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Reclaiming Rights, Rebuilding Lives

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REPORT ON REVIEW OF THE INTELLECTUAL PROPERTY BILL, 2020

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1. INTRODUCTION

In 2020, Kenya through its Ministry of Industrialization and Enterprise Development embarked on a process to consolidate its multiple intellectual property laws including the Trademarks Act, Industrial Property Act and Copyright Act. A comprehensive Intellectual Property Bill 2020 and the Statute ((Miscellaneous Amendments) Act 2020 were proposed to among other things consolidate the various IP Offices i.e., Kenya Copyright Board (KECOBO), Anti-counterfeit Authority (ACA) and Kenya Industrial Property Institute (KIPI) under one office to be called the Intellectual Property Office of Kenya (IPOK). Notably, the merger of the three offices was part of the recommendations contained in the 2013 Presidential Taskforce on Parastatal Reforms and at the time the proposal was to merge the three offices into one, namely the Kenya Intellectual Property Office (KIPO).1 Apart from institutional reforms, the IP Bill will reform the current provisions contained in law on IP protection and enforcement.

The right to health is enshrined under Article 43(1)(a) of the Constitution as follows: 'Everyone has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.' Access to medicine is therefore protected under this Article and should be safeguarded in laws and policies being enacted by the government.

Consequently, the proposed Industrial Property Bill, 2020 will be an important milestone for enhancing access to medicines by ensuring that the flexibilities available under the Industrial Property Bill, 2001 are maintained and strengthened. What is more the IP Bill should also make sure that any attempt

[1]Report of the Presidential Taskforce on Parastatal Reforms, October 2013, p. 107. https://www.scac.go.ke/2015-02-16-09-56-36/reports.

to weaken or undermine the existing TRIPS flexibilities at the national level is defeated.

Therefore, this study audits the IP bill with the intention of identifying not only how the flexibilities have been incorporated in the proposed IP Bill but also identifies any potential provisions that may undermine the full utilization of the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as confirmed by the Doha Declaration, 2001.

The overall objective of the study is to review the Intellectual Property Bill 2020 and develop a policy brief containing recommendations.

The specific objectives of the study are:

a. Review of the Intellectual Property Bill 2020
b. Development of a Policy Brief

2. METHODOLOGY

To develop the preliminary sections, the study utilised a desktop review of key secondary literature to establish the linkages between trade, IP, and access to medicines. Some of the key documents reviewed include TRIPS Agreement; Doha Declaration; the 2020 report of the WHO/WIPO and WTO; the 2016 Report of the UN Secretary General's High-Level Panel; CESCR General Comments Nos 14 and 17; Human Right Council (HRC) and African Commission on Human and Peoples' Rights resolutions among others.
To analyse the issue of TRIPS flexibilities incorporation, the study relied mainly on the 2019 TRIPS study report published by KELIN and CEHURD. The study also referred to the TRIPS Agreement, Industrial Property Act, 2001 and the IP Bill to compare word for word all their provisions relating to TRIPS flexibilities with the intention of identifying any textual disparities that may prove to be significant.

Finally, in relation to TRIPS plus provisions, the study developed a framework of issues using the most common TRIPS plus provisions available currently. The study then used this as a reference to review the IP Bill to identify if there are any notable TRIPS plus provisions that may have been sneaked into the IP Bill.

3. LIMITATION

The study did not delve deep into the issues of trademark, copyright, and anti-counterfeiting legislation since the link between access to medicines and trade has mainly been about patents and affordability of medicines by the less privileged especially in developing countries. There is however no doubt that trademark, copyright and anticounterfeiting has an impact on access to medicines.

4. THE LINKAGE BETWEEN TRADE, IP & ACCESS TO MEDICINES

The link between trade, IP and access to medicines is domiciled in the full utilisation of TRIPS Agreement flexibilities as captured below;

4.1 The WHO/WIPO/WTO Tripartite Arrangement

The World Health Organisation (WHO) pursuant to Health Assembly resolutions and the Global strategy and plan of action on public health, innovation and intellectual property has intensified its collaboration with other international organizations, in particular through trilateral collaboration with WIPO and WTO to foster a better understanding of the linkage between public health and intellectual property policies and enhancing a mutually supportive implementation of those policies.[2] The three global institutions have published a second edition of the report on promoting access to medical technologies and innovation: Intersection between public health, intellectual property and trade.[3] The scope of the study covers

[2]World Health Organization Road map for access to medicines, vaccines and other health products 2019-2023 (2019) pp. 16-17.

[3]'Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, 2nd Edition' (World Trade Organization, World Health Organization and World Intellectual Property Organization, 2020), https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf. The first edition was published in 2013.

both medicines and vaccines as well as 'medical devices, including diagnostics, due to their importance for achieving public health outcomes.'[4] The report notes that the Paris Convention and the TRIPS Agreement are the substantive multilateral standards for patent protection. However, the Paris Convention failed to regulate 'what is considered patentable' until the TRIPS Agreement was adopted in 1995. Prior to the TRIPS Agreement there was considerable diversity in national law and practice in this respect.[5] The report quotes a 1988 WIPO report which cited about '49 countries that either did not grant patent protection for pharmaceutical products at all or only provided a limited form of such protection.'[6] On TRIPS flexibilities, the report notes that there is currently an agreement in place between WIPO and WHO of 22 December 1995 whereby

WIPO provides legal and technical assistance relating to the TRIPS Agreement. Government Offices in charge of drafting laws frequently request advice from WIPO regarding how to use the TRIPS flexibilities in their countries. Advice is provided after careful consideration of the flexibilities, consistency in relation to the TRIPS Agreement and their legal, technical, and economic implications. However, the ultimate decision regarding the choice of legislative options lies exclusively with each individual member state.[7]

In line with the above, the WHO's Road map for access to medicines, vaccines, and other public health products 2019-2023 provides for technical support and capacity building and among the deliverables expected is

Technical support provided (as appropriate, upon request, in collaboration with other competent international organizations), including to policy processes and to countries that intend to make use of the provisions contained in TRIPS, such as the flexibilities recognised by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to TRIPS, in order toto promote access to pharmaceutical products….[8]

4.2 Committee on Economic, Social and Cultural Rights

The Committee on Economic, Social and Cultural Rights (CESCR) has canvassed this issue under both General Comment No. 14 and General Comment No. 7 on the right to health (article 12) and the right of everyone to the benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15(1)(c) of the International Covenant on Economic, Social and Cultural Right (ICESCR) respectively. Moreover, the African Commission on Human and Peoples' Rights has also addressed this issue in its resolution 141 on access to health and needed medicines in Africa. The CESCR General Comment No. 14 (2000) on the right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights) provides for the availability, accessibility, acceptability, and quality right to health framework.[9] In relation to economic accessibility (affordability), the CESCR notes that "health facilities, goods and services must be affordable for all." One of the core obligations provided for under General Comment No. 14 is the obligation "[t]o provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs."[10] The CESCR

[4]Ibid, 27.

[5]Ibid, 66.

[6]Ibid. See also Annex II of the WIPO document MTN.GNG/NG11/W/24/Rev.1. page 96.

[7]Ibid, 91. For a copy of the Agreement see also https://www.wipo.int/treaties/en/text. jsp?file_id=305582. See particularly Article 4 of the Agreement on legal assistance and technical cooperation.

[8]WHO's Road map for access to medicines, vaccines and other public health products, 2019-2023, page 46, https://apps.who.int/iris/bitstream/handle/10665/330145/9789241517034-eng.pdf?sequence=1&isAllowed=y.

[9]E/C.12/2000/4, 11 August 2000, Para 12.

[10]Ibid. para 43(d).

General Comment No. 17 (2005) on the right of everyone to the benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1(c), of the Covenant), provides that "The right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions cannot be isolated from the other rights recognized in the Covenant. State parties are therefore obliged to strike an adequate balance between their obligations under article 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant."[11] General Comment No. 17 specifically notes that "State parties thus have a duty to prevent unreasonably high costs of access to essential medicines, plant seeds or other means of food production, or schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education."[12]

4.3 Human Rights Council

The Human Rights Council (HRC) has also adopted numerous resolutions insisting on the full utilisation of TRIPS flexibilities to promote access to medicines. The latest is HRC resolution 50/13 on access to medicines, vaccines and other health products in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health adopted on 7 July 2022.[13] This resolution "calls upon States to promote timely, equitable and unhindered access to safe, effective, quality and affordable medicines, vaccines, diagnostics and therapeutics, and other health products and technologies, for all, including through the full use of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provide flexibility for that purpose, while recognizing that the protection of intellectual property is important for the development of new and innovative medicines and vaccines, and the concerns about its effects on prices and public health."

4.4 UN High Level Panel

In November 2015 and in line with the vision 2030 agenda and a recommendation by the Global Commission on HIV and the Law, the UN Secretary-General Ban Ki-moon appointed a High-Level Panel on Innovation and Access to Health Technologies. The Panel published its report in September 2016.[14] In relation to the right to health, the report observes that the exigencies of trade dictate how the rules that spur innovation and govern their protection and diffusion evolve it is crucial 'that national and multilateral policies balance objectives: trade promotion and liberalization versus protection of domestic industries and citizens.'[15] Accordingly, the flexibilities under the TRIPS Agreement should 'enable signatories to tailor and employ national intellectual property law, competition law, medical regulations and procurement laws to fulfil their human rights and public health obligations.' [16]

4.5 The African Commission on Human and Peoples' Rights

The African Commission on Human and Peoples' Rights resolution 141 on access to health and needed medicines in Africa is based on article

[11]E/C. 12/GC/17, 12 January 2006, para 35.

[12]Ibid

[13]A/HRC/RES/50/13.

[14]Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies, September 2016, https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

[15]Ibid, 17.

[16]Ibid,18.

16 of the African Charter on Human and Peoples' Rights on the right to enjoy the best attainable state of physical and mental health and that States must ensure that everyone has access to medical care.[17] It calls on states "to promote access to medicines by refraining from measures that negatively affect access such as implementing intellectual property policies that do not take full advantage of all flexibilities in the WTO Agreement on Trade Related Aspects of Intellectual Property that promote access to affordable medicines, including entering "TRIPS Plus" free agreements."[18]

5.0 PUBLIC HEALTH-RELATED TRIPS AGREEMENT FLEXIBILITIES AND IP BILL

To safeguard public health, there are certain flexibilities contained under the TRIPS Agreement as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health (2001).

[17]ACHPR/Res.141(XXXXIV)08

[18]Ibid

TRIPS Agreement Flexibilities	Explanation[19]	How it is captured currently in the Kenyan IP Law	How it is captured in the proposed IP Bill	Recommendation
TRIPS Article 6: Exhaustion/ Parallel imports: For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.	Goods legitimately placed on another market may be imported from another market without permission of the right holder because of the exhaustion of the patent holder's exclusive marketing rights.	Section 58(2) of the IPA, 2001 provides: 'The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.	Clause 84(2) provides: The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya by the owner of the patent or with his express consent.	International exhaustion principle maintained, and the scope expanded to include the consent of the owner as a means to exhaust rights which was previously missing under IPA, 2001.
TRIPS Article 27: Patentability criteria Article 27(1) provides: Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.	WTO Members may develop their own definitions of 'novelty', 'inventive step' and 'industrial application.' They can also refuse to grant patents for certain subject matter, e.g., plants and animals.	Section 22(1) of the IPA, 2001 provides for the protection of new inventions as follows: '[a] n invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use.'	Clause 48 of the IP Bill Provides: "An invention is patentable if it is new, involves an inventive step, and is industrially applicable.	Kenya's patentability criteria under IPA, 2001 is arguably low, meaning that ever-greening of patents is possible in Kenya. The IP Bill has remedied the situation by removing "new use" as part of the criteria for patentability. India Patent Law Section 3(d) is best practice:

[19]Adopted from the UN High Level Panel Report, page 18.

				The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine, or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable.
Article 30: General exceptions & "Bolar" exception	WTO Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.	In Kenya, a Bolar exception is provided for under section 58(1) which provides that "[t]he rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research."	Clause 84(1) provides: The rights under the patent shall extend only to acts done for industrial or commercial purposes and not to acts done for scientific research.	No change observed.

TRIPS Article 31: Compulsory licensing	A non-voluntary license may be granted by a duly authorised administrative, quasi-judicial or judicial body to a third party to use a patented invention without the consent of the patent holder, subject to the payment of adequate remuneration in the circumstances of each case.	Compulsory licensing is provided for under sections 72 to 78 of the Industrial Property Act, 2001. Section 75(2)(b) provides for limited predominant supply of the domestic market.	Clause 84(5) provides: The rights under the patent shall be limited by the provisions on compulsory licenses for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions. Clauses 97-102 deals with the details of compulsory licensing under the IP Bill. Clause 100(b) on grants and terms of compulsory licenses provides for its limitation predominantly for the supply of the domestic market.	The limitation on predominant supply of the domestic market can be improved to allow for EAC supply and supply under AfCFTA or any country with no or limited manufacturing capacity.
Article 31: Government use	A government authority may decide to use a patent without the consent of the patent holder for public, non-commercial purposes, subject to the payment of adequate remuneration in the circumstances of each case.	Government use orders are dealt with under section 80, 'Exploitation of the patented inventions by the Government or by third persons authorized by the Government or government use' Section 80(1)(9) provides that the exploitation of the invention pursuant to an order under this section shall be primarily for the supply of the market in Kenya.	Clause 105 allows for exploitation of the patented inventions by the Government or by third persons authorised by the government. Clause 105(13) provides that the exploitation of the invention pursuant to an order under this section shall be primarily for the supply of the market in Kenya.	See previous recommendation on compulsory licensing and especially in relation to supplying EAC market/ AfCFTA markets.

TRIPS Articles 8, 31 (k), 40: Competition-related provisions	Members may adopt appropriate measures to prevent or remedy anti-competitive practices relating to intellectual property. These include compulsory licenses issued based on anti-competitive conduct and control of anti-competitive licensing.	The IP Act, 2001 section 80(1)(b), also empowers 'the Managing Director of KIPI to recommend the issuance of a government use order by the Minister for Trade where the Managing Director determines that the manner of exploitation of an invention by the owner of a patent, or licensee thereof, is not competitive.'	Clause 105(1)(b) provides that one of the conditions for exploiting a patented invention by government shall be when the Director General determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive.	No change observed.
Patent term TRIPS Article 33 provides the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.	The term of a patent is the maximum time during which it can be maintained in force.[20]	Section 60 of the IPA, 2001: A patent shall expire at the end of twenty years from the filing date of the application.	Clause 86 provides: A patent shall expire at the end of twenty years from the filing date of the application.	No change observed.
Patent term opposition (TRIPS Article 62(5) of the TRIPS Agreement contemplates patent term opposition but does not distinguish whether its pre or post-grant opposition.)		Kenya's patent law implements a revocation as opposed to an opposition procedure under its section 103(2), which provides that "[a] n interested person may,	Clause 129 provides: Any interested person may institute proceedings instituted against the owner of a patent…request the tribunal to revoke or invalidate the patent…	No pre-grant opposition process provided for.

[20]https://en.wikipedia.org/wiki/Term_of_patent.

		within a period of nine months from the date of publication of the grant of a patent…request the Tribunal to revoke or invalidate the patent….”	Subsection 2 provides that the owner means a holder of patent.	
Right of a prior user	A prior user right is the right of a third party to continue the use of an invention where that use began before a patent application was filed for the same invention. Prior user rights are provided for by the different national legislations and such provisions in national legislation only have national effect.[21]	Section 56 (1) of the IPA, 2001. Notwithstanding the provisions of section 54, a patent shall have no effect against any person (hereinafter referred to as “the prior user”) who, in good faith, for the purposes of his enterprise or business, before the filing date or, where priority is claimed, the priority date of the application on which the patent is granted, and within the territory where the patent produces its effect, was using the invention or was making effective and serious preparations for such use; any such person shall have the right, for the purposes of his enterprise or business, to continue such use or to use the invention as envisaged in such preparations.	Clause 82(1): Notwithstanding the provisions of section 105, prior use of a patent shall have no effect against any person (hereinafter referred to as “the prior user”) who, in good faith, for the purposes of his enterprise or business, before the filing date or, where priority is granted, and within the territory where the patent produces its effect, was using the invention or was making effective and serious preparations for such use; any such person shall have the right, for the purposes of his enterprise or business, to continue such use or to use the invention as envisaged in such preparations.	No change observed.

[21] https://www.uspto.gov/sites/default/files/ip/global/prior_user_rights.pdf

6.0 OTHER IMPORTANT OBSERVATIONS

There are other observations that were made in the IP Bill that may have an impact on access to medicines.

First, clause 4(e) on guiding principle provides protection and promotion of intellectual property as a guiding principle. However, there is no mention of full utilisation of TRIPS Agreement flexibilities in that section or anywhere else in the document.

Second, this same trend is observable in clause 6(3)(a) dealing with the IP strategy whereby the full utilisation of TRIPS Agreement flexibility is completely left out.

Last, another relevant clause of interest is clause 8(f) which deals with the functions of the intellectual property office of Kenya and provides that the Office shall advise the government through the Cabinet Secretary on relevant policies and measures on intellectual property. One only hopes that the same will include matters to do with public health and access to medicines which can be addressed through the full utilisation of TRIPS Agreement flexibilities. Better clarity is needed in that provision.

7.0 TRIPS-PLUS PROVISIONS

Apart from the flexibilities available under the TRIPS Agreement as confirmed by the Doha Declaration, there is increasingly reliance on bilateral and regional free trade agreements (FTAs) between governments which has progressively expanded the protection of patent and test data protection on health technologies.[22] The "TRIPS-plus" provisions 'further exacerbate policy incoherence by narrowing the options provided by the TRIPS Agreement and the Doha Declaration for governments to ensure that intellectual property protection and enforcement does not undermine their human rights obligations and public health priorities.'[23] Luckily, the draft IP Bill does not have controversial provisions that are common in many FTAs relating to: patent linkage; data exclusivity/ pharmaceutical data protection; biologics; and patent term extensions.

8.0 CONCLUSION

The study has established that most of the gains made under the IPA, 2001 have been maintained in the current proposed IP Bill. In fact, there are some improvements including on the patentability criteria by the removal of new uses. However, the same can be strengthened by adopting the Indian section 3(d) which makes it hard to register weak patents and therefore help in curbing the ever-greening of patents. Another unique feature of the IP Bill is that it has maintained the international exhaustion principle and even went further to expand the means through which rights can be exhausted to include consent by the owner of a patent. This is unique and commendable because it allows for greater market access in terms of parallel importation.

Some misses were also observed. For instance, the provisions on compulsory licensing still insist on the limitation on predominant supply of the domestic market which can be legally improved to allow for EAC supply and supply under AfCFTA or in fact any country with no or limited manufacturing capacity. The IP Bill should also consider providing for a pre-grant opposition process instead of the current revocation or invalidation process. It is interesting though that the nine months period after the publication of the grant of a patent has been removed from the IP Bill.

The IP Bill also has some provisions that could be improved to embrace for example full utilization of TRIPS flexibility as a guiding principle.

Lastly, the Act has generally avoided the TRIPS plus pitfalls that is associated with many FTA. This is important because TRIPS-plus provisions undermine the policy space necessary to intervene in relation to public interest which includes public health and access to medicines.

[22]Report of the UNSR High Level Panel, page 19.

[23]Ibid

KELIN
Reclaiming Rights, Rebuilding Lives

NAIROBI OFFICE
Kuwinda Lane, Off Lang'ata Road, Karen C
P O Box 112 - 00202, KNH Nairobi
Tel: +254 020 2515790
Mobile: +254 710 261 408 / +254 788 220 300
Fax: 020 386 1390

KISUMU OFFICE
Nyalenda Railways Estate, Block 9/220
Off Nairobi Road Opposite YMCA
P.O Box 7708 - 40100, Kisumu - Kenya
Tel: +254 057 204 1001/+254 020 251 5790
Cell: +254 716 978 740/+254 710 261 408