

# IMPACT OF FREE TRADE AGREEMENTS ON ACCESS TO MEDICINES IN KENYA





# Table of Contents

<b>ACKNOWLEDGEMENT</b> .....	4
<b>ACRONYMS</b> .....	5
<b>1.0: INTRODUCTION:</b> .....	6
Background.....	7
<b>GENERAL OVERVIEW OF FREE TRADE AGREEMENTS, INTELLECTUAL PROPERTY RIGHTS AND TRIPS AGREEMENT</b> .....	<b>8</b>
FREE TRADE AGREEMENTS (FTAS) .....	8
KENYA - TRADE AGREEMENTS.....	8
INTELLECTUAL PROPERTY RIGHTS .....	8
Patents.....	9
Copyrights .....	9
Trademarks.....	9
Industrial Designs .....	9
Trade Secrets.....	9
Geographical Indications.....	9
TYPES OF MEDICAL PATENTS .....	9
Medical Device .....	9
Chemical Products and Pharmaceutical Drugs .....	10
Health Care Information Technology.....	10
Medical and Surgical Methods .....	10
Regenerative Medicine .....	10
<b>LEGAL AND INSTITUTIONAL FRAMEWORK LAWS / CONVENTIONS ON IPR</b> .....	<b>11</b>
<b>LEGAL AND INSTITUTIONAL FRAMEWORK ON ACCESS TO MEDICINES IN KENYA AND MANAGEMENT OF HIV /AIDS</b> .....	<b>12</b>
<b>TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS AGREEMENT)</b> .....	<b>15</b>
DOHA Declaration on the TRIPS Agreement and Public Health .....	16
TRIPS Flexibilities.....	17
How Free Trade Agreements with TRIPS PLUS Provisions adversely affect access to medicine .....	18
<b>CASE STUDIES</b> .....	<b>21</b>
<b>CONCLUSION AND RECOMMENDATION</b> .....	<b>25</b>
<b>REFERENCES</b> .....	<b>28</b>

# Acknowledgement

---

The Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) Kenya appreciates Agnes Nduku (Lead consultant) for drafting this report. Special appreciation to the KELIN project team led by Timothy Wafula (Programme Manager, HIV, TB and Key & Affected Populations) and Okania Pesa (Programme Officer, HIV, TB and Key & Affected Populations) for their invaluable support towards the conclusion of this report.

KELIN acknowledges and appreciates the technical and financial support from Aidsfonds Foundation towards this study.

Published April 2025.

Every effort has been made to verify the accuracy of the information contained in this report. All information was believed to be correct as of April 2025. Nevertheless, KELIN cannot accept responsibility for the consequences of its use for other purposes or in other contexts.

## Acronyms

AGOA	African Growth and Opportunity Act
ANDA	Abbreviated New Drug Applications
ARIPO	African Regional Intellectual Property Organization
CEWG	Consultative Expert Working Group
COMESA	Common Market for Eastern and Southern Africa
DRC	Democratic Republic of Congo
EAC	East African Community
FTAs	Free Trade Agreements
GSP	Generalised System of Preferences
HCC	Hepatocellular Carcinoma
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IPR	Intellectual Property Right
KEMSA	Kenya Medical Supplies Authority
KELIN	Kenya Legal & Ethical Issues Network on HIV and AIDS
KIPI	Kenya Industrial Property Institute
LDCs	Least Developed Countries
MEDS	Mission for Essential Drugs and Supplies
NASCOP	National AIDS and STIs Control Programme
NSDCC	National Syndemic Diseases Control Council
PIDOC	Patent Information and Documentation Centre
R&D	Research and Development
RCC	Renal Cell Carcinoma
SACU	Southern African Customs Union (SACU)
STIP	Strategic Trade and Investment Partnership (STIP)
TB	Tuberculosis
TPP	Trans-Pacific Partnership
TPPA	Trans-Pacific Partnership Agreement
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
USTR	United States Trade Representative's
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



## 1.0: INTRODUCTION

Every human being has the right to access the highest attainable standards of health, which is now fully recognized by numerous national laws and treaties. The Universal Declaration of Human Rights postulates that everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services. This right is also provided in Article 16 of the African Charter on Human and Peoples' Rights (Banjul Charter) (1981), which states that "every individual has the right to the best attainable state of physical and mental health." In Kenya, this right is recognized in the Constitution<sup>1</sup> which provides that every person has the right to the highest attainable standard of health and that a person shall not be denied emergency medical treatment.

Medical access entails several dimensions i.e., *availability* at the time of need at a facility within *geographical* reach of the patient; *affordability*, which entails the absence of financial barriers at the point of care; *safety, efficacy* and *quality* of the medicine; and *appropriateness* of the medicine for the patient and the condition being treated, and for the health-care setting.<sup>2</sup> In the context of HIV, access to safe and affordable antiretroviral drugs and other medicines plays a critical role in HIV care. This access is key to the enjoyment of the highest attainable standard of health as guaranteed in the Constitution of Kenya 2010.

WHO Statistics show that globally, an average of 39.0 million people are living with HIV, with Kenya estimated with 1.4 million people living with the disease<sup>3</sup> and 1.2 million people under antiretroviral therapy. Antiretroviral medicines have greatly improved the lives of people living with HIV. However, access to these medicines continues to be impacted negatively by intellectual property barriers, specifically patents.

This view is buttressed by the Kenya Pharmaceutical Policy 2012, which posits that critical and essential medicines remain unaffordable to most Kenyans. These include medicines for chronic illnesses like diabetes and hypertension, essential diagnostics as well as new 2nd and 3rd line essential medicines for the treatment of some infectious diseases like malaria, HIV and TB.

---

<sup>1</sup>Article 43 of the Constitution of Kenya, Laws of Kenya

<sup>2</sup>Kenya Pharmaceutical Policy 2012

<sup>3</sup>National Syndemic Diseases Control Council

## Background

International trade is essential for access to medicines more so antiretroviral drugs, mainly for underdeveloped and developing countries. Free Trade Agreements play a great role in international trade with policy settings, such as patents, tariffs on medicines, pharmaceutical ingredients and medical technologies playing a direct role in their accessibility.

Patents pose several challenges to access to medicines more so in the low and middle-income nations. The World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS) requires a 20-year patent protection for all goods, not excluding pharmaceutical products, which reduces the opportunities for competition within the health sector, particularly production of generic medicines.

Most national intellectual property laws have not incorporated the TRIPS flexibilities, therefore restricting the policy and legal spaces for countries to manage intellectual property from a public health perspective. In reality, underdeveloped and developing countries may not be fully aware of the options available to them, or perhaps they face pressure not to use TRIPS flexibilities to protect public health.

The Doha Declaration on the TRIPS Agreement and Public Health was adopted by WTO Member States in 2001, confirming the importance of public health. This Declaration emphasized the right to use the flexibilities provided in the TRIPS Agreement to enhance access to medicines for nations with low or no pharmaceutical production capacity.

In November 2015, the WTO TRIPS Council adopted an extension of the TRIPS exemption over pharmaceutical products for the least developed countries until January 2033. During this period, the United Nations Secretary-General also announced the establishment of a high-level panel on Intellectual Property and health technologies to recommend remedies for the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in line with improving access to health technologies. The panel was formed following the recommendation of the Global Commission on HIV and the Law.

The main research question in this study is what the impact of Free trade agreements (FTAs) on Access to Medicine in Kenya is.

The main objective of the research is to evaluate the impact of FTAs on access to medicine in Kenya and develop a policy brief.

The specific research objectives included:

- i. To analyse the impacts of FTAs on access to medicine.
- ii. To evaluate the impact of Intellectual Property rights in FTAs and access to medicines.
- iii. To conduct a comparative analysis of case studies of FTAs with IP provisions.
- iv. To give recommendations on safeguarding the right to access on medicine while negotiating FTAs.



## 2.0: GENERAL OVERVIEW OF FREE TRADE AGREEMENTS, INTELLECTUAL PROPERTY RIGHTS AND TRIPS AGREEMENT

### a) Free Trade Agreements (FTAs)

An FTA is an agreement between two or more countries where the countries agree on the reduction or elimination of barriers to trade and investment, among others. Under FTAs, countries agree on certain obligations that affect trade in goods and services, and protections for investors and Intellectual Property rights, among others. FTAs provide certainty and security for traders and investors and are legally binding.

### b) Kenya - Trade Agreements

Kenya has entered into several bilateral and multilateral trade agreements. These include:

#### Multilateral Trade System (MTS)

The World Trade Organization (WTO) is an international organization dealing with the global rules of trade between countries.<sup>4</sup> Kenya has been a member of the WTO since January 1995.

### Regional Markets

Kenya is a member of the East African Community (EAC) and a member of the Common Market for Eastern and Southern Africa (COMESA). Imports and Exports within member countries enjoy preferential tariff rates.

Other agreements that Kenya is party to entail the: ACP/Cotonou Partnership Agreement, the African Growth and Opportunity Act (AGOA), the Generalized System of Preferences (GSP) and bilateral agreements with several countries.<sup>5</sup>

### c) Intellectual Property Rights

Intellectual Property (IP) refers to creations of the mind, such as inventions, literary and artistic works, designs, symbols, names and images used in commerce.<sup>6</sup> Intellectual Property rights enable the owners to earn recognition and financial benefit from what they create or invent. They also foster creativity and innovation.

<sup>4</sup>[https://www.wto.org/english/thewto\\_e/whatis\\_e/whatis\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm)(visited 29/08/2023)

<sup>5</sup><https://www.trade.gov/country-commercial-guides/kenya-trade-agreements>(visited29/08/2023)

<sup>6</sup>World Intellectual Property Organization (WIPO) <https://www.wipo.int> (visited 26/08/23)

## Intellectual Property is classified into:

### Patent

A patent is an exclusive right granted for an invention. It gives the patent owner the right to decide how or whether the invention can be used by others.

### Copyright

These are rights that creators have over their artistic and literary works. The works covered by copyrights range from music, books, paintings, sculpture, films, computer programs, databases, advertisements, technical drawings and maps.

### Trademarks

A trademark is a sign that serves to distinguish the goods of an industrial or a commercial enterprise or a group of such enterprises. The sign may consist of one or more distinctive works, letters, numbers, drawings or pictures, monograms, signatures, colours or combination of colours.<sup>7</sup>

### Utility Model

They constitute any form, configuration, or disposition of element of some appliance, utensil, tool, electrical and electronic circuitry, instrument, handicraft mechanism or other object or any part of the same allowing a better or different functioning, use, or manufacture of the subject matter or that gives some utility, advantage, environmental benefit, saving or technical effect not available before and includes micro-organisms or other self-replicable material, products of genetic resources, herbal as well as nutritional formulations which give new effect.<sup>8</sup>

## Industrial designs

Industrial design is any composition of lines or colours or any three-dimensional form, whether or not associated with lines or colours, provided that such composition or form gives a special appearance to a product of industry or handicraft and can serve as a pattern for a product of industry or handicraft.<sup>9</sup> They constitute the ornamental or aesthetic aspect of an article.

### Trade secrets

These are IP rights on confidential information which may be sold or licensed. The unauthorized use, acquisition or disclosure of such trade secret information in a manner contrary to honest commercial practices by others is regarded as an unfair practice and a violation of trade secret protection.

### Geographical indications

These are defined as indications that identify a good as originating in the territory of a member, a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin.

**This study focuses mainly on patents.**

## Types of Medical Patents

Some of the Medical patents include:

### 1. Medical Devices

This category includes physical devices used by hospitals and physicians. They include items such as diagnostic instruments, implantable devices (prostheses), surgical tools, surgical

<sup>7</sup><https://www.kipi.go.ke/index.php/trademarks> (visited 30/08/2023)

<sup>8</sup>Sec 2 of the Industrial Property Act, Laws of Kenya

<sup>9</sup>Sec 84 ibid

suite equipment, sterilization hoods, patient lifts, patient or monitoring devices, drug and food delivery devices and systems, IV bags, tubing, assisted breathing equipment, patient feeding apparatus, heart/breathing monitoring equipment, heart pacemaker, artificial heart valves etc.

## 2. Chemical Products and Pharmaceutical Drugs

They include chemical compounds such as vitamins, compounds used to manufacture drugs, tissue sterilization and cleaning material, materials used to treat infectious disease (e.g., antimicrobials, vaccines, antibiotics), or a physical condition (such as aging, chemical/hormonal imbalance, e.g. insulin/diabetes, dementia, high blood pressure, Alzheimer's, Parkinson's disease).

## 3. Health Care Information Technology

This focuses on streamlining the flow of medical history information through e-medical records, health information exchange systems within or among hospital systems and/or physicians, patient data, picture archiving web-based medical software applications, computerized physician order entry, digital imaging among others. This category of patents has been the fastest growing in recent years.<sup>10</sup>

## 4. Medical and Surgical Methods

This includes methods and techniques for providing and performing surgical and medical procedures, streamlining procedures for administering care and, or diagnosing

a medical condition, surgical methods for repairing a rotator cuff, and for performing spine surgery to avoid contact with nerves etc. While the US allows for the patenting of medical procedures and treatment methods, more than 80 countries exclude medical procedures from patentability.<sup>11</sup>

## 5. Regenerative Medicine

This category of medical patents includes stem cell therapeutics, tissue transplant technologies e.g., knee cartilage replacement rejuvenation and cosmetic reconstructive procedures. Stem cell therapeutics is the next best and biggest medical innovation in human health care.<sup>12</sup>

### Rights of a Patent Owner

A patent confers upon the owner exclusive rights, in case of a product patent, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing and in case the subject matter of a patent is a process, exclusive rights to prevent others from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.<sup>13</sup>

Patent rights are crucial as they allow pharmaceutical companies to recoup and profit from the high research and development costs infused in making a drug, thus incentivizing the creation of new medication. However, due to the owner's temporary monopoly power, patent rights allow the holder to charge prices for the drug that may be prohibitively high for some developing nations.<sup>14</sup>

<sup>10</sup>Mayfield DL. Medical Patents and How New Instruments or Medications Might Be Patented. *Mo Med.* 2016 Nov-Dec;113(6):456-462. PMID: 30228529; PMCID: PMC6139778

<sup>11</sup>Rastogi, Priyanka, Worldwide: World Wide Legal Status of Medical Method Patents: An Overview, Mondaq,

<sup>12</sup>Using Technology to Improve Health, Kaiser Permanente (last visited 20/08/2023), [https://www.dor.kaiser.org/external/DORExternal/research\\_report/research\\_technology.aspx](https://www.dor.kaiser.org/external/DORExternal/research_report/research_technology.aspx).

<sup>13</sup>Sec 28 1a and 1b of the TRIPS Agreement

<sup>14</sup>Mark C. Lang, What a Long, Strange "TRIPS" It's Been: Compulsory Licensing From the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration, 3 J. MARSHALL REV. INTELL. PROP. L. 331, 331 (2004)



### 3.0: LEGAL AND INSTITUTIONAL FRAMEWORK LAWS / CONVENTIONS ON IPR

Kenya has several legislative instruments on IPR, which include: the Anti-Counterfeit Act (2008); Copyright Act No. 12 of 2001; Industrial Property Act (IPA) No. 3 of 2001; Trade Marks Act Cap 506 and the Seed and Plant Varieties Act, Cap 326.

These acts are administered by three different institutions with separate and distinct parent ministries. The IPA and the Trademarks Act are administered by the Kenya Industrial Property Institute (KIPI) in the Ministry of Investments Trade and Industry.

The Kenya Copyright Board administers the Copyright Act, The Anti-counterfeit Agency administers the Anti-counterfeit Act and the Kenya Plant and Health Inspectorate Service is in charge of the Seeds and Variety Act under the Ministry of Agriculture & Livestock Development.

Kenya is also a member of the African Regional

Industrial Property Office (ARIPO) and the World Intellectual Property Organization (WIPO), which administers the Patent Cooperation Treaty (PCT).

#### Patent administration in Kenya

Kenya Industrial Property Act of 2001 came into effect on 1st May 2002 and aims to provide for the promotion of inventive and innovative activities, to facilitate the acquisition of technology through the grant and regulation of patents, utility models, technovations and industrial designs. The Act provides for the registration of patents and the patentability criteria. It also provides for the enforcement of patent rights and exceptions.

The Kenya Industrial Property Institute (KIPI) grants and regulates patents for inventions and deals with both local and international patents under the relevant national and international instruments.



## 4.0: LEGAL AND INSTITUTIONAL FRAMEWORK ON ACCESS TO MEDICINES IN KENYA AND MANAGEMENT OF HIV /AIDS

Kenya has several institutions and laws involved in the administration of medicine and management of HIV/AIDS. These include:

### Constitution of Kenya

This is the supreme law of the land and provides for the right to health care. Article 43 (1) (a) of the Constitution provides that every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. It goes on to state that a person shall not be denied emergency treatment and that the State shall provide appropriate social security to persons who are unable to support themselves and their dependants.

With this right enshrined in the constitution, this is an indication that Kenya recognizes this right. Further, the State is bestowed with constitutional obligations to ensure that the right to health of the population is fulfilled.

### The HIV and AIDS Prevention and Control Act No 14 of 2006.

This Act postulates the right to access health care and requires every health institution, whether public or private, and every health management organization or medical insurance provider to facilitate access to healthcare services to persons with HIV/AIDS without discrimination based on their HIV status.

The Act also requires the government to take the steps necessary to ensure access to essential healthcare services, including access to essential medicines at affordable prices by persons with HIV/ AIDS and those exposed to the risk of HIV infection.<sup>15</sup>

The Act also establishes the HIV and AIDS Tribunal<sup>16</sup> with powers to hear and determine complaints arising out of any breach of the provisions of the Act.

---

<sup>15</sup>Sec 19 of the Act

<sup>16</sup>Sec 26 of the HIV and AIDS Act

## Pharmacy And Poisons Act CAP 244

This Act has a primary objective of making a better provision for the control of the profession of pharmacy and the trade in drugs and poisons. It defines a drug as to include any medicine, medicinal preparation, or therapeutic substance and medicine as any medicament, curative, or preventive substance, whether proprietary or in the form of a preparation.<sup>17</sup>

The Act establishes the Pharmacy and Poisons Board which has the responsibility of registering drugs, licensing manufacturers, importers, and exporters of drugs/medicine. Further, the Board is concerned with the registration of medical products and health technologies, inspections and enforcement of good practices for manufacturing and distribution, post-market surveillance, clinical trials, vigilance, and appropriate use of products to ensure their quality, safety, efficacy, and economic value.

## The Kenya Health Policy, 2014–2030

This policy gives direction to ensure significant improvement in the overall health status in Kenya in line with the Constitution, Vision 2030, and global commitments.<sup>18</sup> The policy aims to:

- i. Eliminate communicable conditions
- ii. Halt and reverse the rising burden of non-communicable conditions
- iii. Reduce the burden of violence and injuries
- iv. Provide essential health-care
- v. Minimize exposure to health risk factors
- vi. Strengthen collaboration with private and other health-related sectors

## Kenya National Pharmaceutical Policy

The policy succeeds the Kenya National Drug policy of 1994. It aims to guide reforms that are

necessary to be undertaken on pharmaceuticals to attain national health and economic goals, in particular, equitable access to essential medicines, health products, and technologies for the population.

## Consumer Protection Act, 2012

The purpose of the Act is to promote and advance the social and economic welfare of consumers in Kenya, including providing for the protection of the consumer and preventing unfair trade practices in consumer transactions.

The Act provides for the establishment of the Kenya Consumers Protection Advisory Committee with a mandate of advising the Cabinet Secretary on aspects of consumer protection and also the formulation of policy and legislative proposals in the interest of consumers, among other functions.

## National AIDS and STI's Control Programme (NAS COP)

NAS COP was established in 1987 to spearhead the Ministry of Health's interventions in the fight against HIV/AIDS. It operates as a unit within the Ministry of Health and is mainly involved with the technical coordination of HIV and AIDS programmes in Kenya and contribution to the implementation of the Kenya Aids Strategic Framework (KASF).

## National Syndemic Diseases Control Council

This is a State Corporation established under Section 3 of the State Corporations Act, Cap 446, through the National AIDS Control Council Order, 1999, as amended by legal notice number 143 of 2022. The Council is mandated to manage HIV, sexually transmitted infections, malaria, leprosy, tuberculosis, and lung disease.

<sup>17</sup>Sec 2 of the Pharmacy and Poisons Act.

<sup>18</sup><https://ncikenya.go.ke/resources/policies/kenya-health-policy.pdf>

## **Kenya Medical Supplies Authority Act of 2013**

This Act establishes the Kenya Medical Supplies Authority with a primary objective of developing and operating a viable commercial service for the procurement and sale of drugs and medical supplies to public health institutions. Section 4 of the Act provides for the function of the Authority, which entails the procurement, warehousing, and distribution of drugs and medical supplies for prescribed public health programmes, the national strategic stock reserve, prescribed essential health packages and national referral hospitals, among other functions.

This public supply system has in place quality assurance mechanisms, which include quality control testing at the National Quality Control Laboratory (NQCL).

## **Other institutions involved in the supply of medicine**

Private and non-profit organizations involved in the supply of medicines include the Mission for Essential Drugs and Supplies (MEDS), MedSource, owned by Management Sciences for Health, pharmaceutical manufacturers, medicine importers, distributors, wholesalers, and retail pharmacies.



## 5.0: TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS Agreement)

Trade-Related Aspects of Intellectual Property Rights is Annex 1c of the Marrakesh Agreement Establishing the World Trade Organisation signed in Marrakesh on 15th April 1994.

The Agreement came into effect on 1 January 1995, and is to date the most comprehensive Multilateral Agreement on Intellectual Property. It establishes minimum standards for the availability, scope, and use of the various forms of Intellectual Property.

The TRIPS Agreement imposes obligations to members to adhere to and provide minimum TRIPS standards of protection of Intellectual Property, establish comprehensive IPR systems covering patents, copyrights, trademarks, industrial designs, and trade secrets, and to put in place provisions on judicial and administrative procedures relating to dispute settlement, monitoring and review of the implementation of the minimum standards.

To that extent, Member States are also required to observe the following:

- i. Make patents available for any inventions, whether products/goods or processes, in all fields of technology, including patents for pharmaceutical processes and products.<sup>19</sup>
- ii. Allow enjoyment of patent rights without

discrimination as to the product's origin or its place of invention.

- iii. Adopt and incorporate the national treatment and the Most Favoured Nation standards in their national laws as enshrined in the TRIPs Agreement.

Article 27.1 of the TRIPS Agreement states that patents shall be available for any inventions, provided that they are **“new, involve an inventive step and are capable of industrial application.”** These three conditions are recognized as the basic tests of patentability. Disclosure of the invention is also considered as a substantive condition. Novelty/new shows a new characteristic that has not been disclosed before to the public, or that is not anticipated by prior art. This safeguards against the patenting of technologies that are already available and ensures that a patented invention is a genuine contribution to existing knowledge.

Inventive step/non-obvious is understood in many jurisdictions to mean that the invention must represent a sufficient advance concerning the state of the art having regard to the prior art relevant to the application claiming the invention, and that it would not have been obvious to a person skilled in the art.<sup>20</sup>

<sup>19</sup>Article 27 of TRIPS

<sup>20</sup>Sec 24 of the TRIPS Agreement

Industrial applicability means that the invention must be capable of being used in any industry.

The TRIPS Agreement permits members to exclude inventions from being granted a patent even where they would meet the substantive and formal conditions outlined above. This can be done on three grounds, explained below.

- *Ordre public or morality* - members have the discretion of excluding from patent availability, inventions that are considered contrary to *ordre public* or morality.
- *Methods of treatment* - members are allowed to exclude from patentability; diagnostic, therapeutic, and surgical methods for treating humans or animals.
- *Plants and animals* - Members are not required to provide patent protection for plants and animals inventions and their biological processes for their production. They are, however, required to provide patent protection for micro-organisms and non-biological and microbiological processes for the production of plants and animals.

The minimum term of protection that a country must make available under the TRIPS Agreement is 20 years from the filing date of a patent application.

Although patent rights are an important incentive for the development of new health-care products, their protection and enforcement should balance the interests of the holder of the property rights and the consumer. This is supported by Article 7 of the TRIPS Agreement, which provides that the protection and enforcement of Intellectual Property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

## Doha Declaration on the TRIPS Agreement and Public Health

Agreed by WTO members in 2001, the Doha Declaration on TRIPS Agreements and Public Health helped to frame the health policy context of the Intellectual Property system. It emphasised the need for the TRIPS Agreement to be part of the wider national and international action to address public health problems afflicting many developing and least developed countries, such as HIV/AIDS, tuberculosis, malaria, and other epidemics.

The Declaration<sup>21</sup> clarified the TRIPS flexibilities as of direct relevance to public health. Such flexibilities entailed the inclusion of a new mechanism that aims to facilitate access to medicines for WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. Under the mechanism, special compulsory licences can be granted to generic suppliers to manufacture medicines exclusively for export to countries in need.

The Declaration also gave countries the discretion to determine what constitutes a "national emergency" or "other circumstance of extreme urgency." It further affirmed that public crises such as HIV/AIDS, tuberculosis, malaria, and other epidemics can present such circumstances.

Further, the transition period for least developed country members was extended to 1 January 2033 from 1 January 2016. LDCs are thus exempted from any obligation to protect or enforce rights relating to patents or undisclosed information for pharmaceutical products. A General Council decision also waives the obligations to grant exclusive marketing rights and to provide for the possibility of filing mailbox applications for LDC Members until 1 January 2033.

## TRIPS FLEXIBILITIES

The availability of flexibilities in the TRIPS creates the legal space for the production of generic medicines, hence enhancing the right to access to healthcare. UNCTAD considers TRIPS flexibilities as an important element to promote generic pharmaceutical investment and domestic enterprise development under sustainable investment policy frameworks.<sup>22</sup> Under Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all), the full use of TRIPS flexibilities is being targeted to protect public health and to provide access to medicines for all.<sup>23</sup> It, however, notes that for such frameworks to be effective, policymakers should avoid discrepancies between the use of TRIPS flexibilities, the enforcement of Intellectual Property Rights (IPRs), and domestic laws and policies on drug regulation.

TRIPS provides for the following flexibilities:

### a) Compulsory licences

This is a mechanism used by governments/public authorities to authorize the use of a patent-protected invention by the government or third parties without the consent of the patent holder. In return, patent holders are entitled to adequate compensation in the form of a royalty. As per the Doha Declaration, WTO Members are free to determine the grounds upon which compulsory licences may be granted. Practice shows that the licences may be issued on various grounds of general interest, for example, public health, which is a common feature of patent law in both developed and developing countries.

Compulsory licensing allows developing countries to produce or buy generic versions

of the patented medication, thus reducing the cost of the medicine. In compliance with the TRIPS and Doha Declaration, Kenya has provided for compulsory licensing under the Industrial Property Act.

Countries have employed this flexibility successfully. For example, In 2004, Malaysia and Indonesia issued compulsory licenses for the importation of HIV/AIDS medications, becoming the first middle-income countries to do so. Thailand also issued a compulsory license for importation of the generic version of Efavirenz (an HIV/AIDS medication) in 2006. Further, Brazil issued a decree issuing a compulsory license for the Merck-owned HIV/AIDS drug Efavirenez.<sup>24</sup> After the licence was issued, the price of the drug (Efavirenez) dropped from US \$1.60 per dose to US \$0.45 per dose for the imported generic version of the drug. It is estimated that the Brazilian Government's policies and the use of TRIPS flexibilities, saved approximately US \$1.2 billion on antiretroviral drug purchasing costs between 2001 and 2005.<sup>25</sup>

### b) Parallel imports

Parallel importation is a mechanism that allows importers to buy goods from a foreign country for a cheaper price than they would ordinarily buy in their domestic market. Commonly referred to as 'grey goods' parallel imports are often genuine products that have been brought into a market by a rights holder (which may be the trademark owner or licensee) in one territory and then subsequently sold to a third party in a different territory without the consent of the original rights holder. Parallel imports enhance the availability of medicine as they allow countries to import cheaper generic medicines.

<sup>22</sup>For more information on UNCTAD's Investment Policy Framework for Sustainable Development (IPFSD), see [http://www.iisd.org/tool-kits/sustainability-toolkit-for-trade-negotiators/wp-content/uploads/2016/06/diaepcb2012d5\\_en.pdf](http://www.iisd.org/tool-kits/sustainability-toolkit-for-trade-negotiators/wp-content/uploads/2016/06/diaepcb2012d5_en.pdf) (visited 31/08/2023)

<sup>23</sup>[https://unctad.org/publication/trips-flexibilities-and-anti-counterfeit-legislation-kenya-and-east-african-community#:~:text=UNCTAD%20considers%20the%20use%20of,under%20sustainable%20investment%20policy%20frameworks.\(visited%2031/08/2023\)](https://unctad.org/publication/trips-flexibilities-and-anti-counterfeit-legislation-kenya-and-east-african-community#:~:text=UNCTAD%20considers%20the%20use%20of,under%20sustainable%20investment%20policy%20frameworks.(visited%2031/08/2023))

<sup>24</sup>Vera Zolotaryova, 2008, Are We There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication, Brooklyn Journal of International Law, Volume 33, Issue 3 <https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1209&context=bjil> (Visited on 27/08/23)

<sup>25</sup>Ibid

Section 58 of the Kenya Industrial Property Act provides for the exhaustion of rights allowing for parallel importing of medicines in the country. This has become the most utilized TRIPS flexibility in the country. KELIN posits that when parallel importation began in Kenya, the price of ARVs became as low as KSh 500 (about USD 6) a month, down from KSh 6000 (about USD 75) a month only in one year.

### c) Bolar provision/regular exception

This permits the use of a patented invention without authorization from the patent owner to obtain marketing approval for a generic product before the patent expires. It allows a generic product to enter the market more quickly after patent expiry, facilitating access to cheaper medicines. Mexico has taken advantage of this exception. While its Industrial Property Act establishes the exclusive rights conferred by a patent, the Health Commodities Regulations establishes that registration of the generic form of a drug whose active substance or ingredient is patent protected may be requested during the three years<sup>26</sup> before the patent's expiration to conduct research, tests, and experimental production, on the understanding that, in such cases, sanitary registration shall not be granted until the patent has expired. This has made it possible to import a primary or active substance that is patent-protected. The application of this exception has been successful, and generic drugs have been granted sanitary registration in a timely and adequate manner while respecting patent rights.

### d) Exemptions for least developed countries

The Doha Declaration extended the transition period for least developed country members to 1 January 2033 from 1 January 2016. This extension frees LDCs from TRIPS obligations in pharmaceuticals till 2033 or until the economic status of the country changes from being an LDC.

## How Free Trade Agreements with TRIPS PLUS Provisions adversely affect access to medicine

TRIPS-plus provisions in the regional and bilateral free trade agreements are intellectual property provisions that go beyond the minimum standards required by TRIPS. They impede access to medicine through:

### a) Restricting Patent Oppositions

Monopolies granted by patents on medical products keep prices high and block local manufacturers from supplying low-cost generic drugs. Opposition proceedings play a critical role in the patenting process as it provides an additional administrative layer of review that prevents the grant of invalid patents through the participation of third parties in the review process.<sup>27</sup> It ensures that only those inventions that are “worth” protecting for the purposes of facilitating innovation and meeting the broad public interest would obtain patent protection.

However, some FTAs and laws prevent opposition proceedings pre-patent grants. A good example is the **US-Bahrain FTA**. Entered into force on 11 January 2006, the FTA restricts patent opposition. Article 14.8 (4)<sup>28</sup> states that “Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available prior to the grant of the patent.”

Further, a closer glance home at the Kenyan Industrial Property Act shows that it does not provide for pre-patent grant opposition. The public can only oppose a patent once the same has already been granted.

<sup>26</sup><https://www.engage.hoganlovells.com/knowledgeservices/news/mexico-new-federal-law-for-protection-of-industrial-property-amendments-to-federal-copyright-law-criminal-code> (Visited on 31/08/23)

<sup>27</sup>[https://www.wipo.int/scp/en/revocation\\_mechanisms/opposition/index.html#:~:text=A%20pre%E2%80%91grant%20opposition%20system,the%20validity%20of%20granted%20patents.](https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html#:~:text=A%20pre%E2%80%91grant%20opposition%20system,the%20validity%20of%20granted%20patents.) (Visited on 31/08/23)

<sup>28</sup>[https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset\\_upload\\_file211\\_6293.pdf](https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset_upload_file211_6293.pdf) (Visited on 31/08/23)

Without patent oppositions, invalid patents would be granted. Patent owners would have a monopoly over obvious processes, hence impeding innovation and manufacturing of drugs. Access to medicine would, in turn, be hampered. Studies have shown that in the context of lifesaving and essential medical products, patent oppositions in India have successfully prevented undeserved patent monopolies, allowing timely generic production and supply to bring the price of medicines down for patients and health programmes both in India and across the world.<sup>29</sup>

### b) Extending the patent duration

This prolongs the patent monopoly and further restrains the entrance of generic competitors to the markets. The US -Bahrain FTA Article 14.87 states inter alia *“When a Party provides for the grant of a patent on the basis of a patent granted in another territory, that Party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other territory.”*

Extending patent duration is a Trips-Plus provision that inhibits competitions as generic competitors can not manufacture generic drugs. Studies found that TRIPS-plus provisions in the proposed Thailand-United States FTA would have resulted in consumer welfare losses<sup>30</sup> an increase in drug expenditure and a delay in the market entry of generics.<sup>31</sup>

### c) Broadening Patentability

The TRIPS Agreement does not require patent protection of new uses or new forms of known

substances. However, there have been efforts to introduce provisions that allow the patenting of new forms and new uses of known substances, which create the threat of “evergreening” of pharmaceutical patents. Evergreening extends patent protection by introducing modifications on the molecules that do not significantly improve the therapeutic effect of medicines or in the case of new uses of known substances, demand patent protection for discovery of new uses, rather than actual invention.

### d) Test Data Exclusivity

Data exclusivity is the provision of protection of test data produced by pharmaceutical companies during the clinical trials and during the development of new chemical entities or NCEs for a certain specified period, so that no third party can use that data or no other company can ask for market approval based on that data before that period.

This adds an extra layer of protection for the drugs irrespective of the patent protection status, thus controlling access to medicine. Article 39.3 of the TRIPS Agreement does not require testing data exclusivity while it protects undisclosed data from unfair commercial use. However, some FTAs have required countries to adopt and implement such measures.

In the case of the ***Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union***, Lexchin<sup>32</sup>, opines that the data exclusivity provisions would have increased the average duration of market exclusivity for patented drugs by 358.4 days, or 0.98 years, which would bring an additional yearly cost of \$C795 million, or 6.2% of the total annual cost of patented drugs. If data exclusivity were extended to non-innovative

<sup>29</sup>[https://msfaccess.org/sites/default/files/2022-07/IP\\_TechBrief\\_India%20Pre-Grant%20Opposition%20FAQ\\_Eng\\_July2022.pdf](https://msfaccess.org/sites/default/files/2022-07/IP_TechBrief_India%20Pre-Grant%20Opposition%20FAQ_Eng_July2022.pdf) Last accessed on 8/11/2023.

<sup>30</sup>Yoongthong T. Social cost of market exclusivity extension for patented medicines in Thailand: analysis of the effect of trips-plus provisions. Bangkok: National Institute of Development Administration; 2012

<sup>31</sup>Kessomboon N, Limpananont J, Kulsomboon V, Maleewong U, Eksaengsri A, Paothong P. Impact on access to medicines from TRIPS-Plus: a case study of Thai-US FTA. Southeast Asian J Trop Med Public Health. 2010;41(3):667–677

<sup>32</sup>CETA and pharmaceuticals: impact of the trade agreement between Europe and Canada on the costs of prescription drugs. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4108121/> (Visited on 31/08/23)

drugs, the average delay would increase by 741 days, or 2.03 years, representing an additional yearly cost of \$C1,645 million, or 12.9% of the total costs of patented drugs.

### e) Patent Registration Linkage

Some FTAs also impose patent registration linkages, which would prevent the approval of new medicines by national drug regulatory authorities if they could potentially infringe existing patents. With such provisions, national regulatory authorities are discouraged from registering new medicines and may be forced to deregister medicines, even when there is no proof that a patent has actually been violated.

There is growing evidence that this trend exerts a negative impact on public health. A recent study in Thailand projected that if a 10-year patent extension were granted as proposed under the Thai-US FTA, the following negative consequence would accrue over the next 20 years: a 32% increase in the price index for medicines; spending on medicines would increase from baseline to approximately USD 11,191 million with the domestic industry losing USD 3,370 million.<sup>33</sup>

Patent linkage and the data exclusivity provisions have a harrowing effect on generic competition and compulsory licensing. According to Abbott, they are designed to prevent registration and marketing approval of generics and appear designed to negate the effective use of compulsory licensing by blocking the marketing of third-party medicines during the term of patents.<sup>34</sup>

### f) Stringent enforcement of Intellectual property rights

Increased intellectual property enforcement can impede medicine access. A good example is the seizure of essential medicines from India to various developing countries by European customs authorities on at least 17 occasions while in transit through the EU in 2008- 2009. The seizures took place on the suspicion that medicines violated fictional patent and, or trademark rights even though the medicines were lawfully produced in India and could be lawfully sold and consumed in destination countries. One of the shipments seized was a 49-kilogram consignment of abacavir sulfate tablets (an antiretroviral drug) purchased by UNITAID destined for Nigeria.<sup>35</sup>

---

<sup>33</sup>Ibid

<sup>34</sup>Abbott, Frederick The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements, Quaker United Nations Office, Occasional Paper 14, April at <http://www.quno.org> 1, 7 (2004)

<sup>35</sup>Supra note 3



## 6.0: CASE STUDIES

### A case study of Thai-US FTA

In 2003, the US and Thailand agreed to negotiate a bilateral free trade agreement. Nusarapon conducted a study<sup>36</sup> to assess the impact of the Thai-US Free Trade Agreement on access to medicines in Thailand. The first interpretation was of the sixth round table of Thai-US negotiations in 2006 on intellectual property rights (IPR). A macroeconomic model was used to assess the impact of the IPR on access to medicines. The estimated impact was based on the current IPR situation and the proposed changes to IPR. The FTA TRIPS Plus provisions entailed patent period extension, which dealt with compensation for delays in patent registration and, or drug registration, data exclusivity that would result in a delay in generic drug entry, and the enforcing role of the Thai Food and Drug Administration of patent linkages. The worst case scenario for this single provision, a 10-year patent extension would be given to compensate for delays in patent and, or drug registration. As per the study, the impact on access to medicine, in the year 2027 would be as follows:

*With a 32% increase in the medicine price index, spending on medical drugs would increase to approximately USD 11,191 million (USD1 = THB 33.9 on September 2, 2009), and the domestic industry could lose USD 3.3 million.*

These results clearly suggest that there would be a severe restriction on the access to medicines under the TRIPS-Plus proposal and they should be excluded from FTA negotiations.

### TRIPS Agreement In Latin America and Caribbean Countries and Its implication on public health

Oliveria et,<sup>37</sup> conducted a study of Latin America and Caribbean countries to determine whether implementation of the TRIPS Agreement in these countries had generated patent legislation that is sensitive to public health needs.

The study analysed eleven legislations in 11 Latin American and Caribbean countries. The issued analysed entailed: the term of patents issued,

---

<sup>36</sup>Supra note 31

<sup>37</sup>Oliveira, M. A., Bermudez, J. A., Chaves, G. C., & Velásquez, G. (2004). Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health? *Bulletin of the World Health Organization*, 82(11), 815–821.

patentable subject matter, transition periods (that is, time until legislation was enacted), reversal of the burden of proof of patent infringement, exhaustion of rights, compulsory licensing and the early working exception (which allows a country to complete all procedures necessary to register a generic product before the original patent expires).<sup>38</sup>

The findings indicated that all the countries studied had reformed their legislation to conform to the TRIPS by the year 2000. Brazil and Argentina used the transition period until 2005 to grant patents in the pharmaceutical industry. Further, all countries except Panama, made use of the safeguards and flexibilities available through the agreement by including mechanisms for compulsory licensing in their legislation. Argentina, Bolivia, Peru, Colombia, Ecuador, Venezuela, Panama, and the Dominican Republic included mechanisms for parallel importation. Mexico did not. Brazil only permits parallel importation after a compulsory licence has been issued.

It was observed that not all countries had incorporated all of the TRIPS flexibilities and were not adequately taking advantage of them to obtain better health for the public, regarding gaining access to medicines. The study forecasted that the situation may deteriorate in the future if other agreements established more restrictive rules for intellectual property rights.

## Patenting in India

India is a leading producer of generic medicines and caters to most developing nations by providing lower-priced drug formulations. The Indian pharmaceutical industry is also one of the leading filers of Abbreviated New Drug Applications (ANDA) in the USA and further, supplies finished formulations to the European region.

Initially, the Indian patent law did not allow product patents. Only process patents could be granted for inventions relating to food, drugs, and

chemicals. This contributed to the flourishing of the Indian pharmaceutical industry. For example, Indian pharmaceutical manufacturer Cipla, in 2001 produced the first generic fixed-dose combination antiretroviral therapy that was traded to non-governmental organizations (at US\$ 350 per patient per year) and African governments (at US\$ 600 per patient per year).<sup>39</sup> This cost was less than US\$ 1 per day (less than half the cost of the three originator drugs). The Cipla single-pill generic drug revolutionized HIV/AIDS care in the developing world by simplifying treatment and kick-starting a process of expanding access to antiretroviral therapy through further price reductions in underdeveloped and developing countries.

However, In 2005, India amended its Patent Act to make it fully TRIPS-compliant to grant patents to pharmaceutical products. Despite the move, India preserved most of the important flexibilities provided within TRIPS, hence securing the capacity of its industry to produce and export affordable, and non-patented medicines.<sup>40</sup> The salient features of the amended Indian Act entailed:

- *Extension of product patent protection to products in sectors of drugs, foods and chemicals.*
- *The term for protection of product patent shall be for 20 years.*
- *Introduction of a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity, provided such importing country has either granted a compulsory license for import or by notification or otherwise allowed importation of the patented pharmaceutical products from India (per the Doha Declaration on TRIPS and Public Health)*
- *Inclusion of Section 3 (d) regarding patentability, which prohibited patenting of*
- *the mere discovery of a new form of a*

<sup>38</sup>Ibid

<sup>39</sup>Intellectual Property and access to health technologies [https://www.unaids.org/sites/default/files/media\\_asset/JC2820\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/JC2820_en.pdf) (Visited on 31/08/23)

<sup>40</sup>Vipin Mathur, Patenting of Pharmaceuticals: An Indian Perspective

*known substance that does not result in the enhancement of the known efficacy of that substance, 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.*<sup>41</sup>

The patent law provided the grounds for issuance of a Compulsory license, which include: (i) the reasonable requirements of the public concerning the patented invention have not been satisfied, or (ii) the patented invention is not available to the public at a reasonably affordable price, or (iii) the patented invention is not worked in the territory of India. However, a compulsory license can be granted only after the expiration of three years from the date of the patent grant.<sup>42</sup>

The compulsory licensing provision has so far been successfully employed to enhance access to medicine. In the landmark case of **“Natco Pharma Ltd (India) vs Bayer Corporation, (USA)”**, the Controller of Patents granted the first compulsory license for patents in India to Natco Pharma Ltd in patent number 215758 granted to M/S Bayer Corporation.<sup>43</sup> The patent related to the Sorafenib tosylate drug sold under the brand name Nexavar by Bayer. Nexavar is indicated in Renal Cell Carcinoma -RCC (kidney cancer)<sup>44</sup> and Hepatocellular Carcinoma – HCC (liver cancer). By this ruling, Natco was entitled to manufacture and sell a generic version of Nexavar in RCC and HCC. Natco was also required to pay a 6% royalty on the net sales to Bayer at the end of each quarter. Further, it was not allowed to charge more than Rs 8800 for a monthly dose of 120 tablets of

the drug. Basing the ruling on section 84 of the Indian Patent Act, the Controller found that the reasonable requirements of the public concerning the patented invention had not been satisfied since only 2% of the total kidney, and liver cancer patients were able to access Bayer’s drug and the patented invention was not available to the public at an affordable price as Bayer was charging about Rs 2.8 lakhs for therapy of one month of the drug. The Controller also found that the patented invention was also not worked in the territory of India since Bayer was not manufacturing the product in India.<sup>45</sup>

### Analysis of the impact of the Kenya-US FTA had it been implemented in Kenya

In March 2020, the United States (US) and Kenya officially made known their intention to negotiate a bilateral free trade agreement. IP featured heavily in the negotiating objectives laid out by the US, with it seeking provisions governing intellectual property rights that reflect a standard of protection similar to that found in their law, including, but not limited to, protections related to trademarks, patents, copyright, and related rights (undisclosed test or other data, and trade secrets).<sup>46</sup> The inclusion of these provisions in the agreement would have negatively affected access to medicines.

Kenya and the US both adhere to the standards set out in the TRIPs Agreement. However, the US has a proven track record of building on the content set out in TRIPs. These provisions include copyright term extensions, patent term extensions and periods of data exclusivity.<sup>47</sup>

According to Dr. Mellisa, Luisa et,<sup>48</sup> If a TRIPs-plus approach to this FTA had been applied, Kenya

<sup>41</sup>Indian Patent Act as amended in 2005

<sup>42</sup>Sec 84 of the Indian Patent law

<sup>43</sup>Supra note 48

<sup>44</sup>Bayer Corporation Vs. Union of India and Others <https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Bayer%20Corporation%20Vs.%20Union%20of%20India%20and%20Others%20IPAB%202013.pdf>

<sup>45</sup>bid

<sup>46</sup>[https://ustr.gov/sites/default/files/Summary\\_of\\_U.S.-Kenya\\_Negotiating\\_Objectives.pdf](https://ustr.gov/sites/default/files/Summary_of_U.S.-Kenya_Negotiating_Objectives.pdf) Last visited on 8/11/2023.

<sup>47</sup><https://orig.africalegalnetwork.com/kenya/news/proposed-us-kenya-fta-impact-kenyas-intellectual-property-laws/> (visited 28/08/2023)

<sup>48</sup>US-Kenya Free Trade Agreement (FTA) between ALN Kenya | Anjarwalla & Khanna (A&K) and the Strathmore University Centre for Intellectual Property and Information Technology Law (CIPIIT-SU) collaborative series <https://orig.africalegalnetwork.com/kenya/news/proposed-us-kenya-fta-impact-kenyas-intellectual-property-laws/> (visited 28/08/2023)

would have had to consider whether it would have to eliminate some of the flexibilities in the TRIPS Agreement assured to its members in pursuit of universal access to medicines.

Further, these provisions could hinder access to medicines in a country with a large population of persons suffering from diseases like HIV/AIDS and tuberculosis. This is because TRIPS-plus standards in the FTA would have meant higher prices on medicines, and limitations on competition from generic products.

Fortunately, these negotiations did not see the light of the day as they were abandoned and the U.S -Kenya Strategic Trade and Investment Partnership (STIP) was launched instead. The STIP aims to increase investment, promote sustainable and inclusive economic growth, benefit workers, consumers, and businesses (including micro, small and medium-sized enterprises), and support African regional economic integration.<sup>49</sup> It focuses

on agriculture, anti-corruption, digital trade, environment and climate action, micro, small, and medium-size enterprises, protecting worker's rights and protections, supporting the participation of women, youth, and others in trade, standards collaboration, trade facilitation and customs procedures, and services domestic regulation.

From these case studies, it is evident that TRIPS Plus provisions hinder access to medicine and that countries should use TRIPS flexibilities to achieve the lowest possible prices for products of assured quality. To retain the benefits of TRIPS Agreement flexibilities, countries, at minimum, should avoid entering into FTAs that contain TRIPS-plus obligations that can impact pharmaceuticals price or availability. While negotiating the STIP, Kenya should ensure that an IP chapter going beyond what is in the TRIPS is not introduced in subsequent negotiations in the best interest of a majority of its citizens.

---

<sup>49</sup><https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/october/united-states-and-kenya-hold-second-negotiating-round-under-strategic-trade-and-investment> Last visited on 8/11/2023



## 7.0: CONCLUSION AND RECOMMENDATIONS

### Conclusion

This study makes the finding that IP provisions that go beyond the minimum standards of the TRIPS Agreement deter competition and foreign generic investment, hence keeping the cost of medicine high. This, in turn, hampers the right to access to medicine as envisioned in the Constitution and Universal Declaration of Human Rights.

Access to medicine is not a commodity to be bought by the highest bidder. Countries must safeguard the right to access to medicine. To do so, they should take advantage of the TRIPS flexibilities as enshrined in the TRIPS Agreement and the Doha Declaration. Further, an appropriate balance between IP flexibilities, IPR enforcement, and drug regulation should be maintained as this is an essential element of a country's sustainable pharmaceutical investment framework.

### Recommendations

Kenya and other developing countries should implement the following measures to safeguard access to medicine for people living with HIV/AIDS.

#### a) Invest in Research and Development

From experience in the developed world, great research demands resource investment and a good flow of funds, which gives autonomy to create and sustain an innovation culture. Developing countries like South Africa and India spent 0.62% and 0.66% of their GDP on R&D (World Bank data (2022)). On the contrary, Japan, Austria, and Germany have much higher spending from their GDP on R&D. This therefore concludes that the developing countries are still investing way less in their R&D.

The Global Strategy and Plan of Action (GSPOA) on public health, innovation and Intellectual Property, negotiated through the World Health Assembly, provides a global framework for better investment in R&D for neglected diseases. In addition, there are initiatives to develop a global patent pool through which patent-holding drug companies would allow the development of generic versions of their drugs, including combinations with drugs of other companies. There is a need for concrete national strategies to implement these initiatives for improved access to medicines and to continue providing leadership in these endeavors in the region.

Governments from developing countries like Kenya should, therefore, deliberately review their R&D funding allocations and adopt emerging trends in R&D. These initiatives will contribute to advanced R&D capacities and growth of the pharmaceutical industry hence bridging the gap of supply and over-reliance on foreign supplies of pharmaceuticals.

### **b) Incentives in the pharmaceutical industry**

From the analysis conducted, some research indicates that patents may provide incentives for innovation. The WHO “Global Strategy and Plan of Action of Public Health, Innovation and Intellectual Property” acknowledges that IPRs serve an important incentive function, but notes, “This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain (WHA61.21.6).”

This implies that incentive only holds when markets offer sufficient financial incentives for a return on investment. Many developing countries may be unable to provide a profitable market for treatments against diseases that disproportionately affect their populations.

Patents alone, therefore, are not enough incentives for R&D and innovation in the production of medicines. The governments in these developing countries ought to grant incentives e.g., local preference in public procurement, tax waivers, export incentives, and fast-tracking of market authorization subsidies, which have a significant positive effect on innovation performance. This will increase the production of essential medicines, and improve their affordability, availability, and quality.

### **c) Collaboration with academia, research institutions, civil society and pharmaceutical industries**

Stakeholder collaboration in research and development, will lead to strengthened and

targeted efforts in the pharmaceutical field. School curriculums should be restructured to fit the emerging trends in international trade, medical access, and any other emerging trends.

Further, stakeholder participation before signing trade agreements should be taken into consideration. The involvement of civil society and the private sector would help articulate the issues affecting the sector well and inform the policy-makers while negotiating.

### **d) Regulation and Rationalization of Medicine Prices**

Kenya and other developing countries should endeavour to regulate and rationalize medicine prices through:

- Promoting transparency in the pricing structure of medicines by pharmaceutical manufacturers and industry players
- Establishing/supporting a multi-disciplinary mechanism to monitor and advise on medicine prices and affordability
- Pooling procurement for the regional and subregional purchase of antiretroviral drugs and other essential medicines for HIV care and the treatment of opportunistic infections
- Using relevant pricing information during procurement negotiations with pharmaceutical companies and;
- Eliminating taxes and tariffs and controlling mark-ups where appropriate and where consistent with countries’ broader strategic trade and industry policy objective.<sup>50</sup>

### **e) Constant prioritisation of essential medicines by governments**

Governments need to prioritise the provision of essential medicines. They should rationalize their public health policy choices and include

<sup>50</sup>UN AIDS, Policy Brief, Using TRIPS flexibilities to improve access to HIV treatment , [https://www.unaids.org/sites/default/files/media\\_asset/JC2049\\_PolicyBrief\\_TRIPS\\_en\\_1.pdf](https://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf) (Visited on 31/08/23)

the provision of essential medicines. To effectively do these, developing countries need to establish a national drug policy (or enforcement of drug policies in cases where the policies are already in place). Such drug policy would address access to quality and rational use of medicines and outline the list of essential medicines concerning national priorities and disease challenges. A national drug policy, including an up to date list of essential medicines and standard treatment guidelines, can increase the use of generics, improve prescribing practices, and protect against drug resistance.

Developing countries should ensure that essential drug lists for their countries are regularly updated to maintain their relevance to national healthcare needs. Updating the lists is a core function of the government, and it should be based on available evidence of efficacy, safety, quality, and cost-effectiveness.<sup>51</sup>

#### **f) Adoption of TRIPS flexibilities**

Developing countries should fully adopt and utilize the TRIPs flexibilities, for example, compulsory licensing, parallel importing, and bolar exemptions, which allow for the production and importing of generic medicines, hence reducing the price of medicine for people living with HIV/AIDS. This will greatly improve access to medicine.

#### **g) Provision of pre-grant oppositions in legislation**

Pre-grant patent opposition offers the public an opportunity to comment and oppose patent applications that do not meet the patentability criteria before they can be granted. Currently, in Kenya, section 103 of the Industrial Property Act only allows post-grant opposition, which means that the public can only oppose those patents once they have been granted. There is a need to review this legislation to allow pre-grant opposition to eliminate patenting of subjects that do not meet the criteria. This would, in turn, curb patent monopolies, allowing timely generic production and supply to bring the price of medicines down for patients.

#### **h) Evidence-based trade negotiations**

Policy makers and negotiators should invest in research, and such negotiations should be based on evidence. During negotiations of FTAs, due regard should be given to the right to access medicine for people living with HIV/AIDS. An impact assessment of the effect of the trade agreement should be done before the negotiators can ratify an agreement. Policymakers should ensure that new trade agreements are not contradictory to the Doha Declaration. There must be a deliberate policy framework to safeguard the TRIPs flexibilities.

---

<sup>51</sup>Kenya Pharmaceutical policy

## REFERENCES

### Bilateral Trade Agreements

- Thai-US FTA
- US-Bahrain FTA.
- Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union

### Treaties

- Trade-Related Aspects of Intellectual Property
- Doha Declaration on Intellectual property and Public Health
- Patent Cooperation Treaty (PCT)

### National Laws and Policies

- Anti- Counterfeit Act (2008)
- Consumer Protection Act 2019
- Constitution of Kenya 2010
- Copyright Act No. 12 of 2001
- Industrial Property Act (IPA) No. 3 of 2001
- Kenya Medical Supplies Act No. 20 of 2013
- Kenya Pharmaceutical Policy 2012
- Kenya Health Policy 2014-2030
- Pharmacy and Poisons Act Cap 244
- Seed and Plant Varieties Act, Cap 326.
- State Corporations Act, Cap 446
- Trade Marks Act Cap 506

### Articles and website links

- Abbott, Frederick The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements, Quaker United Nations Office, Occasional Paper (2004) <https://quino.org/sites/default/files/resources/TRIPS-Public-Health-FTAs.pdf>
- CETA and pharmaceuticals: impact of the trade agreement between Europe and Canada on the costs of prescription drugs. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4108121/> (Visited on 31/08/23)
- For more information on UNCTAD's Investment Policy Framework for Sustainable Development (IPFSD), see [http://www.iisd.org/toolkits/sustainability-toolkit-for-trade-negotiators/wp-content/uploads/2016/06/diaepcb2012d5\\_en.pdf](http://www.iisd.org/toolkits/sustainability-toolkit-for-trade-negotiators/wp-content/uploads/2016/06/diaepcb2012d5_en.pdf) (visited 31/08/2023)
- [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (Visited on 20/8/2023)
- Global R&D Forecast Funding Report 2016, Available at <https://www.iriweb.org/resources/>
- Indian Pharmaceuticals Industry Analysis, Available at <http://www.ibef.org/industry/indian-pharmaceuticals-industryanalysis-presentation#sthash.qPW/Nb7FZ.dpuf> (visited on 21/08/23)

- Kessomboon N. Limpananont J. Kulsomboon V. Maleewong U. Eksaengsri A. and Paothong P. Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-US FTA. *Southeast Asian Journal of Tropical Medicines and Public Health*, 2010, 41(3): 667-677, at 637-638.
- Mark C. Lang, What a Long, Strange "TRIPS" It's Been: Compulsory Licensing From the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration, 3 *J. MARSHALL REV. INTELL. PROP. L.* 331, 331 (2004)
- Mayfield DL. Medical Patents and How New Instruments or Medications Might Be Patented. *Mo Med.* 2016 Nov-Dec;113(6):456-462. PMID: 30228529; PMCID: PMC61397
- Oliveira, M. A., Bermudez, J. A., Chaves, G. C., & Velásquez, G. (2004). Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health? *Bulletin of the World Health Organization*, 82(11), 815–821.
- Rastogi, Priyanka, *Worldwide: World Wide Legal Status of Medical Method Patents: An Overview*, Mondaq
- Unnikrishnan, C. H., Marks Mixed Trend For Pharma Sector, Available at <http://businessworld.in/article/2015-MarksMixed-Trend-For-Pharma-Sector/> (Visited on 20/08/23)
- WIPO, *Statistical Country Profiles-India: WIPO statistics database*, Available at [http://www.wipo.int/ipstats/en/-statistics/country\\_profile/profile.jsp?code=IN](http://www.wipo.int/ipstats/en/-statistics/country_profile/profile.jsp?code=IN)
- World Intellectual Property Organization (WIPO) <https://www.wipo.int> (visited 26/08/23)
- Yoongthong T. *Social cost of market exclusivity extension for patented medicines in Thailand: analysis of the effect of trips-plus provisions*. Bangkok: National Institute of Development Administration; 2012
- UN AIDS, *Policy Brief, Using TRIPS flexibilities to improve access to HIV treatment*, [https://www.unaids.org/sites/default/files/media\\_asset/JC2049\\_PolicyBrief\\_TRIPS\\_en\\_1.pdf](https://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf) (Visited on 31/08/23)
- Kenya Trade Agreements <https://www.trade.gov/country-commercial-guides/kenya-trade-agreements>(visited29/08/2023)
- [https://theconversation.com/kenya-us-free-trade-talks-are-under-way-what-nairobi-must-get-right-from-start-144129#:~:text=The%20United%20States%20and%20Kenya,agreement%20on%208%20July%202020.&text=Kenya%20exported%20goods%20worth%20US,other%20spacecraft%2C%20polymers%20and%20medicaments.\(Visited](https://theconversation.com/kenya-us-free-trade-talks-are-under-way-what-nairobi-must-get-right-from-start-144129#:~:text=The%20United%20States%20and%20Kenya,agreement%20on%208%20July%202020.&text=Kenya%20exported%20goods%20worth%20US,other%20spacecraft%2C%20polymers%20and%20medicaments.(Visited) 28/08/2023)
- [https://unctad.org/publication/trips-flexibilities-and-anti-counterfeit-legislation-kenya-and-east-african-community#:~:text=UNCTAD%20considers%20the%20use%20of,under%20sustainable%20investment%20policy%20frameworks.\(visited](https://unctad.org/publication/trips-flexibilities-and-anti-counterfeit-legislation-kenya-and-east-african-community#:~:text=UNCTAD%20considers%20the%20use%20of,under%20sustainable%20investment%20policy%20frameworks.(visited) 31/08/2023)
- <https://orig.africalegalnetwork.com/kenya/news/proposed-us-kenya-fta-impact-kenyas-intellectual-property-laws/> (visited 28/08/2023)
- <https://www.everycrsreport.com/reports/RL32314.html> (Visited on 31/08/23)
- [https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset\\_upload\\_file211\\_6293.pdf](https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset_upload_file211_6293.pdf) (Visited on 31/08/23)
- [https://www.wipo.int/scp/en/revocation\\_mechanisms/opposition/index.html#:~:text=A%20pre%20grant%20opposition%20system,the%20validity%20of%20granted%20patents.\(Visited](https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html#:~:text=A%20pre%20grant%20opposition%20system,the%20validity%20of%20granted%20patents.(Visited) on 31/08/23)
- [https://www.wipo.int/scp/en/revocation\\_mechanisms/opposition/index.html#:~:text=A%20pre%20grant%20opposition%20system,the%20validity%20of%20granted%20patents.\(Visited](https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html#:~:text=A%20pre%20grant%20opposition%20system,the%20validity%20of%20granted%20patents.(Visited) on 31/08/23)

- [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (Visited on 20/8/2023)
- [https://www.unaids.org/sites/default/files/media\\_asset/JC2049\\_PolicyBrief\\_TRIPS\\_en](https://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en)(Visited on 23/08/23)
- <https://ncikenya.go.ke/resources/policies/kenya-health-policy.pdf> (Visited on 24/08/23)



