	Lichtenstein	Papua New Guinea	Sierra Leone
Benin	Central African Republic	Grenada	Macao	St Kitts and Nevis	Solomon Islands
Botswana	Chad	Guinea-Bissau	Madagascar	Saint Lucia	Tonga
Burkina Faso	Djibouti	Haiti	Maldives	Saint Vincent and the Grenadines	Vanuatu

Table 5: **Top 25 WTO members most frequently placed on the USTR Special 301 Report for inadequate IP protection in the pharmaceutical sector (1994-2021)**

Rank	Country	# Times on Special 301 Report (PWL/WL)
1	India	25 (25 PWL / 0 WL)
2	Argentina	24 (24 PWL / 0 WL)
3	Pakistan	24 (10 PWL / 14 WL)
4	Egypt	23 (8 PWL / 15 WL
5	Chile	20 (15 PWL / 5 WL)

6	Brazil	20 (3 PWL / 17 WL)
7	Indonesia	18 (15 PWL / 3 WL)
8	Vietnam	18 (0 PWL / 18 WL)
9	Thailand	17 (11 PWL / 6 WL)
10	Turkey	17 (3 PWL / 14 WL)
11	Venezuela	16 (13 PWL / 3 WL)
12	Guatemala	16 (0 PWL / 16 WL)
13	Israel	14 (12 PWL / 2 WL)
14	Dominican Republic	14 (1 PWL / 13 WL)
15	Ecuador	14 (1 PWL / 13 WL)
16	Canada	13 (3 PWL / 10 WL)
17	Colombia	13 (2 PWL / 11 WL)
18	Peru	13 (0 PWL / 13 WL)
19	Mexico	12 (0 PWL / 12 WL
20	Russia	10 (10 PWL / 0 WL)
21	China	10 (10 PWL / 0 WL)
22	Costa Rica	10 (0 PWL / 10 WL)
23	Poland	9 (2 PWL / 7 WL)
24	UAE	9 (0 PWL / 9 WL)
25	Malaysia	8 (0 PWL / 8 WL)

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