Vawda, Yousuf A.; Shozi, Bonginkosi

Research Report

Utilising public health flexibilities in the era of COVID-19: An analysis of intellectual property regulation in the OAPI and MENA regions

Research Paper, No. 141

Provided in Cooperation with:
South Centre, Geneva

Suggested Citation: Vawda, Yousuf A.; Shozi, Bonginkosi (2021) : Utilising public health flexibilities in the era of COVID-19: An analysis of intellectual property regulation in the OAPI and MENA regions, Research Paper, No. 141, South Centre, Geneva

This Version is available at:
https://hdl.handle.net/10419/248642

141 Research Paper
November 2021

Utilising Public Health Flexibilities in the Era of COVID-19: An Analysis of Intellectual Property Regulation in the OAPI and MENA Regions

Yousuf A Vawda and Bonginkosi Shozi

SOUTH CENTRE

RESEARCH PAPER

141

UTILISING PUBLIC HEALTH FLEXIBILITIES IN THE ERA OF COVID-19: AN ANALYSIS OF INTELLECTUAL PROPERTY REGULATION IN THE OAPI AND MENA REGIONS

Yousuf A Vawda BA, BProc, LLM, LLD[*]
Bonginkosi Shozi LLB, LLM, PhD Candidate[**]

SOUTH CENTRE

NOVEMBER 2021

[*] Senior Research Associate, School of Law, University of KwaZulu-Natal, vawday@ukzn.ac.za.
[**] Doctoral Fellow with the African Health Research Flagship, University of KwaZulu-Natal, 214511633@stu.ukzn.ac.za.

The authors are grateful to Eman S. Ibrahim and Safiatou Simpore Diaz for their time and helpful comments. The views expressed in this paper, however, are solely those of the authors.

SOUTH CENTRE

In August 1995 the South Centre was established as a permanent inter-governmental organization. It is composed of and accountable to developing country Member States. It conducts policy-oriented research on key policy development issues, and supports developing countries to effectively participate in international negotiating processes that are relevant to the achievement of the Sustainable Development Goals (SDGs). The Centre also provides technical assistance and capacity building in areas covered by its work program. On the understanding that achieving the SDGs, particularly poverty eradication, requires national policies and an international regime that supports and does not undermine development efforts, the Centre promotes the unity of the South while recognizing the diversity of national interests and priorities.

NOTE

Any comments on this paper or the content of this paper will be highly appreciated. Please contact:

South Centre
International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

Follow the South Centre's Twitter: South_Centre 

ABSTRACT

The paper explores the unique approaches to IP protection in the countries belonging to the Organisation Africaine de la Propriété Intellectuelle/African Intellectual Property Organization (OAPI) and the Middle East and North Africa (MENA) regions; the limited extent to which legal and policy frameworks with regard to TRIPS flexibilities have been adopted and implemented in pursuit of access to medicines in those countries; and makes recommendations in order to optimise the use of the flexibilities in advancing public health objectives. In the context of the COVID-19 pandemic, the impact of IP rights on access, and some approaches to countering the challenges to access are also discussed.

Le document explore les approches uniques de la protection de la PI dans les pays appartenant à l'Organisation Africaine de la Propriété Intellectuelle (OAPI) et à la région du Moyen-Orient et de l'Afrique du Nord (MENA); le degré limité d'adoption et de mise en œuvre des cadres juridiques et politiques relatifs aux flexibilités de l'Accord sur les ADPIC dans le but d'assurer l'accès aux médicaments dans ces pays; et il formule des recommandations afin d'optimiser l'utilisation des flexibilités dans la poursuite des objectifs de santé publique. Dans le contexte de la pandémie de COVID-19, l'impact des droits de propriété intellectuelle sur l'accès et certaines approches pour contrer les défis de l'accès sont également discutés.

El documento explora los enfoques únicos de la protección de la propiedad intelectual en los países pertenecientes a la Organización Africana de la Propiedad Intelectual (OAPI) y a las regiones de Oriente Medio y Norte de África (MENA); el limitado grado de adopción y aplicación de los marcos jurídicos y políticos relativos a las flexibilidades del ADPIC para lograr el acceso a los medicamentos en esos países; y formula recomendaciones para optimizar el uso de las flexibilidades en la promoción de los objetivos de salud pública. En el contexto de la pandemia de COVID-19, también se analizan las repercusiones de los derechos de propiedad intelectual en el acceso, así como algunos enfoques para contrarrestar los problemas de acceso.

TABLE OF CONTENTS

INTRODUCTION

The global COVID-19 pandemic has once again forced the world to recognise how stringent intellectual property (IP) protection can obstruct access to life-saving medicines by both limiting supply and inflating prices beyond the reach of all but the most wealthy and privileged. This is because, as discussed previously,[1] the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[2] attempts to standardise the minimum protection to be granted to intellectual property rights (IPRs) around the world, and in so doing places an obligation on Member States of the World Trade Organization (WTO) to adopt policies and legislation which give strong protection to these rights. This often works against the best interests of many Member States, particularly developing countries that lack the infrastructure to support domestic production of pharmaceuticals. It may also lead to higher prices for IPR-protected medicines due to lack of competition in the market as a result of temporary monopolies assured by patents and other exclusive rights. In the context of the COVID-19 pandemic, there are concerns on the role of IP in limiting the supply and unequal distribution of the diagnostics, vaccines and treatments needed to address COVID-19.

Such concerns have led to several recent proposals at the international level to mitigate the impact or circumvent the IP regime for COVID-19 related medical products, such as the establishment of a voluntary pool of patent and other rights on COVID-19 related subject matter,[3] a waiver of relevant provisions of the TRIPS Agreement for the duration of the pandemic[4] and the use of the TRIPS Article 73 security exception.[5] While such proposals may appear promising, some are limited by the fact that they rely on voluntary compliance by pharmaceutical companies, while others require both multilateral and domestic actions to give them effect. It would be unacceptable for countries (particularly those in the global South) to place the health and safety of their citizens solely in the hands of industry, given the experience of profiteering during healthcare crises.[6] Some countries, including developed countries, have begun to explore legal mechanisms such as compulsory licences to secure access to COVID-19 treatments and vaccines,[7] and work around the strictures of Article 31 of TRIPS. In addition, in response to the very real prospect of a prolonged delay in bringing an end to the pandemic, South Africa and India have approached the TRIPS Council with a proposal to waive the relevant IP rights related to COVID-19, in order to:

> 'ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of

---

[1] See, YA Vawda and B Shozi, *Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa*, Research Paper, No. 103 (Geneva, South Centre, 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.

[2] World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights (1994). Available from https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm.

[3] Norman Warthmann, "WHO Asked to Create Voluntary Intellectual Property Pool for Covid-19 Work", *STAT*, 24 March 2020. Available from https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/; Ed Silverman, "European Union Pushes for a Voluntary Pool for Covid-19 Products", *STAT*, 16 April 2020. Available from https://www.statnews.com/pharmalot/2020/04/16/european-union-who-voluntary-pool-covid19-coronavirus/.

[4] WTO, "Members Discuss Intellectual Property Response to the COVID-19 Pandemic", 20 October 2020. Available from https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm.

[5] F Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper, No. 116 (Geneva, South Centre, 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf.

[6] Bonginkosi Shozi, "What Can African Countries Do To Make Sure They Have Affordable Access to a COVID-19 Cure?" *Multilateral Matters*, 12 May 2020. Available from http://ip-unit.org/2020/multilateral-matters-6-what-can-african-countries-do-to-make-sure-they-have-affordableaccess-to-a-covid-19-cure/.

[7] Silverman, "European Union Pushes for a Voluntary Pool for Covid-19 Products".

> research, development, manufacturing and supply of medical products essential to combat COVID-19'.[8]

Even if the waiver proposal succeeds, countries will still have to pass the necessary emergency legislation to action the waiver, because such international agreements are not self-executing. In addition, developing countries in particular will need to take measures, such as the health-related flexibilities provided for in the TRIPS Agreement, as elaborated by the Doha Declaration[9] to protect the health of their citizens. However, doing so often requires enabling provisions within their domestic legislation. The question addressed here is: what legal mechanisms in the context of the IP system can African countries utilise to promote access to COVID-19 treatments and vaccines?

In this paper, we review the patent laws of: (1) the Member States of the OAPI, and (2) the African states in the MENA region. In each part, we provide an overview of IP law, an analysis of the extent to which the current law provides for patent-related flexibilities, and how this has impacted access to medical products.

This paper advances our previous work, entitled *Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa*.[10] Accordingly, we use the same definitions for the relevant flexibilities as in the prior work. For consistency and ease of reference, we describe each of the flexibilities, and their definitions, in the table below:

Table 1: Key definitions

LDC Transition Period	In terms of Article 66.1 of TRIPS, Least Developed Countries (LDCs) have been granted a transition period, during which they are not obligated to enforce certain provisions of the TRIPS agreement, including the provision requiring WTO Members to provide patent protection for pharmaceutical products.
Patentability Criteria	As key terms in the patentability criteria prescribed by TRIPS in Article 27.1 are not further defined, countries have relative freedom in determining their patentability criteria and may choose to interpret criteria in ways that promote access by setting a high bar for what inventions should be patentable.
Patent Examination	Examination of patent applications can occur in three ways: 1. Formality examination only—patent applications are decided purely on formal requirements being satisfied (completion of required forms, declarations and payment of necessary fees). 2. Formality examination and prior art search—after the formality requirements are met and a search report of a prior art search establishes the novelty of the invention in terms of the applicable national law, a patent is granted without substantive examination. 3. Formality examination, prior art search and substantive examination (SSE) — once the formality requirements have been met, the examiner conducts a prior art search and substantive examination, which is meant to establish whether the requirements of novelty, inventive step and industrial applicability have been met.
Pre-Grant Opposition	Entails a party opposing the grant of a patent to give notice and allege the grounds on which the opposition is based. The legality of administrative opposition procedures is addressed in Article 62 of the TRIPS Agreement.
Patent Terms	A basic tenet of patent law is that the state, in return for public disclosure of the invention, gives the inventor a time-limited monopoly to exploit that

[8] WTO, Communication from India and South Africa, Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, document IP/C/W/669. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.
[9] WTO, The Doha Declaration on the TRIPS Agreement and Public Health, document WT/MIN (01)/DEC/W/2. Available from https://www.who.int/medicines/areas/policy/tripshealth.pdf?ua=1.
[10] Vawda and Shozi, *Eighteen Years After Doha*.

	invention. The patent secures for its holder the right to exclude others from using the invention and thereby delays competition. The length of a patent term is thus relevant to the entry of competition by the manufacturers of generics, which is essential to driving down prices. Shorter patent terms, in the absence of utilising other flexibilities, such as the LDC transition provision, are one mechanism by which states can promote access to healthcare. This option would apply only to LDCs.
Bolar Exception	The regulatory review exception—also known as the 'Bolar' or 'early working' exception—refers to provisions that allow for the use of a patented invention in order to comply with regulatory requirements for market approval for a generic product before the expiry of the relevant patent.
Non-voluntary Licensing	This may take one of two forms. Compulsory licensing and government use. A compulsory licence is an authorisation granted by a government allowing third parties to produce a patented product or to utilise a patented process without the consent of the patent holder. In a similar vein, 'government use' or 'crown use' is an authorisation by the government, to itself or other entities or contractees acting on behalf of the government, to make use of a patented product or process without the consent of the patent holder. In both instances, a royalty is required to be paid to the patent holder.
Research Exception	The premise underlying the publication of patents is to allow for the dissemination of information in order to promote the research and development necessary for innovation. In the case of pharmaceuticals, disallowing such an exception delays the availability of potentially cheaper generic life-saving drugs until after the term of a patent expires. Such an exception is permissible under Article 30 of the TRIPS Agreement and widely in use for both commercial and non-commercial purposes.
Parallel Imports	Parallel importation refers to the practice of 'comparison-shopping' in other countries to secure a patented product at a favourable price. This flexibility is enabled by Article 6 of the TRIPS Agreement. This is based on the notion that once a product has been placed on the market and sold into commerce, the patent holder loses any proprietary rights to it.
Post-Grant Opposition	As with pre-grant opposition, permitting third parties to challenge the validity of a patent after it has already been granted plays an important role in enforcing patentability criteria under a non-examining system.

PART 1: OAPI

1.1 ORIGINS OF OAPI AND THE BANGUI AGREEMENT

OAPI is the regional IP office for the large majority of Francophone countries in Africa,[11] which presently has 17 Members.[12] It originated as an initiative by the newly-independent French-speaking countries with the establishment of the African and Malagasy Industrial Property Office (OAMPI), which would act as a national industrial property office for each Member Country, under the Libreville Agreement concluded in 1962. OAMPI morphed into OAPI with the signing of the Bangui Agreement in 1977 (the Agreement).[13]

OAPI represents, in many ways, the legacy of French colonial rule. During the colonial period, the laws applicable in the colonies were promulgated in France – formal laws, decrees, executive orders, and local customs. Executive and judicial power in the colonies resided with the governor general.[14] Needless to say, the law and administration were intended to primarily serve the interests of the metropole.

Various commentators allude to the abiding impact of colonialism on the approach to law and public affairs in the post-colonial era. Often cited are the economic, political and intellectual dependence on France and foreign donors such that officials are perceived to have been socialised to 'concur with, or defer to, French policy advice and expertise'.[15]

This is further borne out in the design of OAPI. In regard to matters of intellectual property, OAPI Member States are administered akin to the colonial construct. Dating back to the Libreville Accord, the main features of this design are: uniform legislation on intellectual property; a common authority serving as a national IP office; and centralisation of procedures so that a single title issued by the regional office would create IP rights in each Member State.[16] In effect, countries 'renounced' their national sovereignty in IP matters.[17] Additionally, signatories to the Bangui Agreement agreed to accede to the international treaties and conventions specified in the Agreement.

Under this uniform system, a title granted by OAPI creates IP rights in each Member Country. In line with this design, priority claims and restoration of patents are brought before the administrative jurisdiction of OAPI. However, licensing, infringement claims, nullification and forfeiture actions must be instituted in national courts. Nonetheless, judicial decisions on the validity of titles in one Member State are authoritative in all OAPI Member States, except with regard to circumstances based on public order and morality.[18]

---

[11] World Intellectual Property Organization (WIPO), African Intellectual Property Organisation (OAPI). Available from https://www.wipo.int/export/sites/www/patent_register_portal/en/docs/oapi.pdf.
[12] Member countries are: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, and Togo.
[13] R Jourdain, "Intellectual Property Rights and Public Health in the Revised Bangui Agreement", in *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, C Bellmann and R Melendez-Ortiz, eds. (Routledge, 2013).
[14] Encyclopedia.com, "Law, Colonial Systems of, French Empire", 2020. Available from https://www.encyclopedia.com/history/encyclopedias-almanacs-transcripts-and-maps/law-colonial-systems-french-empire.
[15] See, for example: C Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press, 2009), pp. 240–286.
[16] Adams & Adams, "Organisation Africaine de la Propriété Intellectuelle". Available from https://www.adams.africa/works/oapi/.
[17] Ibid.
[18] C Correa, "The Status of Patenting Plants in the Global South", Research paper (The Hague, Oxfam & Geneva, South Centre, 2018). Available from https://www.southcentre.int/wp-

1.2 REVISIONS TO THE BANGUI AGREEMENT

This section traverses two sets of revisions to the Agreement – the first completed in 1999, and a second proposed set of revisions contained in a 2015 document.

The Agreement was subject to revision in 1999[19] in order to bring it into alignment with the prescripts of TRIPS.[20] This revision, however, looked only to strengthen the rights of patent holders, and paid little heed to flexibilities such as the least developed country (LDC) transition period.[21] It can be considered to be TRIPS-plus in that no provision had been made for opposition procedures or the Bolar exception, the compulsory licensing provisions were impractical, and the form of parallel importation was based on regional exhaustion, in circumstances where the region lacked local manufacturing capacity. As such, countries within OAPI have not utilised the flexibilities afforded to them under the TRIPS Agreement, due to the absence of enabling provisions in the Agreement. This anomaly appears set to change with the approved 2015 revision to the Agreement once it comes into effect, which makes greater provision for public health flexibilities.[22] Unfortunately, it is not clear when this will happen, as no date has been specified for the 2015 Revision coming to effect in the 6 years since it was finalised.

In the following paragraphs, we compare the core provisions of the 2015 Revision relating to public health flexibilities, compared to the 1999 Revision. These findings are further summarised in the table below (Table 2).

a) Patentability criteria

As with the 1999 Revision, general provisions relating to patents are primarily found in Annex I to the 2015 Revision. In this annexure, the 2015 Revision reinforces the Agreement's adherence to TRIPS in Article 2(1), which outlines criteria for patentability as provided for in Article 27.1 of the TRIPs Agreement. The 2015 Revision fails to define the criteria for patentability in a way that is conducive to creating rigorous standards for the approval of patents, such as through the exclusion of new forms of existing substances or new uses. In this sense, the 2015 Revision does not advance the public interest in access to medicines from the position in the 1999 version of the Agreement.[23] The 2015 Revision does, however, retain a standard of absolute novelty for patentable inventions,[24] as contained in the 1999 Revision.[25]

b) Patentability of pharmaceuticals

The 1999 Revision makes no provision for its Member States to exempt pharmaceuticals from patentability, which left the OAPI region's twelve LDCs (two-thirds of all its Member States)

---

content/uploads/2019/03/SC_Oxfam_Research-Report_The-Status-of-Patenting-Plants-in-the-Global-South_2018.pdf.

[19] Organisation Africaine de la Propriété Intellectuelle (OAPI), Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization, February 24, 1999 (1999 Revision).

[20] Jourdain, "Intellectual Property Rights and Public Health in the Revised Bangui Agreement".

[21] Ibid.

[22] Organisation Africaine de la Propriété Intellectuelle (OAPI), Accord de Bangui Instituant Une Organisation Africaine de La Propriete Intellectuelle, Acte Du 14 Decembre 2015 (2015 Revision). Note that an official English translation of the Agreement has not yet been published, thus the authors rely on unofficial translations of this document.

[23] See, Article 2 of the 1999 Revision.

[24] 2015 Revision Annex I Article 3(1).

[25] 1999 Revision Annex I Article 3(2).

potentially without recourse to the utilisation of the LDC transitional period flexibility.[26] This gap is explicitly addressed in the main text of the 2015 Revision, under the heading: 'Transitional provisions relating to pharmaceutical products', which provides that OAPI Member States that are classified as LDCs are not required to grant patents relating to pharmaceutical products until the 1st of January 2033, or until they cease to be LDCs. It now effectively incorporates Article 66.1 of the TRIPS Agreement, read with paragraph 7 of the Doha Declaration into the laws of OAPI Member States, thus enabling them to take advantage of this flexibility if they so choose.[27]

c) Examination of patents

The 2015 Revision provides purely for formal examination of patents,[28] a position that appears to remain largely unchanged from the 1999 Revision.[29] This has been the position in OAPI from its inception, due to limited human and technical resources necessary for substantive examination.[30]

d) Non-voluntary licences

The 2015 Revision makes provision for any interested party to make an application for a compulsory licence on grounds related to failure to use/work the patented invention[31] similar to the 1999 Revision; however, in line with Article 5A of the Paris Convention for the Protection of Industrial Property, this is subject to the condition that either 4 years have passed from the date of filing the patent application, or 3 years have elapsed since the patent was granted (whichever is later).

The 2015 Revision also provides that a patent may be made subject to a non-voluntary licence regime through an 'administrative act' where doing so is in the national interest, including public health, or where the present exploitation is insufficient to meet the country's need.[32] This formulation is an improvement from the position under the 1999 Revision, which created confusion and legal uncertainty by ostensibly providing that non-voluntary licences sought in the public interest could be denied if the patent holder provided a legitimate excuse for their failure to work.[33]

e) Patent term

The 2015 Revision adheres to the TRIPS standard of a minimum 20-year patent term.[34] This is one of many strong IP rights protections introduced in the 1999 Revision and a minimum requirement for compliance with TRIPS. Prior to this, the Agreement granted patent protection for a period of 10 years.

---

[26] These states are Benin, Burkina Faso, the Central African Republic, Chad, Congo, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo.
[27] 2015 Revision Article 46.
[28] 2015 Revision Annex I Article 23.
[29] 1999 Revision Annex I Article 20 (2).
[30] Jourdain, "Intellectual Property Rights and Public Health in the Revised Bangui Agreement", p.145.
[31] 2015 Revision Annex I Article 49.
[32] 2015 Revision Annex I Article 58.
[33] In terms of the 1999 Revision, Article 56 (3) provided that licences issued on the grounds of 'vital to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the satisfaction of the country's needs' were subject to the same conditions as non-voluntary licences for failure to work under Article 46. Article 46(2) contained the waiver that even if all the conditions for granting a non-voluntary licence are met, the licences may not be granted if the patent holder provides 'legitimate reasons' for non-working. This, then, created a situation where an application for a non-voluntary licence on the grounds of public health could be resisted if the patent holder alleged they had good reasons for their failure to meet the demands of the country – an unnecessary obstruction to ensuring expedient access to medicines through the use of this flexibility.
[34] 2015 Revision Annex I Article 8.

f) 'Bolar' exception

The 2015 Revision saw the introduction of the 'Bolar' exception into the Agreement by providing that patent rights do not extend to studies and tests necessary for placing a medicinal product on the market.[35] No such provision was present in the 1999 Revision.

g) Parallel imports

The 1999 Revision was silent on the issue of parallel importation. However, it has been reported that the OAPI Members operated under a regime of regional exhaustion of patent rights.[36] This lacuna is addressed by the 2015 Revision which permits a system of international exhaustion. Thus, patent rights do not extend to patented products lawfully imported into a Member State if they were legally placed on the market elsewhere in the world.[37]

h) Research exception

Both the 1999 Revision[38] and the 2015 Revision provide for an exception for scientific and technical research.[39]

i) Patent opposition

Both pre-grant and post-grant opposition mechanisms for patent applications are absent from the 1999 Revision, which appears to have been a deliberate omission in light of the fact that these mechanisms do exist for other forms on IP in the same document.[40] The 2015 Revision, on the other hand, has specific provisions for opposing patents both before and after they have been granted. On pre-grant opposition, it provides that any interested party may oppose the grant of a patent within three months of the application being published.[41] Post-grant opposition is available to any interested party who may bring an action before the courts for the revocation of patent on the ground that it fails to meet the criteria for patentability, but the period of three months required for bringing such an application is extremely short and impractical.[42]

[35] 2015 Revision Annex I Article 7(1)(d).
[36] Deere, *The Implementation Game,* p. 256.
[37] 2015 Revision Annex Article 7(1)(a).
[38] 1999 Revision Annex I Article 8(c).
[39] 2015 Revision Annex I Article 7(1)(c).
[40] See, for example, the procedure for opposing trademarks in Annex V Article 9.
[41] 2015 Revision Annex I Article 20.
[42] 2015 Revision Annex I Article 46.

Table 2: Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization 24 February 1999 vs. 14 December 2015

	Patentability criteria	**Patentability of Pharmaceuticals**	**Examination**	**Non-voluntary Licences**	**Term**	**Bolar Exception**	**Parallel Imports**	**Research Exception**	**Patent Opposition**
1999 Revision	Complies with Article 27.1 Absolute novelty	Pharmaceuticals patentable in all Member Countries	Formal	Non-voluntary licence granted for non-working, or where there is insufficient exploitation 'Ex officio' licence may be granted in the public interest, including for public health Licences may not be granted if patent holder provides a legitimate reason for failure to work	20	N/A	Regional exhaustion	Yes	N/A
2015 Revision	Complies with Article 27.1 Absolute novelty	LDC Member States not required to patent pharmaceuticals	Formal	Non-voluntary licence granted for non-working, or where there is insufficient exploitation Non-voluntary licence may be granted in the public interest, including for public health	20	Yes	International exhaustion	Yes	Any interested party may oppose the grant of a patent. Any interested party may approach the court to have a patent revoked.

1.3 USE OF TRIPS FLEXIBILITIES AND IMPACT OF REGULATION ON PHARMACEUTICAL PRICES

Having outlined the general features of patent regulation under the OAPI regime, we proceed to consider what impact this regulatory regime has had on access to medicines in some of the OAPI Member States. This discussion is divided into two subsections: in the first subsection, we present data on the utilisation of TRIPS flexibilities within the OAPI Member States. In the second subsection, we review data on medicine pricing in those states.

1.3.1 THE UTILISATION OF TRIPS FLEXIBILITIES BY OAPI MEMBER STATES

The OAPI regional office depends almost entirely on the World Intellectual Property Organization (WIPO) for technical assistance, which is heavily focused on IP compliance and enforcement, and rarely on the use of public health flexibilities. One report suggests that WIPO conducted 94 trainings for OAPI in Cameroon during the period 2009-2019.[43] Thus, the pro-IP holder orientation of the OAPI office is hardly surprising. One other source of financial support, resources and training has been the European Union (EU), mostly with regards to ensuring stronger IP protection.[44] A case in point is the accession of many OAPI countries to the European MEDICRIME Convention which entered into force in 2016, and which is the first international criminal law instrument obliging state parties to, among others, criminalise the manufacturing of 'counterfeit medical products'.[45] This Convention (through provisions in the Agreement) obliges Member States to impose severe criminal law sanctions for specific infringements of IP rights.[46] No evidence was found of initiatives under the auspices of OAPI to obtain technical assistance by other United Nations (UN) agencies or international organizations providing pro-public health and pro-public interest training.

Despite the absence of support from a regional level, individual states within OAPI have made some progress in securing access to essential medicines by taking advantage of TRIPS flexibilities. For example, the importation of generics for health reasons has reportedly occurred in Burkina Faso, the Central African Republic, Chad, Guinea, Guinea-Bissau and Mali despite the absence of enabling regulatory infrastructure.[47]

We discuss here reported uses of TRIPS flexibilities, primarily drawing from the TRIPS Flexibilities Database.[48] This information is summarised in a table below (Table 3). Thus far, only two flexibilities have been utilised by the OAPI Members: the LDC transition provision, and compulsory licensing. No other flexibilities discussed in this study, nor others outside it (such as the security exception alluded to above) have reportedly been utilised.

---

[43] WIPO, Technical Assistance Database. Available from https://www.wipo.int/tad/en/activitysearchresult.jsp?vcntry=CM.

[44] European Union, Annex 1 of the Commission Implementing Decision on the financing of the Annual Action programme 2019 Part 1 for the Pan-African Programme: Action Document for "Intellectual Property Rights (IPRs) Action for Africa" (2019), reference C(2019)2648. Available from https://ec.europa.eu/transparency/regdoc/rep/3/2019/EN/C-2019-2648-F1-EN-ANNEX-1-PART-1.PDF.

[45] Council of Europe, Convention on the counterfeiting of medical products and similar crimes involving threats to public health. Available from https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211.

[46] Institute of Research against Counterfeit Medicines (IRACM), "Sub-Saharan Africa and its legislation to combat fake medicines". Available from http://www.iracm.com/en/geographic-observatory/sub-saharan-africa-and-its-legislation-to-combat-fake-medicines-chad/.

[47] EFM `t Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers, 2009). Available from http://www.amb-press.nl/theglobalpoliticsofpharmaceuticalmonopolypower.

[48] Medicines Law & Policy, The TRIPS Flexibilities Database. Available from http://tripsflexibilities.medicineslawandpolicy.org/ (TRIPS Flexibilities Database).

a) LDC Transition provision

According to the TRIPS flexibilities database, eight OAPI Members have utilised the LDC transition provision, provided for in paragraph 7 of the Doha Declaration, in order to waive patent protection for certain pharmaceuticals. These Member States are Benin, Burkina Faso, Chad, Comoros, Guinea–Bissau, Niger, Senegal and Togo. The majority of these cases occurred in the mid-2000s, and the pharmaceuticals in question were antiretrovirals (ARVs), indicating that the utilisation of this flexibility was largely in response to the HIV/AIDS pandemic. However, none of these LDCs have amended their domestic legislation to ensure that the LDC transition is self-executing for both the pharmaceutical and the general extension permitted by Article 66.1 of the TRIPS Agreement.

b) Compulsory licences

The TRIPS flexibilities database records 11 cases where compulsory licences were utilised by OAPI's Member States. These uses occurred in five OAPI Member States: Central African Republic, Congo, Gabon, Guinea, and Ivory Coast. Congo and Ivory Coast account for the majority of compulsory licences, at three apiece. These uses too seem to have been motivated by the HIV/AIDS pandemic as all the compulsory licences related to ARVs.

Table 3: Summary of use of TRIPS Flexibilities

Country	**LDC transition provision**	**Compulsory licensing**
Benin	Utilised for ARVs in 2004, 2007 and 2009.	N/A
Burkina Faso	Utilised for ARVs in 2005.	N/A
Cameroon	N/A	N/A
The Central African Republic	Utilised for ARVs in 2004 and 2005.	N/A
Chad	Utilised for ARVs in 2005 and all medicines in 2007.	N/A
Comoros Islands	Utilised for ARVs in 2007.	N/A
Congo	N/A	Utilised for ARVs in 2005, 2007, 2014.
Equatorial Guinea	N/A	Utilised for ARVs in 2009.
Gabon	N/A	Utilised for ARVs in 2005 and 2006.
Guinea	Utilised for ARVs in 2005.	Utilised for ARVs in 2004 and 2005.
Guinea-Bissau	Utilised for ARVs in 2005.	N/A
Ivory Coast	N/A	Utilised for ARVs in 2004 and twice in 2007.
Mali	N/A	N/A
Mauritania	Utilised for ARVs in 2004.	N/A
Niger	Utilised for all medicines in 2004, and ARVs in 2008.	N/A
Senegal	Utilised for ARVs in 2006.	N/A
Togo	Utilised for all medicines in 2004, and ARVs in 2008 and 2009.	N/A

1.3.2 EXAMINING MEDICINES PRICING IN OAPI MEMBER STATES

As all OAPI Member Countries are governed by the Agreement, there are no individual patent laws to examine (as undertaken in a previous study[49]). Instead, it is useful to look at how the patent practices of OAPI may have impacted access to medicines in the countries in the region. In order to do so, we reviewed available data on medicines prices. Such data were sourced primarily from the World Health Organization (WHO)/ Health Action International's (HAI) Database of Medicine Prices, Availability, Affordability and Price Components (WHO/HAI Database),[50] which has produced numerous medicine pricing surveys based on the standardised method for measuring medicine prices, availability, affordability, and price components, and which was launched in 2003.[51] Additionally, we also refer to data from the Global Health Observatory, a collection of health-related data obtained by the WHO from its Member States through a variety of sources.[52]

This data, while dated, represents a collection of the most recent research on medicine prices on the African continent. By referring to this data, we do not suggest that patent protection is the sole or even the main factor that determines medicine prices, but one of several factors which may influence high prices on medicines. However, the extent to which (as will be shown below) prices for pharmaceuticals tend to be significantly higher for originator brands when compared to generics, suggests that patent protection is a significant factor.

Due to limited research on medicine pricing on the African continent, we could obtain data only on five OAPI Member States: Burkina Faso, Cameroon, Chad, Congo and Mali. While this is admittedly a small sample size, recurring features between them provide grounds for reasonable conclusions on the impact of patents on medicine pricing in other Member States.

Median consumer price ratio is widely regarded as a useful metric for comparing medicine prices in a particular state against the global standards. Median consumer price ratio is the ratio of the median price of a medicine across various outlets against the median international reference price (IRP). The IRP used in the studies referred to below utilises the Management Sciences for Health median IRP for the year preceding the study.[53]

According to the WHO/HAI Database, the median consumer price of all medicines in the private sector in Burkina Faso was 21.24 times the IRP for the respective originator brand. This factor was 21.93 and 18.94 for Chad and Mali, respectively. According to the Global Health Observatory's data on median consumer price in the public sector between 2007 and 2013, selected generic medicines cost 6.5 times the IRP in Congo.[54] The same medicines were 11.5 times the IRP in the private sector in that country.

These numbers are, in many cases, well above the WHO benchmark which recommends that governments should be paying prices close to the IRPs in the public sector, and consumers should pay no more than 4 times the IRP in the private sector, factoring in supply chain costs. This may partially be attributed to unusually high mark-ups on medicines amongst OAPI

[49] See, Vawda and Shozi, "Eighteen Years After Doha".
[50] World Health Organization (WHO) and Health Action International (HAI), Database of Medicine Prices, Availability, Affordability and Price Components. Available from http://www.haiweb.org/MedPriceDatabase/.
[51] WHO and HAI, *Measuring Medicine Prices, Availability, Affordability and Price Components* (Geneva, 2008). Available from https://apps.who.int/iris/handle/10665/70013.
[52] WHO, The Global Health Observatory. Available from https://www.who.int/data/gho.
[53] Management Sciences for Health (MSH), *The International Drug Price Indicator Guide* (Virginia, 2015). Available from https://www.msh.org/sites/default/files/msh-2015-international-medical-products-price-guide.pdf.
[54] WHO, the Global Health Observatory. See, specifically, the indicator "Median Consumer Price Ratio of Selected Generic Medicines - Public". Available from https://www.who.int/data/gho/data/indicators/indicator-details/GHO/median-consumer-price-ratio-of-selected-generic-medicines---public.

Member States. [55] While the impact of other confounding factors cannot be discounted, a significant factor influencing how much the public pays for medicines appears to be the extent to which holders of exclusive rights over these drugs enjoy unrestricted freedom to levy prices for their medicines. In the private sector, the WHO/HAI Database reveals retail mark-ups of about 33% for originator brand Amoxicillin and Captopril.[56]

In order to illustrate the extent of the impact of mark-ups such as these on the prices consumers pay for their medicines, we highlight the example of the cost of *glibenclamide*, a commonly used first line treatment for type-2 diabetes mellitus (T2DM),[57] given the increased prevalence of T2DM in Africa over the past few decades.[58] Sanofi-Aventis hold several patents on this medicine filed in the OAPI region, some only expiring in 2022.[59] The prices illustrated here relate to patients procuring their drugs from the private sector, for the reason that 50% to 90% of the population in many developing countries (such as the five OAPI Member States) purchase medicines out-of-pocket because they are not provided in the public sector, and most patients in these countries are not covered by private medical insurance.[60]

Based on survey data from July 2009 which were drawn from the WHO/HAI Database, the median treatment price for a 30-day course of glibenclamide 5mg capsules or tablets from the originator was USD 5400 – a price enabled by their monopoly. The pharmaceutical companies which produce the originator brand continue to exercise their hold over the market even after patents have expired, as indicated by comparing this price to the lowest priced generic, which was USD 600. In a similar vein, study data for Cameroon in 2005 show that the median treatment price for glibenclamide in the private sector was USD 5655.

To place these numbers in context, the WHO/HAI uses the number of day's wages that would be required to pay for a medicine as a metric to measure affordability. Among the five OAPI Member States, people who need glibenclamide to treat the debilitating (and potentially life-threatening) disease of T2DM would need to pay between 4 and 8 days' wages for a month's treatment. By comparison, the median treatment price of the same medicine from a manufacturer in India in 2004 was about USD 40, which equates to 0.3 days of work for 30 days of treatment.[61]

---

[55] A Cameron *et al*, "Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis", *The Lancet*, vol.373, No. 9659 (2009), p. 246.
[56] These mark-ups are, for the most part, comprised of wholesale markup – in this case amounting to 27 and 24% of the drug respectively. This indicates that prices were driven up by the originators – an act enabled by their monopolies and the attendant, an absence of competitors.
[57] Although metformin has become more widely accepted as a first line treatment in recent years.
[58] E O Ojuka and V Goyaram, "Increasing Prevalence of Type 2 Diabetes in Sub-Saharan Africa: Not Only a Case of Inadequate Physical Activity", *Diabetes and Physical Activity*, vol.60 (2014), p. 27.
[59] In the study referred to, the manufacturer of gilbenclamide was Sanofi-Aventis. According to Google Patents, Aventis has had multiple patents relating to gilbenclamide (or combinations with metformin) in the OAPI region since the early 2000s, many of which continue to be valid: https://patents.google.com/?q=Glibenclamide&assignee=Aventis+Pharma+Gmbh&country=OA.
[60] WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action", WHO/EDM/2004.4 (Geneva, World Health Organization, 2004). Available from https://apps.who.int/iris/bitstream/handle/10665/68571/WHO_EDM_2004.4_eng.pdf?sequence=1&isAllowed=y.
[61] This is based on results from studies in Karnataka, Chennai and Haryana, conducted in 2004, and extracted from the WHO/HAI Database.

1.4 DISCUSSION

The high level of IP protection which was incorporated into the 1999 Revision of the Agreement is often justified on the ground that it promotes innovation. If we accept that the number of patents filed in a territory can be used as a marker for levels of innovation, data on patent applications in the last 25 years show a paradoxical general *decline* in the number of patent applications to the OAPI since 1999.[62] According to Motari *et al*, the number of patents filed annually with the OAPI patent office was highest to date in 1999, and only exceeded that number 4 times in the past 20 years: in 2002, 2005, 2008 and 2014. These data indicate the flaws in the premise that strong IP protection promotes innovation and, in particular, local innovation. Historically, the majority of patent filings with OAPI were of European origin, notably France whose share alone was of 50% of all filings in the 1980s. Since the 1990s, approximately 78% of filings were from foreign countries with European countries accounting for 47% and the USA for 31%.[63]

These concerns, considered together, clearly indicate the need for significant reforms in the approach of the OAPI office in order to ensure access to medicines. In the next section, we provide recommendations on what form this intervention should take.

[62] M Motari *et al*, "The Role of Intellectual Property Rights and Access to Medical Products in the WHO African Region: 25 Years After the Trips Agreement", *BMC Public Health* (September 2020). Available from https://www.researchsquare.com/article/rs-62959/v1.

[63] GD Graaf, PG Pardey., “Inventions and patenting in Africa: Empirical trends from 1970 to 2010”, *The Journal of World Intellectual Property*, vol. 23, Issue 1-2 (November 2019), pp. 40-46. Available from https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12139.

1.5 RECOMMENDATIONS

The changes contemplated in the 2015 Revision, while a step in the right direction, are insufficient in terms of the utilisation of TRIPS public health flexibilities, Accordingly we propose changes in the following respects:

At the OAPI level:

1.5.1 The institution of substantive examination of pharmaceutical patents to thoroughly assess the merits of all applications.
1.5.2 The adoption of strict patentability requirements and examination guidelines in order to avoid the grant of secondary patents on new forms and new uses of known compounds, among others.

At the country level:

1.5.3 The adoption of a relevant decree to operationalise the general and pharmaceutical transition periods.
1.5.4 The expansion of the grounds on which non-voluntary licences may be granted, including public health and anti-competitive grounds.
1.5.5 The institution of a streamlined and user-friendly administrative procedure for the grant of non-voluntary licences.

PART 2: AFRICAN MEMBERS OF THE MENA REGION

2.1 BACKGROUND TO IP LEGISLATION

The African countries of the MENA region are unique from other countries in the continent because they represent a large geographic area that lacks any supra-national structure regulating IP policy. This is so despite common features between these countries that would suggest that a degree of co-operation between them would be beneficial. For instance, none of them is an LDC, with Libya not having any classification as it is not a Member of the WTO (see Table 4). It is generally accepted that regional economic blocs can maximise access to medicines by coordinating the use of flexibilities and sharing the resources required to procure and distribute essential medicines.[64] Yet, structures for such co-operation are absent in this region, with most countries having undertaken reforms to their IP laws in the early 2000s in order to comply with the TRIPS Agreement. Five of the MENA countries are within the African continent. In this section of the paper, we discuss the legal position with regard to IP in these countries, and consider the extent to which it has impacted on access to medicines (see Table 6).

Table 4: IP laws and LDC status of MENA African countries

State	LDC Status	Patent Law
Algeria	No	Ordinance No. 03-07 of 19 Joumada El Oula 1424 corresponding to July 19, 2003, on Patents
Egypt	No	Law No. 82 of 2002 Pertaining to the Protection of Intellectual Property Rights
Libya	Non-WTO	Law No.8 of the year 1959 on Patents and Industrial Designs and Models.
Morocco	No	Dahir No. 1-00-91 of 9 Kaada 1420 (February 15, 2000) on the Enactment of Law No. 17-97 on the Protection of Industrial Property
Tunisia	No	Law No. 2000-84 of August 24, 2000, on Patents

[64] SF Musungu, S Villanueva and R Blasetti, *Utilizing Trips Flexibilities For Public Health Protection Through South-South Regional Frameworks*, South Perspective Series (Geneva, South Centre, 2004). Available from http://apps.who.int/medicinedocs/pdf/s4968e/s4968e.pdf.

2.2 INCORPORATION OF TRIPS FLEXIBILITIES

The following is an overview of the current law relating to TRIPS flexibilities in Algeria, Egypt, Libya, Morocco and Tunisia. We also discuss the extent to which TRIPS public health flexibilities have been utilised as gleaned from the TRIPS Flexibilities Database. This discussion is divided into two parts. In the first part, we discuss pre-grant flexibilities (see Table 5), namely those that 'apply before the grant of a patent and normally concern the granting process. They involve preventing the issuing of patents for products or processes that do not merit a patent for lack of innovative or novel content, or because there is no obligation to grant patents'.[65] These include:

- Patentability of Pharmaceuticals
- Patentability Criteria
- Patent Examination
- Pre-Grant Opposition

In the second part, we discuss post-grant flexibilities (see Table 6), which 'refer[s] to exceptions that allow for governments (or other interested parties) to engage in activities – for example, that are necessary to promote access to healthcare – that would otherwise amount to an infringement of patent rights'.[66] These include:

- Patent Terms
- Regulatory Review Exception (also known as the Bolar exception),
- Non-voluntary Licences (Compulsory licensing and Government use)
- Research Exception
- Parallel Importation
- Post-Grant Opposition

2.2.1 PRE-GRANT FLEXIBILITIES

a) Patentability of Pharmaceuticals

Libya, the sole non-WTO state, is the only country in this region that excludes pharmaceuticals from patentability. The relevant provision provides that:

> 'Chemical inventions related to foodstuff, *drugs or pharmaceutical formulas* unless these products are made through special methods or chemical processes, where in the latter case, the patent shall be granted to the method of production rather than to the products themselves'.[67] (emphasis added)

This suggests that while pharmaceuticals themselves may not be patentable, the processes for making them are. It is worth noting that Libya's IP law pre-dates TRIPS by several decades.

The remaining states are all non-LDC WTO Member States, and provide legal protection for all subject matter, including pharmaceuticals. Morocco's IP law explicitly names pharmaceuticals as patentable subject matter.[68]

---

[65] Vawda and Shozi, "Eighteen Years After Doha", p. 13.
[66] Ibid.
[67] Libyan Law Article 2(b)(2).
[68] Moroccan Law Article 21.

b) Patentability Criteria

The countries examined here, for the most part, require the standard patentability criteria outlined in Article 27.1 of TRIPS. Notably, Algeria,[69] Egypt[70] and Tunisia[71] do take some advantage of their freedom to define these criteria in access-friendly terms by adopting standards of absolute novelty. Additionally, a strict enforcement of patentability criteria enabled Egypt to reject patents on pharmaceuticals, such as sofosbuvir.[72]

Gilead Sciences applied to the Egyptian patent office for a patent on sofosbuvir, a ground-breaking Hepatitis-C drug, during 2013. In 2014 the patent application for the drug was denied.[73] This was because it was deemed by the Egyptian patent office to lack both novelty and inventiveness, and thus failed to meet the criteria for patentability. Shortly thereafter, the patent application for sofosbuvir was also denied in China for similar reasons, amidst a global outcry about Gilead's excessively high pricing of the medicine in certain jurisdictions such as the US.[74] By denying the patent, both these countries were able to open the door to generic variants of sofosbuvi*r* to be made available to the public, at a much lower price than Gilead's product.

c) Patent Examination

Most African countries in this region do not provide for substantive examination of patents, with the exception of Egypt[75] and Morocco.[76]

d) Pre-Grant Opposition

Egypt,[77] Libya[78] and Tunisia[79] all provide mechanisms for patents to be challenged prior to their grant. In all these countries, this opportunity is available to 'any interested party'. However in Tunisia the party in question must initiate court proceedings rather than make an application to the patent office. Additionally, Egyptian law also vests the Minister of Health with special powers to intervene in patent applications in respect of health-related products, presumably to ensure that patents which are contrary to public health are not granted.[80] The following provision in the Egyptian law enables the ministers of Defence, Military Production, Interior and Health to intervene, as they have to be notified of patent applications relating to their portfolios within 10 days of their examination, as well as thereafter:

> 'The Minister of Defence, the Minister of Military Production, the Minister of Interior or the Minister of Health, as might be the case, may, within 90 days from the date of notification, oppose the publication of the application acceptance. Where the acceptance of the application is made public, the competent Minister may oppose the procedure to grant a patent within 90 days from the date of the publication, in the

[69] Algerian Law Article 4.
[70] Egyptian Law Article 3.
[71] Tunisian Law Article 4.
[72] For a useful overview of the issue, see: CLFB Bognar *et al*., "Compulsory Licenses for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications?", *Journal of Global Oncology*, vol. 2, Issue 5 (2016), p. 294.
[73] Heba Wanis, "Egypt Will Not Patent New Hepatitis C Drug", 23 May 2014. Available from https://www.madamasr.com/en/2014/05/23/opinion/society/egypt-will-not-patent-new-hepatitis-c-drug/.
[74] Z Kmietowicz, " China Rejects Patent on Hepatitis C Drug Sofosbuvir". *BMJ*, 23 June 2015. Available from https://www.bmj.com/content/350/bmj.h3429.
[75] Egyptian Law Article 16.
[76] Moroccan Law Article 43.
[77] Egyptian Law Article 16.
[78] Libyan Law Article 19.
[79] Tunisian Law Article 34.
[80] Egyptian Law Article 17.

Patent Gazette, of the decision to accept the patent application, if it appears that the application relates to defence, military production, security or is of military, security or health significance. Opposition in the aforementioned cases shall stop the procedure of granting the patent'.

Table 5: Pre-Grant Flexibilities in MENA African states

State	Patentability of Pharmaceuticals	Patentability Criteria	Patent Examination	Pre-Grant Opposition
Algeria	Patentable	Art 27.1 of TRIPS compliant Absolute novelty	Formal	N/A
Egypt	Patentable	Art 27.1 of TRIPS compliant Absolute novelty	Substantive	Pre-Grant opposition application may be made to the patent office by any interested party. Ministers of Health and specified portfolios may also oppose applications.
Libya	Not patentable	Art 27.1 of TRIPS compliant	Formal	Pre-grant opposition application may be made to the patent office by any interested party.
Morocco	Patentable	Art 27.1 of TRIPS compliant	Substantive	N/A
Tunisia	Patentable	Art. 27.1 compliant Absolute novelty	Formal	Pre-grant opposition may be made via a court challenge, which suspends the grant process.

2.2.2 POST-GRANT FLEXIBILITIES

a) Patent Term

All the 5 MENA African countries, with the exception of Libya, provide a 20 year protection for patents as required under TRIPS. Libya provides for a 15 year term, with the opportunity to renew for an additional 5 years.[81] Additionally, if a patent is not used for longer than 3 years, the patent may be cancelled.[82]

b) Bolar Exception

Despite the scant use of flexibilities generally, two countries within this region specifically make provision for the regulatory review exception. They are Egypt[83] and Tunisia.[84] Oddly, in the case of Tunisia this exception extends only to the 'manufacture of generic drugs' and specifically prohibits any commercial exploitation. The Egyptian law provides that:

> 'Where a third party proceeds, during the protection period of a product, with its *manufacturing, assembly, use or sale*, with a view to obtain a marketing license, provided that, the marketing starts after the expiry of such a protection period'. (emphasis added).

The language used here is considerably more liberal and appears to allow generic manufacturers to stockpile products prior to patent expiry. If so, this measure could enable them to market the generic product as soon as the originator patent expires.

c) Non-voluntary Licences

Algeria,[85] Egypt,[86] Morocco[87] and Tunisia[88] all cater for non-voluntary licences in some form as provided for in Article 31 of TRIPS, although the grounds available for granting these licences vary. In most cases, they are related to a failure to work the patent at all, or a failure to do so to a degree sufficient to meet the demand within that country. The same grounds apply in relation to government use licences, which may be authorised according to the needs of the state in Egypt[89] and Tunisia.[90] Libya is unique in that it provides only for government use 'compulsory licences'.[91] For the compulsory licence to be available exclusively at the instance of the state unduly limits this flexibility. It cannot be in the interests of public health to exclude other interested parties, for example, generic competitors or public interest groups, from using this flexibility. No evidence has been found of the use of compulsory licensing in Libya.

In addition to the standard provisions for non-voluntary licences, Algeria[92] and Egypt[93] also specify that non-voluntary licences (sometimes labelled 'ex officio' licences) may be issued where doing so is the public interest, which includes the public interest in protecting public

[81] Libyan Law Article 10.
[82] Libyan Law Article 28.
[83] Egyptian Law Article 10(5).
[84] Tunisian Law Article 47(e).
[85] Algerian Law Article 38.
[86] Egyptian Law Article 23(1).
[87] Moroccan Law Article 60.
[88] Tunisian Law Article 69.
[89] Egyptian Law Article 25.
[90] Tunisian Law Article 28.
[91] Libyan Law Article 30.
[92] Algerian Law Article 49.
[93] Egyptian Law Article 23(2).

health. Despite the availability of such grounds for non-voluntary licences on medicines, there has been only a single reported instance of the use of this flexibility by African countries in the region. In 2002, Egypt reportedly issued a compulsory licence for a medication used to treat erectile dysfunction.[94]

d) Research Exception

Algeria,[95] Egypt,[96] Morocco[97] and Tunisia[98] all provide for a research exception.

e) Parallel Importation

Only Algeria[99] and Tunisia[100] make provision for parallel importation in their domestic laws, although there is no evidence of this flexibility having been used in either country.

f) Post-Grant Opposition

All the study countries, with the exception of Libya, provide for post-grant opposition in their patent laws through an application to the court. In addition to being open to all interested persons, both Egypt[101] and Tunisia[102] make provision for state officials to bring such applications – thereby giving the government an opportunity to redress the granting of patents that should not have been granted, whether or not a third party has an interest in having the patent revoked.

[94] See, R Beall and R Kuhn, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis.", *PLOS Medicine*, e1001154 (January 2012).
[95] Algerian Law Article 12(1).
[96] Egyptian Law Article 10(1)
[97] Moroccan Law Article 55(d).
[98] Tunisia Law Article 47 (b).
[99] Algerian Law Article 12(2).
[100] Tunisian Law Article 47(d).
[101] Egyptian Law Article 28.
[102] Tunisian Law Article 55.

Table 6: Post-Grant Flexibilities in MENA African states

State	Term	Non-voluntary Licences	Parallel Imports	Research Exception	'Bolar' Exception	Post-Grant Opposition
Algeria	20	Compulsory Licence (CL) may be granted for failure to work or insufficient exploitation; and public interest, including health, or anti-competitive practices.	Yes	Yes	N/A	Post-grant opposition application may be made to court by any interested party
Egypt	20	CL may be granted for failure to work, as well as specifically for pharmaceuticals if requested by Minister of Health and licence is in the interests of public health. Patents may be 'expropriated' by government to serve the needs of the state.	N/A	Yes	Yes	Patent Office or any interested party may ask Tribunal to repeal a patent
Libya	15	CL may be granted through a decision issued by the Minister of National Economy to utilise the invention due to reasons related to 'pro bono publico' or national defence.	N/A	N/A	N/A	N/A
Morocco	20	CL may be granted for failure to work and insufficient exploitation. 'Ex officio' licences may be granted for medicines in the interests of public health.	N/A	Yes	N/A	Post-grant opposition application may be made to court by any interested party
Tunisia	20	CL may be granted for failure to work. Minister may formally call upon the owners of patents to undertake the working thereof in such a way as to meet the needs of the national economy or the need to safeguard the environment. Failing which the patent is under an ex officio licence regime. Medicines may be subject to ex officio licence for public health reasons.	Yes	Yes	Yes	Post-grant opposition may be brought before the court Public Prosecution Service may 'ex officio' invalidate a patent

2.3 EXAMINING MEDICINE PRICING IN THE AFRICAN MENA COUNTRIES

In addition to an examination of the patent laws in the African MENA countries studied here, an analysis of medicine prices in this region similar to Part 1 is instructive in outlining the reality of access to medicines in these countries. The WHO/HAI Database[103] records data on three countries within this group: Egypt, Morocco and Tunisia. These data are discussed below.

a) Medicine prices in the 3 African MENA countries

In stark contrast to the shockingly high prices for medicines in the OAPI region, according to the HAI Database, the median consumer price of all medicines in the private sector in Egypt was just 4.48 times the IRP for the originator brand in 2013. This is within range of the WHO benchmarks recommending that consumers should pay no more than 4 times the IRP in the private sector. However, Morocco and Tunisia do not fare as well, at 12.38 and 11.89 times the IRP for the originator in 2004, respectively. However, even these figures are below the lowest factor for OAPI members, such as in the case of Cameroon, where consumers pay a median of 16.24 times the IRP for medicines in the private sector. While relatively low compared to the countries of OAPI, the numbers for Morocco and Tunisia are inordinately high.

b) The example of sofosbuvir

Despite the generally negative trend recounted here, the case of sofosbuvir offers great hope for affordable pricing of medicines. Prior to the refusal of the patent, the drug cost could reach as much as USD 84 000 for a full treatment as, for example, in the USA. The facts that the drug is not patented in Egypt, and the ability of a local manufacturer Pharco Pharmaceuticals to produce a generic version, have resulted in a drastic drop in the price for the generic version, available in Egypt and supplied to other countries such as Malaysia for USD 300 for the twelve weeks of treatment.[104]

[103] WHO/HAI Database.
[104] Matt Fellows, “New hepatitis C combo boasts cure for just $300”, *Pharmafile*, 12 April 2018. Available from http://www.pharmafile.com/news/517047/new-hepatitis-c-combo-boasts-97-cure-rate-just-300.

2.4 DISCUSSION

The African countries within the MENA region, with the exception of Libya, have all amended their patent laws to become TRIPS-compliant. As noted, some flexibilities have been included, such as the research exception provided for in all 5 countries, and the patentability criteria of Algeria, Egypt and Tunisia. However, significant gaps remain. For instance, even Egypt – which has both applied strict patentability criteria and issued a compulsory licence – does not make provision for parallel importation. Additionally, despite provisions that allow for flexibilities being present in varying degrees in each of these countries, very little use has been made of them. As in the case of OAPI countries, the existence of patents may impact adversely on some African MENA countries, though not to the same extent.

As indicated above, Egypt boasts the region's best success story with the experience of sofosbuvir in achieving a degree of affordable access, and illustrates how the flexibility of applying strict standards of patentability can be effectively utilised to ensure access.

2.5 RECOMMENDATIONS

In light of the various weaknesses identified among the IP regulatory regimes of MENA countries, there is clearly a need for regulatory reform to fully cater for the utilisation of public health related flexibilities. It is our recommendation that these three particular areas be addressed as soon as possible:

2.5.1 Where applicable, those countries which do not cater for opposition procedures, parallel importation, and the Bolar exception should incorporate these into their legislation.

2.5.2 All countries should include an expanded list of the grounds on which compulsory licences may be granted, including public health and anti-competitive grounds.

2.5.3 All countries should allow interested third parties to apply for a compulsory licence authorization.

2.5.4 The institution of a streamlined and user-friendly administrative procedure for processing requests for non-voluntary licences and their grant.

3. FINAL REMARKS

Africa has been severely affected by the COVID-19 pandemic. As of mid-April 2021, there have been approximately 4.4 million reported cases and over 117 000 deaths,[105] although these figures could possibly be higher due to both the limited number of tests carried out, as well as the number of excess natural deaths reported compared to the pre-COVID period. For example, researchers have estimated that while the 'official' death toll in South Africa around early February 2021 was 46 473, the actual death toll could have been in the region of 114 000 to 128 000, almost two and a half times more.[106]

From the earliest days of the pandemic, African countries experienced shortages of materials for testing, leading the head of the Africa Centres for Disease Control and Prevention (Africa CDC) to declare that 'the collapse of global cooperation and a failure of international solidarity have shoved Africa out of the diagnostics market'.[107] For example, South Africa's testing programme was significantly delayed when Cepheid and Roche, on whose platforms its testing was based, experienced supply shortages yet were unwilling to license their technology to enable local manufacture of their test materials.[108] South Africa was fortunately able to overcome the IP barriers in this case by procuring test materials that are compatible with non-proprietary systems, enabling its national laboratory service to bolster its capacity and resume its testing programme.[109] Other African countries have not been as successful, and the low level of testing across the continent has caused the WHO to warn that COVID-19 would turn into a 'silent epidemic'.[110]

The situation is even more dire in respect of vaccines. The WHO reports that as at the first week of April 2021, less than 2% of the 690 million COVID-19 vaccine doses administered globally have been in Africa.[111] To a large extent, this is the result of high income countries buying up and hoarding much of the available supply, in what has come to be termed 'vaccine nationalism'.[112] Intellectual property protections, including patents and trade secrets, loom large in the supply shortages, and the refusal of pharmaceutical companies to license multiple manufacturers has resulted in the call by civil society globally and Low and Middle-Income Country governments for the suspension of IP barriers to COVID-19 related health products during the pandemic.[113] The pharmaceutical industry has attempted to oppose the proposal on the grounds, among others, that a waiver will not speed up manufacturing or supply because there is no spare manufacturing capacity globally.[114] In response, access advocates point to the existence of significant under-utilised manufacturing capacity not only in developed

---

[105] S Galal, "Coronavirus cases in Africa as of April 15, 2021, by country", *statista*, 16 April 2021. Available from https://www.statista.com/statistics/1170463/coronavirus-cases-in-africa/.
[106] News24, "SA's shocking 'actual' Covid-19 death toll could be 128 000 – more than double the official deaths", 4 March 2021. Available from https://www.news24.com/news24/southafrica/investigations/sas-shocking-actual-covid-19-death-toll-could-be-128-000-more-than-double-the-official-deaths-20210304.
[107] J Nkengasong, "Let Africa into the market for COVID-19 diagnostics", *Nature*, 28 April 2020. Available from https://www.nature.com/articles/d41586-020-01265-0.
[108] C Tomlinson, "COVID-19: NHLS reducing its dependency on "a few suppliers", *spotlight*, 22 July 2020. Available from https://www.spotlightnsp.co.za/2020/07/22/covid-19-nhls-reducing-its-dependence-on-a-few-suppliers/.
[109] Ibid.
[110] L Mogoatlhe, "Lack of COVID-19 Testing Is Leading to a 'Silent Epidemic' in Africa, warns WHO", *Global Citizen*, 1 May 2020. Available from https://www.globalcitizen.org/en/content/covid-19-testing-lack-in-africa-who/.
[111] WHO, "Less than 2% of world's COVID-19 vaccines administered in Africa", 8 April 2021. Available from https://www.afro.who.int/news/less-2-worlds-covid-19-vaccines-administered-africa.
[112] H. Lock, "Vaccine Nationalism: Everything You Need to Know", *Global Citizen*, 11 February 2021. Available from https://www.globalcitizen.org/en/content/what-is-vaccine-nationalism/.
[113] Editorial, "It's time to consider a patent reprieve for COVID vaccines", *Nature*, 30 March 2021. Available from https://www.nature.com/articles/d41586-021-00863-w.
[114] Ibid.

countries but also in developing countries such as Egypt, Senegal, South Africa, India, Bangladesh, Brazil, Argentina and Mexico.[115]

Africa is beginning to address its near-total dependence on imports to meet its pharmaceutical needs as evidenced from a mere 1% of its vaccines being manufactured on the continent. A recent vaccine summit convened by Africa CDC and the African Union has pledged to increase that share to 60% by 2040 with an ambitious plan to scale up local production on the continent.[116]

However, the continent will still have to confront IP barriers to increasing access to vaccines and other health products.[117] It is a reality that the challenges with legislation in the countries studied here existed before the COVID-19 pandemic. However, some of these challenges may be overcome through an adoption of the recommendations set out in this paper – including the utilisation of existing flexibilities specifically aimed at supporting generic products and increased global production that can improve access to COVID-19 diagnostics, vaccines, treatments. and other related products in the African region. An IP waiver for COVID-19 related products, if adopted, will provide the legal cover at a global level for countries to reform their legislation in several respects. First, they may, for example, legislate for and issue compulsory licences on the COVID-19 related vaccines and treatments, without the fear of retaliatory action by IP rights holders or countries housing IP-rich industries. Secondly, by adopting the security exception in the laws of many countries, they will help to establish a community of practice for the easy and consistent use of such a flexibility.

Early on in the pandemic, the South Centre had issued a call to the Directors-General of the WHO, WIPO and WTO to the effect that the security exception permitted by Article 73 of the TRIPS Agreement could be invoked by any Member of the WTO during the pandemic. This would be in order to take 'any action which it considers necessary for the protection of its essential security interests' and appealing to these leaders to support developing and other countries to use this provision to suspend the enforcement of various IP rights that 'may pose an obstacle to the procurement or local manufacturing of the products and devices necessary to protect their populations'.[118]

The review made in this document has highlighted the limited use of TRIPS public health flexibilities in the study countries, and suggests the adverse effects of patent monopolies on medicines pricing. As already alluded to, the COVID-19 pandemic has made the case for the use of flexibilities all the more necessary.

It is also to be noted that none of the study countries, nor does OAPI as a regional IP office, recognises the security exception permitted by Article 73. It is accordingly recommended that countries consider adding this flexibility to their arsenal of measures to ensure access to medicines.

The adoption, by countries, of all available public health flexibilities will also advance the cause of continental harmonisation (in particular as it relates to intellectual property regulation) with

---

[115] Public Citizen, "Waiver of the WTO's Intellectual Property Rules: Facts vs Common Myths", *Public Citizen*, 29 March 2021. Available from https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/.

[116] A. Irwin, "How COVID spurred Africa to plot a vaccines revolution", *Nature*, 21 April 2021. Available from https://www.nature.com/articles/d41586-021-01048-1.

[117] Bonginkosi Shozi, "What Can African Countries Do To Make Sure They Have Affordable Access to a COVID-19 Cure?", *Multilateral Matters*, 12 May 2020. Available from http://ip-unit.org/2020/multilateral-matters-6-what-can-african-countries-do-to-make-sure-they-have-affordableaccess-to-a-covid-19-cure/.

[118] South Centre, "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", 4 April 2021. Available from https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf.

the launch of the African Continental Free Trade Area.[119] This process can be effectively facilitated through the involvement of Africa's eight Regional Economic Communities (RECs).[120] Syam and Munoz Tellez have proposed that the RECs play a more central role in guiding Member Countries to design and adopt development-oriented IP policies, and that fundamental reform of OAPI as well as of the African Regional Intellectual Property Organization (ARIPO) is critical.[121]

Finally, it is in the interests of all developing countries, including the countries studied here, to support global efforts such as the proposal for the waiver at the WTO in order to remove the obstacles to the expansion of the manufacturing of diagnostics, vaccines, therapeutics and other health products, so that global equity in the distribution of these goods becomes a reality.

[119] African Union, CFTA – Continental Free Trade Area. Available from https://au.int/en/ti/cfta/about
[120] African Union, Regional Economic Communities (RECs). Available from https://au.int/en/organs/recs.
[121] N Syam and V Munoz Tellez, *Innovation and Global Intellectual Property Regulatory Regimes: The Tension Between Protection and Access*, Research Paper, No. 67 (Geneva, South Centre, 2016). Available from https://www.southcentre.int/wp-content/uploads/2016/06/RP67_Innovation-and-Global-IP-Regulatory-Regimes_EN.pdf.

SOUTH CENTRE RESEARCH PAPERS

No.	Date	Title	Authors
1	November 2005	Overview of the Sanitary and Phytosanitary Measures in QUAD Countries on Tropical Fruits and Vegetables Imported from Developing Countries	Ellen Pay
2	November 2005	Remunerating Commodity Producers in Developing Countries: Regulating Concentration in Commodity Markets	Samuel G. Asfaha
3	November 2005	Supply-Side Measures for Raising Low Farm-gate Prices of Tropical Beverage Commodities	Peter Robbins
4	November 2005	The Potential Impacts of Nano-Scale Technologies on Commodity Markets: The Implications for Commodity Dependent Developing Countries	ETC Group
5	March 2006	Rethinking Policy Options for Export Earnings	Jayant Parimal
6	April 2006	Considering Gender and the WTO Services Negotiations	Meg Jones
7	July 2006	Reinventing UNCTAD	Boutros Boutros-Ghali
8	August 2006	IP Rights Under Investment Agreements: The TRIPS-plus Implications for Enforcement and Protection of Public Interest	Ermias Tekeste Biadgleng
9	January 2007	A Development Analysis of the Proposed WIPO Treaty on the Protection of Broadcasting and Cablecasting Organizations	Viviana Munoz Tellez and Andrew Chege Waitara
10	November 2006	Market Power, Price Formation and Primary Commodities	Thomas Lines
11	March 2007	Development at Crossroads: The Economic Partnership Agreement Negotiations with Eastern and Southern African Countries on Trade in Services	Clare Akamanzi
12	June 2007	Changes in the Governance of Global Value Chains of Fresh Fruits and Vegetables: Opportunities and Challenges for Producers in Sub-Saharan Africa	Temu A.E and N.W Marwa
13	August 2007	Towards a Digital Agenda for Developing Countries	Dalindyebo Shabalala
14	December 2007	Analysis of the Role of South-South Cooperation to Promote Governance on Intellectual Property Rights and Development	Ermias Tekeste Biadgleng
15	January 2008	The Changing Structure and Governance of Intellectual Property Enforcement	Ermias Tekeste Biadgleng and Viviana Munoz Tellez
16	January 2008	Liberalization of Trade in Health Services: Balancing Mode 4 Interests with Obligations to Provide Universal Access to Basic Services	Joy Kategekwa

17	July 2008	Unity in Diversity: Governance Adaptation in Multilateral Trade Institutions Through South-South Coalition-Building	Vicente Paolo B. Yu III
18	December 2008	Patent Counts as Indicators of the Geography of Innovation Activities: Problems and Perspectives	Xuan Li
19	December 2008	WCO SECURE: Lessons Learnt from the Abortion of the TRIPS-plus-plus IP Enforcement Initiative	Xuan Li
20	May 2009	Industrialisation and Industrial Policy in Africa: Is it a Policy Priority?	Darlan F. Marti and Ivan Ssenkubuge
21	June 2009	IPR Misuse: The Core Issue in Standards and Patents	Xuan Li and Baisheng An
22	July 2009	Policy Space for Domestic Public Interest Measures Under TRIPS	Henning Grosse Ruse – Khan
23	June 2009	Developing Biotechnology Innovations Through Traditional Knowledge	Sufian Jusoh
24	May 2009	Policy Response to the Global Financial Crisis: Key Issues for Developing Countries	Yılmaz Akyüz
25	October 2009	The Gap Between Commitments and Implementation: Assessing the Compliance by Annex I Parties with their Commitments Under the UNFCCC and its Kyoto Protocol	Vicente Paolo Yu III
26	April 2010	Global Economic Prospects: The Recession May Be Over but Where Next?	Yılmaz Akyüz
27	April 2010	Export Dependence and Sustainability of Growth in China and the East Asian Production Network	Yılmaz Akyüz
28	May 2010	The Impact of the Global Economic Crisis on Industrial Development of Least Developed Countries	Report Prepared by the South Centre
29	May 2010	The Climate and Trade Relation: Some Issues	Martin Khor
30	May 2010	Analysis of the Doha Negotiations and the Functioning of the World Trade Organization	Martin Khor
31	July 2010	Legal Analysis of Services and Investment in the CARIFORUM-EC EPA: Lessons for Other Developing Countries	Jane Kelsey
32	November 2010	Why the IMF and the International Monetary System Need More than Cosmetic Reform	Yılmaz Akyüz
33	November 2010	The Equitable Sharing of Atmospheric and Development Space: Some Critical Aspects	Martin Khor
34	November 2010	Addressing Climate Change through Sustainable Development and the Promotion of Human Rights	Margreet Wewerinke and Vicente Paolo Yu III
35	January 2011	The Right to Health and Medicines: The Case of Recent Negotiations on the	Germán Velásquez

		Global Strategy on Public Health, Innovation and Intellectual Property	
36	March 2011	The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries	Gurdial Singh Nijar
37	March 2011	Capital Flows to Developing Countries in a Historical Perspective: Will the Current Boom End with a Bust?	Yılmaz Akyüz
38	May 2011	The MDGs Beyond 2015	Deepak Nayyar
39	May 2011	Operationalizing the UNFCCC Finance Mechanism	Matthew Stilwell
40	July 2011	Risks and Uses of the Green Economy Concept in the Context of Sustainable Development, Poverty and Equity	Martin Khor
41	September 2011	Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing	Carlos M. Correa
42	December 2011	Rethinking Global Health: A Binding Convention for R&D for Pharmaceutical Products	Germán Velásquez and Xavier Seuba
43	March 2012	Mechanisms for International Cooperation in Research and Development: Lessons for the Context of Climate Change	Carlos M. Correa
44	March 2012	The Staggering Rise of the South?	Yılmaz Akyüz
45	April 2012	Climate Change, Technology and Intellectual Property Rights: Context and Recent Negotiations	Martin Khor
46	July 2012	Asian Initiatives at Monetary and Financial Integration: A Critical Review	Mah-Hui (Michael) Lim and Joseph Anthony Y. Lim
47	May 2013	Access to Medicines and Intellectual Property: The Contribution of the World Health Organization	Germán Velásquez
48	June 2013	Waving or Drowning: Developing Countries After the Financial Crisis	Yılmaz Akyüz
49	January 2014	Public-Private Partnerships in Global Health: Putting Business Before Health?	Germán Velásquez
50	February 2014	Crisis Mismanagement in the United States and Europe: Impact on Developing Countries and Longer-term Consequences	Yılmaz Akyüz
51	July 2014	Obstacles to Development in the Global Economic System	Manuel F. Montes
52	August 2014	Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain	Carlos M. Correa
53	September 2014	Regional Pooled Procurement of Medicines in the East African Community	Nirmalya Syam
54	September 2014	Innovative Financing Mechanisms: Potential Sources of Financing the WHO Tobacco Convention	Deborah Ko Sy, Nirmalya Syam and Germán Velásquez

55	October 2014	Patent Protection for Plants: Legal Options for Developing Countries	Carlos M. Correa
56	November 2014	The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines	Sangeeta Shashikant
57	November 2014	Globalization, Export-Led Growth and Inequality: The East Asian Story	Mah-Hui Lim
58	November 2014	Patent Examination and Legal Fictions: How Rights Are Created on Feet of Clay	Carlos M. Correa
59	December 2014	Transition Period for TRIPS Implementation for LDCs: Implications for Local Production of Medicines in the East African Community	Nirmalya Syam
60	January 2015	Internationalization of Finance and Changing Vulnerabilities in Emerging and Developing Economies	Yılmaz Akyüz
61	March 2015	Guidelines on Patentability and Access to Medicines	Germán Velásquez
62	September 2015	Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines	Carlos M. Correa
63	October 2015	Foreign Direct Investment, Investment Agreements and Economic Development: Myths and Realities	Yılmaz Akyüz
64	February 2016	Implementing Pro-Competitive Criteria for the Examination of Pharmaceutical Patents	Carlos M. Correa
65	February 2016	The Rise of Investor-State Dispute Settlement in the Extractive Sectors: Challenges and Considerations for African Countries	Kinda Mohamadieh and Daniel Uribe
66	March 2016	The Bolar Exception: Legislative Models and Drafting Options	Carlos M. Correa
67	June 2016	Innovation and Global Intellectual Property Regulatory Regimes: The Tension between Protection and Access in Africa	Nirmalya Syam and Viviana Muñoz Tellez
68	June 2016	Approaches to International Investment Protection: Divergent Approaches between the TPPA and Developing Countries' Model Investment Treaties	Kinda Mohamadieh and Daniel Uribe
69	July 2016	Intellectual Property and Access to Science	Carlos M. Correa
70	August 2016	Innovation and the Global Expansion of Intellectual Property Rights: Unfulfilled Promises	Carlos M. Correa
71	October 2016	Recovering Sovereignty Over Natural Resources: The Cases of Bolivia and Ecuador	Humberto Campodonico
72	November 2016	Is the Right to Use Trademarks Mandated by the TRIPS Agreement?	Carlos M. Correa
73	February 2017	Inequality, Financialization and Stagnation	Yılmaz Akyüz

74	February 2017	Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements	Carlos M. Correa
75	March 2017	Implementing Farmers' Rights Relating to Seeds	Carlos M. Correa
76	May 2017	The Financial Crisis and the Global South: Impact and Prospects	Yılmaz Akyüz
77	May 2017	Access to Hepatitis C Treatment: A Global Problem	Germán Velásquez
78	July 2017	Intellectual Property, Public Health and Access to Medicines in International Organizations	Germán Velásquez
79	September 2017	Access to and Benefit-Sharing of Marine Genetic Resources beyond National Jurisdiction: Developing a New Legally Binding Instrument	Carlos M. Correa
80	October 2017	The Commodity-Finance Nexus: Twin Boom and Double Whammy	Yılmaz Akyüz
81	November 2017	Promoting Sustainable Development by Addressing the Impacts of Climate Change Response Measures on Developing Countries	Martin Khor, Manuel F. Montes, Mariama Williams, and Vicente Paolo B. Yu III
82	November 2017	The International Debate on Generic Medicines of Biological Origin	Germán Velásquez
83	November 2017	China's Debt Problem and Rising Systemic Risks: Impact of the global financial crisis and structural problems	Yuefen LI
84	February 2018	Playing with Financial Fire: A South Perspective on the International Financial System	Andrew Cornford
85	Mayo de 2018	Acceso a medicamentos: experiencias con licencias obligatorias y uso gubernamental- el caso de la Hepatitis C	Carlos M. Correa y Germán Velásquez
86	September 2018	US' Section 301 Actions : Why They are Illegitimate and Misguided	Aileen Kwa and Peter Lunenborg
87	November 2018	Stemming 'Commercial' Illicit Financial Flows & Developing Country Innovations in the Global Tax Reform Agenda	Manuel F. Montes, Daniel Uribe and Danish
88	November 2018	Assessment of South-South Cooperation and the Global Narrative on the Eve of BAPA+40	Yuefen LI
89	November 2018	History and Politics of Climate Change Adaptation at the United Nations Framework Convention on Climate Change	Harjeet Singh and Indrajit Bose
90	December 2018	Compulsory Licensing Jurisprudence in South Africa: Do We Have Our Priorities Right?	Yousuf A Vawda
91	February 2019	Key Issues for BAPA+40: South-South Cooperation and the BAPA+40 Subthemes	Vicente Paolo B. Yu III

92	March 2019	Notification and Transparency Issues in the WTO and ' November 2018 Communication	Aileen Kwa and Peter Lunenborg
93	March 2019	Regulating the Digital Economy: Dilemmas, Trade Offs and Potential Options	Padmashree Gehl Sampath
94	April 2019	Tax Haven Listing in Multiple Hues: Blind, Winking or Conniving?	Jahanzeb Akhtar and Verónica Grondona
95	July 2019	Mainstreaming or Dilution? Intellectual Property and Development in WIPO	Nirmalya Syam
96	August 2019	Antivirales de acción directa para la Hepatitis C: evolución de los criterios de patentabilidad y su impacto en la salud pública en Colombia	Francisco A. Rossi B. y Claudia M. Vargas P.
97	August 2019	Intellectual Property under the Scrutiny of Investor-State Tribunals Legitimacy and New Challenges	Clara Ducimetière
98	September 2019	Developing Country Coalitions in Multilateral Negotiations: Addressing Key Issues and Priorities of the Global South Agenda	Adriano José Timossi
99	September 2019	Ensuring an Operational Equity-based Global Stocktake under the Paris Agreement	Hesham AL-ZAHRANI, CHAI Qimin, FU Sha, Yaw OSAFO, Adriano SANTHIAGO DE OLIVEIRA, Anushree TRIPATHI, Harald WINKLER, Vicente Paolo YU III
100	December 2019	Medicines and Intellectual Property: 10 Years of the WHO Global Strategy	Germán Velásquez
101	December 2019	Second Medical Use Patents – Legal Treatment and Public Health Issues	Clara Ducimetière
102	February 2020	The Fourth Industrial Revolution in the Developing Nations: Challenges and Road Map	Sohail Asghar, Gulmina Rextina, Tanveer Ahmed & Manzoor Illahi Tamimy (COMSATS)
103	February 2020	Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa	Yousuf A Vawda & Bonginkosi Shozi
104	March 2020	Antimicrobial Resistance: Examining the Environment as Part of the One Health Approach	Mirza Alas
105	March 2020	Intersección entre competencia y patentes: hacia un ejercicio pro-competitivo de los derechos de patente en el sector farmacéutico	María Juliana Rodríguez Gómez
106	March 2020	The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership: Data Exclusivity and Access to Biologics	Zeleke Temesgen Boru

107	April 2020	Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents	Carlos M. Correa
108	April 2020	Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective	Thamara Romero
109	May 2020	Non-Violation and Situation Complaints under the TRIPS Agreement: Implications for Developing Countries	Nirmalya Syam
110	May 2020	Estudio preliminar del capítulo sobre propiedad intelectual del acuerdo MERCOSUR – UE	Alejandra Aoun, Alejo Barrenechea, Roxana Blasetti, Martín Cortese, Gabriel Gette, Nicolás Hermida, Jorge Kors, Vanesa Lowenstein, Guillermo Vidaurreta
111	May 2020	National Measures on Taxing the Digital Economy	Veronica Grondona, Abdul Muheet Chowdhary, Daniel Uribe
112	June 2020	La judicialización del derecho a la salud	Silvina Andrea Bracamonte and José Luis Cassinerio
113	June 2020	La evolución de la jurisprudencia en materia de salud en Argentina	Silvina Andrea Bracamonte and José Luis Cassinerio
114	June 2020	Equitable Access to COVID-19 Related Health Technologies: A Global Priority	Zeleke Temesgen Boru
115	July 2020	Special Section 301:US Interference with the Design and Implementation of National Patent Laws	Dr. Carlos M. Correa
116	August 2020	The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic	Frederick Abbott
117	September 2020	Data in Legal Limbo: Ownership, sovereignty, or a digital public goods regime?	Dr. Carlos M. Correa
118	September 2020	Re-thinking Global and Local Manufacturing of Medical Products After COVID-19	Dr. German Velásquez
119	October 2020	TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection	Joshua D. Sarnoff
120	October 2020	Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19	Srividya Ravi
121	November 2020	The World Health Organization Reforms in the Time of COVID-19	German Velásquez
122	November 2020	Analysis of the Overcapacity and Overfishing Pillar of the WTO Fisheries Subsidies Negotiations	Peter Lunenborg

123	November 2020	The United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas: One Step Forward in the Promotion of Human Rights for the Most Vulnerable	Maria Natalia Pacheco Rodriguez and Luis Fernando Rosales Lozada
124	November 2020	Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19	Muhammad Zaheer Abbas, PhD
125	December 2020	Designing Pro-Health Competition Policies in Developing Countries	Vitor Henrique Pinto Ido
126	December 2020	How Civil Society Action can Contribute to Combating Antimicrobial Resistance	Mirza Alas Portillo
127	December 2020	Revisiting the Question of Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – The Need to Rebalance	Daniel Opoku Acquah
128	February 2021	Intellectual Property in the EU–MERCOSUR FTA: A Brief Review of the Negotiating Outcomes of a Long-Awaited Agreement	Roxana Blasetti In collaboration with Juan I. Correa
129	March 2021	The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines	Henrique Zeferino de Menezes
130	April 2021	Misappropriation of Genetic Resources and Associated Traditional Knowledge: Challenges Posed by Intellectual Property and Genetic Sequence Information	Nirmalya Syam and Thamara Romero
131	June 2021	TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space is Retained?	Vitor Henrique Pinto Ido
132	June 2021	Interpreting the Flexibilities Under the TRIPS Agreement	Carlos M. Correa
133	August 2021	Malaria and Dengue: Understanding two infectious diseases affecting developing countries and their link to climate change	Mirza Alas
134	September 2021	Restructuring the Global Vaccine Industry	Felix Lobo
135	September 2021	Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements	Carlos M. Correa, Nirmalya Syam and Daniel Uribe
136	September 2021	Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case	Muhammad Zaheer Abbas, PhD
137	October 2021	The Ocean Economy: trends, impacts and opportunities for a post COVID-19 Blue Recovery in developing countries	David Vivas Eugui, Diana Barrowclough and Claudia Contreras
138	October 2021	Beyond Corporate Social Responsibility: Strengthening Human Rights Due Diligence through the Legally Binding Instrument on Business and Human Rights	Daniel Uribe Terán

139	October 2021	Governing Seed for Food Production: The International Treaty on Plant Genetic Resources for Food and Agriculture	Nina Isabella Moeller
140	November 2021	Del SIDA al COVID-19: La OMS ante las crisis sanitarias globales	German Velásquez

International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

ISSN 1819-6926