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Access to Medicines and Intellectual Property: taking advantage of TRIPS flexibilities for post-COVID-19 resilience in Africa

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ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY: TAKING ADVANTAGE OF TRIPS FLEXIBILITIES FOR POST-COVID-19 RESILIENCE IN AFRICA

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ABSTRACT

The call by India and South Africa for the provisional lifting of patents on pharmaceutical products has had the merit of putting the issue of access to medicines and public health back on the agenda. However, the difficulty of reconciling access to medicines and intellectual property has many factors which cannot be reduced solely to the commitments of WTO member states. A more in-depth analysis reveals the intrinsic limitations of some of its members. These include the weakness of the legislative and regulatory framework in some countries, such as those on the African continent. Consequently, the aim of this article is to demonstrate that effective use of the flexibilities in the TRIPS Agreement is only possible if African countries equip themselves with an appropriate legal framework, in addition to the judicial institutions that are supposed to guarantee the effectiveness of the standards adopted. The methodology used consisted of an exegesis of various documents, including articles, working documents of the TRIPS Council, declarations and resolutions of various bodies, as well as the national case law of certain WTO members, etc. This method led us to conclude that the compatibility between access to medicines and intellectual property is caught between human rights and economic interests. However, for the TRIPS flexibilities to be fully utilized by African countries, they would benefit from reforming their legal frameworks to take advantage of the flexibilities in the TRIPS Agreement.

L'appel de l'Inde et de l'Afrique du Sud pour la levée provisoire des brevets applicables aux produits pharmaceutiques a eu le mérite de remettre à l'ordre du jour, la problématique de l'accès aux médicaments et de la santé publique. Toutefois, la difficulté à concilier accès aux médicaments et propriété intellectuelle a de multiples facteurs qui ne peuvent être réduits qu'aux engagements des Etats membres de l'OMC. Une analyse plus approfondie révèle des limites intrinsèques à certains de ses membres. Parmi ces dernières, il y figure la faiblesse du cadre législatif et réglementaire de certains pays, à l'instar de ceux du continent africain. Par conséquent, l'objectif de cet article est de démontrer qu'une jouissance effective des flexibilités de l'Accord Adpic n'est possible que si les pays africains se dotent d'un cadre légal approprié, en sus des institutions judiciaires censées garantir l'efficacité de normes adoptées. La méthodologie utilisée a consisté à faire une exégèse de divers documents dont : des articles, des documents de travail du conseil des Adpic, des déclarations et résolutions de divers organismes, ainsi que la jurisprudence nationale de certains membres de l'OMC, etc. Cette méthode nous a amené à constater que la compatibilité entre accès aux médicaments et propriété intellectuelle est pris en étau entre les droits humains et les intérêts économiques. Toutefois, pour que ces flexibilités soient accessibles aux pays africains, ils gagneraient à réformer leur cadre légal pour tirer parti des flexibilités de l'Accord Adpic.

El llamamiento de India y Sudáfrica en favor del levantamiento provisional de las patentes sobre productos farmacéuticos ha tenido el mérito de volver a poner en el orden del día la cuestión del acceso a los medicamentos y la salud pública. Sin embargo, la dificultad de conciliar el acceso a los medicamentos y la propiedad intelectual tiene muchos factores que no pueden reducirse únicamente a los compromisos de los Estados miembros de la OMC. Un análisis más profundo revela las limitaciones intrínsecas de algunos de sus miembros. These include the weakness of the legislative and regulatory framework in some countries, such as those on the African continent. En consecuencia, el objetivo de este artículo es demostrar que el uso eficaz de las flexibilidades del Acuerdo sobre los ADPIC sólo es posible si los países africanos se dotan de un marco jurídico adecuado, además de las instituciones judiciales que deben garantizar la eficacia de las normas adoptadas. La metodología utilizada consistió en una exégesis de diversos documentos, entre ellos: artículos, documentos de trabajo del Consejo de los ADPIC, declaraciones y resoluciones de diversos órganos, así

como la jurisprudencia nacional de algunos miembros de la OMC, etc. Este método nos llevó a concluir que el Acuerdo sobre los ADPIC no es suficientemente flexible. Este método nos llevó a concluir que la compatibilidad entre el acceso a los medicamentos y la propiedad intelectual se encuentra entre los derechos humanos y los intereses económicos. Sin embargo, para que los países africanos puedan acceder a estas flexibilidades, les convendría reformar sus marcos jurídicos para aprovechar las flexibilidades del Acuerdo sobre los ADPIC.

印度和南非呼吁暂时解除药品专利保护，这一举措的积极意义在于将药品可及性与公共卫生问题重新提上了议程。然而，在协调药品可及性与知识产权方面面临的困难涉及诸多因素，不能仅归因于世界贸易组织成员国的承诺。更深入的分析揭示了部分成员国固有的局限性。其中包括某些国家（如非洲大陆国家）立法和监管框架的薄弱。因此，本文旨在阐明：除非非洲国家建立起适当的法律框架，并配备能够保障所采纳标准有效性的司法机构，否则就无法有效利用《与贸易有关的知识产权协定》（TRIPS）**中的灵活性条款。本文采用的方法包括**对各类文件的阐释，涵盖相关文章、《与贸易有关的知识产权协议》理事会工作文件、各机构的声明与决议，以及部分世贸组织成员的国家判例法等。通过这种方法，我们得出结论：药品可及性与知识产权之间的兼容性，正处于人权与经济利益的夹缝之中。然而，非洲国家若要充分利用《与贸易有关的知识产权协定》（TRIPS）中的灵活性，就应改革其法律框架，从而充分利用《与贸易有关的知识产权协定》中的这些灵活性。

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INTRODUCTION

The resistance to the call for a waiver of certain obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) from South Africa and India to respond to the Covid-19 pandemic has put the difficulties encountered by a number of countries in terms of access to medicines back on the agenda. The recognition of intellectual property rights has had an impact on the ability of some States to guarantee sufficient and affordable access to medicines for their populations. Yet the supply of essential medicines is one of the fundamental obligations of States in terms of the right to health. The emergence of the HIV/AIDS pandemic made African countries major players in ensuring that their human rights obligations are taken into account in a context of trade liberalisation within the World Trade Organization (WTO). The activism of these countries in leading the WTO Ministerial Conference in Doha to adopt the Declaration on the TRIPS Agreement and Public Health contributed to reaffirm the right of each WTO member to reconcile intellectual property with its public health imperatives. However, the Covid-19 crisis has highlighted the difficulties WTO members have in making use of the flexibilities provided for in the TRIPS Agreement. A simplistic interpretation would suggest that these difficulties are attributable solely to the provisions of the TRIPS Agreement and perhaps to pressure from other members[1]. However, an in-depth analysis reveals that these flexibilities are not being exploited for a variety of reasons. As some studies have concluded, if developing countries are to take full advantage of the flexibilities offered by the TRIPS Agreement, it is important that they take the appropriate domestic measures to do so.[2] A favourable multilateral framework could enable them to take greater advantage of it, but the prerequisite remains an internal initiative to upgrade.

The aim of this article is to demonstrate that effective use of the flexibilities in the TRIPS Agreement is only possible if African countries equip themselves with an appropriate legal framework, in addition to the judicial institutions that are supposed to guarantee the effectiveness of the standards adopted.

The methodology used consisted of an exegesis of various documents, including articles, working documents of the TRIPS Council, declarations and resolutions of various bodies, as well as the national case law of certain WTO members, etc.

It is through the prism of the Covid-19 crisis that this method has led us to observe that the compatibility between access to medicines and intellectual property is caught in a vice between human rights and economic interests (see Part I). However, despite the intrinsic limitations of the multilateral trade framework, to fully utilize the flexibilities provided by the TRIPS Agreement African countries would need to reform their legal framework (see Part II).

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[1] Ismaelline Eba Nguema, «Propriété intellectuelle et santé publique : vers une prise de conscience de la part des pays africains?», *Revue Québécoise de Droit international*, Vol. 35, No. 2 (2022), pp.148-149.

[2] Carlos M. Correa, “Guidelines for the examination of patent applications relating to pharmaceutical products” (New York, UNDP, 2016). Available from https://ipaccessmeds.southcentre.int/wp-content/uploads/2019/12/UNDPpatents.pdf.

I. Access to medicines and intellectual property: between human rights and economic interests

A. The Right to Health and its Implications for Access to Medicines

Prior to accession to the WTO, very few African countries had laws relating to intellectual property. Only a few had inherited them from their colonial past, such as South Africa with its 1978 *Patent Act.*[3] For the majority, the entry into force of the WTO was a step into the unknown. In 1995, the implications of intellectual property on national public health policies, and more particularly on access to medicines, were unknown.[4] Prior to the TRIPS Agreement, several countries granted patents to various inventions, but not to pharmaceutical products, because of the sensitivity of this sector to human health.[5] The duplication of a molecule was not perceived by these national orders as an infringement of intellectual property or as constituting a counterfeit.[6] This process has led to the development of the generic industry in countries such as India and Canada.[7] Generic drugs sometimes cost 50% less than the original molecule. Recognition of intellectual property, like the liberalisation of certain sectors such as agriculture, would have consequences for human rights, including a significant proportion of small economies.

Most African countries directly or indirectly recognise the right to health as a supreme norm. This is the case, e.g., in Côte d'Ivoire, where Article 7 of the Constitution states that "the State shall ensure equal access to health for all citizens [...]", and in South Africa, where Article 27-1 of the Constitution recognises the right of everyone to obtain health care, social security and appropriate social assistance.[8] Furthermore, on the continent, the right to health often enjoys triple recognition (national, regional and international). African countries are party to the African Charter on Human and Peoples' Rights (ACHPR), which incorporates the provisions of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which recognises the right of everyone "to the enjoyment of the highest attainable standard of

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[3] Republic of South Africa, Government Gazette*, Staaskoerant Van Die Reubliek Van Suid-Afrika*, 17 May 1978. Available from https://www.gov.za/documents/patents-act-9-apr-2015-0827 . Yusuf Vawda, "The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property", Policy Brief, No. 99 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/policy-brief-99-august-2021/.

[4] Intellectual property was introduced into the Uruguay Round negotiations by some industrialised countries to ensure the long-term solvency of their balance of payments and to offset their losses. For example, the United States' losses in intellectual property royalties were estimated at between 43 and 61 billion dollars a year. Frédéric Benech, « La place du droit de la propriété intellectuelle dans le droit international économique *», Revue Générale de droit*, vol. 22, n°2 (1991), p. 426.

[5] G. Velasquez & P. Boulet, «Mondialisation et accès aux médicaments, perspectives accords de l'Accord sur l'Adpic de l'OMC», Série économie de la santé et médicaments, version révisée, n°7 (Genève, Organisation Mondiale de la Sante, 1999), pp. 20-21.

[6] *Ibid*.

[7] World Trade Organization, *Canada-Patent Protection for Pharmaceutical Products, Complaint by the European Communities and their Member States, Panel Report* (Geneva, 2000), pp. 41-42. Jaime R. Hornecker, "Generic Drugs: History, Approval Process, and Current Challenges", *Generic Drug Review suppl*. (2009), pp. 26-30. Thierry Libaert and Jean-Marie Pierlot, « Les Médicaments Génériques en Inde », dans *Les Nouvelles Luttes Sociales et Environnementales* (Vuibert, 2015), Chap. 8, pp.183 à 187.

[8] Sanogo Yanourga, "The right to health in national constitutions" (2014). Available from https://www.village-justice.com/articles/droit-sante-constitutions-nationales,16194.html.

physical and mental health".[9] The right to health is therefore a composite right , the realisation of which depends on various factors, including access to drinking water, healthy and nutritious food, housing, medical goods and services, including medicines, and so on. In *Free Legal Assistance Group et al v Zaire*, the African Commission on Human and Peoples' Rights "ruled that: the government's inability to provide essential services such as drinking water and electricity, as well as the lack of medicines, are violations of Article 16 of the Charter, which stipulates that States Parties undertake to take the necessary measures to protect the health of their populations".[10]

At the 44th session of the African Commission on Human and Peoples' Rights, African Union (AU) member states adopted resolution ACHPR/Res.141(XXXXIV)08 on access to health and essential medicines in Africa.[11] Under this resolution, members undertake to guarantee unrestricted access to essential medicines.[12] To achieve this, States have an obligation to promote, protect and fulfil.

The obligation to promote requires the State not to hinder or impede equitable access to essential medicines.[13] Resolution ACHPR/Res.141(XXXXIV)08 specifies that accession to an agreement containing intellectual property standards higher than those of the WTO TRIPS Agreement would constitute a breach of the obligation to protect.[14]

The obligation to protect requires States Parties to take appropriate legal measures by adopting a legal framework that guarantees the safety, quality and efficacy of medicines available on the national market, and by stimulating competition.[15]

Finally, the obligation to fulfil commits States to take "all necessary and appropriate *positive measures,* to the maximum of their available resources, to promote, provide and facilitate access to essential drugs[16]". Resolution ACHPR/Res.141(XXXXIV)08 recognises that the realisation of the right to health varies according to the financial means of each State[17]. However, it requires them to adopt minimum standards, including ensuring the availability and affordability of medicines without compromising the participation of individuals and groups in decisions affecting access to medicines.[18]

B. Access to Medicines in WTO Law Put to the Test by Covid-19

In recalling the primacy of human rights over other international treaties, the Committee on Economic, Social and Cultural Rights, in its General Comment 14, recalls the obligation of

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[9] Organisation of African Unity, Art. 16, African Charter on Human and Peoples' Rights.
[10] *Free Legal Assistance Group and Others v. Zaire*, African Commission on Human and Peoples' Rights, Comm. No. 25/89, 47/90, 56/91, 100/93 (1995) cited by Fédération internationale des ligues des droits de l'homme*, Guide pratique, La cour Africaine des droits de l'homme et des peuples vers la Cour africaine de justice et des droits de l'Homme*, Avril 2010, p. 9.
[11] Resolution on Access to Health and Essential Medicines in Africa - ACHPR/Res.141(XXXXIV)08, 2008.
[12] *Ibid.*, preamble.
[13] *Ibid*.
[14] *Ibid*.
[15] *Ibid*.
[16] *Ibid.*
[17] *Ibid*.
[18] *Ibid*.

States to ensure compatibility between the right to health and the obligations arising from the international treaties to which they accede[19]. With a view to reconciling health and intellectual property, TRIPS sets out the right of members to take the necessary measures to balance intellectual property rights protection and enforcement with health and the public interest.[20] In Patria Asera and Attorney General, the Kenyan High Court of Justice held that, "If such intellectual property rights are to be protected, where, as in this case, their protection is likely to jeopardise fundamental rights such as the right to life of others, [they] must give way to the fundamental rights of citizens [...]"[21]

The TRIPS Agreement contains flexibilities designed to reconcile the imperative of public health and patent protection. However, the use of TRIPS flexibilities by developing members has not always been without difficulty. In this case, the limited number of panel reports on intellectual property and health is not a reliable indicator of the effectiveness of the use of these flexibilities.

At the end of the 1990s, at a time when a large proportion of the South African population was seriously affected by HIV/AIDS, with one of the highest prevalence rates in the world, South Africa tried to make use of the flexibilities provided for in TRIPS through a law on parallel importation of medicines. During this period, despite the health emergency, 39 pharmaceutical companies took South Africa to the Pretoria High Court of Justice.[22] As soon as the trial was announced, demonstrations were organised by associations defending the rights of people living with HIV/AIDS. Media pressure led the laboratories to withdraw their complaint.[23] The repercussions of this trial were soon felt beyond the South African capital. On 30 May 2000, the United States asked the WTO to open consultations with the Brazilian authorities. They challenged law no. 9279 of 14 May 1996 on industrial property, which provides for the grant of compulsory licenses in case of lack of local working of patented inventions.[24] However, on 5 July 2001, following the repercussions of the Pretoria trial, the United States abandoned the procedure.[25] Similarly, after the failure of the Seattle Ministerial Conference, access to medicines became a priority for the launch of the Doha Development Round. In November 2001, the members adopted by consensus the Declaration on the TRIPS Agreement and Public Health[26]. It reaffirmed the legitimate right of each Member to use the flexibilities provided for in TRIPS in accordance with its objectives and principles. Article 8.1 states that

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[19] *Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights, General Comment No. 14 (2000), The right to the highest attainable standard of health (art. 12 of the International Covenant on Economic, Social and Cultural Rights),* Economic Council, 11 August 2000, E/C.12/2000/4, §39.

[20] Art. 8, Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

[21] Emmanuel Kolawole Oke, *The right to heath in pharmaceutical patent disputes*, Research Paper, No. 145 (Geneva, South Centre, 2022), p. 22. Available from https://www.southcentre.int/wp-content/uploads/2022/02/RP-145-The-Right-to-Health-in-Pharmaceutical-Patent-Disputes_EN.pdf.

[22] Maurice Cassier, « Propriété industrielle et santé publique », *Revue Projet,* vol. 2, n°270, pp. 47-55.

[23] Médecin sans Frontières, "*Pretoria: chronicle of a bad trial*", 23 January 2014. Available from msf.fr/actualites/pretoria-chronique-d-un-mauvais-proces.

[24] World Trade Organization, Brazil - Measures affecting patent protection. Available from https://www.wto.org/french/tratop_f/dispu_f/cases_f/ds199_f.htm.

[25] World Trade Organization, Brazil - Measures affecting patent protection, notification of mutually agreed solution, WT/DS199/4; G/L/454; IP/D/23/Add. Available from https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

[26] Organisation Mondiale du Commerce (OMC), Déclaration sur l'Accord sur les ADPIC et la santé publique, adoptée le 14 novembre 2001, WT/MIN (01)/DEC/2, en ligne : https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

"Members may, when formulating or amending their laws and regulations, adopt such measures as may be necessary to protect public health [...]"[27] In the *Australia - Tobacco Packaging* case, the Panel, after recalling that "Articles 7 and 8 are of essential relevance in establishing the objectives and principles which, in accordance with the Doha Declaration, express the object and purpose of the TRIPS Agreement relevant to its interpretation," considered that "this paragraph of the Doha Declaration can, in our view, be regarded as constituting a 'subsequent agreement' of WTO Members within the meaning of Article 31(3)(a) of the Vienna Convention". [28]

The Doha Declaration crowns the activism of the members of the African Group within the WTO. It also reaffirms the primacy of public health over economic interests. Nevertheless, almost two decades after the adoption of this declaration, African countries still seem to be experiencing difficulties in implementing the flexibilities of the TRIPS Agreement.

In October 2020, in the midst of the Covid-19 crisis, South Africa and India called for the lifting of intellectual property rights on Covid-19 related products.[29] The aim of this call for international solidarity was to guarantee wider access to vaccines and other needed technologies. Nevertheless, the joint communication from South Africa and India received a mixed reception. For the European Union (EU) representative at the WTO, "there is no evidence that intellectual property rights impede in any way access to medicines and technologies related to COVID-19".[30]

As soon as the first vaccines against Covid-19 came onto the market, inequalities in access to pharmaceutical products were exacerbated. In February 2022, the United Nations Human Rights Council noted that "the way in which vaccines have been deployed [...] has revealed glaring inequalities. At the time of writing, just over 10% of adults in low-income countries have received at least a first dose of vaccine, compared to 67% in high-income countries [...]. Even vaccines produced in Africa have been shipped to countries where most of the population is already vaccinated, whereas [this was not the case in Africa]".[31]

Among the “solutions” that have been identified by some major trading powers as sufficient to deal with the Covid-19 crisis are voluntary licences. This is a contract under which the patent holder authorises a laboratory to produce a drug, in return for payment of a fee for use of the patent. It is the patent holder who most often sets the resale prices according to the level of economic development of a given country or region (low, intermediate, high). During the Covid-19 crisis, the four main vaccines developed in Western countries (Pfizer/BioNTech, Moderna, Johnson & Johnson and Astra Zeneca/Oxford) were not included in the voluntary licensing

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[27] Art 8.1, TRIPS Agreement.

[28] World Trade Organization, Australia - Certain measures relating to trademarks, geographical indications and other plain packaging requirements for tobacco products and their packaging, Panel Report, 28 June 2018, WT/DS435/R; WT/DS441/R; WT/DS458/R; WT/DS467/R, §7.2408.

[29] OMC, Conseil des ADPIC, *Dérogation à certaines dispositions de l’Accord sur les ADPIC pour la prévention, l’endiguement et le traitement de la Covid-19*, Communication de l’Inde et l’Afrique du Sud, OMC doc IP/C/W/669, 2 octobre 2020, aux para. 3, 12, en ligne : docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=r:/IP/C/W669.pdf&Open=True.

[30] Ann Danaiya Usher, “South Africa and India push for COVID-19 patents ban”, *Lancet*, vol. 396, Issue 10265 (December 05, 2020), pp. 1790-1791.

[31] Human Rights Council, *Human Rights Implications of the Gaps in Timely, Equitable and Universal Access to and Affordability of Coronavirus Vaccines (COVID-19) and of the Widening Inequalities between States*, Geneva, Switzerland, Forty-ninth Session, 1st February 2022, A/HRC/49/35, §3.

programme of the World Health Organization (WHO)'s Medicine Patent Pool (MPP).[32] Rather, it is under the aegis of the WHO Covid-19 Technology Access Pool (C-TAP), now renamed as the Health Technology Access Pool, that laboratories have been called upon to enter into voluntary licensing agreements to guarantee access to treatments aimed at limiting the spread of Covid-19.[33] The above-mentioned laboratories have benefited from public subsidies. The Oxford/Astra Zeneca vaccine received nearly $2.7 billion, Johnson & Johnson $1.5 billion, Moderna $5.75 billion and Pfizer/ BioNTech $2.5 billion.[34] In this context, the contribution of public funds could have played a role in favour of the renunciation, at least temporarily, of the rights of the above-mentioned laboratories. For the co-sponsors of the TRIPS waiver proposal by South Africa and India: "Instead of heeding the appeal made by the co-authors, the opponents advocated voluntary arrangements and donations as the only solution to ensure equitable distribution. In reality, however, an infinitesimally small number of voluntary licences have been used, and their strict conditionalities have made it impossible to respond to the global crisis. And there have been no voluntary licences or licensing arrangements for the vaccines most widely used in developed countries".[35]

It was not until 17 June 2022, almost two years after the appearance of Covid-19, that members agreed to lift certain patent provisions applicable to Covid-19 vaccines.[36] By this time, however, African countries were less and less concerned about the availability of vaccines, but were now faced with the additional challenge of convincing their populations to take up vaccination on a massive scale. On 21 December 2023, the co-sponsors declared that "the WTO has failed to provide a global response to the pandemic and, even when it has achieved results on COVID-19 vaccines, it has been too little, too late".[37]

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[32] Medicine Patent Pool. Available from https://medicinespatentpool.org/fr. The MPP is a public health organisation whose mission is to facilitate access to medicines in low- and middle-income countries.
[33] Medicine Patent Pool, “C-TAP: a new agreement aims to improve access to COVID-19 screening technologies worldwide”, 16 June 2022. Available from https://medicinespatentpool.org/fr/news-publications-post/c-tap-un-nouvel-accord-vise-a-ameliorer-lacces-aux-technologies-de-depistage-de-la-covid-19-partout-dans-le-monde .
[34] Oxfam, “Pharmaceutical giants pay billions to shareholders while the world faces vaccine apartheid”, 22 April 2021. Available from https://www.oxfam.org/en/press-releases/pharmaceutical-giants-shell-out-billions-shareholders-world-confronts-vaccine.
[35] World Trade Organization, Revised communication presented by the co-sponsors of the proposal for a derogation to the TRIPS Agreement following the meeting of the General Council on 13-15 December 2023, WT/GC/W/920, §1.6.
[36] Carlos M. Correa and Nirmalya Syam, *The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?*, Research Paper, No. 169 (Geneva, South Centre, 2022). Available from https://www.southcentre.int/research-paper-169-8-november-2022/ .
[37] *Ibid*.

II. A READING OF THE TRIPS AGREEMENT TO PROMOTE ACCESS TO MEDICINES IN AFRICA: ADAPTING NATIONAL LEGISLATION TO FLEXIBILITIES

A. Compulsory Licences: the Field of Possibilities

During the Covid-19 crisis, the problem of availability and affordability arose as soon as the first vaccines were released. During the first year on the market, the rush for vaccines led to a very uneven distribution of vaccine doses. On 08 May 2021, 30.9% of the population in North America had received a first dose of vaccine, 13% in Europe, 4.5% in South America and 1% in Africa.[38] The unavailability of sufficient doses of vaccines and other pharmaceutical products for the treatment of Covid-19 led some WTO members to issue compulsory licences. In March 2020, Israel issued a compulsory licence to import generic versions of lopinavir/ritonavir, after the Ministry of Health determined that the drug could be a possible treatment for patients with Covid-19.[39] Compulsory licences are one of the flexibilities available under the TRIPS Agreement.[40] They may be issued by a Member State after the proposed user of the compulsory license has made efforts to obtain a voluntary license from the patent holder on reasonable terms and conditions, and such efforts have not been successful within a reasonable period of time. However, in the event of a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use, or to remedy a practice determined to be anticompetitive by a judicial or administrative authority, a compulsory license can be issued without any prior effort of obtaining a voluntary license. A compulsory licence may be issued ex officio by the competent authorities of a Member in such situations (more appropriately called 'government use authorization' in this case). [41]

Following Israel's example during Covid-19, many countries have amended their legislation to authorise the use of compulsory licences in the event of a health emergency.[42] Some have adapted their legislation to the specific case of Covid-19, as was the case in Canada, Chile and Ecuador.[43] Despite the possibility of recourse to compulsory licences, African countries have not issued any. In a joint communication, the African and other developing country members referred to the pressure exerted by the major powers to prevent them from issuing such licences.[44] They referred to the Special 301 Report of the Office of the United States Trade Representative, which continues to equate compulsory licensing with anti-competitive measures.[45] Moreover, very few African members have a legal framework for compulsory

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[38] Michaël Rochoy, Eric Billy, Matthieu Calafiore, "What is the point of an ex-officio licence if it is not used during a pandemic?" *Therapies*, vol. 76, No. 4 (12 May 2021).
[39] Hilary Wong, "The case for compulsory licensing during COVID-19", *Journal of Global Heath*, Vol. 1, n°1 (2020), pp. 3 to 4.
[40] Art. 31, TRIPS Agreement.
[41] Weinian Hu, "Compulsory licensing and access to future Covid-19 vaccines", CEPS Research Report, n°2, July 2020.
[42] Hilary Wong, "The case for compulsory licensing during COVID-19", *Journal of Global Heath*, Vol. 1, n°1 (2020), pp. 3 to 4.
[43] *Ibid*.
[44] Council for TRIPS, *Response to questions on intellectual property difficulties encountered by members in a Covid-19 context contained in document IP/C/W/671*, WTO doc IP/C/W/673, p. 6.
[45] Ismaelline Eba Nguema, « Propriété intellectuelle et santé publique : vers une prise de conscience de la part des pays africains ? », *Revue Québécoise de Droit International*, Vol. 35, No. 2 (2022), pp.148-149. Julio Nogués, "Patents and Pharmaceutical Drugs, Understanding the Pressures on

licensing. Nevertheless, a few have done so and have made use of it, despite some difficulties. This is the case in Zimbabwe, Rwanda, Mozambique and Zambia.[46] Indeed, the sometimes inadequately designed national legislation has prevented some of them from taking full advantage of compulsory licences, the case of Zambia being a perfect illustration.

Zambia is one of the least developed countries (LDCs) that under Article 66.1 of TRIPS has a period of exemption from the application of patents to pharmaceutical products.[47] Despite the extension of the transition period applicable to patent protection for pharmaceutical products, which was initially extended to 2016, Zambia, like other LDCs, has not enacted legislation to take advantage of this. On the contrary, during the HIV/AIDS pandemic, to ensure the supply of antiretroviral (ARV) drugs to its population, Zambia declared a state of emergency on three ARVs before resorting to compulsory licensing in 2004. However, in principle, as an LDC, this country is exempt from such a procedure, which is in fact less easy to implement than the provisions of Article 66.1 of the TRIPS Agreement. Moses Nkomo notes other limitations of the Zambian approach. Indeed, "subsequent research revealed that the two right holders concerned had not filed applications and did not hold the corresponding patents in Zambia. Similarly, the royalties were significantly higher than what Zambia could negotiate on the basis of its position in the Human Development Index (HDI). According to the WHO/UNDP document on royalties, on the basis of the HDI royalty rates, Zambia's compulsory licence could have been limited to a margin of 0.32%".[48] The Zambian case could perhaps be transposed to other countries. In this respect, it is important to point out that, according to the World Intellectual Property Organization (WIPO) data, while patent applications grew significantly on the African continent between 2012 and 2022, by around 5.1%, they remain relatively marginal compared with other regions.[49] In 2022, they accounted for just 0.7% of all applications worldwide.[50]

The inadequacy of its international commitments and its legal framework would appear to be one of the causes of the under-utilisation of compulsory licences. In fact, Article 31 of TRIPS allows the competent authorities to issue compulsory licences for various reasons. A government may issue a licence in accordance with the principles of TRIPS for public health reasons. In the case of a "national emergency or other circumstances of extreme urgency or in the event of public non-commercial use", the State is not required to make a prior request for voluntary licences from the patent holder.[51] A compulsory licence may also be issued in the event of use by the government to facilitate access to medicines for its population, in response to anti-competitive practices, in the event of abuse of rights and in the absence of local exploitation. In order to issue compulsory licences, WTO members must first have incorporated these elements into their national legislation or regulations.[52] However, few African countries have legislation enabling compulsory licences to be issued. As a result, in 2019, less than half of African countries had a legal framework incorporating the use of

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Developing Countries*"*, World Bank, International Economics Department Working Paper WPS 502 (Washington, 1990).

[46] The South Centre, "The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation", Policy Brief, N°7 (Geneva, 2011), p. 8.

[47] *Ibid*.

[48] *Ibid.*

[49] World Intellectual Property Organization (WIPO), Patent applications by region, 2012 and 2022, WIPO databases. Available from https://patentscope.wipo.int/search/en/search.jsf.

[50] *Ibid.*

[51] Art. 31, b, TRIPS Agreement.

[52] Art. 31, TRIPS Agreement.

compulsory licences.[53] Of the 23 African countries listed by WIPO that have legislation incorporating compulsory licences, the majority explicitly provide for no exploitation of a patented invention as a ground for issuing compulsory licenses.[54] According to the French National Institute of Intellectual Property, a patent is considered not to have been worked when: the patent holder "has not begun to work the invention covered by the patent, nor has he made effective and serious preparations to do so; if he has not marketed the product covered by the patent in sufficient quantities to satisfy the needs of the national market, or if he has abandoned the working or marketing of the patent for more than three years".[55]

The issuing of compulsory licences in the public interest, to correct abuses of patents, for use by the government, etc. is only very rarely explicitly provided for by law. To our knowledge, only Algeria, South Africa and Egypt have relatively exhaustive national legislation on intellectual property.[56] The South African law on intellectual property (Patent Act of 1978), although less comprehensive than that of Algeria and Egypt, has the merit of having been invoked on several occasions before the competent national courts.[57]

In South Africa, the issuing of compulsory licences for anti-competitive practices allows the government to take corrective measures following a court decision. In "the case of Hazl Tau and others v GlaxoSmithKline and Boehringer Ingelheim, the plaintiffs alleged that the prices charged by the patent holders for their essential medicines were directly responsible for premature, foreseeable and avoidable loss of life".[58] Under the Competition Act of 1993, the Competition Commission was able to rule on the case and "find the two companies guilty of excessive pricing and of failing to grant licences to generic manufacturers in circumstances which, in the Commission's view, merited such licences. However, in order to avoid a damaging precedent, the two companies entered into a number of agreements which enabled generic versions of their patented products to be made available for the first time in South Africa".[59]

By providing legal remedies against laboratories that charge excessively high prices on a given market, the grant of compulsory licences may force the laboratory to lower prices. In the case of Treatment Action Campaign v. Bristol-Myers Squibb (BMS), after the civil society brought a lawsuit against BMS because of the "excessive" prices charged by the laboratory for a pharmaceutical product that was not covered by a patent on national territory, BMS preferred to reach an out-of-court settlement and lower the prices of the drug concerned by almost 80%.[60]

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[53] African Intellectual Property Organization *(OAPI),* OAPI database, 2024. Available from https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html .
[54] *Ibid.*
[55] France, National Institute of Intellectual Property. Available from https://www.inpi.fr/faq/53.
[56] World Intellectual Property Organization, Database on Flexibilities in the Intellectual Property System. Available from https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html.
[57] *Ibid.*
[58] Moses Nkomo, "The under-utilization of TRIPS flexibilities by developing countries: the case of Africa", Research Paper from the WIPO-WTO colloquium for teachers of intellectual properly law (2010), p.132.
[59] *Ibid.*
[60] *Ibid.*

B. From Compulsory to Voluntary Licences: Strengthening National Legislation as a Means of Constraint

During the Covid-19 pandemic, contrary to the position of India and South Africa, many members argued that the granting of voluntary licences was an alternative to the provisional lifting of patents. For the EU, voluntary licences are a sufficient response to the lack of supply of medicines and medical devices capable of combating Covid-19.[61]

Whether voluntary licences can encourage technology transfer will depend on the terms of the licence acceptable to the patent holder. In June 2022, as part of the MPP, an Arm Messenger technology transfer centre was set up in partnership with Univercells and the South African firm Afrigen biologics.[62] The aim is to disseminate this technology in various low-and middle-income countries. Although late in developing a vaccine against Covid-19, host countries will be able to acquire technologies that will benefit them in the medium to long term. During this period, the pressure exerted by the coalition formed around India and South Africa has accelerated technology transfer through voluntary licences.[63] It is important to note that Article 66.2, which advocates the transfer of technology from developed countries to LDCs, remains ineffective.[64] Nevertheless, in accordance with Article 8.2 of TRIPS, members may take "appropriate measures [...] to prevent the abuse of intellectual property rights".[65] Consequently, members with an appropriate legal framework can encourage laboratories to conclude voluntary licences incorporating local exploitation clauses. This, at least, is what we can learn from South Africa's jurisprudential experience. In *Hazel Tau et al v GlaxoSmithKline and Boehringer Ingelheim*, the Competition Commission "found the two companies guilty of excessive pricing and of failing to grant licences to generic manufacturers in circumstances which, in the Commission's view, merited such licences".[66] After the case was referred to the Competition Tribunal, the two companies entered into agreements to produce generics in South Africa. However, of all the African countries that have legislation authorising compulsory licences, very few have included provisions or regulations relating to the misuse of patents. This is the case in South Africa, Egypt, Algeria and Swaziland.[67] This is not the case in Ghana, Kenya, Nigeria, Zambia and Morocco, etc., which do not explicitly recognise the misuse of intellectual property rights.[68]

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[61] Ismaelline Eba Nguema, «Propriété intellectuelle et santé publique : vers une prise de conscience de la part des pays africains?» *Revue Québécoise de Droit international*, Vol. 35, No. 2 (2022), p. 152.
[62] The Medicines Patent Pool, "We welcome the agreement between Afrigen and Univercells to develop the first African vaccine against COVID-19", 21 June 2022. Available from https://medicinespatentpool.org/fr/news-publications-post/le-medicines-patent-pool-se-felicite-de-laccord-conclu-entre-afrigen-et-univercells-aux-fins-du-developpement-du-premier-vaccin-africain-contre-la-covid-19 .
[63] See https://medicinespatentpool.org/fr?s=covid .
[64] World Trade Organization, TRIPS Council*, Paragraph 8 of the TRIPS Decision*, Informal Thematic Session for Input from External Stakeholders, Report by the Chair, 23 October 2023, IP/C/W/706, p. 7.
[65] Art 8.2, TRIPS Agreement.
[66] Moses Nkomo, "The under-utilization of TRIPS flexibilities by developing countries: the case of Africa", Research Paper from the WIPO-WTO colloquium for teachers of intellectual properly law (2010), p.132.
[67] World Intellectual Property Organization, Database on Flexibilities in the Intellectual Property System. Available from https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html.
[68] *Ibid*.

C. Exhaustion of Rights: an Underused yet Necessary Mechanism

The Covid-19 crisis has brought back into focus the impact that patent recognition has had on access to medicines for the poorest populations. Although pharmaceutical companies did not rush to Africa to apply for patents, the companies that supplied them with generics could no longer do so. This is because a patent provides its holder with an exclusive right of exploitation. According to Article 6 of the TRIPS Agreement, nothing in the Agreement shall be used to address the issue of exhaustion of intellectual property rights. Therefore, WTO members have the full freedom to determine their own regime of exhaustion of intellectual property rights. Accordingly, the exclusive rights of the patent holder can be deemed to have been exhausted "as soon as the patented product is put on the market for the first time with the consent of the holder"[69] or by any other legitimate means. The right holder's monopoly on the product no longer extends to imports and sales.[70] Thus, by resorting to parallel imports, members can lower the selling prices of pharmaceutical products and facilitate access to them for as many people as possible.[71] As soon as a patented medicinal product is first placed on the market, a member may freely import it without the authorisation of the patent holder if the selling price charged in another territory is lower than that fixed in its territory. There are 3 types of exhaustion of rights: international, regional and national.

International exhaustion of rights allows a member to import medicines without any restrictions from all countries in the world.[72] Regional exhaustion restricts a member to the region to which it belongs.[73] National exhaustion, on the other hand, is even more restrictive in that it limits a country's ability to import products without the authorisation of the patent holder until the product is put by the patentee or authorized licensee in the national market.[74] Members are free to choose the exhaustion system they consider most appropriate.[75] Moreover, not all exhaustion methods are the same. In principle, African countries should have chosen international exhaustion. In fact, it would enable these countries to lower prices by importing patented medicines into the territories where they are sold at a lower price than their own.

However, according to WIPO data, only a few African countries have a legal framework for this.[76] And of those that do, very few have opted for international exhaustion. Algeria, Botswana, Ghana, Liberia, Morocco, Mozambique, Namibia, Swaziland, Tunisia and Uganda have opted for exhaustion of national rights.[77] Only a few countries, including Egypt and Kenya, have opted for international exhaustion of rights.[78] In practical terms, during the Covid-

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[69] Action Programme on Essential Drugs and Vaccines, WHO, "Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement", Health Economics and Medicines Series, No. 7, revised version (1999), p. 23.
[70] Art. 6, TRIPS Agreement.
[71] ACT UP Paris, "Access to generics and intellectual property", p. 6. Available from https://www.actupparis.org/wp-content/uploads/2003/11/03_11-DocIP-E.pdf.
[72] Action Programme on Essential Drugs and Vaccines, WHO, "Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement", Health Economics and Medicines Series, No. 7, revised version (1999), p. 23.
[73] *Ibid*
[74] *Ibid.*
[75] Art. 6, TRIPS Agreement.
[76] World Intellectual Property Organization, Database on Flexibilities in the Intellectual Property System. Available from https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html.
[77] *Ibid.*
[78] *Ibid.*

19 crisis, only the latter two countries mentioned above would have been able to purchase vaccines in other territories without the agreement of the patent holder. In 2021, a dose of Astrazeneca cost €4.32 in South Africa and only €1.78 in the EU.[79] As a result, a dose of this vaccine cost 2.5 times more in South Africa than in the EU, while at the time only 1.5% of the African population was vaccinated.[80] In Kenya, "During parliamentary debates on the 2001 Act, it was stated that the parallel importation provision was specifically introduced to allow the importation into Kenya of drugs necessary for human life, in particular [for the treatment] of HIV/AIDS and [other] opportunistic diseases, as well as malaria".[81]

The existence of an enabling legal provision is important for access to medicines, but not a guarantee. In this respect, the existence of standards is not enough to guarantee their effectiveness; it is also necessary for the judicial authorities to understand the scope of such provisions in order to implement them. In *Pfizer Inc v Cosmos Limited*, Pfizer alleged that Cosmos had infringed the patent for azithromycin dihydrate 6 because Cosmos had made parallel imports into India, Bangladesh and China without the consent of the rights holder.[82] However, Article 58(2) of the Kenyan Intellectual Property Act states that: "the rights conferred by the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or any other country or imported into Kenya by the patentee or with his express consent".[83] However, in a rather curious and confusing way, the Court confused parallel importation with compulsory licences and voluntary licences. According to the court, "parallel importation ... is applicable, for example, where the government has authorised a third party to exploit the patent, and that third party imports the product from other countries where it is legitimately marketed ... This can also be done with the authorisation of the patent owner by means of a contractual or voluntary licence".[84] The Kenyan court seems to have confused compulsory licences, voluntary licences and parallel imports, whereas the exhaustion of rights regime chosen by Kenya gives them the possibility of importing medicines without geographical restriction.

D. Recourse to the Transition Period or Self-Limitation of LDCs

Art 66.1 exempts LDCs from the application of the provisions of TRIPS with the exception of Articles 3, 4 and 5.[85] This exemption has been extended three times at their request, i.e. 2006-2013, 2013-2021 and 2021-2034.[86] Unlike the other TRIPS flexibilities, this one seems easier to implement, as it requires fewer technical and financial resources. Yet some LDCs are still struggling to make use of it, partly due to the lack of an appropriate legal framework. For Yusuf

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[79] TV5 Monde, « Covid-19: l'Afrique paie ses vaccins au prix fort », 03 aout 2021, en ligne : https://information.tv5monde.com/afrique/covid-19-lafrique-paie-ses-vaccins-au-prix-fort-35535.
[80] *Ibid.*
[81] Emmanuel Kolawole Oke, *The right to heath in pharmaceutical patent disputes*, Research Paper, No. 145 (Geneva, South Centre, 2022), p. 22. Available from https://www.southcentre.int/wp-content/uploads/2022/02/RP-145-The-Right-to-Health-in-Pharmaceutical-Patent-Disputes_EN.pdf.
[82] *Ibid.*
[83] Quoted in *Ibid*.
[84] *Ibid.*
[85] Art 66.1, TRIPS Agreement.
[86] Olugbenga Ajani Olatunji, "Going It Alone or Acting as a Collective? Evaluating the East African Community Policy on Implementing TRIPS Obligations", *Journal of African Law*, vol. 68. N°1 (2024), pp.19-39.

Vawda, African countries are finding it hard to shake off the colonial legacy of intellectual property[87], a legacy that is still there, and which, despite pandemics, continues to influence judges and bureaucrats.[88] In Malawi, for example, intellectual property is still governed by the 1957 Patent Act, which was revised in 2014 and 2018.[89] Other African LDCs also retain laws that predate their accession to the WTO, such as Tanzania's Patents Act of 1987.[90]

However, since the early 2000s, more and more LDCs have been updating their legislation to take account of the transition period. For example, Article 18.9 of Law no. 31/2009 on the protection of intellectual property adopted by Rwanda states that "pharmaceutical products shall be excluded from patent protection, even if they constitute inventions [...], for the purposes of applying the international conventions to which Rwanda is a signatory".[91]

While most African LDCs appear to have introduced the necessary reforms, many have made inadequate use of them. In January 2005, Guinea made use of Article 31 of TRIPS to obtain supplies of antiretroviral drugs (ARVs), as did Mozambique in March 2005, Swaziland in June 2005 (HIV treatment), Sao Tome and Principe in August 2006 (HIV treatment) and Zambia in September 2004 and October 2006.[92] However, they could have refrained from using compulsory licences, which require more technical skills and sometimes incur financial costs. The case of Zambia cited above is a perfect illustration.[93]

It is also curious to note that the majority of African LDCs only used Article 66.1 to import HIV/AIDS-related treatments "at the height of the pandemic".[94] Only a few countries are exceptions. They have made use of paragraph 7 of the Doha Declaration on all medicines at least once. These include Angola (November 2005), Chad (February 2007), Gambia (April 2007), Lesotho (August 2004), Malawi (September 2024), Niger (August 2004), Rwanda (November 2004) and Tanzania (January 2008).[95]

To take advantage of the transition period, LDCs were encouraged to develop partnerships with the private sector to develop the local generic industry.[96] However, the lack of technology transfer and policies to develop the local pharmaceutical industry led some African LDCs that had enacted national legislation relating to the transition period to favor imports of generics.[97] Nevertheless, during the COVID-19 crisis, to our knowledge, LDCs did not resort to importing

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[87] Yusuf Vawda, “The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property”, Policy Brief, No. 99 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/policy-brief-99-august-2021/. Bryan Mercurio, Tolulope Anthony Adekola, Chimdessa Fekadu Tsega, “Pharmaceutical patent law and policy in Africa: a survey of selected SADC member states”, *Legal Studies*, vol. 43. n°2 (2023), pp. 331-350.

[88] *Ibid.*

[89] Malawi, Patent Act, Chapter 49.02 (1957).

[90] Tanzania, The Patents Act (1987).

[91] Sangeeta Shashikant, T*he African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines*, Research Paper, No. 56 (Geneva, South Centre, 2014). Available from https://www.southcentre.int/research-paper-56-november-2014/.

[92] Medicines Law & Policy, “The TRIPS Flexibilities Database”. Available from https://tripsflexibilities.medicineslawandpolicy.org/.

[93] See s*upra*, §II,A.

[94] Yousuf Vawda, *op.cit*, p. 2.

[95] Medicines Law & Policy, “The TRIPS Flexibilities Database”. Available from https://tripsflexibilities.medicineslawandpolicy.org/.

[96] Nirmalya Syam, *La période de transition accordée aux PMA pour mettre en œuvre l’accord sur les ADPIC et ses incidences sur la production locale de médicaments dans la CAE*, document de recherche 59 (Genève, Centre Sud, 2014), pp. 6-7.

[97] *Ibid*., pp.13-16.

generics under Article 66.1. There may be many reasons for this, including the shortage of generic pharmaceutical products or medical devices due to the shortages observed.

Some developing countries, such as Chile, Honduras and Peru, made use of the provisions of Article 31 of TRIPS, as they were unable to make use of the waiver provided for in Article 66.1 of the same agreement.[98]

It is important to note that such a provision could undoubtedly prove necessary during future pandemics and/or to combat certain diseases such as Hepatitis C, cancer or malaria. Furthermore, the use of generics is likely to be threatened in certain LDCs due to the inappropriate use of anti-counterfeiting laws. In 2014, Uganda adopted the *Industrial Property Act*, which, unlike the previous law (Patent Act Cap 216), incorporates the provisions of Article 66.1 of TRIPS, as well as the criteria for patentability and compulsory licences.[99] However, these advances are currently threatened by an anti-counterfeiting bill. In its version of 11 March 2024, *the Anti-counterfeit Goods and Services Bill Memorandum* could restrict imports of generics into Uganda, due to its overly broad definition of counterfeit goods.[100] At first glance, the proliferation of pharmaceutical products unfit for consumption in sub-Saharan Africa poses a real challenge for national drug control and regulatory authorities. Both generics and brand-name drugs are susceptible to be falsified. Falsified medicines are those that do not meet the testing and quality control requirements to which pharmaceutical products are subject. It is therefore not surprising that their circulation and consumption pose a danger to public health. Nevertheless, extending the term "counterfeiting" to intellectual property in general, including medicines, is likely to undermine access to generics. However, the protection of so-called commercial intellectual property is different from the imperative of drug safety. The revised 2024 version of Uganda's Anti-Counterfeiting Bill includes a relatively broad definition of counterfeiting. A counterfeit product would include "the manufacturing, producing, packaging, re-packaging, labeling, selling, or marketing, whether in Uganda or outside Uganda, of the subject matter of an intellectual property, or a colourable imitation of it so that the other goods are likely to be confused with or be taken as being the goods of the owner or licensee or any goods manufactured, produced, or made under his or her license [...]."[101] Such a definition raises several difficulties when applied to medicines. In this regard, for reasons of drug safety, generics and brand-name drugs may have similar names.[102] This is because the name is often based on the "International Nonproprietary Name of the active ingredient."[103] The same applies to the size, shape, and color of a drug, "because changing the shape, size, and even color of a medicine can affect bioequivalence, and because it is important to reduce consumer confusion over originator products and generics being equivalent, to encourage generic substitution adherence to treatment."[104] Furthermore, the Ugandan bill explicitly includes what constitutes counterfeiting for medicines: "the deliberate

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[98] Medicines Law & Policy, “The TRIPS Flexibilities Database”. Available from https://tripsflexibilities.medicineslawandpolicy.org/.
[99] CEHURD, KELIN and aidsfonds, “Utilizing flexibilities in the TRIPS agreement to advance access to medicines in Kenya and Uganda, Challenges and opportunities for access to medicines for HIV, TB, Hepatitis and Non-Communicable diseases”, January 2019, pp.18-19.
[100] *Ibid*.
[101] Uganda, “The Anti-Counterfeit Goods and Services Bill Memorandum, Version of March 11, 2024”, Part I, §I,2a (ii).
[102] United Nations Development Programme (UNDP), “Anticounterfeit laws and public health: what to look for”, Discussion paper (2015), p.18.
[103] *Ibid.*
[104] *Ibid.*

or fraudulent labeling of the drug with respect to its identity, source or ingredients [...]"[105] which adds even more confusion between generics and counterfeits. Such provisions could be considered TRIPS-plus because they no longer take into account compulsory licenses and parallel imports that are obtained without the consent of the rights holder.

Article 61 of the TRIPS Agreement criminalizes counterfeiting in terms of "deliberate acts of counterfeiting of trademarks [...]" by recommending that States adopt a legal framework that penalizes such practices.[106] Penalties may include imprisonment and/or fines.[107] They should be accompanied by the seizure, confiscation, etc. of the infringing products.[108] The wording of this article cannot therefore apply to pharmaceutical products, since in the case of generics, it is not a "deliberate act" of counterfeiting, but a reproduction of a brand-name product which, as mentioned above, may include certain similarities in terms of packaging, form, etc. in order to meet a public health requirement. The applicability of this provision to pharmaceutical products could lead to seizures of generics by customs officials for the sole reason that a generic product is similar in form to an original product. This is also the conclusion reached by South African judge Harms.[109]

The immediate consequence of such measures could be a shortage of generics on the local market. However, in Uganda, as in other African countries, the lives of a significant proportion of the population depend on the availability of generics. This is particularly the case for people living with HIV/AIDS.

In East Africa, other countries have adopted anti-counterfeiting laws, including Tanzania (Merchandise Marks Regulations 2008), Malawi (Anticounterfeit Law of 2011), and Kenya (Anticounterfeit Act of 2008).[110] In Kenya, the 2008 anti-counterfeiting law was challenged in the High Court by three people living with HIV/AIDS. They argued that such a provision would likely hinder the supply of generic drugs and thus threaten the right to health, which is constitutionally recognised in Kenya.[111] The Kenyan courts agreed with the plaintiffs, ruling that: "The Act is vague and could hinder access to affordable generic medicines because it fails to make a clear distinction between counterfeit and generic medicines".[112] On the other hand, in Uganda, the right to health is not explicitly recognised by the constitution, which could hamper recourse to constitutional justice in the event of a presumed incompatibility between the Anti-Counterfeit Goods and Services Bill Memorandum and public health policies aimed at improving people's access to medicines.[113]

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[105] Uganda, “The Anti-Counterfeit Goods and Services Bill Memorandum, Version of March 11, 2024”, *op. cit.*, Part I, §I,2a (iv).
[106] Article 61, TRIPS Agreement.
[107] *Ibid.*
[108] *Ibid.*
[109] UNDP, *op. cit.,* p. 18.
[110] *Ibid.*, p.12.
[111] CEHURD, KELIN and aidsfonds, “Utilizing flexibilities in the TRIPS agreement to advance access to medicines in Kenya and Uganda, Challenges and opportunities for access to medicines for HIV, TB, Hepatitis and Non-Communicable diseases”, January 2019, pp.18-19.
[112] UNAIDS, “UNAIDS welcomes Kenya High Court ruling on anti-counterfeiting law”, Press statement, 20 April 2012. Available from https://www.unaids.org/sites/default/files/web_story/20120420_PS_kenya_fr_0.pdf.
[113] *Ibid.,* p.17.

E. The Security Exception: Unexplored Flexibility

On 04 April 2020, a few months after India and South Africa's call for solidarity, at a time when a debate on the appropriateness (or otherwise) of a provisional suspension of TRIPS provisions was dividing WTO members, Carlos Correa (Executive Director of South Centre) surprised the world by calling for the implementation of Article 73(b) of TRIPS.[114]

Article 73(b) reproduces identically the provisions of Article XXI(b)(iii) of the 1994 General Agreement on Tariffs and Trade (GATT) relating to the security exception, which allows a member in exceptional circumstances to derogate provisionally from a given agreement or standards.[115]

Article XXI b (iii) was interpreted for the first time in the Russia - Measures Concerning Traffic in Transit case.[116] The panel considered that the security exception can, in the main, only be implemented in the event of war or serious international tension. The expression "serious international tension" means "a situation of armed conflict, or latent armed conflict, or of aggravated tension or crisis, or of general instability engulfing or surrounding a State".[117] At first glance, the terms armed conflict and latent armed conflict would seem to refer to situations of military tension or war as such, which could jeopardise the stability of a State. However, the terms "aggravated crisis or general instability" refer to broader concepts. In another paragraph, the panel backed up its reasoning by stating that "these situations 'give rise to particular types of interests for the Member in question, namely defence or military interests, or interests relating to the maintenance of law and order'".[118] By extension, the maintenance of law and order would mean that all States that have recognised health as a fundamental right and/or made it a constitutional norm could invoke the security exception in the event of a "serious epidemiological crisis" such as a pandemic. As for the concept of public order, it refers to safety, tranquillity and health.[119] The latter is closely linked to public health policies.

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[114] "COVID-19 PANDEMIC: ACCESS TO PREVENTION AND TREATMENT IS A MATTER OF NATIONAL AND INTERNATIONAL SECURITY", Open letter from Carlos Correa, Executive Director of the South Centre, to Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, Francis Gurry, Director-General of the World Intellectual Property Organization, Roberto Azevêdo, Director-General of the World Trade Organization, 04 April 2020.

[115] More specifically, Article 73 (b) provides that "Nothing in this Agreement shall be construed :
(a) as imposing on a Member an obligation to supply information the disclosure of which it considers contrary to its essential security interests
(b) or as preventing a Member from taking any action it considers necessary for the protection of its essential security interests:
(i) relating to fissile materials or materials used in their manufacture;
ii) relating to trafficking in arms, munitions and war material and any trade in other articles and material intended directly or indirectly to supply the armed forces;
iii) applied in time of war or serious international tension
(c) prevent a Member from taking action in pursuance of its obligations under the Charter of the United Nations for the maintenance of international peace and security.

[116] Mona Pinchis-Paulsen, Kamal Saggi and Petros C. Mavroidis, "The National Security Exception at the WTO: Should It Just Be a Matter of When Members Can Avail of It? What About How ?" *World Trade Review*, vol. 23, N°3 (2024), pp. 271-295.

[117] World Trade Organization, document WT/DS567/R, § 7.245. Available https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds567_e.htm.

[118] *Ibid*.

[119] Bruno Planelles, "Public policy: definition, application and evolution", *Exprime Avocat*, 18 October 2024. Available from https://www.exprime-avocat.fr/ordre-public-definition-application-et-evolution/.

In the Saudi Arabia - Measures Concerning the Protection of Intellectual Property Rights case, the panel, transposing the reasoning followed in the Russia - Measures Concerning Traffic in Transit case, considered that with regard to proof of the elements that could justify "essential security interests", "it was generally for each Member to define what it considered to be its essential security interests".[120] However, the panel will have to determine whether the Member State acted in "good faith". Good faith presupposes that the security exception is not used to circumvent the Member's obligations.[121]

In the case of Covid-19, it would have been difficult for a panel to consider that members who had recourse to Article 73(b) in the context of an international health emergency would have been misusing the security exception. Moreover, this is the reasoning followed by Carlos Correa, for whom recourse to the security exception is a right,[122] but African countries would still have had to be able to invoke it. Few of them have laws, regulations or ordinances providing for such a provision. To our knowledge, only Zambia, Zimbabwe, South Africa, Morocco, Malawi, Madagascar, Libya, Kenya, Egypt, the Democratic Republic of Congo and Algeria have incorporated it into their domestic law.[123] However, most of these provisions are not very exhaustive. This is the case of sections 78 to 80 of South Africa's Patents Act, No. 57 of 1978, which do not provide for any cases of exclusion from patentability.[124] This is also the case of articles 17 and 25 of Egypt's Law No. 82 of 2000 (Pertaining to the Protection of Intellectual Property Rights).

Finally, to ensure that the security exception is used, a coordinated approach within the WTO could have been decisive, in addition to overhauling the legislation of African countries. Nevertheless, other flexibilities are likely to help these countries develop an efficient pharmaceutical industry capable of contributing to resilience in the event of a new pandemic.

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[120] World Trade Organization, “Saudi Arabia — Measures Concerning the Protection of Intellectual Property Rights”, 16 June 2020, §7.249, *op.cit*.
[121] *Ibid*., §7.250.
[122] “COVID-19 PANDEMIC: ACCESS TO PREVENTION AND TREATMENT IS A MATTER OF NATIONAL AND INTERNATIONAL SECURITY”, Open letter from Carlos Correa, Executive Director of the South Centre, to Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, Francis Gurry, Director-General of the World Intellectual Property Organization, Roberto Azevêdo, Director-General of the World Trade Organization, 04 April 2020.
[123] World Intellectual Property Organization, Database on Flexibilities in the Intellectual Property System. Available from https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html.
[124] *Ibid*.

III. The ambitious continental pharmaceutical strategy and the TRIPS flexibilities

Covid-19 highlighted the structural weaknesses of African countries, particularly their dependence on imported medicines. Yet Africa has not been spared either epidemics or pandemics (HIV/AIDS). Despite imports, access to medicines and "safe, effective and quality technologies" on the continent remains limited.[125] However, not all African countries have the same degree of dependence. According to data from the African Development Bank (ADB) Group, Egypt, Algeria, Nigeria and South Africa manage to cover more than 50% of their populations' demand for medicines.[126] Morocco, Tunisia and Kenya cover between 20% and 49%; Tanzania, Zimbabwe and Côte d'Ivoire between 5% and 9%.[127] A majority of African countries produce only between 1% and 4%, and sometimes even 0%, of the pharmaceutical products consumed by their populations.[128] According to Faizel Ismail, taken as a whole, the African population is 94% dependent on imported medicines. For vaccines, he puts the figure at around 99%.[129]

It is undoubtedly to ensure post-Covid-19 resilience that the African Union has accelerated the project to create the African Medicines Agency (AMA), the aim of which is to improve access to quality medical products.[130] The creation of the AMA has been virtually juxtaposed with the Pharma Initiative, which also aims to better regulate access to safe medicines, but above all to increase continental production by pooling the efforts of African countries.[131] However, it seems that this initiative is struggling to materialise in practice. Few of the ten pilot countries selected (Ethiopia, Comoros, Djibouti, Kenya, Madagascar, Mauritius, Rwanda, Seychelles, Sudan and Eritrea) have improved their production capacity. At present, the Pharma Initiative has been delayed to some extent by the ineffectiveness of the Continental Free Trade Area, but this does not mean that it is no longer relevant.[132]

Whether at pan-African, regional or national level, the development of the pharmaceutical industry inevitably requires the adoption of an appropriate legal framework, including patentability criteria and the Bolar exception.

In Africa, the development of the generic industry is necessary to ensure stable access to pharmaceutical products. However, it often requires national legislation to be brought up to standard, in order to reconcile intellectual property and public health. Article 27.1 of TRIPS sets out the criteria for patentability, including novelty, the involvement of an inventive step and

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[125] African Union, *Progress report on the creation and operational implementation of the African Medicines Agency,* Executive Council, forty-second ordinary session, 15 to 16 February 2023, Addis Ababa, Ethiopia, EX.CL/1398(XLII), §2.
[126] African Development Bank Group*, New frontier for African pharmaceutical manufacturing industry* (2022), p. 6.
[127] *Ibid.*
[128] *Ibid.*
[129] Faizel, Ismail, “The WTO TRIPS Waiver Should Help Build Vaccine Manufacturing Capacity in Africa”, Policy Brief, N°97 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/07/PB-97.pdf.
[130] Art. 4, African Union, Treaty establishing the African Medicines Agency.
[131] United Nations Economic Commission for Africa, “The Pharma Initiative Transformative Journey”. Available from https://www.uneca.org/sites/default/files/afcfta-pharma-initiative/final_eng_pharma-initiative-transformative-journey-brochure_10022024_all.pdf.
[132] On the Pharma Initiative, see Ismaelline Eba Nguema, *op.cit*.

industrial application.[133] However, the provisions of art 27.1 can be circumvented through "*Evergreening*", which refers to "the filing of a new application for an apparently new product, which in reality differs very slightly from the one about to lose patent protection. The 'new' product can then benefit from an additional twenty years of patent protection".[134] To prevent the proliferation of secondary patents and the delay in generic entry, the Indian Patents Act 2005 deems certain types of subject matter as not constituting patentable inventions in Section 3(d) as a means of limiting *evergreening.*[135] In the case of Novartis v the Indian State, the Supreme Court rejected Novartis' patent application for the anti-cancer drug Glivec on the basis of Section 3(d) of the Act 2005.[136] In the absence of similar provisions in South Africa, in Bayer Pharma AG v Pharma Dynamics, the existence of a secondary patent on a contraceptive enabled Bayer to prevent the entry onto the South African market of a generic produced by Pharma Dynamics even though the patent on Yaz, the original contraceptive, had expired.[137] However, "in the United States [and in some European countries], this patent has been revoked and generic versions are already available".[138] In addition, other African countries have incorporated the provisions of Article 27.1 of TRIPS into their national legislation in a similar way to South Africa, without making any additions or clarifications. This is the case in Botswana, Burundi, Comoros, Gambia, Ghana, Lesotho, Liberia, Madagascar, Malawi, Mauritius, Mozambique, Seychelles, South Sudan, North Sudan, Eswatini, Uganda and Zimbabwe. [139]

The criteria for patentability are not the only elements likely to boost the pharmaceutical industry in Africa; others exist, such as the Bolar exception.

Aware that WTO members have human rights obligations, Article 30 authorises members "...to provide for limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties".[140] However, the aforementioned provision does not mention the permitted exceptions. It was not until the Canada-Patent Protection for Pharmaceutical Products case that the Panel recognised the compatibility of the Bolar exception with Article 30.[141] Henceforth, it is permissible under the aforementioned article to carry out the tests necessary to obtain a marketing authorisation for a generic medicine during

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[133] Art. 27.1, TRIPS Agreement.
[134] Emily Jackson, *Law and the regulation of medicines* (Oxford, Hart Publishing, 2012), p. 81. Quoted in Yousuf A. Vawda, "After the *Novartis* judgment - 'Evergreening' will never be the same again!", *Law, Democracy and Development*, Vol 18 (2014).
[135] *Ibid.* See also, Yousuf A. Vawda and Bonginkosi Shozi, *Eighteen years after Doha: An analysis of the use of public heath TRIPS flexibilities in Africa*, Research Paper, N°103 (Geneva, South Centre, 2020), p.16.
[136] *Ibid*. "Novartis AG v. Union of India and Others", *International Law Reports*, Vol. 175 (2018), pp. 504-585.
[137] Fix the Patent Laws, "Court Case Blocks Cheaper Version of Birth Control Pill", 18 September 2024. Available from https://www.fixthepatentlaws.org/court-case-blocks-cheaper-version-of-birth-control-pill/. *Pharma Dynamics (Proprietary) Limited v Bayer Pharma AG and Another* (468/2013) [2014] ZASCA 123 (19 September 2014).
[138] Fix the Patent Laws, "Court Case Blocks Cheaper Version of Birth Control Pill", 18 September 2024. Available from https://www.fixthepatentlaws.org/court-case-blocks-cheaper-version-of-birth-control-pill/.
[139] *Ibid*., p.17.
[140] Art. 30, TRIPS Agreement.
[141] World Trade Organization, document WT/DS114/R. Available from https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

the period of monopoly conferred by a patent, provided that the product is not marketed before the patent is extended.[142] The justification for the Bolar exception is that marketing authorisation takes time, at least because of the bioequivalence tests required,[143] and in order not to delay the entry onto the market of generics, which are supposed to improve people's economic access to pharmaceutical products.[144] While the Bolar exception is recognised in the United States[145] where it first appeared, as well as in Europe and India, very few African countries have explicitly incorporated it into their national legislation. These include Egypt, Kenya, South Africa and Tunisia. In Egypt, Article 10(5) of Intellectual Property Act No. 82 (2002) states: "The Egyptian patent law exempts from infringement acts if "a third party proceeds, during the period of protection of a product, to its manufacture, assembly, use [...] with a view to obtaining a marketing licence, provided that marketing commences after the expiry of that period of protection".[146] However, of the ten pilot countries selected for the Pharma Initiative, only one recognises the Bolar exception, despite its importance for the development of the pharmaceutical industry.

[142] Mathilde Rauline and François Pochart, “The Bolar Exception”. Available from https://www.aspi-asso.fr/app/uploads/2022/07/3-220607-ExceptionsBOLARsituationactuelleetEvolutions_Final.pdf .
[143] Viviana Munoz Tellez, “Bolar Exception”, in *Access to Medicines and Vaccines*, CM Correa, RM Hilty, eds. (Springer, 2021). Available from https://doi.org/10.1007/978-3-030-83114-1_5.
[144] *Ibid.*
[145] In *Roche Products, Inc. v. Bolar Pharmaceutical Co, Inc*, "the court held that the experimental use exemption for patent infringement in U.S. law (35 U.S.C. § 271(a)) did not permit the trials undertaken by Bolar Pharmaceutical to obtain marketing approval for a generic product. The Hatch-Waxman Act overturned this decision only a few months after its adoption.” Carlos Correa, *The Bolar exception: legislative models and drafting option*, Research Paper, N°66 (Geneva, South Centre, 2016), p. 2.
[146] *Ibid.,* p.13.

CONCLUSION

The implementation of a policy to establish or develop the pharmaceutical industry in Africa and enhance access to medicines in the continent should take into account the WTO commitments to which most of the countries have subscribed using, at the same time to the full extent, the policy space available to introduce public health related flexibilities examined above. Reconciling access to medicines and intellectual property depends on a number of factors, including the existence of a national legal framework that allows Member States to benefit from the flexibilities provided for in TRIPS. However, over and above access to means of redress for citizens and organisations representing them, reconciling access to medicines and intellectual property also depends on the capacity of existing institutions to implement existing legislative and/or regulatory provisions.

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