SOUTH CENTRE

POLICY BRIEF

No. 107 | November 2021

The Doha Ministerial Declaration on TRIPS and Public Health on its Twentieth Anniversary

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1. Introduction[1]

The Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health (hereinafter, referred to as "the Declaration")[2] was adopted on 14 November 2001 by the 4th World Trade Organization (WTO) Ministerial Conference at Doha, Qatar (The Doha Declaration was made by the highest decision-making body of WTO, with the aim of promoting a balanced interpretation and implementation of the provisions of the TRIPS Agreement in a manner that is supportive of a WTO Member's right to protect public health and promote access to medicines for all. Essentially, the Doha Declaration reaffirmed that WTO members can make use of the public health related flexibilities allowed by the TRIPS Agreement,[3] and this is its principal contribution. It also instructed the Council for TRIPS to take action in relation to the use of compulsory

Abstract

This Policy Brief reviews the role of the Doha Declaration on TRIPS and Public Health in the twenty years since its adoption. It finds that the Doha Declaration has contributed to advance the use of the TRIPS flexibilities to promote public health and should be considered an important subsequent agreement to the TRIPS Agreement, despite the continuing challenges for WTO members to implement the TRIPS flexibilities in full. This brief also analyses the extent to which the Paragraph 6 System that became an amendment of the TRIPS Agreement as a new article 31 bis, pursuant to the Doha Declaration, has facilitated access to medicines and vaccines for countries with none or insufficient pharmaceutical manufacturing capacity. It finds that the system to date has not lived up to its promise. The Policy Brief recommends that WTO members assess and identify the challenges for the full use of the TRIPS flexibilities to promote public health, and advances that supplementary tools will need to be designed to never again allow such inequity in access to life saving vaccines and treatments as in the present COVID-19 pandemic.

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Este Informe sobre políticas examina el papel de la Declaración de Doha sobre los ADPIC y la salud pública en los veinte años transcurridos desde su adopción. Considera que la Declaración de Doha ha contribuido a avanzar en el uso de las flexibilidades de los ADPIC para promover la salud pública y debe ser considerada como un importante acuerdo posterior al Acuerdo sobre los ADPIC, a pesar de los continuos desafíos para que los miembros de la OMC apliquen las flexibilidades de los ADPIC en su totalidad. Este informe también analiza la medida en que el sistema del párrafo 6, que se convirtió en una enmienda del Acuerdo sobre los ADPIC como un nuevo artículo 31 bis, de conformidad con la Declaración de Doha, ha facilitado el acceso a los medicamentos y las vacunas para los países que no tienen capacidad de fabricación de productos farmacéuticos o que ésta es insuficiente. Considera que el sistema, hasta la fecha, no ha estado a la altura de su promesa. El Informe sobre políticas recomienda que los miembros de la OMC evalúen e identifiquen los desafíos para el pleno uso de las flexibilidades de los ADPIC para promover la salud pública, y avanza que será necesario diseñar herramientas suplementarias para no permitir nunca más tal desigualdad en el acceso a vacunas y tratamientos que salvan vidas como en la actual pandemia de COVID-19.

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Ce Rapport sur les politiques examine le rôle de la Déclaration de Doha sur les ADPIC et la santé publique au cours des vingt années qui ont suivi son adoption. Elle constate que la Déclaration de Doha a contribué à faire progresser l'utilisation des flexibilités de l'Accord sur les ADPIC pour promouvoir la santé publique et qu'elle doit être considérée comme un accord complémentaire important de l'Accord sur les ADPIC, malgré les difficultés persistantes des membres de l'OMC à mettre pleinement en œuvre les flexibilités de l'Accord sur les ADPIC. Ce document analyse également la mesure dans laquelle le système du paragraphe 6, devenu un amendement de l'Accord sur les ADPIC en tant que nouvel article 31 bis, conformément à la Déclaration de Doha, a facilité l'accès aux médicaments et aux vaccins pour les pays dont les capacités de fabrication de produits pharmaceutiques sont inexistantes ou insuffisantes. Elle constate qu'à ce jour, le système n'a pas tenu ses promesses. Le Rapport sur les politiques recommande aux membres de l'OMC d'évaluer et d'identifier les défis à relever pour utiliser pleinement les flexibilités de l'Accord sur les ADPIC afin de promouvoir la santé publique, et avance que des outils supplémentaires devront être conçus pour ne plus jamais permettre une telle inégalité dans l'accès aux vaccins et aux traitements vitaux, comme c'est le cas dans l'actuelle pandémie de COVID-19.

licenses and the extension of the transition period for least developed countries (LDCs) and reiterated developed countries' commitment to support the transfer of technology to the latter. As discussed below, the implementation of these elements in the Declaration has fallen short of the expectations of its proponents.

This Policy Brief examines, first, the background to the Declaration, notably what the proponents' objectives were and what they reached in relation to the TRIPS flexibilities, the special compulsory license system requested in paragraph 6 of the Declaration and technology transfer to LDCs. Second, it critically discusses the challenges faced in the Declaration's implementation with regard to the use of such flexibilities, particularly compulsory licenses (CLs).

needs. They may be used to stimulate competition, protect the public interest and promote the production of generic medicines to encourage access to medicines at prices affordable to governments and patients.

The extent to which these flexibilities could be effectively implemented raised concerns among health authorities, which had been ostensibly absent in the negotiation of the TRIPS Agreement. Most such authorities learned about the implications that the Agreement could have on access to medicines after its formal adoption at the conclusion of the Uruguay Round.

Box 1 summarizes some of actions taken by the World Health Organization (WHO) that reflected such concerns.

Box 1 – WHO Response to the Adoption of the TRIPS Agreement

In 1996, the World Health Assembly (WHA), passed resolution WHA 49.14 on the Revised Drug Strategy (RDS) requesting the World Health Organization (WHO) "to report on the impact of the work of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate". This resolution provided WHO with the mandate to examine the new architecture of the multilateral trading system brought about by the establishment of the WTO, in relation to public health.

Following the mandate of the RDS, in 1998 the WHO Action Programme on Essential Drugs published a monograph titled, "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement". This guide was written with the objective of informing health policy professionals with limited or no legal background on the potential impact of the TRIPS Agreement on public health and pharmaceutical policy. Although the authors noted that TRIPS imposed standards historically derived from industrialized countries, they maintained that the Agreement still provided considerable discretion to safeguard public health. The monograph examined TRIPS from a public health perspective, identifying the safeguard provisions in the Agreement that enabled countries to protect health and promote access to medicines.

After two years of debate, in 1999 the 52nd World Health Assembly approved a new Revised Drug Strategy resolution WHA 52.38 that urged Member States to "ensure that public health interests are paramount in pharmaceutical and health polices" and requested WHO

"to cooperate with Member States, at their request, and with international organizations in monitoring and analyzing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that… maximize the positive and mitigate the negative impact of those agreements."

2. Background to the Doha Declaration

The TRIPS Agreement brought about significant changes to the standards of intellectual property (IP) protection by requiring all countries to provide patent protection in all fields of technology for a minimum period of 20 years (counting from the patent filing date). Thus, the large number of developing countries that did not recognize product patents in certain areas of technology, such as pharmaceutical inventions, had to amend their laws to become TRIPS compliant and in particular, grant product patents on medicines.

However, the TRIPS Agreement also allowed countries to take measures such as compulsory licenses, parallel imports, exceptions to patent rights, and to apply rigorous patentability criteria to prevent the grant of unwarranted patents that would deter legitimate generic competition. These "flexibilities" can be implemented to balance patent rights with public health

These concerns were justified. The right to make use of the TRIPS flexibilities by developing countries was soon challenged, legally and politically, by multinational pharmaceutical companies and some governments of developed countries. A telling example was the legal case brought by 39 multinational pharmaceutical companies against the South African Government challenging legislation that sought to use the TRIPS flexibilities.[4] After an intense international campaign backing the South African Government, the plaintiffs withdrew the case and the US announced a change in its aggressive policy, but the case left the perception that IP, as protected under the TRIPS Agreement, will create serious barriers for the implementation of public health policies, particularly access to medicines. The issue finally arrived before the WTO on 20 June 2001 through an initiative from African countries. This was the genesis of discussions in WTO that culminated in the Declaration.

The South African court case and other similar actions including the WTO dispute settlement case brought by the US against Brazil on its local working provision on compulsory licensing, resonated with the international community because of their inextricable association with the HIV/AIDS pandemic.

In this context, developing countries sought to clarify the relationship between the TRIPS Agreement and public health. In April 2001, following a proposal by the African Group, the TRIPS Council agreed to hold a Special Session to discuss "...the interpretation and application of the relevant provisions of the TRIPS Agreement, to clarify the flexibilities to which Members are entitled to and, in particular, to establish the relationship between intellectual property rights (IPRs) and access to medicines."[5]

The process initiated by the African Group at the special session of the TRIPS Council had the ultimate objective of clarifying and confirming the right of WTO members to use the TRIPS Agreement's public health safeguards, as described and recommended in the referred to 1998 WHO publication and in other studies and reports.[6]

Developing countries sought action in WTO to ensure that the TRIPS Agreement does not undermine the "… right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health."[7] The developing countries affirmed that "… nothing in the TRIPS Agreement reduces the range of options available to Governments to promote and protect public health …"[8] and they sought a confirmation of this understanding by all WTO members. It was with this objective that the developing countries sought a declaration on TRIPS and Public Health.[9] Box 2 presents elements proposed by developing countries to that end.

In the TRIPS special session of September 2001, the African Group and other developing countries presented a draft text for a Ministerial Declaration on the TRIPS Agreement and Public Health.[10] On the other hand,

Box 2 – Elements of a Declaration Proposed by Developing Countries

Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health.

Members have the right to establish their own policies and rules regarding the exhaustion of IPRs.

Use of the patented subject-matter without the authorization of the right holder can be allowed other than on grounds allowed under Article 30 (research exemption).

Right to grant compulsory licenses without prior attempts to obtain a voluntary license from the patent holder in cases of national emergency, extreme urgency or for non-commercial use.

The right to authorize suppliers within its territory to make and export the product covered by a compulsory license issued by another country, predominantly for the supply of the domestic market of that country.

Waiver of Article 31 (b) and (f) of TRIPS to allow the use of a patented subject matter to remedy a practice that has been determined to be anti-competitive.

Right to establish or maintain marketing approval procedures for generic medicines or applying summary or abbreviated marketing approval procedures based on marketing approvals granted earlier for equivalent products.

Right to disclose or use, in the public interest, information held by the national authorities or the patent holder, including disclosure necessary to effectively implement a compulsory license or other measure.

Extension of the scope of Article 30 of TRIPS to allow governments to authorize the production and export of medicines by persons other than the patent holder to address public health needs in importing Members.

Each Member must restrain from imposing or threatening the imposition of sanctions or granting incentives or other benefits in a manner which could curtail the ability of developing and least developed countries from availing every possible policy option to protect and promote public health

Members must exercise utmost restraint in initiating or pursuing dispute settlement proceedings relating to measures adopted or implemented to protect and promote public health.

Non-violation and situation complaints shall not be applicable to any measure adopted and implemented by Members to protect and promote public health.

Extension of the transition period for developing and least-developed countries.

The TRIPS Council shall monitor and evaluate on an ongoing basis the impact of the TRIPS Agreement on public health, particularly on access to medicines and research and development on medicines for prevention and treatment of diseases predominantly affecting people in developing and least developed countries.

developed countries stressed that IPRs contributed to public health objectives by incentivizing research and development.[11] As a result of protracted negotiations, the Doha Declaration was eventually adopted through last minute compromises (see Box 3). Developing countries were compelled to abandon some of the specific wording and proposals; developed countries, notably the USA, was forced to accept the Declaration despite the strong opposition by the US pharmaceutical industry—and to admit its applicability to all diseases (and not only to malaria, tuberculosis and HIV/AIDS as it proposed).

3. Reaffirmation of TRIPS flexibilities for Public Health

The Declaration has significant positive attributes, despite the compromises made for its adoption. Importantly, it reaffirms the right of WTO members to use the TRIPS flexibilities to the fullest extent possible for the purpose of protecting public health and promoting access to medicines. It recognizes the concerns on the impact of IPRs on prices of medicines (paragraph 3). Reaching consensus on this statement was one of the major political achievements for developing countries.[12]

The scope of the Declaration is not limited to the impact of patents on public health but applies to all IP rights that are within the scope of the TRIPS Agreement, such as test data protection. Moreover, the Declaration is valid for any disease or epidemic.

While the legal status of the Declaration has been a matter of debate, the WTO panel in *Australia-Tobacco Plain Packaging* asserted that it must be considered a "subsequent agreement" concerning the interpretation of the TRIPS Agreement or the application of its provisions in terms the Vienna Convention on the Law of Treaties.[13] The panel also observed that as the Doha Declaration was adopted by a consensus decision at the highest level of the WTO—the Ministerial Conference—its terms and conditions constitutes an agreement between members on the approach to be followed in interpreting the provisions of the TRIPS Agreement. The panel concluded that "[t]his agreement, rather than reflecting a particular interpretation of a specific provision of the TRIPS Agreement, confirms the manner in which "each provision" of the Agreement must be interpreted, and thus bears specifically on the interpretation of each provision of the TRIPS Agreement."[14]

The Declaration provides for an important rule of interpretation in paragraph 4 which, despite the compromise reached, made it clear that the TRIPS Agreement does not force WTO members to subordinate public health policies to the protection of IP. It states that the TRIPS Agreement "does not and should not prevent members from taking measures to protect public health" and that it "can and **should** be interpreted and implemented in a manner supportive of WTO members' right to protect public health, and in particular, to promote access to medicines for all" (emphasis added).

Paragraph 5 of the Doha Declaration reaffirms that the provisions of the TRIPS Agreement shall be interpreted in the light of its object and purpose, as expressed, in particular in its objectives and principles (article 7 and 8 of the TRIPS Agreement).

The Declaration specifies in a non-exhaustive manner in paragraph 5 some of the aspects of the Agreement that provide flexibility for promoting public health and access to medicines. It refers to the right of members to grant CLs and determine the grounds for issuing them. Members have, in fact, full freedom to determine the grounds for granting a compulsory license such as non-working, public health or public interest.

The freedom to determine the grounds for a compulsory license is crucial. In a situation of health emergency countries can grant a compulsory license without the obligation of prior negotiations with the patent owner (article 31.b of TRIPS). Such measures can be maintained if the situation of national emergency or other extreme urgency persists. Moreover, if a dispute is brought before the WTO panel about the declaration of a situation of national emergency or extreme urgency, the burden of proof is on the complainant rather than on the member taking such a measure.

In this regard, the Declaration recognizes the right for each WTO member to determine what constitutes a "national emergency or other circumstances of extreme urgency", with the understanding that public health crises, including HIV/AIDS and Tuberculosis (TB), malaria and other epidemics can represent such a situation.

Moreover, it was also confirmed that Members are free to apply an international principle of exhaustion of rights that allows for parallel importation of an IP protected product that has been legitimately marketed in another country.

4. The Special Compulsory Licensing System

An essential requirement for utilizing CLs is the capacity to locally produce the required medical products. A major limitation for many developing countries and LDCs is the lack of sufficient domestic pharmaceutical manufacturing capacity. In this context, paragraph 6 of the Doha Declaration recognized that countries with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement and instructed the TRIPS Council to find an "expeditious solution" to this problem and report to the General Council by the end of 2002.

Various proposals for resolving this problem were considered by the TRIPS Council in 2002. The European Community (EC) proposed two options: 1) carving out an exception to TRIPS article 31 (f) to enable compulsory licensing for export of products needed to combat public health problems under certain conditions and safeguards; and 2)

interpretation of the limited exceptions clause under article 30 to allow production for exporting to certain countries to combat serious public health problems. The United States proposed a moratorium on WTO complaints against countries that export medicines to countries in need but sought to limit the scope of this to HIV/AIDS, TB and malaria only.

The African Group and other developing countries proposed an amendment to article 31 (f) or an authoritative interpretation of article 30 for allowing production of medicines without the consent of the patent holder.[15] The statement of the representative of WHO made at the TRIPS Council on 16 September 2002 also clearly stated that the limited exception under article 30 was the most consistent solution with the public health principle. It noted that:

> "… countries which does not have the capacity for domestic production of a needed product should be no less protected by compulsory license provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product."[16]

The US however sought to impose very stringent conditions on any solution pursuant to paragraph 6 of the Declaration. It expressed its position in favor of a solution based on a temporary waiver of article 31 (f), with multiple administrative and procedural requirements, These

Box 3 – The Doha Declaration

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

conditions aimed, in particular, to restrict export licenses to "grave" or "urgent" public health crises like HIV/AIDS, TB and malaria, to limit the supply under the mechanism to public and non-commercial purposes and to countries that might benefit from the system,[17] as well as to incorporate anti-diversion guarantees and limitations on re-export.[18] Developing countries were strongly opposed to accepting any disease-specific and other restrictions under the paragraph 6 solution.

The WTO General Council, however, finally adopted a Decision on 30 August 2003 with a number of compromises. The decision—formally a waiver under WTO rules—established a system, known as the "paragraph 6 system", under which a country can issue a compulsory license for the purpose of exporting generic medicines to countries with insufficient or no manufacturing capacity under certain conditions. The text of this Decision has been incorporated as article 31*bis* of the TRIPS Agreement (see below), which entered into force upon receiving the required number of ratifications from WTO members. So far, 133 WTO members have accepted this amendment, but 31 WTO members have not ratified the amendment. For them, the waiver continues to operate, which makes this special compulsory licensing system available to them as well.

5.Transfer of Technology to LDCs

Paragraph 7 of the Doha Declaration reaffirmed the commitment of developed countries under article 66.2 of TRIPS to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDCs in order to enable them to create a sound and viable technological base. The TRIPS Council was also instructed to take necessary action to extend the TRIPS transition period available for LDCs under article 66.1 till 2016, specifically for pharmaceutical products.

Accordingly, the transition period for LDCs in respect of pharmaceutical products was extended till 1 January 2016. This transition period was subsequently extended in November 2015 till 1 January 2033, with earlier expiry upon the graduation of any LDC member.[19] Further, LDCs were also waived from the exclusive marketing rights (EMR) requirements under TRIPS article 70.9 for pharmaceutical products. More recently, the transition period was generally extended by the TRIPS Council till 1 July 2034, or till earlier graduation by an LDC.[20] Thus, LDCs do not have to implement the TRIPS provisions on patents and test data protection till then. However, as some LDC members are likely to graduate in the next few years, the transition period exempting them from implementing these provisions of TRIPS in relation to pharmaceutical products will also expire for them. Currently, the LDC members have submitted a proposal for continuation of the LDC specific support measures under various WTO agreements, including the transition period exempting implementation of TRIPS obligations, for a certain additional period after graduation, in order to achieve sustainable graduation. However, developed countries have not supported the proposal so far.[21]

6. The Doha Declaration: Implementation Challenges

During the twenty years since the adoption of the Declaration, its implementation has faced many challenges and constraints.

6.1 Limited Use of TRIPS Flexibilities

The Doha Declaration is not self-executing and requires amendments to national legislations in order to make full use of the TRIPS flexibilities. Lack of appropriate national legislation for fully implementing the TRIPS flexibilities remains a key challenge for many developing countries.

National IPR legislations should at minimum include rigorous standards for the examination of pharmaceutical patents and thereby avoid the proliferation of patents (often called "evergreening patents") on minor or trivial developments;[22] provisions for compulsory licensing on nationally determined grounds for issuing a compulsory license with simplified procedures; provisions for parallel importation based on an international exhaustion principle; early working ("Bolar") exceptions; and full use of the transition period for developing countries and LDCs.[23]

Important efforts have been made by developing countries to incorporate TRIPS flexibilities to further public health objectives. For example, the East African Community (EAC) adopted in 2013 a Regional Intellectual Property Policy and a Protocol on the Utilization of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.[24] A recent study found 176 instances of the use of TRIPS flexibilities for public health.[25] Some developing countries, such as Argentina, India, Egypt, Indonesia and the Philippines have adopted specific provisions in their national patent laws or examination guidelines to apply rigorous standards of patentability for pharmaceuticals, particularly in relation to new forms of known products.

However, according to a survey by the South Centre and WHO, only 33 developing countries and LDCs had opted for an international exhaustion regime for enabling parallel importation.[26] A recent study noted instead that parallel imports are widely present in developed countries.[27] The same applies to other TRIPS flexibilities, as many developing countries have not fully implemented them yet in their laws and regulations.[28]

The Doha Declaration clarified that compulsory licenses can be issued on the grounds determined by the WTO member, which are not limited to situations of HIV/AIDS, TB or malaria. In fact, compulsory licenses/government use have been widely utilized in developed countries (notably in the USA),[29] generating much less public scrutiny than cases in which developing countries use those mechanisms. For example, in 2007, the Italian Competition Authority imposed the obligation of licensing of the active ingredient finasteride as a remedy to an abuse of dominant position. In 2017, the German Federal Court

issued a compulsory license for Isentress, an HIV/AIDS drug.[30] During the COVID-19 pandemic, Israel issued a compulsory license for Kaletra (then seen as a potential treatment candidate), and Russia and Hungary respectively issued licenses for Remdesivir in later December 2020/early January 2021.

Since the adoption of the Declaration, some developing countries have issued compulsory licenses/government use in order to increase access to medicines, including Brazil, Ecuador, Zambia, Zimbabwe, Malaysia and Indonesia.[31] The range of grounds for the issuance of CLs also increased, including national security, public interest, and non-availability in the country. This confirms that countries are legitimately allowed to make use of CLs outside of health emergency situations, on a broad spectrum of grounds. The South Centre has published a listing of compulsory licenses and government use authorizations issued up to 2021.[32]

Compulsory licenses have been issued in relation to patented products in various disease areas, including for HIV/AIDS, cancer and more recently for COVID-19 treatments. For instance, in 2008, Thailand issued a compulsory license for government use of four anticancer drugs.[33] Thailand had also issued a compulsory license for a heart disease drug – clopidogrel – in 2007. In 2012 India issued a compulsory license for Nexavar—a drug for kidney and liver cancer.

Nevertheless, the decision on the use of compulsory licenses by developing countries continues to be plagued by political considerations. It is appalling that 20 years since the Doha Declaration, pharmaceutical MNEs and developed countries continue to exert commercial and political pressure on developing countries not to make use of such licenses. For example, in 2006, when Thailand authorized the Government Pharmaceutical Organization (GPO) to manufacture generic versions of Efavirenz until 2011 and import the medicine from India until domestic production capacity was achieved, the US demanded Thailand to revoke the compulsory license and negotiate with Merck. Again, in 2007 when Thailand issued a compulsory license for the drug Kaletra (lopinavir/ritonavir), the patent holder Abbott sought to exert commercial pressure by withholding new medications from the Thai market.[34] In Colombia, when the issuance of a compulsory license for Imatinib was being considered by the national government, pressure was exerted by the US Government, which threatened not to support the post-peace process in the country.[35]

In addition, national legislations are often not conducive to a streamlined utilization of CLs. Many contain administrative requirements which are burdensome and entail the participation and approval of several instances and governmental agencies, which hinder the process. In many countries, the grounds for the issuance of CLs remain limited to health emergencies and are therefore constraining.[36] For this reason, more attention has been given to the necessity to streamline procedures – allowing more entities to request a compulsory license, setting pre-determined royalties, ensuring available patent data, among others.[37] In September 2021, Brazil amended its national law to facilitate the compulsory license issuance procedure, including an obligation by the Federal Government to list relevant patents, and broadening the grounds for a compulsory license in the country.[38] The bill included a provision which further required the sharing of the necessary technology know-how for the implementation of such a license.[39]

This example underscores, however, the necessity to ensure that trade secrets and manufacturing capacity issues are included in mechanisms related to compulsory licensing. The COVID-19 pandemic and the manufacturing of vaccines has provided an important example of the caveats of the existing compulsory license system alone (i.e., a country may issue a compulsory license but even with available manufacturing and industrial capacity would not be able to produce it without access to know-how) and calls for the creation of mechanisms to include CLs for trade secrets have been made.[40]

6.2 TRIPS-plus Standards

One of the important explanations for the low use of TRIPS flexibilities is the continued push by developed countries for standards of IP protection and enforcement that go beyond those of the TRIPS Agreement. This has been another major challenge to the effective implementation of the flexibilities confirmed by the Declaration. The imposition of TRIPS-plus standards on developing countries and LDCs through bilateral and regional trade agreements as well as the WTO accession conditions (such as in the cases of Jordan and Cambodia), prevents the use of some of those TRIPS flexibilities. For example, some US free trade agreements (FTAs) extend the scope and length of data protection, introduce a "linkage" between drug registration and patent protection, and require patent term extensions for offsetting the time taken for patent examination or securing marketing approval.[41] These may curb the utilization of CLs to the extent which they do not automatically override data exclusivities and other regulatory constraints that may be attached to the patent subject to the license. While US FTAs generally specify Bolar exceptions, they may have restrictions on foreign markets. In addition, the US continues to make use of its unilateral mechanism under the USTR Special Section 301, which allows the US Trade Representative to evaluate countries in accordance with its own understanding of what an IP system should look like (generally much above the requisites of the TRIPS Agreement). Chile, for example, has been included for allegedly not including a patent linkage system akin to what the US expected, although it has fulfilled its obligations under the US-Chile FTA. The US also continued to question CLs provisions in many countries; in 2021, for the first time, the USTR report did not question such provisions.[42]

On the other hand, some of the Economic Partnership Agreements (EPAs) between the EU and developing countries make reference to the "importance of the Doha

Declaration". Such language has been reiterated and reinforced in newer agreements, affirming the rights of countries to use TRIPS flexibilities—such as in the 2020 Regional Comprehensive Economic Partnership (RCEP), but remains limited in its reach considering the inclusion of TRIPS-plus obligations. However, there is variance in the treatment of the Declaration in different EPAs, and some of them (e.g., Peru-Colombia) include a set of substantive TRIPS-plus obligations that may limit access to medicines. Apart from the US and the EU, the European Free Trade Area (EFTA – Switzerland, Norway, Iceland and Liechtenstein) also include various TRIPS-plus norms in its trade agreements. While the EU has also historically joined the US in opposing to the use of CLs by developing countries, paradoxically, in response to the waiver sponsored by a large number of such countries regarding the TRIPS obligations to address COVID-19, the EU considers that CLs should be the main instrument to deal with the pandemic.[43]

Finally, many such trade agreements also include TRIPS-plus enforcement provisions that may also act as deterrents to the use of public health flexibilities. In Kenya, a landmark judicial ruling struck down a national anti-counterfeiting legislation for conflating illicit products with lawful generics, which would have limited access to medicines.[44] Various recent agreements which do not include more conventional TRIPS-plus norms do include additional enforcement provisions, such as the EU-Mercosur (2019, pending ratification) and the already mentioned RCEP (2020).[45]

In order to promote the use of TRIPS flexibilities in line with the Doha Declaration, it is necessary to improve the legal and technical assistance that is provided to developing countries in relation to IP and public health. The South Centre has updated guidance for the issuance of compulsory licenses and government use authorizations[46] and has a dedicated program of assistance on this matter.[47] Evidence suggests that in the 20 years since the Declaration, technical assistance has often been insufficient or inappropriate in that regard, particularly that which is provided bilaterally by developed countries or by other intergovernmental organizations.[48] Legal and technical assistance to developing countries and LDCs in this area should fully take into account the public health priorities and context of the country concerned in drawing up national IP law and policy.

In the context of the COVID-19 pandemic, the importance of enabling national legislation and guidance on the TRIPS flexibilities has become ever more evident. At the same time, a large part of the WTO membership agreed that in times of an emergency like COVID-19, more comprehensive and globally applicable measures are needed to act fast and provide legal certainty for the rapid scaling up of production of vaccines, treatments and diagnostics.[49] A central problem identified with regards to increasing manufacturing for COVID-19 vaccines is that the CLs and government use tools are limited to patents and cannot address barriers of access to know-how that may be protected by trade secrets. Accordingly, discussion is emerging on new mechanisms to supplement compulsory licensing of patents.[50]

6.3 Constraints of Article 31 *bis*

While the special compulsory license system developed pursuant to paragraph 6 of the Declaration has been characterized as a "solution" to the problems faced by developing countries and LDCs in accessing affordable medicines under patent, in actual practice it has not contributed to address such problems. In the context of the COVID-19 pandemic, the functionality of the system is further put into question; the EU has proposed some clarifications in order to make it more amenable to the needs of potential user countries.[51]

No actual use of the special compulsory license system has occurred since the amendment of the TRIPS Agreement through the incorporation of article 31*bis* came into force. There is only one instance of the system being used—and this was prior to entry into force of the amendment—in the case of Canada and Rwanda. Rwanda used the mechanism to import cheaper life-saving medicines from the Canadian generic company Apotex for 21,000 HIV/AIDS patients, a process fraught with complexities. It took almost 27 months to meet all of the requirements.[52] Moreover, to date, only a limited number of countries have adopted legislation to implement the paragraph 6 system as an exporting country. The South Centre had already cautioned in 2011 that WTO members should carefully examine the reasons behind the limited use of the system and address systemic deficiencies before making it permanent as was the case of article 31*bis* of the TRIPS Agreement.[53]

In the context of the COVID-19 pandemic, Bolivia and Antigua and Barbuda have notified the TRIPS Council of their intention to use the system as importing members. Bolivia has specifically notified its intention to use the system for importing COVID-19 vaccines and identified its specific needs. A company in Canada wished to produce the Johnson & Johnson vaccine under compulsory license for export to Bolivia but the Government has yet to allow it under Canada's Access to Medicines Regime (CAMR) system.[54]

The lack of effective use of the special compulsory license system is not due to lack of need of use. This is evidenced by the referred to recent notifications to WTO. The shortcomings of the system are largely due to its unnecessarily burdensome and complicated conditions. The paragraph 6 system places obligations on importing countries making use of the system that are much more onerous than those for countries that can issue a compulsory license to supply the domestic market.

Some of the key problems in using the system are:[55]

1) Generic companies need to undertake negotiations for voluntary licenses with the patent holder before

applying for a compulsory license. Such negotiations may be protracted and complex, and a source of considerable delay thus discouraging generic manufacturers to participate in the process.

2) The Decision comprises a succession of complex procedural steps. First, a potential purchaser has to forecast the need for a medicine and identify a generic producer willing to participate in the process and fill the drug order. Second, the manufacturer has to try to negotiate a voluntary license with the patent holder. Third, if the negotiations are unsuccessful, a compulsory license application must be filed in the home country of the generic producer. Each of these steps is time-consuming, involves substantial financial expense and holds no guarantee of success. A potential importing country must also send a notification in writing to the WTO TRIPS Council, declaring its intention to import pharmaceutical products. The notification must include the specific names and expected quantities of the product needed. Unless the importing country is classified as an LDC, it must also declare that it lacks sufficient manufacturing capacity in the pharmaceutical sector to develop the pharmaceutical product being procured.

The system also imposes conditions for commercialization of the products made under the compulsory license. They must be clearly identified as being produced under the system through specific labelling; they should be specially packaged to be distinguishable from the branded product and in respect of its shape or color. The generic manufacturer must post specific information about the quantity of the product, its destination and distinguishing features. These "anti-diversion" measures are to ensure that the product will only be exported to the destination stated in the compulsory license.

3) The paragraph 6 system requires a drug-by-drug, country-by-country and case-by-case decision-making process. The compulsory license application must stipulate the destination and the quantity of drugs that are to be purchased and exported under the license. Drug needs must therefore be determined with precision beforehand. If more patients are included, the only way to purchase more drugs is to begin the process again. A stock-out due to the procedural hurdles may lead to the treatment being interrupted and as a consequence patients may develop increased drug resistance (as in case of HIV/AIDS), creating the need for more expensive treatment. Conversely, if the needs have been overestimated, re-exportation of medicines imported under the system to another developing country or LDC in a similar situation is not permitted, unless there is a regional trade agreement between the two and the majority of its members are LDCs.

4) There is substantial scope for the patent holder to undermine the system. For example, the patent holder may decide at any time to offer the medicines at lower cost or for free, thus frustrating any efforts made to use the system in that particular case. This creates a huge uncertainty and additional risk and disincentives for potential suppliers.

6.4 Insufficient Progress during the LDC Transition Period

While the extension of the transition period for LDCs has been a significant gain for these countries, there has been no substantial progress towards realizing the fundamental objective behind the extension of the transition period: to create a "viable technological base" in LDCs (article 66.1 of the TRIPS Agreement). A corresponding obligation under article 66.2 of TRIPS is for developed countries to take measures in their jurisdictions to expand the transfer of technology to LDCs for that purpose, as reaffirmed by the Doha Declaration. However, in practice developed countries have not effectively complied with Article 66.2 obligations. In 2003, the TRIPS Council adopted a decision on implementation of article 66.2 and established a reporting mechanism on actions taken or planned by developed countries under their article 66.2 commitments. Most of the reports submitted by developed countries under this mechanism have failed to meet the reporting criteria, and many have actually reported activities without a real impact in terms of technology transfer, or rather about technical and financial assistance provided under article 67 to enable developing countries and LDCs to implement the TRIPS Agreement by reforming their legal and administrative systems.[56]

7. Final Remarks

Twenty years since the adoption of the Doha Declaration on TRIPS and Public Health, the Doha Declaration remains a landmark achievement for clarifying the relationship between IP and public health. Indeed, since the adoption of the Doha Declaration the concept of "TRIPS flexibilities" has been referenced in a vast body of literature,[57] especially in relation to access to medicines, as well as in numerous resolutions of UN agencies and bodies, including the World Health Organization, the Human Rights Council, the UN General Assembly, and the reports of the UN Special Rapporteur on the Right to Health. The Doha Declaration has also contributed to the mainstreaming of the concept of TRIPS flexibilities in WTO jurisprudence, notably in the panel decision in *Australia-Tobacco Plain Packaging* which deemed the Declaration a "subsequent agreement" under the principles of international law codified in the Vienna Convention on the Law of the Treaties.

The Doha Declaration has also evolved as a tool for guiding the interpretation of the IP provisions in some trade agreements and in national legislation and jurisprudence. In particular, the express reference to the Doha Declaration in treaty provisions has given some normative weight to the principles of the Declaration.

It is worth noting that since the adoption of the Doha Declaration, the use of TRIPS flexibilities for public health has never been challenged by developed countries before

the WTO dispute settlement body. This singularly testifies to the importance of the Doha Declaration for developing countries.

However, there is substantial scope for better implementation of the TRIPS flexibilities in order to secure public health objectives, particularly access to medicines.

Some developing countries are increasingly making use of TRIPS flexibilities for public health purposes, but many still need to adopt the appropriate laws and regulations and to ensure that patent offices act as stewards of the public interest. They also need to resist demands of TRIPS-plus obligations more effectively in exchange for trade or other concessions. Dissemination of information and sharing of experiences among developing countries relating to the grant of compulsory licenses, the application of rigorous standards to avoid "evergreening" of patents and the use of other flexibilities can further contribute to empower countries to make more regular use of the available measures.

There is hence scope for substantial improvement in implementation of the Doha Declaration. Developing countries need to review and amend as necessary their national laws to make full use of the TRIPS flexibilities. There is also a need to ensure that technical assistance and capacity building work of relevant intergovernmental organizations such as WTO and WIPO contribute to this objective.

Moreover, there is a need to undertake a profound assessment of the special compulsory licensing system under article 31 *bis* in light of the impossibility to date during the COVID-19 pandemic for WTO members without manufacturing capacity in the pharmaceutical sector to use the system effectively to promote access to medicines and vaccines. An effective solution to the problem identified in paragraph 6 of the Doha Declaration must be found.

Likewise, it is also necessary to reassess why the commitment to foster transfer of technology to the LDCs, as established in Article 66.2 and reasserted in the Doha Declaration, remains largely unfulfilled and what mechanisms could be put in place to render compliance with such an obligation effective and measurable. It will be pertinent to also consider an extension of the transition period exempting LDC members from implementing the TRIPS provisions for an additional period after their graduation.

The Doha Declaration has played a key role for reasserting the importance and continued relevance of the TRIPS flexibilities to promote public health. The direful response to the global COVID-19 pandemic has shown that supplementary tools need to be designed to never again allow such inequity in access to life saving vaccines and treatments.[58] The main premise and purpose of the Declaration—to ensure access to medicines to all—however, remain valid and should guide the actions by the international community to respond to the current pandemic and beyond.

Endnotes:

[1] This brief is partially based on the South Centre earlier publication "The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation", Policy Brief, No. 7, South Centre, 1 November 2011. Available from https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf.

[2] Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN (01)/DEC/2.

[3] For a description of TRIPS flexibilities to promote public health, see https://ipaccessmeds.southcentre.int/wp-content/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf.

[4] In 1997, South Africa proposed several amendments to its Medicines and Related Substances Control Act to allow parallel importation of pharmaceutical products for reducing the cost of essential medicines.

[5] See submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, TRIPS and Public Health, WTO Document IP/C/W/296, 29 June 2001, p. 2.

[6] See South Centre, The TRIPS Agreement: A Guide for the South. The Uruguay Round Agreement on Trade Related Intellectual Property Rights, November 1997, South Centre, Geneva; United Nations Conference on Trade and Development, The TRIPS Agreement and Developing Countries, United Nations, New York and Geneva, 1996. Available from https://digitallibrary.un.org/record/238306?ln=en.

[7] Ibid, p. 1.

[8] Ibid, p. 3.

[9] Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization, June 2002, p. 2. Available from http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf.

[10] Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Document IP/C/W/312, WT/GC/W/450, 4 October 2001. Available from http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm.

[11] Correa, note 10, p.3.

[12] Correa, note 10, p. 7.

[13] Carlos M. Correa, "Interpreting the Flexibilities under the TRIPS Agreement", in *Access to Medicines and Vaccines: Implementing Flexibilities under Intellectual Property Law* Carlos M. Correa and Reto M. Hilty (eds.) (Springer, 2021), p.24. Available from https://link.springer.com/book/10.1007/978-3-030-83114-1?sap-outbound-id=D373B17C34B74056795B3A9DC07A57A39E8B7BBA.

[14] Ibid, p. 25; see also: Carlos Correa, op. cit., 2002.

[15] Correa, note 10, p. 26.

[16] Statement by the representative of the World Health Organization made at the WTO Council for TRIPS, 16 September 2002, on file with the authors.

[17] These conditions excluded countries with technical manufacturing capacity but insufficient market size, applied a strict standard

"insufficient manufacturing capacity", and applied income limits that would exclude many middle-tier developing countries.

[18] Brook K. Baker, "Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health", 14 *Indiana International & Comparative Law Review,* May 2004, 613-715 at 630.

[19] WTO document IP/C/73, 6 November 2015. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/73.pdf&Open=True.

[20] WTO document IP/C/88, 29 June 2021. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/88.pdf&Open=True.

[21] "1. A least developed country Member shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, as long as the Member remains in the category of least developed country and for a period of twelve years from the date of entry into force of a decision by the UN General Assembly to exclude the Member from the least developed country category." WTO document IPC/C/W/668. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W668.pdf&Open=True.

[22] See, e.g., Carlos Correa, *Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain,* Research Paper No. 52, (Geneva, South Centre, August 2014). Available from https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf.

[23] See, e.g. Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, Oxford University Press, December 2008; *Using TRIPS Flexibilities to Improve Access to HIV Treatment*, UNAIDS, WHO, UNDP Policy Brief, 2011, available from https://www.unaids.org/en/resources/documents/2011/20110315_JC2049_PolicyBrief_TRIPS.

[24] The Protocol seeks to provide guidance to the EAC Partner States on how their IP legislation should be adjusted to enable them to fully use the public health related TRIPS flexibilities, to restrict patentability of pharmaceutical products and medical devices in order to keep them in the public domain, promote a local pharmaceutical industry and ensure access to affordable medicines. See the *EAC Regional Intellectual Property Policy, the Protocol on the Public Health Related WTO TRIPS Flexibilities and the EAC Regional Pharmaceutical Manufacturing Plan of Action.* Available from https://ipaccessmeds.southcentre.int/wp-content/uploads/2019/12/EACTRIPSPolicy.pdf.

[25] Ellen F.M. t'Hoen *et.al.*, "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001-2016", *Bulletin of the World Health Organization*, 2018, vol.96, pp.185-93. Available from http://dx.doi.org/10.2471/BLT.17.199364.

[26] Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, South Perspectives, South Centre and World Health Organization, 2006, Geneva, pp. 47-33. Available from https://apps.who.int/iris/handle/10665/43503.

[27] Irene Calboli (2022), "Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review". In *Access to Medicines and Vaccines*, : Carlos Correa and Reto Hilty (eds.) Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_2.

[28] A study of the patent laws of 11 Latin American and Caribbean countries concluded that these countries have not included all the TRIPS flexibilities in their national laws. See Maria Auxiliadora Oliveira, Jorge Antonio Zepeda Bermudez, Gabriela Costa Chavez and Germán Velasquez, "Has implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favors public health?", *Bulletin of the World Health Organization*, November 2004, 82 (11), pp. 1–7. The situation has not substantially changed after publication of this study as patent law amendments have been rare in the region. See e.g., Guillermo E. Vidaurreta. *Uso Público no Comercial y Licencias Obligatorias en América Latina: Estado de Situación*, (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/10/Bk_2021_Uso-Publico-No-Comercial-y-Licencias-Obligatorias-en-America-Latina_ES.pdf.In relation to the situation in Africa, see Yousuf Vawda; Bonginkosi Shozi. *Eighteen Years after Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa.* Research Paper 103 (Geneva, South Centre, February 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/02/RP103_Eighteen-Years-After-Doha-An-Analysis-of-the-Use-of-Public-HealthTRIPS-Flexibilities-in-Africa_EN.pdf

[29] "Although in the United States the patent law does not provide for compulsory licenses, this is probably the country with the richest experience in the granting of compulsory licenses to remedy anti-competitive practices. More than one hundred such licenses have been granted (Scherer, 1999). Compulsory licenses have been granted in the United States in relation to present and future patents. Generally, such licenses have been granted against a reasonable royalty, generally determined on the basis of the "willing-buyer, willing-seller" formulation. However, in some cases, the compulsory licenses were conferred royalty free. In some cases, moreover, the patentee was required to make the results of its research readily available to other industry members, or to transfer the know-how actually used in production", Carlos Correa. 1999. Intellectual property rights and the use of compulsory licenses: options for developing countries. Trade-Related Agenda, Development, and Equity, Working Papers, South Centre. Available from https://www.dropbox.com/sh/wg8txyimpyu0tvp/AADJKywzs_5Yqzuhxo-Vm7Cja/T.R.A.D.E.%20Working%20Papers/EN?dl=0&preview=WP+5.pdf&subfolder_nav_tracking=1.

[30] See *MSD v Shionogi* (2017), German Federal Court of Justice_0.pdf (unctad.org)

[31] For a detailed discussion on this point, see Carlos M. Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, Research Paper No. 41, (Geneva, South Centre, September 2011) pp. 17–21. Available from https://www.southcentre.int/research-paper-41-september-2011/.

[32] South Centre, Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic. Available from https://www.southcentre.int/wp-content/uploads/2021/03/Compulsory-licenses-table-Covid-19-2-March.pdf.

[33] The Ministry of Public Health and the National Health Security Office, Thailand, *The 10 burning questions on the Government Use of Patents on the four anti-cancer drugs in Thailand*, February 2008.

[34] Vanessa Bradford Kerry and Kelley Lee, "TRIPS, the Doha Declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?", *Globalization and Health*, 2007, 3:3. Available from https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-3.

[35] See e.g., CIMUN, Ifarma, Misión Salud. Open Letter to the Co-Chairs of the UN Secretary-General's High-Level Panel on Access to Medicines. Bogotá, 30 June 2016. Available from https://infojustice.org/archives/36289.

[36] See, for example: Vidaurreta, op. cit. No. 29.

[37] Correa, note 32.

[38] See Brazil, "Presidente Bolsonaro sanciona lei sobre licença compulsória de patentes no caso de emergência de saúde pública", 2021. Available from https://www.gov.br/secretariageral/pt-

br/noticias/2021/setembro/presidente-bolsonaro-sanciona-lei-sobre-licenca-compulsoria-de-patentes-no-caso-de-emergencia-de-saude-publica.

[39] This provision was later vetoed by the President. As of the publication of this policy brief, the Brazilian Congress may still decide to overrule the veto and re-introduce such provision.

[40] See Olga Gurgula, "Accelerating Covid-19 vaccine production via involuntary technology transfer". Policy Brief No. 102, South Centre, September 2021. Available from https://www.southcentre.int/wp-content/uploads/2021/09/PB102_Accelerating-COVID-19-Vaccine-Production-via-Involuntary-Technology-Transfer_EN.pdf.

[41] Such provisions can be found in various US FTAs, for example, with Jordan, Morocco, Singapore.

[42] See South Centre Webinar Emerging Trends in FTAs and Public Health: Are the EU, USA and China shifting positions? 7 October 2021, Available from https://www.youtube.com/watch?v=nIJIOJWb4Pg&t=2151s.

[43] See, e.g., Olga Gurgula, "Compulsory Licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?" Policy Brief, No. 104, South Centre, October 2021. Available from https://www.southcentre.int/policy-brief-104-october-2021/.

[44] See Allan Maleche and Emma Day, "Right to Health Encompasses Right to Access Essential Generic Medicines: Challenging the 2008 Anti-Counterfeit Act in Kenya", *Health and Human Rights*, vol. 16 (no. 2), 2014. Available from https://www.hhrjournal.org/2014/11/right-to-health-encompasses-right-to-access-essential-generic-medicines-challenging-the-2008-anti-counterfeit-act-in-kenya/.

[45] See e.g., Roxana Blasetti and Juan I. Correa. *Intellectual Property in the EU-Mercosur FTA: A Brief Review of the Long-Awaited Agreement.* Research Paper No. 128, (Geneva, South Centre, February 2021). Available from https://www.southcentre.int/research-paper-128-february-2021/; Vitor Henrique Pinto Ido, *TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space is Retained?* Research Paper No. 131 (Geneva, South Centre, June 2021). Available from https://www.southcentre.int/research-paper-131-june-2021/.

[46] Carlos M. Correa, *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents*, Research Paper No.107 (Geneva, South Centre, April 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/04/RP-107.pdf.

[47] See South Centre, A Public Health Approach to Intellectual Property Rights: Promoting IPR Regimes that are Supportive of Public Health. Available from https://ipaccessmeds.southcentre.int/.

[48] This subject was examined in Duncan Matthews and Viviana Munoz-Tellez, "Bilateral Technical Assistance and TRIPS: The United States, Japan and the European Communities in Comparative Perspective", *The Journal of World Intellectual Property*, vol.9, issue 6, November 2006.

[49] Henrique Zeferino de Menezes, *The TRIPS Waiver Proposal: An Urgent Measure to Expand Access to the COVID-19 Vaccines,* Research Paper No. 129 (South Centre, Geneva, March 2021). Available from https://www.southcentre.int/research-paper-129-march-2021/; Carlos Correa, *Expanding the production of Covid-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South*, Policy Brief 92, April 2021. Available from https://www.southcentre.int/policy-brief-92-april-2021/; see also Gurgula, note 44

[50] See Gurgula, note 41.

[51] WTO document IP/C/W/681; see also: Gurgula, note 44.

[52] After the generic medicine Triavir from Apotex was approved in June 2006, Rwanda notified the WTO of its intent to import the medicine from the Canadian company Apotex in July 2007 and the first batch was delivered to Rwanda in September 2008.

[53] See note 1.

[54] See Muhammad Zaheer Abbas, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, Research Paper No. 136 (Geneva, South Centre, September 2021). Available from https://www.southcentre.int/tag/biolyse-pharma/.

[55] See: Carlos Correa, "Will the Amendment to the TRIPS Enhance Access to Medicines". Policy Brief No. 57, South Centre, January 2019. Available from https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf.

[56] See Suerie Moon, *Meaningful Technology Transfer for the LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2*. Policy Brief No. 9, ICTSD, April 2021. Available from https://www.files.ethz.ch/isn/138434/technology-transfer-to-the-ldcs.pdf.

[57] See: Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines: Implementing Flexibilities under Intellectual Property Law* (Springer, 2021), p. 24. Available from https://link.springer.com/book/10.1007/978-3-030-83114-1?sap-outbound-id=D373B17C34B74056795B3A9DC07A57A39E8B7BBA; Carlos Correa, *Interpreting the Flexibilities Under the TRIPS Agreement.* Research Paper 132 (Geneva, South Centre, June 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/06/RP-132.pdf.

[58] Germán Velásquez and Nirmalya Syam. *A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?* Policy Brief 93, South Centre, May 2021. Available from https://www.southcentre.int/tag/pandemic-treaty/.

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