USE OF TRIPS FLEXIBILITIES IN PROMOTING ACCESS TO ESSENTIAL MEDICINES IN KENYA

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This research paper is dedicated to my late father and first teacher James Mucheru Muiri.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>ARVs</td>
<td>Antiretrovirals</td>
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<tr>
<td>COMESA</td>
<td>Common Market for Eastern and Southern Africa</td>
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<td>EAC</td>
<td>East African Community</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturers &amp; Associations</td>
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<td>IP</td>
<td>Intellectual Property</td>
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<td>IPA</td>
<td>Industrial Property Act</td>
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<td>IPRs</td>
<td>Intellectual Property Rights</td>
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<td>KIPI</td>
<td>Kenya Industrial Property Institute</td>
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<td>LMICs</td>
<td>Low- And Middle-Income Countries</td>
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<td>MNCs</td>
<td>Multinational Corporations</td>
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<td>MPP</td>
<td>Medicines Patent Pool</td>
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<td>PEPFAR</td>
<td>US Presidents Emergency Plan for AIDS Relief</td>
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<td>PLWHAs</td>
<td>People Living With HIV/AIDS</td>
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<td>PPB</td>
<td>Pharmacy &amp; Poisons Board</td>
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<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
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<td>UNCTAD</td>
<td>United Nations Conference on Trade and Development</td>
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<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>WIPO</td>
<td>World Intellectual Property Organization</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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LIST OF NATIONAL AND INTERNATIONAL LAWS

Kenya

Anti-Counterfeit Act 2008
Competition Act 2010
Constitution of Kenya 2010
Copyright Act 2001
Industrial Property Act 2001
Pharmacy and Poisons Act 2012
Trademarks Act 2012
Value Added Tax Act 2013

India

Designs and Patents Act, 1911
Patents Act 1970
Patents (Amendment) Act 2002
Patents (Amendment) Act 2005

International Treaties

Agreement on Trade Related Aspects of Intellectual Property Rights, 1 January 1995
Paris Convention for the Protection of Industrial Property, 28 September 1979
Universal Declaration of Human Rights, 10 December 1948
LIST OF CASES

Bayer Corporation & Ors v Union of India & Ors 162 (2007) DLT 371

BDR Pharmaceuticals Pvt. Ltd. v Bristol Myers Squibb, CLA No. 1 of 2013 before the Controller of Patents, Mumbai 29 October 2013

India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/10/Add.4 WT/DS79/6, 16 April 1999

Lords Healthcare Limited v Salama Pharmaceuticals Limited, Civil Suit 334 of 2007

NATCO Pharma Limited v Bayer Corporation, Compulsory Licence Application No.1 of 2011 before Controller of patents Mumbai

Novartis AG v. Union of India (UOI) and Ors.; Natco Pharma Ltd. v. UoI & Ors.; M/S Cancer Patients Aid Association v. UoI & Ors., Civil Appeal No. 2706-2716 of 2013

Patricia Asero Ochieng and 2 others v the Attorney General & Another Constitutional Petition Number 409 of 2009

Pfizer Inc v Cosmos Limited, Industrial Property Tribunal in Nairobi Case No. 49 of 2006

ABSTRACT
This study examines legal flexibilities in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), particularly those designed to secure access to essential medicines in Low and Middle-Income Countries such as Kenya. Kenya grapples with a high disease burden of communicable diseases such as HIV/AIDS, malaria and tuberculosis. Diseases such as these are likely to cause nation-wide epidemics and are usually too expensive to treat in LMICs. The WHO has developed a Model List of Essential Medicines to assist countries in prioritizing public health needs. The study examines international and Kenya’s legal frameworks which implement public health related TRIPS flexibilities. To analyze the problem, research data was collected from an organization working with People Living With HIV/AIDS (PLWHAs), government institutions that deal with essential medicines and a comparative study of India as a best practice done, to observe how best Kenya can give effect to the legal provisions governing TRIPS flexibilities. The research data generated indicates that Kenya’s domestic legislation is largely consistent with TRIPS since joining the WTO in 1995. However, in practice, use of TRIPS flexibilities to attain public health objectives in Kenya is still lagging behind. This study investigates barriers to full utilization of public health related TRIPS flexibilities in Kenya and makes recommendations.
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CHAPTER ONE: BACKGROUND OF THE STUDY

1.0 Introduction

In 2017, the number of People Living With HIV/AIDS (PLWHAs) globally was 36.7 million, but only about 12.9 million people in Eastern and Southern Africa were accessing antiretroviral therapy (ARVs) out of an estimated 19.6 million.¹ The people affected by lack of access to medicines are mostly living in Low- and Middle-Income Countries (LMICs) such as East and South African Countries. Lack of consistent access to medicines is due to among other challenges, the prohibitively high cost of ARVs. The unavailability of essential life-giving medicines especially for communicable diseases such as HIV, tuberculosis, hepatitis C and so forth can lead to drug resistance if administered inconsistently.

The lack of consistent access to essential medicines led to the 2001 Ministerial Conference of the World Trade Organization (WTO) which adopted the Doha Declaration on the (The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health (Doha Declaration). In the African continent, the advent of intellectual property rights (IPRs) is largely attributed to TRIPS which was adopted as part of a single undertaking with other WTO agreements. TRIPS, an international agreement, required signatory states to the WTO to implement minimum standards of protection of IPRs on a non-discriminatory basis. TRIPS attempts to strike a balance between individual interests by providing incentives for inventors through protection of IPRs and societal interests by permitting the use existing inventions.

TRIPS introduced ‘flexibilities’ which have been used to promote access to medicines in LMICs. The term ‘flexibilities’ in the context of the Doha Declaration and according to the World Intellectual Property Organization (WIPO) Standing Committee on the Law of Patents, denotes ‘the right of WTO Members to exploit various options and legal tools when

implementing the TRIPS Agreement at the national level, so that both national interests, including protection of public health, “are accommodated and TRIPS provisions are also complied with.” This paper discusses the following TRIPS flexibilities related to public health:- compulsory licensing, government use, parallel importation, Bolar exception and exceptions to grant of patent rights as implemented in India and Kenya’s legislation.

The Doha Declaration on TRIPS and Public Health recognized that even though developing countries could take advantage of the TRIPS flexibilities, many still lacked the political will and capacity whether through establishment of appropriate legal frameworks or infrastructural capacity. In the field of pharmaceuticals, “the purpose of TRIPS flexibilities is to strike a balance between promoting access to existing medicines and promoting research and development of new medicines.” This paper therefore addresses the challenges faced at the national level in implementing TRIPS flexibilities as well as hurdles faced in local manufacture and importation of pharmaceutical products. In addition, this paper examines Kenya’s capacity to maximize on TRIPS flexibilities to achieve public health objectives.

Several developing countries including Kenya have declared HIV/AIDS a national disaster. TRIPS grants WTO members the freedom to take measures to promote public health through full utilization of TRIPS flexibilities. Kenya as a founding WTO member is expected to implement measures that promote public health objectives for instance import of essential

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2 WIPO Standing Committee on the Law of Patents, “Constraints Faced by Developing Countries and LDCs in Making Full Use of Patent Flexibilities and Their Impacts on Access to Affordable Especially Essential Medicines For Public Health Purposes In Those Countries”(Twenty-Sixth Session Geneva, July 3 to 6 2017).
3 TRIPS 1995 art 31.
4 TRIPS (n 3) art 31(b).
5 TRIPS (n 3) art 6.
6 TRIPS (n 3) art 8.
7 TRIPS (n 3) art 30.
9 President Daniel Arap Moi made this ‘roadside declaration’ that was gazetted months later, see Robert Lewis-Lettington and Peter Munyi, ‘Willingness and Ability to use TRIPs Flexibilities: Kenya Case Study’ (The DFID Health Systems Resource Center, 2004) 27.
medicines under a compulsory licence to ensure access to essential medicines. “The Global Fund to Fight AIDS, Tuberculosis and Malaria, a financing institution, providing support to countries in the response to AIDS, Malaria and Tuberculosis epidemics,” urged ARV recipients in developing countries to “use the provisions of the TRIPS Agreement as interpreted in the Doha Declaration, including the flexibilities therein, to ensure the lowest possible price for products of assured quality.” The full utilization of TRIPS flexibilities within the context of public health, may be defined as maximum use of legal options provided under TRIPS depending on the circumstances of a State for optimal results to resolve public health issues. Use of TRIPS flexibilities have been known to encourage production of generic medicines which has promoted competition and therefore lowered the price of generic medicines.

For example, in the wake of pressure from the international community especially the World Health Organization and NGOs to increase accessibility to essential medicines, patent holders in developed countries opted for voluntary licensing under the threat of compulsory licensing. After 2008, the “use of TRIPS flexibilities for HIV/AIDS treatment globally decreased because voluntary licensing had become more common.”

Public interest litigation in Kenya especially on access to generic medicines is often led by donor funded NGOs. In Patricia Asero & 2 others Vs The Attorney General and Aids Law Project, the petitioners living with HIV/AIDS, contended that their rights under the Constitution of Kenya (2010) were threatened by the enactment of the Anti-Counterfeit Act, 2008, particularly sections 2, 32 and 34. They argued that the provisions affected or were likely to affect their access to affordable and essential medicines including generic medicines which

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are mainly imported thereby infringing their fundamental right to life, human dignity and health as envisaged by Articles 26(1), 28 and 43 of the Constitution which encompasses access to affordable and essential medicines including generic medicines. The main contention was that the Anti-Counterfeit Act failed to distinguish generic medicines and counterfeit goods thereby making it an offense to procure the generic HIV/AIDS medicines. The Court held that the Anti-Counterfeit Act severely limited access to essential medicines and the Act further infringed on the petitioners’ fundamental right to life, human dignity and health as provided under the Constitution. The Court also observed that it is the Governments responsibility to ensure that its citizens attain the highest standard of health. This case demonstrates how poorly drafted legislation can have adverse effect on access to essential medicines.

The initiatives taken by international organizations are crucial in ensuring access to essential medicines to millions of patients in LMICs. The World Health Organization (WHO) developed a model list, which is regularly updated, of high-priced essential medicines. In addition, WHO hosts UNITAID, an international organization which invests in preventing, diagnosing and treating communicable diseases such as HIV/AIDS. UNITAID’s innovative financing mechanism supports the establishment of the Medicines Patent Pool (MPP) and contributes to increasing access to HIV/AIDS, malaria and tuberculosis treatment, particularly in LMICs. MPP is a voluntary licensing mechanism that will be recommended as a mechanism to improve access to essential medicines in LMICs such as Kenya.

TRIPS provides that Member States have “a right to adopt measures for public health and other public interest reasons in sectors of vital importance to their socio-economic development.”

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16 TRIPS (n 3), art 8.
Kenya’s Industrial Property Act\textsuperscript{17} provides for some implementation mechanisms for TRIPs flexibilities. One of these mechanisms is effected by establishing the Industrial Property Tribunal which determines when rights under a patent may be limited through grant of “compulsory licences for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions.”\textsuperscript{18} This notwithstanding, the Tribunal is yet to make any order for compulsory licensing with respect to medicines and other pharmaceutical products. In addition, following the landmark judgement in the Patricia Asero Case, there have been policy recommendations and amendments to the Anti-Counterfeit Act in 2014 which included revision of the term ‘counterfeiting’ to avoid penalizing generic drug manufacturers. This demonstrates that Kenya as a developing country and founding member of WTO has to some extent responded to TRIPS flexibilities according to its needs and policy objectives.

In 2017, the newest generic form of ARV was introduced in Kenya. The drug, Dolutegravir (DTG) imported from the United Kingdom and sold under the trademark Tivicay has however been criticized for causing birth defects in HIV/AIDS patients. “A box of 30 pills of DTG, which lasts a month, costs between Kenya shillings (Kshs.) 2,000 to Kshs. 5,000. The generic version only costs Kshs. 400.”\textsuperscript{19} The Ministry of Health later banned the medicine due to its extreme side effects.\textsuperscript{20} This paper examines other possible complementary solutions that can facilitate full utilization of TRIPS flexibilities in order to increase access to essential medicines for example increasing the manufacturing capacity of domestic pharmaceutical companies, creation of free trade areas to lift trade barriers to allow free flow of generic medicines to

\textsuperscript{17} The Industrial Property Act, 2001.
\textsuperscript{18} ibid s 58 (5) & 72 (1).
\textsuperscript{19} Agence France-Presse, ‘Kenya gets generic version of most effective HIV drug’, \textit{Daily Nation} (Nairobi, 28 June 2017).
stimulating competition and creation of MPPs to ease the cost burden imposed by individual patent holders.

A patented pharmaceutical product is a key benefit for LMICs in that the invention must be disclosed and this disclosure facilitates information dissemination through publication of patent applications. Generic manufacturers can therefore use this information to produce affordable medicines, usually through reverse engineering processes, to determine the composition of patented medicines. The generic manufacturer therefore avoids reinventing the wheel and cuts research and development related costs of the medicine and saves time taken up by regulatory and market approval processes. As a result of this, cheaper drugs are manufactured.

This paper undertakes a case study of India which is categorized as a developing country. However, India now has a robust generic pharmaceutical industry and has emerged as a global exporter of pharmaceutical products. This development has been attributed to adequately utilizing TRIPS flexibilities.

India is a key jurisdiction in this study due to the exponential growth of its generic pharmaceutical industry. According to Nair, “the Indian national pharmaceutical industry went about developing innovative processes and methods of standardization including bio-equivalence studies for process development, manufacture and marketing generic equivalents which are therapeutically equivalent to the innovator products,”21 This development occurred during the transition periods granted to developing countries permitting the delay of patent protection. Reverse engineering technics were employed over patent protected medicines and eventually India’s population has benefited from access to affordable generic medicines produced. According to a United Nations Programme on HIV/AIDS Strategy Report, “India’s

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generic pharmaceutical industry has played a central role in achieving price reductions and saving millions of lives, producing 80% of HIV medicines consumed in Africa.”

1.1 Problem Statement

Most LMICs face the challenge of access to medicines for treating diseases such as HIV/AIDS as well as access to technologies that could potentially treat life threatening diseases that afflict human beings. Multi-National Corporations (MNCs) in developed countries hold patents to high priced essential medicines which are unaffordable in the developing countries and which would alleviate the disease burden. However, MNCs usually perceive LMICs markets as unattractive since they are unlikely to recoup costs related to research and development for drug discovery and development. This perception exists because only a small size in the market can afford medicines at the prices set in developed countries. Therefore, the manufacture, sale and marketing of essential medicines is not targeted at these countries. Patents encourage research and development and provide incentives to pharmaceutical industry due to the likelihood of a return on investment. However, in the same breath, patents could potentially prevent technology dissemination by permitting restrictive arrangements for critical technologies.

Regional Trade Agreements that create free trade areas are a pivotal avenue to enhance access to essential medicines. Trade between countries facing similar disease burden challenges can be promoted by eliminating of trade barriers. Kenya has signed some bilateral and multilateral trade agreements including the Treaty for the Establishment of the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA). These two essential trade treaties have barely assisted in the implementation of TRIPs flexibilities nor the

progressive realization of the right to health.\textsuperscript{23} A robust intentional regional trade system would for example support parallel importation of finished generic pharmaceutical products or ingredients for production of generic medicines at little or no extra cost by eliminating custom duties which would significantly reduce the price of essential medicines.

Lack of manufacturing capacity for generic ARV medicines would be a problem if supply from generic medicine producing countries such as India is curtailed or dwindles for one reason or other. For example, some big generic medicines producers fall below acceptable WHO Good Manufacturing Practices for quality assurance which could lead to procurement disruption of essential ARVs.\textsuperscript{24} So far, India-China–Africa partnerships allow for export of ARV medicine which provides for some temporary security\textsuperscript{25} but a long-term solution is needed to secure unrestricted access as well as transfer of technology relating to ARVs and other essential medicines.

\textbf{1.2 Justification of The Study}

Given the importance of generic medicines in ensuring prolonged human life and the crucial role that IP plays in the development and procurement of these essential medicines, which is a public health issue, it is important for critical analysis to be done to determine how generic medicines can be accessed by the poor at an affordable cost. According to Johanna Kehl, “though many States agree the HIV/AIDS crisis meets the definition of ‘national emergency’ there is no firmly entrenched concept of emergency in international law.”\textsuperscript{26} This means that developing States need to have a proactive approach rather than reactive one so that emergency situations are foreseen through enactment of appropriate policies and legislation, allowing

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{23} This is a universal human right see art 25, The Universal Declaration of Human Rights, United Nations General Assembly, Paris, France, 10 December 1948 \<http://www.un.org/en/universal-declaration-human-rights/> accessed on 10 March 2018
\item \textsuperscript{24} UNAIDS (n 22).
\item \textsuperscript{25} ibid.
\item \textsuperscript{26} Johanna Kehl, ‘TRIPS art 31(b) and the HIV/AIDS Epidemic’ (2002) vol. 10 University of Georgia Journal of Intellectual Property Law \<https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1245&context=jipl> accessed on 12 March 2018
\end{itemize}
\end{footnotesize}
importation of generic medicines to increase competition in the market in order to lower the costs of essential medicines and ensuring that administrative and regulatory bottlenecks are eliminated.

It is important to examine TRIPS flexibilities from an administrative perspective. Government regulatory agencies tasked with granting market approval for generic medicines and administration of IPRs particularly patents require sufficient technical capacity and manpower. For example, lack of guidelines on how approval should proceed for generic medicines may cause uncertainty and bottlenecks in the regulatory systems which may dis incentivize local manufacturing companies. Though the administrative or regulatory issues are not strictly speaking directly linked to IPRs issue, effective regulatory mechanisms play a critical role in complementing TRIPS flexibilities in promoting full utilization. For example, when a compulsory license is issued in cases of national emergencies there needs to be an efficient approval mechanism for the medicines to be promptly registered and distributed. In addition, lack of sufficient patent information in the public domain that links the medicines to patents may mean that patent examination offices cannot strictly adhere to the patentability criteria to prevent strategies that delay generic entry such as patenting around an invention and to avoid erroneous grant of patent.

Often, ingredients for generic medicines or raw materials are procured from one country, processed in another and the finished products utilized in a third country. The cost of medicines would be greatly reduced if all processes took place in one country through domestic manufacture. LMICs generally lack capacity to manufacture pharmaceutical products and high production costs impact negatively on essential medicine prices. The focus needs to shift from importing already finished generic medicines to focus on building local manufacturing capacity. In 2018, the Government of Kenya plans to construct a new Sh7.5 billion medicines
manufacturing plant in collaboration with a Bangladesh pharmaceutical company. 27 It was reported that “the construction of a local pharmaceutical manufacturing plant will bring significant industrial benefits, including technology transfer and demand for education and training, development of the pharmaceutical production sector and create employment opportunities, as envisaged in Kenya’s Vision 2030.”28 This demonstrates that Kenya is keen on developing capacity to manufacture generic medicines to ensure cheaper access of essential medicines to Kenyans and perhaps later for export purposes. Procurement of ARVs in “LMICs is controlled by just three major buyers, the US Presidents Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, and South Africa, who together purchase 80% of all LMIC requirements.”29 This illustrates the huge market gap that LMICs could tap into if generic drugs were manufactured locally. Local generic manufacturers can then tap into economies of scale, essential for the survival of the generic medicines production industry.

Despite the capacity to spur creativity and innovation due to high returns on investment, patents can limit access to important technologies and essential medicines due to the high costs associated with licensing the patented products. In fact, according to WHO, “ARVs were the first class of new essential medicines that were widely patented.”30 Patent protection is often seen as curtailing access to ARVs or essential generic medicines because the patent holder is granted exclusive monopolistic rights that prevent third parties from interfering with the invention for example through sale or manufacture. In addition, the monopoly that patents create in the market leads to anti-competitive practices that leads to higher costs of essential medicines. The use of TRIPs flexibilities has “helped create and sustain generic competition that brings down the price of HIV medicines.”31 There is therefore a need to investigate how

28 Ibid
29 Brian Elliott, HIV/AIDs Drugs for developing World Face Threat of Disruption, Financial Times (London, 16 March 2017) <https://www.ft.com/content/95b58372-0a58-11e7-ae5a-903b21361b43> accessed on 15 March 2018
30Ellen FM ‘t Hoen et al. (n 12).
31 Ibid.
these flexibilities can effectively be used for the benefit of LMICs like Kenya. In fact, according to the WIPO Indicators Report, “the number of resident patent applications relative to gross domestic product, population, research and development spending or other variables commonly referred to as ‘patent activity intensity’ indicators... was highest ranking [in Africa] particularly in Morocco and Kenya.” This is a positive indicator that Kenya has the innovative capacity to develop its own domestic generic manufacturing industry.

1.3 Research Objectives

The objectives of this study are as follows:

1. To conceptualize property law, intellectual property law and international intellectual property law with a focus on TRIPS flexibilities.

2. To identify Kenya’s legislative, regulatory and policy framework on TRIPS flexibilities and challenges that prevent access to essential medicines.

3. To undertake a case study of India’s legislative framework which implements TRIPS flexibilities.

4. To recommend possible solutions to ensure full utilization of TRIPS flexibilities.

1.4 Research Questions

The research questions to be answered under this study are:

1. How has Kenya adopted TRIPS flexibilities within its legislative framework to promote access to generic medicines?

2. What are the legislative and institutional challenges Kenya faces in implementing TRIPS flexibilities?

3. How are TRIPS flexibilities implemented under India’s legislative framework?

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4. What are the best practices that Kenya can borrow from India to guide legislative reform?

5. What institutional reforms can Kenya undertake to actualize implementation of TRIPS flexibilities?

1.5 Theoretical Framework

The theoretical framework is important because it provides answers to the problem questions and explains why the author’s approach to solving this problem or question is feasible. The theoretical assumption discussed under this study seeks to shed light on the importance of patent protection on one hand and provide insights on the restrictive nature of patents to support the argument that patents should work for the benefit of society on the other hand.

The theory of Social Engineering is propounded by Roscoe Pound, one of the most influential proponents of sociological jurisprudence best-known for conceptualizing law in his theory of social engineering. Pound posited that “like an engineer’s formulae, laws represent experience, scientific formulations of experience and logical developments of the formulations, also inventive skill in conceiving new devices and formulating their requirements by means of a developed technique.” This means that law should be used as an instrument in directing proper functioning of society. Law should efficiently guide society in order to fulfill societal needs. “The law should therefore work towards balancing competing interests within the society to achieve the greatest benefits.” Pound defined interest as “claims or wants or desires which men assert de facto about which the law must do something if organized societies are to endure”. Pound noted that interests protected under the law are classified under three categories. This paper will discuss only two of those interests which are relevant in relation to

35 ibid.
patent protection vis-à-vis society’s need for technological advancement and technology dissemination.

The first are individual interests which in this context means exclusive rights granted to the patent holder to work the invention to the exclusion of third parties although this right is not absolute. The second category of interests are societal interests which are claims or demands in terms of social life. “There is need to fulfill all the needs of a society for effective operationalization and preservation of it.” 36 Under this study, societal interests override individual interests for example, government use of a patent, without the authorization of the patent holder. Compulsory licensing is another good example of upholding societal interests. This form of license is granted to a third party by the government for example in a situation where a patent holder has not supplied essential life giving generic medicines contained in the patent on reasonable terms or has refused to do so. The right to use the patented product is therefore granted to a third party without the patent holders authorization.

The essence of patent protection is founded on a social contract. The patent holder enters into contract with the State which allows the enjoyment of exclusive rights and which prevents others from interfering with the invention for a limited duration of time. The patent holder in exchange must disclose the workings of the invention. This ensures that even after the patent duration expires, the invention can still be utilized or improved upon.

1.6 Research Methodology

This paper uses qualitative research methods to address the questions raised and undertakes a comparative research study of India and Kenya to obtain data on the generic medicines industry and the role that the patent protection regime has played in increasing or limiting access to these medicines. The author will primarily focus on desktop research to collect data which

36 ibid.
includes library research and internet searches. Information and data collected will be obtained from reliable and accurate secondary sources such as national intellectual property office reports, legislative instruments as well as authoritative journal articles.

To satisfy the objectives of this Research, data collection primarily focuses on testing the theories advanced in this paper. The objective of qualitative study is to test or verify the hypothesis which becomes a framework for the entire study. 37

This section contains the rationale used in determining the methods of data collection using desktop-based research corroborated by the expert opinions of key informants interviewed in this study. Primary data sources such as case law, local and international statutes were employed as well as secondary data sources such as online journal articles, books, newspaper reports, data reports and academic dissertations.

Interview respondents were purposefully selected based on areas of expertise and the frequency of dealing with TRIPS flexibilities related to access to essential medicines as well as persons who are affected directly by legislation or regulatory measures on essential medicines. Prior to conducting the interviews, the interviewees were provided with the background and objectives of the study. The interviews were conducted to shed light on specific challenges faced in implementing TRIPS flexibilities that have been largely undocumented despite the array of publicly available literature.

1.7 Literature Review

The WHO defines access to medicines as “the equitable availability and affordability of essential medicines during the process of medicine acquisition.” 38 WHO et al, note that access to medicines is a key component within the broader subject of access to health care. The WHO Model List of Essential Medicines is meant to assist countries achieve their public health

objectives. WHO et al, note that there are certain determinates that point to a functional health care system for example, access to quality essential medicines require an effective national regulatory system, consistent supply of medicines requires a consistently funded public health kitty, full utilization of TRIPS flexibilities requires proactive and knowledgeable government agencies tasked with giving effect to the legal framework providing for these flexibilities and local pharmaceutical manufacturers with sufficient production capacity. The collaborative publication by WHO, WIPO and WTO referenced in this paper provides an invaluable perspective on the interplay between three separate yet intertwined systems namely, public health, trade and IPRs and their effect on access to essential medicines.

Most developing countries face challenges in adequately utilizing TRIPS flexibilities despite the scientific and technological advancement realized in the 21st century. The public health sector in these countries is still grappling with the disease burden especially in relation to preventable communicable diseases such as HIV/AIDS. The Doha Declaration “recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector may face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”39 Other challenges according to Musungu include “lack of technical expertise effectively to implement the TRIPS flexibilities; insufficient technical and infrastructural capacities for medicines regulations; bilateral and other pressures not to use the TRIPS flexibilities for public health purposes; difficulties in regulating anti-competitive practices and abuse of intellectual property rights; and difficulties in accessing pricing and patent status information.”40 WHO et al., observed that TRIPS flexibilities are not self-actuating and therefore proactive action is needed at the domestic level to implement such flexibilities. This would for example involve “the national IP regime response to each country’s individual needs

40 Sisule F. Musungu et al., ‘Utilizing Trips Flexibilities for Public Health Protection Through South-South Regional Frameworks’ (South Center, 2004)< http://apps.who.int/medicinedocs/pdf/s4968e/s4968e.pdf > accessed on 1 August 2018.
and public health policy objectives.” One can add that political will is also required since the State has primary responsibility to implement sound public health policies and legislation for its citizens.

HIV/AIDS has had devastating effects on people in LMICs because essential medicines have been unaffordable and inaccessible. The report recommends that countries need to “scale up quality services and reduce costs of health products by, inter alia, expanding community service delivery and promoting competition among pharmaceutical suppliers [in addition] to drive down prices, countries need to fully leverage their negotiating potential, including pooling procurement, strategically designing tendering processes and other market shaping mechanisms.”

Lowering administrative and regulatory hurdles can complement the implementation of TRIPS flexibilities for example procurement of generic medicines from local generic manufacturers or importation of generic medicines should not face undue hardships.

The impact of stronger IPR regimes is encouraged by the TRIPS Agreement and use of the TRIPS flexibilities has catapulted the Indian pharmaceutical industry to greater heights such that India is now recognized as a leading low cost generic drug manufacturer. One of the reasons for this is that, the 1970s India’s patents laws did not protect product patents for drugs but provided for process patents. In effect, India has been able to manage the HIV/AIDS crisis through use of reverse engineering techniques to produce low cost ARVs for its huge populace and export surplus medicines to LMICs. The objective of TRIPS is “the protection and enforcement of IPRs” while contributing “to the promotion of technological innovation and

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42 ibid.
43 TRIPS (n 3), art 7.
to 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.”^{44} In addition, one of TRIPS principles is that “WTO members have the freedom to adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development.”^{45} Most of the amendments to India’s patent laws have been made to ensure compliance with TRIPS.

One of the suggestions offered by WIPO, for dealing with the incapacity to manufacture generic medicines focuses on international trade and more so regional trade “which is critical to enabling access to medicines, particularly for developing countries lacking domestic manufacturing capacity as trade stimulates competition and improves economies of scale.”^{46}

There is a maze of bilateral and multilateral free trade agreements that could contribute to access to generic medicines. According to Musungu, “a regional approach to the use of TRIPS flexibilities will enable similarly situated countries to address their constraints jointly by drawing on each others’ expertise and experience and by pooling and sharing resources and information.”^{47} A country’s ability to integrate TRIPS flexibilities into domestic legislation will determine its ability to fully utilize these flexibilities. Difficulties that are unrelated to manufacturing capacity include the “lack of capacity to address anti-competitive practices and abuse of patent rights as well as difficulties in accessing patent status information.”^{48} In addition to examining these challenges, this paper will also look the factors that prevent Kenya from incorporating TRIPS flexibilities into their domestic legislation.

^{44} ibid.
^{45} TRIPS (n 3), art 8.
^{47} Sisule f. Musungu et al (n 40).
^{48} Ibid.
According to Lettington and Munyi, “the asymmetry in the treatment of imported vs. locally manufactured products should be corrected [reason being that] Kenya’s parallel importation provisions allow for the importation of a broad range of products under flexible conditions that do not usually require government intervention.” The procedures for local generic drug producers to obtain manufacturing approval are not properly documented and the law contains ambiguities. This paper analyzes the legislative, regulatory and technical procedures that affect potential generic manufacturers in order to demonstrate the necessity of establishing supportive administrative procedures.

1.8 Hypothesis

The hypothesis is that there is a direct correlation between full utilization of TRIPS flexibilities and increased access to essential medicines in LMICs such as Kenya.

1.9 Thesis Outline

Chapter One introduces the topic of research. It contains the problem statement research justification and highlights the research questions and objectives. This chapter also contains the theoretical framework and hypotheses upon which the research shall be founded, an overview of the literature review and the research methodology.

Chapter Two deals with conceptual framework of the study, introduces property law, intellectual property law and international intellectual property law and focuses on TRIPS flexibilities from a public health perspective.

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Chapter Three provides the current legislative framework in Kenya on TRIPS flexibilities and institutions tasked with implementation of the flexibilities and identifies challenges faced by these institutions and assesses actual utilization of the flexibilities in Kenya.

Chapter Four contains a case study of the patent regime and practices of the Indian pharmaceutical industry. India plays a major role in the generic pharmaceutical industry as a procurer or producer of ARVs. This Chapter focuses on factors that have contributed to the unprecedented growth of India as one of the top manufacturers and exporters of generic medicines and medical technologies for local and foreign consumption.

Chapter Five concludes the research and provides recommendations in Kenya’s context based on the findings of the comparative study and responses from study participants.
CHAPTER TWO: CONCEPTUALISATION OF INTELLECTUAL PROPERTY AND TRIPS FLEXIBILITIES

2.0 Introduction

The concept of property has been in existence since time immemorial. The historical concept of property may be referred to as “a bundle of rights that may be exercised with respect to an object.” Property law has however developed to include rights and obligations relating to tangible and intangible property. Intellectual Property (IP) is a form of intangible property. Intellectual property has been regarded “as the recognition, protection and promotion of the work or product of the human mind and of human creativity embodied in tangible form.” IP is divided into two broad categories namely copyright and related rights and industrial property which includes patents, trademarks, trade secrets, industrial designs, utility models, geographical indications, layout design of integrated circuits and plant breeders rights. These categories qualify for and are legally protected by IP rights. Intellectual Property Rights (IPRs) are ownership rights which enable inventors to earn credit or profit from their work. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to create a situation in which ingenuity and technological advancement can flourish.

IPRs are regulated under international law through various treaties which countries may ratify to implement treaty provisions within national legislation. For example, the Patent Cooperation Treaty streamlines the international patent application system for protection of patents in multiple countries. The advent of international commerce has necessitated the creation of laws that govern the protection, distribution and use of IP within the global context. This paper focuses on TRIPS, an international legal instrument ratified by members States of the WTO.

TRIPS came into force on 1 January 1995 and has been described as the first constituent agreement of the WTO that prescribes ‘positive law’ by requiring members to establish a set of substantive IPR standards within their national legal systems and “requiring them to establish enforcement measures and procedures to meet these minimum standards.” TRIPS is crucial in harmonizing substantive IPR standards. The need for the harmonization of IPRs arose from the realization that the existing IP Agreements such as the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty, did not comprehensively deal with the distortions and impediments on international trade by effectively and adequately protecting IPRs.

This paper will examine TRIPS in relation to the use patents to achieve public health objectives. Patents are the dominant form of IP protection in the development and commercialization of pharmaceutical products such as essential medicines. TRIPS establishes minimum standards for IP protection for the various branches of IP including patents. Patents play an important role in providing incentives for research and development on new medicines for profit. The pharmaceutical industry relies heavily on the patent system to get a return on investment. A patent holder is granted a government protected right to prevent the use of his invention provided he has met universally accepted requirements for patent protection. According to Sihanya, “patents deal with high technology inventions rather than lower level innovations or discoveries; inventions that embody scientific intervention or a qualitative leap of technology.” Patents therefore consume high costs in terms of research and development due to the unpredictability in research outcomes, approval processes and promotion of the patented product. It is therefore crucial for a potential inventor to get a return on investment. This means that the cost of patented medicines can be very high hence people in LMICs cannot access

53 Ibid.
54 Ben Sihanya (n 51).
these lifesaving medicines. This is a major concern in LDCs and LMICs which needs to be addressed.

The lack of consistent access to essential medicines in LMICs led to the 2001 Ministerial Conference of the World Trade Organization (WTO) which adopted the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health (Doha Declaration). The Doha Declaration aimed at promoting public health objectives in accessing existing medicines and creation of new medicines. Under TRIPS for example, members of the WTO have the freedom to “adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development in compliance with TRIPS.”

Further, a ‘pharmaceutical product’ as referenced in the Doha Declaration may be defined “as any patented product, or product manufactured through a patented process in the pharmaceutical sector that is needed to address public health problems such as HIV/AIDS, tuberculosis, malaria and other epidemics.” This indicates that patents play a key role in the development of medicines however, the exclusive nature of patent protection may curtail access to essential medicines.

TRIPS however provides legal options to LMICs allowing the adoption of public health related measures to scale up access to affordable essential medicines. The first step in maximizing the benefits offered under public health related TRIPS flexibilities is incorporation of these flexibilities into the national legislative framework.

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55 Art 8 TRIPS.
2.1 Trips Flexibilities

2.1.1 Transition Periods

The transition period according to article 65.1 of TRIPS allowed developing countries to delay implementation of the minimum standard requirements under TRIPS for 5 years. This grace period was granted to prevent undue constrain on developing countries in implementation of minimum standard under TRIPS. An additional 5 years was granted under Article 65.4 of TRIPS to developing countries which did not grant product patents protection prior to the entry into force of TRIPS (I January 1995). Hence, these countries had a 10 year grace period up to the year 2005 to introduce such protection. Least Developed Countries (LDCs) were not required meet TRIPS obligations initially for 11 years but have to comply with “national treatment and most favoured nation treatment obligations.” The transition period for LDCs has been extended on three occasions. India is classified as an LMIC according to a World Bank report on development indicators. These transition periods had and continue to have implications on future access to essential medicines. According to Musungu and Oh, “the expiry of the transition deadlines has important implications for the future supply and availability of generic versions of patented essential medicines and impacts on prices and affordability”. Implementation of the transition period flexibility ensures that patent protection is not a hurdle in procurement and distribution of generic medicines.

58 The UN Economic and Social Council (ECOSOC) reviews the list of LDCs every 3 years based on gross national income per capita, level of human capital and structural vulnerability to economic and environmental shocks, see LDC Identification Criteria & Indicators <https://www.un.org/development/desa/dpad/least-developed-country-category/ldc-criteria.html> accessed on 2 October 2018.
59 TRIPS art 66 (1).
60 TRIPS (n 57) “The first extension was granted by the TRIPS Council in 2005. This extension provided that LDCs would not be obliged to implement or enforce patent and test data obligations with respect to pharmaceutical products until 1 July 2013. The second extension, approved by the TRIPS Council in 2013, provided that LDCs would not have to apply the provisions of TRIPS, until 1 July 2021. In November 2015, the Council further extended this transition until 1 January 2033.”
The delay in recognition of patent protection has enabled the speedy development of the generic pharmaceutical industry worldwide which thrives by reverse engineering patented pharmaceutical products. On account of this flexibility, India has, for example, been able to manufacture affordable generic medicines which greatly improved access to essential medicines for its citizens.

2.1.2 Patentability Criteria

TRIPS provides that patent protection is granted for, “any inventions that are new, involve an inventive step and are capable of industrial application”63 In addition, TRIPS provides that “WTO member States are required to grant patents for product and process inventions, without discriminating as to the field of technology”.64 TRIPS does not define an invention but instead provides the patentability criteria for grant of patent protection for inventions. TRIPS provides that inventions fall under “all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”65 By not defining the term ‘invention’ a gap is created allowing WTO member States the freedom to determine what constitutes an invention. The patentability criteria adopted by States can be used to achieve public health objectives for example, through raising the standards required for protection of new medicines through elimination of frivolous claims or protection of already know substances. This ensures continued research and development for new medicines and access to technologies. TRIPS “excludes diagnostic, therapeutic and surgical methods for the treatment of humans or animals”66 from patentable subject matter.

63 TRIPS art 27.
64 TRIPS art 27.1.
65 ibid.
66 TRIPS art 27.3 (a).
2.1.3 Compulsory licensing

Article 31 of TRIPS, does not explicitly use the term compulsory licensing however it provides for other use of a patent by the government or third parties without authorization of the right holder. According to Musungu et al, “a compulsory licence is granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder.”67 This therefore means that compulsory licensing is a statutory creation.

Compulsory licensing is a mechanism introduced under TRIPS in a bid to balance out exclusive rights of the Patent holder vis-à-vis social benefits of accessing essential medicines as well as attaining the basic human right to health. Compulsory licenses limit the patentee’s exclusive rights in exploitation of a patent and therefore only granted under certain conditions aimed at protecting the legitimate interests of the patentee. Article 31 of TRIPS lists minimum conditions which States must comply with, which include, among others, “the authorization for compulsory use which is considered on a case by case basis on individual merits”68, the compulsory license applicant must also “have made an unsuccessful attempt at obtaining a voluntary license from the patentee”69, “the scope and duration of such use must be limited in terms of the scope of the authorized purpose.”70 Where for example, administrative authorities determine that patent exploitation is anti-competitive then “a compulsory licence can be issued without the need to prove that a voluntary licence has been successfully negotiated.”71 These minimum standards provide leeway for WTO members States to provide for conditions for granting compulsory licenses within their national legal framework in order to promote public health objectives.

67 Sisule Musungu et al. (n 40).
68 TRIPS art 31 (a).
69 TRIPS art 31 (b).
70 ibid.
71 TRIPS art 31 (k).
Section 5 (b) of the Doha Declaration on TRIPS and Public Health affirms that “countries have the freedom to determine the conditions for granting compulsory licenses and to determine national emergency circumstances that can warrant issuance of a compulsory licence.”72 This means that the governments or a third party can use this flexibility even in cases of disease epidemics such as HIV/AIDS to scale up access to essential medicines.

2.1.4 Parallel Importation

TRIPS under article 6 provides that:

“[f]or the purposes of dispute settlement under this Agreement....nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

This clause indicates that TRIPS does not define the limits of parallel importation except in dispute settlement scenarios. The exhaustion doctrine arises “when the IP right holder cannot prevent the further distribution or resale of goods after consenting to the first sale and in such a situation, the right holder is considered to have exhausted its rights over these goods.”73 This means that the cost of pharmaceutical products is significantly reduced by introducing cheaper versions of the patented product thus promoting competition. The rationale for parallel importation is that the patent holder has fully benefitted from the first sale and that the patent rights have been fully exploited to exhaustion. The Doha Declaration stipulates that member States are “free to establish their own regime for such exhaustion without challenge.”74

The main juridical “doctrine governing the permissibility of parallel imports is exhaustion of IP rights or the point in the distribution process at which at the IP rights to control further

73 World Trade Organization, Medical technologies: the access dimension <https://www.wto.org/english/tratop_e/trilatweb_e/ch4c_trilat_web_13_e.htm> accessed on 12 June 2018
distribution are extinguished or ended."\textsuperscript{75} Parallel imports are also known as grey area products. Once a patented product is legitimately introduced into the market, then the patent holder’s exclusive rights have been exhausted upon the first sale. The two key rationales for grey area products in relation to generic medicines is that, first “parallel importation exists where the price differential between two markets is so high as to make it profitable to purchase from one and sell in another market”\textsuperscript{76} This means that the price of the generic product in the country of importation will be significantly cheaper than the price in the country of origin where research and development occurred. The second rationale is that, since consumers have been denied the patented pharmaceutical product by the local producer given the high cost making it unaffordable and inaccessible, they may secure the product from a foreign patent licensee who will import the product to sell it locally.\textsuperscript{77} Parallel imports are particularly significant for LMICs in realization of public health objectives because usually a patentee will not perceive LMICs as an attractive market due to low uptake of patented medicines at the price set by marketers, which in effect means the patentee is not likely to recoup investment costs.

2.1.5 Bolar Exception

The Bolar exception, also known as the early working provision, was originally conceived in the US.\textsuperscript{78} The exception is an instrument that ensures generic manufacturers obtain marketing authorization by obtaining regulatory approvals prior to the expiry of a patent. The Bolar exception relates to a situation where a patented invention is used “during the patent protection term without the consent of the patent holder for the purposes of developing information to obtain marketing approval.”\textsuperscript{79} The rationale behind the exception is that since regulatory

\textsuperscript{76} ibid.
\textsuperscript{77} ibid.
\textsuperscript{78} This theory was first conceived in the case of Roche Products Inc. v.Bolar Pharm. Co. Inc.,733 F.2d858 (Fed. Cir. 1984) in which Bolar, a pharmaceutical company, argued that under the “US Patent Act, use of a patented product did not amount to infringement as per the experimental use exception. The US Congress upheld Bolar’s argument and passed a law permitting use of patent protected products in experiments to obtain approval in accordance with the Federal Food and Drug and Cosmetic Act.”
\textsuperscript{79} Sisule Musungu et. al (n 40).
approvals may take a few years to obtain, a generic manufacturer and patients stand to benefit from lower prices of the medicines if regulatory approvals are obtained immediately prior to the expiry of the patent. On average, regulatory approvals take about 3 years and during this time the patent holder continues to enjoy de facto monopoly in the market despite expiry of the patent. This means that the patent holder should not continue to enjoy monopolistic position after the expiry of patent protection period especially where the invention can assist in achieving public health objectives.

TRIPS provides for exceptions to patent rights without going into details on the nature and extent of the circumstances under which the patent holder’s rights are limited. Article 30 provides as follows: -

“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, taking account of the legitimate interests of third parties.”

The non-specific nature of this provision can be interpreted to mean that WTO member States have the freedom to decide the circumstances in which a patent holder’s rights may be limited. The WTO Panel in the Canada-Patent Protection of Pharmaceutical Products Case assessed three conditions that must be fulfilled in compliance with TRIPS article 30. The exception should: - “i) be limited to certain circumstances; ii) not unreasonably conflict with a normal exploitation of the patent; and iii) not unreasonably prejudice the legitimate interests of the patent owner taking account of the legitimate interests of third parties.” In this case, the European Community Member States objected to the introduction of the Bolar exception into Canada’s patent laws in 1999. In its ruling, the WTO panel noted that “refusal to allow testing of generic medicines for the purposes of foreign regulatory submissions during the term of patent protection, while permitting it for domestic submissions, would needlessly delay the

TRIPS art 30.
regulatory review process in many countries.”\textsuperscript{81} The WTO panel held that Canada was not in violation of TRIPS by permitting the submission of data needed for market approval prior to expiry of the patent.

A strict interpretation of article 30 vis-à-vis the Bolar exception and within the context of the Doha Declaration, would be that all the three conditions should apply for the Bolar exception to be valid. Third parties with legitimate interests within this context can be PLWHAs as well as generic manufacturers. PLWHAs have legitimate interests in promptly accessing affordable essential medicines while generic manufacturers have an interest in increasing market penetration for their generic products as soon as the patent holder’s rights expire. In any event, the 20-year patent protection period is taken to be sufficient for the patent holder to recoup his cost for research and development and make a profit.

\textbf{2.2 Conclusion}

This chapter has dealt with the conceptual framework of this study by introducing intellectual property, intellectual property rights and international intellectual property law within the global context. This chapter also discussed TRIPS and TRIPS flexibilities. The next chapter examines the implementation of TRIPS in Kenya’s legislative and regulatory framework.

CHAPTER THREE: IMPLEMENTATION OF TRIPS FLEXIBILITIES IN KENYA’S LEGISLATION AND INSTITUTIONS TO PROMOTE ACCESS TO ESSENTIAL MEDICINES

3.0 Introduction

Kenya, according to a UNAIDS report, has about “1.5 million people living with HIV/AIDS.”82 The National Aids Council reportedly requires “Kshs. 45 billion annually to place PLWHAs on treatment alone.”83 “The cost per patient is estimated at Kshs. 20,000 for ARV treatment for a year.”84 The report further notes that previous dependence on donor support to finance HIV programs is not sustainable. This is an indication of the high financial burden on the government in providing ARVs for its citizens. In fact, Kenya is one of the ‘focus’ countries receiving support from the United States government through the provision of ARVs through a public health initiative dubbed PEPFAR85. Between 2004 and 2017, Kenya received over USD 5 billion worth of support through the purchase of ARV treatment, HIV testing services and so forth.86 These statistics indicate that Kenya faces a huge disease burden in relation to HIV/AIDS. The statistics also indicate that the government relies heavily on foreign aid to fund its HIV/AIDS program in the country. Without this external assistance, many PLWHAs would probably not have accessed lifesaving ARV treatments. A 2018 report indicates that “one of PEPFARs HIV/AIDS programs namely, the Global Fund to Fight AIDS cut funding by Kshs 3.1 billion over corruption allegation claims.”87 Funding cuts will adversely affect the purchase

84 Ibid
85 PEPFAR, Partnering to Achieve HIV/AIDS Epidemic Control, Kenya 2018 <https://www.pepfar.gov/documents/organization/199606.pdf > accessed on 27 August 2018. PEPFAR initiative is in line with “UNAIDS, 90-90-90 global goal to help end HIV/AIDS epidemic. UNAIDS aims to achieve the following targets by 2020: -90% of all people living with HIV will know their HIV status; 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy; and 90% of all people receiving antiretroviral therapy will have viral suppression.” See http://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf accessed on 27 August 2018.
86 Ibid
of ARVs that prolong the lives of thousands of PLWHAs. The report notes that 35% of the costs of healthcare for infectious disease such as malaria, “HIV/AIDS and malaria is donor funded and 28% is funded by the Kenya government.”\textsuperscript{88} This is an indication that Kenya relies heavily on external donors to fund its HIV/AIDS program.

Following the public health provisions provided for under the 2001 Doha Declaration, member States especially LMICs like Kenya still had concerns over the actual implementation of the TRIPS flexibilities. One of the concerns raised is the lack of capacity to manufacture generic drugs to leverage the TRIPS flexibility on compulsory licensing to help address the disease burden in LMICs. This challenge was occasioned by article 31(f) of TRIPS which restricted the use of compulsory licensing “predominantly for the supply of the domestic market of the member authorizing such use.”\textsuperscript{89} The WTO members further clarified these concerns through “the interpretation of paragraph 6 of the Doha Declaration in 2003 by specifying when countries can import drugs produced elsewhere under compulsory licensing.”\textsuperscript{90}

This chapter examines the extent to which Kenya, a founding member of WTO since 1995, has incorporated TRIP flexibilities into its domestic legislation to promote its public health objectives. The aim is to identify the challenges in the legislative, regulatory or administrative mechanisms that prevent the full realization of TRIPS flexibilities namely: -compulsory licensing, government use, patentability criteria, parallel importation, early working exception (Bolar exception). These are some of the options that may be used to promote access to essential medicines. The incorporation of TRIPS flexibilities into domestic legislation is important in securing the progressive realization of the right to health. There are other non-IP related measures that Kenya can consider in promoting access to essential medicines such as

\textsuperscript{88} ibid.
\textsuperscript{89} TRIPS (n 3) article 31(f).
creating a competitive environment through facilitation of multiple suppliers and building local production capacity of manufacturers in the pharmaceutical industry.

3.1 Laws Incorporating TRIPS Flexibilities in Kenya

The Constitution of Kenya provides that “the general rules of international law form part of the law of Kenya and in addition any treaty ratified by Kenya forms part of its laws.”

Kenya has ratified several conventions stipulating the governments obligation to “achieve the progressive realization of the right to health.”

The Universal Declaration on human rights contains basic human rights which Kenya has adopted under the Bill of Rights as envisaged under the Constitution. A country’s Constitution embodies its principles and is the supreme law and is therefore sacrosanct.

Kenya’s Constitution provides for the right of health as follows:

“Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.”

Further, the Constitution provides that the government “has the obligation to take legislative, policy and other measures, including the setting of standards, to achieve the progressive realisation of certain rights which include the right to health.”

These provisions seek to promote access of health. On the other hand, the Constitution also provides that it is the State’s “duty to support, promote and protect the IPRs of the people of Kenya” and may only limit IPRs in prescribed circumstances. These provisions indicate that the law endeavours to strike

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91 The Constitution of Kenya 2010, art 2 (5) and (6).
92 “The right to health under international law is subject to progressive realization subject to resource limitations. It imposes obligations on governments to guarantee that the right will be exercised without discrimination,” see World Health Organization article on human rights -based approach to health <http://www.who.int/topics/human_rights/en/> accessed on 1 August 2018.
93 Ibid (n 91) art 43(1).
94 Ibid art 21(2).
95 Ibid 131 art 40(5).
a delicate balance between individual interests in protection of IP and societal interests in promoting public health objectives as does TRIPS.

3.2 TRIPS Compliant Provisions in Kenya

3.2.1 Compulsory Licensing and Government Use

Compulsory licensing, if incorporated effectively as public health tool, has the potential to have the greatest effect in terms of enabling affordable access to essential medicines. According to Musungu et al, the implementation and effective use of certain TRIPS flexibilities “presupposes the existence of certain factors such as the existence of local research and pharmaceutical manufacturing capacities and the existence of adequate regulatory measures for use of medicines as well as for quality control which many developing countries find it difficult to implement.”

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The key piece of legislation that covers compulsory licensing is the IPA. The IPA provides for the regulation of the patent regime in Kenya. The Act provides that the “patent holder has a right to prevent others from exploiting the protected invention for example by selling it without the patent holders authorization.” 97 This is a ‘negative right’ in the sense that patent protection does not grant the patent holder a right rather it prevents third parties from exploiting the invention. The rights of a patent holder are not absolute and may be limited when a compulsory licence is granted.

The Industrial Property Tribunal (Tribunal) in Kenya may grant a compulsory license 98 “for reasons of public interest or based on interdependence of patents.” 99 These are the main justifications for grant of a compulsory licence in Kenya. The first justification is usually granted in cases of “failure to work a patent following the grant of a patent.” 100 This

96 Sisule Musungu et al. (n 40)
97 Industrial Property Act (2001), s 54.
98 Ibid s 75.
99 Ibid s 58 (5).
100 section 72 (1) of the IPA provides that “at any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the Tribunal for a licence to exploit the patented invention on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya.”
justification is in line with TRIPS which permits member States to take public interests measures to achieve public health objectives which includes the promotion of access to essential medicines for all. Failure to work a patent would curtail access to essential medicines.

The IPA does not expressly define the term public interest however, the meaning can be inferred from a reading of section 80 of the IPA which addresses use of patents by the government or by third parties authorized by the government. Public interest scenarios include “national security, nutrition, health, environmental conservation, or the development of any other vital sector of the national economy.”\textsuperscript{101} It can be argued that this broad terminology is useful in permitting the Tribunal more freedom and discretion to determine what cases may be a threat to public health.

The second justification for granting a compulsory licence which is based on “interdependence of patents refers to cases where a patented invention cannot be worked without infringing the patent rights derived from an earlier patent.”\textsuperscript{102} The Tribunal may grant the licence only “if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent.”\textsuperscript{103} This scenario can arise in cases of “ARV triple therapy fixed dose combinations whereby the majority of the constituent components of the dosage are protected by patents held by various patent holders.”\textsuperscript{104} While the ideal situation would be that voluntary licenses are obtained from the various patent holders, this consent may not be forthcoming. Voluntary licensing is ideal because it saves time that would have been spent on the application process and grant of the compulsory licence. India’s 2005 Patents (Amendment) Act provides for a limit of 6 months\textsuperscript{105} for negotiation of a voluntary licence failure to which the applicant can apply for grant of a compulsory licence.

\textsuperscript{101} ibid s 80 (1a).
\textsuperscript{102} ibid s 73 (1).
\textsuperscript{103} Ibid.
\textsuperscript{104} Robert Lewis-Lettington and Peter Munyi (n 49).
\textsuperscript{105} Patents (Amendment) Act 2005, s 84 (6) (iv).
Kenya nearly granted a compulsory licence in respect of a patented AIDS drug owned by German based company Boehringer Ingelheim and British based company GlaxoSmithkline, to local medicines generic manufacturer Cosmos Pharmaceutical Limited. In 2004, American pharmaceutical company Pfizer, sued Kenyan pharmaceutical company, Cosmos for infringement of its patent known as “azithromycin dihydrate”. Cosmos initially argued the patent was not in force in Kenya since the ARIPO granted patent had been allowed to lapse due to non-payment of renewal fees. The Industrial Property Tribunal rejected this argument since patents granted by ARIPO are enforceable in Kenya. Cosmos relied on exhaustion of rights provision under section 58 (2) of the IPA arguing that it could import, manufacture, sell and export the patented product without the patent holder’s authorization. However, this argument did not hold as parallel importation under the IPA is restricted to import and export and not manufacture of a patent product. Cosmos did however present evidence that the product had been imported from certain Asian countries. The Tribunal in its dicta stated that parallel importation applies in circumstances in which the government allows a third party to import the patented product from other countries where it is legitimately put on the market. This could be with “the authority of the patent holder by way of contractual or voluntary license.” The Tribunal failed to distinguish between a government-use order and parallel importation. Importation of cheaper generic medicines through parallel importation does not require the patentee authorization. The Tribunal held that Cosmos had infringed Pfizer’s patent rights. This decision indicates that the court failed to recognize the right to health as a fundamental human right and instead prioritized individual patent rights and trade gains over the human right to health.

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108 Industrial Property Act, 2001 s 59.
The patent holder has the “right to apply for cancellation of the compulsory license within 2 years if the patent has not been sufficiently worked.”

Generic manufacturers must therefore ensure rapid development of generic medicines as soon as a compulsory licence is issued.

A compulsory licence can be granted to exploit the patented invention on grounds that the market is not being supplied on reasonable terms in Kenya. The IPA provides that a duration of “3 years from grant of patent or 4 years from the application date must expire before an application is made.” This is linked to the first justification on grant of a compulsory license based on public health interest. The Tribunal may grant the compulsory licence should the following conditions in the IPA be fulfilled. The first condition is that the licence applicant must satisfy the Tribunal that the patent holder has turned down a “request for a voluntary licence on reasonable commercial terms and within a reasonable time.”

The requirement to obtain the patent holder’s consent will be waived in cases of national emergency or other circumstances of extreme urgency in which case the patent holder will merely be notified that a compulsory licence has been issued. It is important to note that the circumstances of ‘national emergency’ and ‘extreme urgency’ are not defined. This allows the government freedom in determining the scope of emergency situations which may include HIV/AIDS epidemic.

The IPA provides for circumstances that warrant issuance of a Government Use Order. Section 80 of the IPA provides that the Government may exploit patented inventions or may authorize third parties to do so in cases of public interest such as health, national security and when the patentee is engaged in anti-competitive practices. This form of compulsory licence carries the obligation of payment of compensation to the patent holder which may only be waived in

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110 IPA s 77 (2) provides that “the Tribunal may cancel a compulsory licence on the application of the owner of the patent, if, within two years from the grant of the licence, the licensee has not taken the necessary steps to work the relevant invention sufficiently so as to remedy the deficiencies or to satisfy the requirements which gave rise to his application for the said licence.”

111 Ibid s 72 (1).

112 Ibid 74 (1a).
certain cases at the discretion of the Government.\textsuperscript{113} The government may authorize a 3\textsuperscript{rd} party “to import, manufacture or supply a patented product without notice to the patentee.”\textsuperscript{114} Kenya can therefore be considered TRIPS compliant regarding use without the patentee authorization. However, the mere compliance with TRIPS does not guarantee access to essential medicines if Kenya does not proactively implement the legal provisos.

3.2.2 Parallel Importation

The doctrine of parallel importation holds “that once a patent holder has introduced a product into the market under patent protection without any restrictions, then the patent holder’s exclusive right with respect to the product has been exhausted.”\textsuperscript{115} The rationale for parallel importation is that once patented products are placed on the market with the patentees consent and subsequently imported into another country then his rights have been exhausted and he may not object to the resale of the patented product.

The key piece of legislation that regulates parallel importation in Kenya is the IPA. Since the inception of TRIPS, there has been contention over implementation of parallel importation given that TRIPS does not shed much light on it. In addition, developed States feel that the resale of patented products at a cheaper cost undermines the exclusive rights granted to a patentee. The IPA provides for parallel importation under the sub-title limitation of rights which is in relation to the rights of a patent holder.

The IPA states that:

\textsuperscript{113} IPA s 80(1).
\textsuperscript{114} Ibid.
\textsuperscript{115} Ben Sihanya (n.51)
“58 (2) 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.”

Prior to repeal of the previous IPA, which was repealed by IPA of 2001, the IPA Bill proposed to delete the words “by the owner of the patent or with his express consent.” However, this implies that the patentee’s consent is required upon the first distribution of a patented product in the market. It can be argued that the import of these words is that the patentee’s consent is required for parallel importation of products. This is not the case since the patentee’s consent is only required upon the first sale and not upon further distribution of the product. The current parallel importation provision bypasses the need to negotiate licenses with the patentee for importation of the medicine into the country which would likely drive up its price due to payment of royalties. Patent holders argue that parallel importation stifles the incentive to innovate since the ability to recover costs of research and development is hindered due to availability of cheaper drugs in the market. On the converse, presence of generic medicines creates a competitive market environment hence lowering of the costs of medicines. The IPA is therefore in alignment with TRIPS which permits member States to take measures that promote public health interest. This freedom is further reinforced under TRIPS since member States cannot bring a complaint under the WTO dispute resolution mechanism regarding parallel importation.

As this study demonstrates, Kenya is yet to develop some plausible manufacturing capacity. It would therefore make sense for the government to encourage cheaper imports of generic medicines which encourages competition. To counter anti-competitive practices, TRIPS allows

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116 Industrial Property Act 2001, s 58 (2).
117 Industrial Property Act Cap 509, s 38(2).
countries to adopt “appropriate measures that may be needed to prevent the abuse of IPRs by patentees or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

The Lords Healthcare Limited v Salama Pharmaceuticals Limited best illustrates how the Courts have addressed legal issues related to parallel importation. Although the case touched on a non-communicable condition, asthma, the case is worth mentioning since about 3 asthma medicines are on WHO Model List of Essential Medicines. The plaintiff contended that the defendant, a parallel importer, had infringed on its rights by importing the asthma medicine whereas the plaintiff was the authorized distributor. The court held that in addition to the fact that both parties had registered the drug under the Pharmacy and Poisons Act and could therefore import the medicine, the plaintiff had “failed to establish the existence of the exclusive rights for use of the trademark to market the medicine in Kenya.” The defendant contended that the trademarked products are supplied by Cipla Ltd, an Indian company in more than one country and parallel importation allows for importation of the same product from such other markets. The Court upheld this argument.

This case demonstrates that the judiciary as part of the public administration agencies have a crucial mandate in giving effect to TRIPS flexibilities by interpreting legal provisions in a manner that promotes Kenya’s public health objectives.

The Pfizer v Cosmos Case also touched on the issue of exhaustion of rights, however, as mentioned earlier, the Court failed to appreciate the essence of the exhaustion doctrine as extinguishing the patentee rights once products have been put in the market with his authority then imported to another country. By finding that Cosmos was not entitled to import the

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119 TRIPS art 8.2.
patented medicine, the Court did not consider legislature’s intention of securing access to essential medicines to millions of PLWHAs in Kenya.

3.2.3 Counterfeit Versus Generic Products

There is a popular misconception around imported goods particularly pharmaceutical products. This misconception has resulted in imported generic medicines being labeled as substandard and, in some instances, counterfeit goods. This perception was apparent in Kenya prior to the Patricia Asero Case. This case brought to light the misconception that generic medicines which are legally imported through parallel trade are counterfeit products, which are illegal.

The provision on counterfeit goods in the Anti-Counterfeit Act (ACA) was declared unconstitutional in 2012 following the judgment in the Patricia Asero Case. The petitioners contended that their rights under the Constitution of Kenya (2010) were violated by sections 2, 32 and 34 of the Anti-Counterfeit Act, 2008. Section 2 of the ACA was therefore amended to define anti-counterfeiting as follows: -

“Counterfeiting means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods:

(a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods.

(b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence.
(c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author’s rights or related rights.

(d) in relation to medicine, the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging, ”

The above definition clearly touches on IPRs namely: - trademarks because of the branding aspects such as packaging and labeling as well as patents due to production and manufacture of products and copyright because of the aspect of making copies. For example, infringement cases involving medicines branded in a manner that infringes a trademark owner’s mark should be brought under the Trademarks Act. All these infringement actions are termed as offences under the ACA since the rights holder’s authorization is absent. Section 32 and 34 of the ACA leads to seizure of generic medicines by criminalizing the importation of generic medicines. Law enforcement agencies such as the customs and border control officers are not aware of the difference between generic and counterfeits. This delays access to essential medicines which are usually imported. Plain reading of this definition would interpret generic products as counterfeit goods. The lack of awareness of what constitutes generics, has led to condemnation of generic products as illegal or substandard goods. This definition was one of the contentious clauses enumerated in the Patricia Asero Case because the ACA attempted to deal with IPR matters and yet there are laws in place dealing with infringements on various categories of IP such as the IPA, Copyright Act\textsuperscript{122} and Trademarks Act\textsuperscript{123}.

\textsuperscript{122} Copyright Act, No. 12 of 2001, Laws of Kenya.
\textsuperscript{123} Trademarks Act Cap 506 of 2012, Laws of Kenya.
3.2.4 Early Working Exception (Bolar Exception)

According to Musungu et. al, the Bolar exception is “an important mechanism in facilitating the production of and accelerating the introduction of generic substitutes on patent expiry.”

The Bolar exception allows the use of the patented invention to obtain regulatory authorization prior to the expiry of patent protection. The Bolar exception is particularly useful to generic pharmaceutical manufacturers who need to obtain market approval for their generic products by carrying out bioequivalence tests. It has been estimated that procedures for marketing approval of generics may delay their commercialization by 2-3 years. Timely implementation of this exception has implications on LMICs such as India that have generic manufacturing capacity and Kenya which could potentially fully develop its domestic manufacturing capacity or import generic substitutes upon expiry of the patent protection over the essential medicine.

In Kenya, section 54 (2) of the IPA provides that for the Bolar exception as follows: -

“The rights conferred on the owner of the patent under this section shall not apply to acts by third parties necessary to obtain approval or registration of a product from a relevant authority, for the purpose of commercialising the product after expiry of the patent.”

This provision, from the above analysis of the 3-step criteria, means that Kenya is TRIPS compliant by virtue of its legislative framework and it is quite clear that the exception is strictly with regard to regulatory approval. However, section 105 of the IPA titled “acts constituting infringement” contradicts 54 (2). Section 105 states as follows: -

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124 Sisule Musungu and Cecilia Oh (n 8).
126 Industrial Property Act No. 3 of 2001 s 54 (2), as last amended by Act No. 11 of 2017.
“.....any act specified in section 54 or 92 and performed by a person other than the owner of the patent or of the registered utility model or industrial design without the owner’s authorization, in relation to a product or a process falling within the scope of a validly granted patent or certificate of registration shall constitute an infringement.”

Plain reading of this section seems to suggest that the patentee’s consent is required prior to utilization of the Bolar exception. Section 105 negates the essence of the Bolar exception which is to prevent delay of the entry of generics in the market. The Act can be interpreted in such a manner as to cure the ‘mischief’ which is the requirement to obtain the patentee’s consent to avoid delay in generic entry. Interestingly, provisos on compulsory licensing, government use and parallel importation are excluded for the ambit of section 105 of the IPA. Since the Bolar exception was introduced via an amendment in 2017, perhaps not much thought was put into the effect of the amendment on other sections of the IPA. The practice however, in Kenya is that the patent holder’s consent is not needed for use of this exception.

It is in going beyond the mere enactment of the Bolar exception in domestic legislation to actual implementation that LMICs may face hurdles including lack of domestic manufacturing capacity, delay in processing regulatory approvals even the general lack of awareness by generic manufactures that the Bolar exception exists. These challenges could potentially reduce access to essential medicines.

According to a 2018 newspaper report, “Kenya is currently the largest producer of pharmaceutical products in the COMESA region, supplying about 50 per cent of the regions’ market and out of the region’s estimated 50 recognised pharmaceutical manufacturers, 32 are based in Kenya.”

Kenya therefore could be said to have potential to grow its domestic production capacity using local and international medicine manufactures. The report notes that

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Kenya hosts “major European and American MNCs which work through locally incorporated affiliates, technical representative offices and local technical agents.” This means that generic manufacturers can adequately tap into the benefits of the Bolar exception.

3.2.5 The Patentability Criteria

In Kenya, only inventions are patentable. The IPA defines “an invention as a solution to a specific problem in the field of technology.”

Kenya’s IPA provides for the 3-step patentability criteria. First, the evaluation for novelty in inventions is determined vis-a-vis the entire world such that similar innovations generated anywhere in the world constitute prior art. Second, the inventive step which relates to the “non-obviousness of the invention to an ordinary person skilled in the art to which the invention pertains.” Third, industrial applicability relates to the ability to use the invention in any kind of industry. Examples provided under the IPA are agriculture, medicine, fishery The IPA provides for non-patentable inventions such as plant varieties and inventions contrary to public morality. The 3 step criteria curbs anti-competitive practices such as ‘evergreening.’ According to Musungu et. al, this practice refers to “protection of new uses, from existing products for purposes of extending the patent protection period and blocking generic entry.”

Lack of expertise and access to prior art documents may open the patent examination system to abuse through the protection of medicines with minor modifications to already existing or known medicines. This practice would lead to anti-competitive behaviour whereby existing patents get a longer duration of protection, over 20 years, simply due to some minor modifications made to existing medicines. This practice eventually blocks the entry of generic

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128 ibid.
129 Industrial Property Act of 2001 s 21
130 ibid s 23
131 ibid s 24
132 ibid s 25
133 Sisule Musungu and Cecilia Oh (n 8).
medicines. The new drug discovery process should at least involve identification of new
chemical entities or involve new use of already known substances.\textsuperscript{134}

\textbf{3.2.6 Implementation of TRIPS flexibilities by Government Agencies and Institutions.}

This study involved the collection of primary data through interviews to shed light on specific
challenges faced by the relevant government agencies tasked with implementing TRIPS
flexibilities.

The interviews respondents\textsuperscript{135} were purposefully selected based on areas of expertise and the
frequency of dealing with TRIPS flexibilities related to access to essential medicines as well
as the pharmaceutical industry which is directly affected by legislation and regulatory measures
related to essential medicines.

\textbf{3.2.6.1 Kenya Industrial Property Institute (KIPI)}

KIPI is an autonomous parastatal established on 2nd May 2002 under the auspices of the
Ministry of Trade, Industry and Cooperatives. KIPI was established following the enactment
of the IPA which provided that KIPIs functions include “considering applications for and grant
of industrial property rights.”\textsuperscript{136}

KIPI as an industrial property rights administrative body, plays a key role in ensuring that
Kenya complies with its WTO obligations in the implementation of TRIPS flexibilities. KIPIs
Managing Director for example, may recommend that the Minister of Trade issue a

\textsuperscript{134} See how Indian pharmaceutical companies are developing “biosimilars”. “Biosimilars are defined as an officially approved
new version of innovative biotherapeutic products for which the patent has expired,” Balganesh, T., Kundra, T. K.,

\textsuperscript{135} Interview with Nelson Juma Otwoma, Executive Director, National Empowerment Network of people living with
HIV/AIDS in Kenya (NEPHAK) held on 18 September 2018; Interview with Cleophas Ojode, Pharmaceuticals Patent
Examiner, Kenya Industrial Property Institute (KIPI) held on 19 September 2018; Interview with Edward Abwao, Head of
Clinical Trials Unit Pharmacy and Poisons Board (PPB) held on 20 September 2018. Interview with Dr. Francis Karanja,
Executive Member of Kenya Association of Pharmaceutical Industry (KAPI) [note that KAPI represents research and
development pharmaceutical companies] held on 26 September 2018; Interview with Dr. Willie Wanjagi Kiragu, Quality
Assurance Manager at Sphinx Pharmaceuticals Ltd held on 28 September 2018; Peter Njenga, Regulatory Affairs, Cosmos
Pharmaceutical Limited held on 8 October 2018.

\textsuperscript{136} IPA s 5(a).
government-use order where the “Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is anti-competitive.”

KIPI however faces certain challenges in carrying out its mandate that prevents full utilization of TRIPS flexibilities as follows:

**Question 1: In substantive examination of applications for pharmaceutical patents related to essential medicines, what are the main challenges you face?**

According to respondent O:

“KIPI uses databases in the public domain to access information on patent application and grant. Some databases are privately owned and require payment of access fees but they may contain information we need. KIPI does not subscribe to these databases. Once a patent is granted there may be opposition proceedings to object to grant of patent on grounds of lack of novelty.”

According to a WIPO press release, “resources that directly link patents or patent applications to medicines already on the market are scarce and limited and in addition, information directly linking granted patents to medicines is only available publicly in certain countries.” This means that the 3-step patentability criteria as provided under TRIPS may not be strictly adhered to in Kenya due to lack of access to sufficient prior art documents. KIPI only relies on information in publicly available databases. Compliance with the novelty step presents a challenge due to this lack of access of patent related information. WHO et al note that “erroneously granted patents potentially impede access and further research and are therefore not in the public’s interest.”

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137 IPA s 80(1).
139 WHO, WIPO and WTO (n 41).
In Kenya, publicly accessible patent information on pharmaceuticals is available although the pharmaceutical patent information collated is not exclusively focused on pharmaceutical patents and is hosted in a University resource database. In addition, the information on whether patents are still in force and whether patent fees have been paid is lacking. This would still require a visit to KIPI offices to get information on each patent. Publicly available and accessible comprehensive patent information promotes the continued research and development on expired patents and encourages the production of off-patent medicines.

The practice of evergreening may also be rampant in Kenya whereby pharmaceutical companies make minimal improvements to an already existing patent in one part of the world then apply for patent protection in Kenya. The risk of detection is low especially since KIPI can only access patent information in public databases. According to WIPO et al, “patent status and legal status information helps to determine the freedom to operate and to evaluate the scope of patent protection and determine whom licences must be negotiated with.” Freedom to operate is an essential aspect in generic medicines manufacture.

In addition to the lack of access to patent information, another challenge identified by KIPI in a 2012 is that there is inadequate exposure to emerging technologies and required skills for dealing with such technologies.

According respondent O: -

“There are about 8 patent examiners while the classes of inventions are numerous. Not all specialization areas are covered by corresponding specialized personnel. IP is evolving, and emerging technologies require further training to build the capacity of

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140 Strathmore University, ‘Center for Intellectual Property and Information Technology Law,’ <https://www.cipit.org/index.php/blog/resources/databases?start=110> accessed on 21 October 2018
141 Anne Krattiger (n 46).
existing staff. Most inventions are scientific in nature while existing personnel may not have the capacity to review scientific related patents. In addition to the role of patent examiner, our key mandate is to advice on IP law and policy formulation which requires some background in IP. Therefore, most patent examiners opt to advance their education in IP rather than scientific courses such as biochemistry."

These limitations of adequate technical expertise and staffing issues may lead to anti-competitive behaviour for example anti-competitive practices such as evergreening and delay in processing approvals. KIPI may lack the technical expertise to identify such practices in new patent applications which prevent entry of generics in the market.

Musungu et al. note that the “acquisition and strategic use of patent portfolios to prevent competition by producing similar but non-infringing products is one of the strategies used by large MNCs to retain market monopoly.”

**Question 2: What is the number of expired pharmaceutical patents related to essential medicines in Kenya? Have generic manufacturers taken up the production of generic substitutes following the expiry of these patents?**

The respondents in the generic pharmaceutical production field were generally unaware of the estimated number of expired patents related to essential medicines in Kenya. This information is crucial in creating the freedom to operate environment so that local generic manufacturers can produce off-patent medicines. The reason for this lack of knowledge could be that few generic manufacturers in Kenya even have capacity to produce off-patent medicines. A 2017 newspaper report indicates that only three companies in Kenya have capacity to manufacture ARVs with one of them, Universal Corporation’s ARV medicine Lamozid, being awarded

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143 Sisule Musungu et al. (n 40)
WHO prequalification status in 2011.\(^{145}\) Achievement of WHO prequalification status allows local manufacturers to tap into lucrative tenders floated by government or donors for the supply of essential medicines. Pharmaceutical manufacturing companies in Kenya lack sufficient capacity to manufacture essential medicines therefore, these companies are not well positioned to utilize this information to produce off-patent medicines.

**Question 3: How many compulsory licensing applications related to essential medicines have been made since the inception of the Industrial Property Act (IPA) in 2001?**

Most of the respondents particularly those from pharmaceutical companies did not have any record of having submitted compulsory licensing applications related to essential medicines. The information is available on KIPIs website however it is not easily accessible on KIPIs website since IPRs information is contained into monthly journals. It is quite cumbersome to sift through all journals to obtain this information.

### 3.2.6.2 Pharmacy and Poisons Board

Full utilization of TRIPS requires full support and participation of relevant regulatory bodies. The Pharmacy and Poisons Board (PPB) is empowered to regulate medicinal substances imported into Kenya.\(^{146}\) The PPB is a medicines regulatory authority operating under the Ministry of Health.

The WIPO Committee of Patents in its report addressing the challenges facing LDCs in the uptake of TRIPS flexibilities, noted that “use of various provisions in the national/regional laws


\(^{146}\) Pharmacy and Poisons Act s 44 (1)
by various stakeholders at the practical level requires a supportive and coherent legal framework.”  

The PPB developed a “draft Legal Framework for Parallel Importation of Medicinal Substances in Kenya in a bid to make essential medicines accessible and affordable to all.” The PPB is yet to roll out these guidelines which would offer much needed guidance on operationalization of this flexibility, including differentiating between generic medicines and counterfeit products.

Parallel importation has the effect of promoting competition since pharmaceutical products are purchased at a cheaper price and imported into the Kenya by an approved parallel importer and sold at a cheaper price. These products compete with more expensive branded or patented products in the market driving down the costs of essential medicines. The draft framework notes that the cost of essential medicines is significantly high vis-à-vis the price of similar products in other countries.

The draft framework notes that the contention with parallel importation is not strictly an IPR issue but one of ‘price differentiation’ which arises in a situation where “the price of pharmaceutical products substances in Kenya is significantly expensive in comparison to the price of the same products other countries because of lack of price regulation in Kenya.” Prices differences attracts importers of pharmaceutical products since the margin between the patented medicine and the imported product is significant enough to allow profit making. The availability of cheaper imported medicines promotes competition and offers an array of options for consumers. Absence of parallel imports means that the patent holder eventually controls pricing and distribution of medicines in the market. The Kenya Essential Medicines List  

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147 WIPO Standing Committee on the Law of Patents (n 2)  
148 Pharmacy and Poisons Board, ‘Parallel importation of drugs to lower cost of medication’ (2015)  
149 ibid  
PPB/MIP/CTL/GUD/003 <https://pharmacyboardkenya.org/clinical-trials> accessed on 4 September 2018
contains “a list of medicines for treating communicable and non-communicable diseases developed in 2016 by the Ministry of Health.”\textsuperscript{151} The essential medicines list is “intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.”\textsuperscript{152} WHO has a Model List of Essential Medicines which is reviewed after two years. “The purpose of the WHO Model List is to provide guidance for the prioritization of medicines from a clinical and public health perspective.”\textsuperscript{153}

\textbf{Question 4: What are the main challenges facing access to essential medicines such as ARVs in Kenya?}

Many of the respondents believed that the cost of essential patented medicines is prohibitively high and therefore the cost is a barrier to access. Respondent P pointed out that there are two areas of challenge in accessing essential medicines: -

\begin{quote}
“a) The government of Kenya relies heavily on external donor support to procure cheaper ARVs. In fact, the public health sector is externally driven which means that donors such as PEPFAR and the Global Fund play a critical role in funding Kenya’s HIV/AIDS Care and Treatment Program; b) PLWHAs often suffer from opportunistic diseases such as Tuberculosis and Pneumonia due to low immunity levels which requires treatment. This significantly drives up the overall cost of HIV treatment.”
\end{quote}

This view ties in with the report that Kenya received up to USD 5 billion from PEPFAR to support its HIV/AID Program and this funding was later slashed due to corruption allegations.\textsuperscript{154} In addition to this challenge, due to opportunistic diseases, PLWHAs must incur extra costs in obtaining treatment for these diseases and although generic medicines exist,
availability may be low. In a report on the cost of HIV Treatment Programs in Kenya, comprehensive HIV treatment is defined as both ARV treatment and supportive care which is central to HIV management and also includes treatment of opportunistic infections. The 2013 report estimates that “the comprehensive treatment cost per patient per year is about USD 158.08.” This cost is quite high given that the number of PLWHAs in Kenya is estimated at 1.5 million.

According to respondent Q: -

“Many generic medicine companies may only have access to information in the public domain on an existing or expired of the patent but lack the know-how that is crucial in working the patent or even the test data required for bioequivalence studies. Generic companies may also lack the technical infrastructure and expertise to reverse engineer to determine the actual composition of the patented product. The company may resort to importing semi-finished or finished products which are subject to importation taxes. This may eventually drive up the cost of the medicine.”

The Value Added Tax Act provides that “inputs or raw materials (either produced locally or imported) supplied to pharmaceutical manufacturers in Kenya for manufacturing medicaments, as approved from time to time by the Cabinet Secretary in consultation with the Cabinet Secretary responsible for matters relating to health” are zero rated. This means that prices of finished pharmaceutical products will likely be low. For zero-rated items, suppliers may recover tax incurred in generating the items.

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156 Ibid. The cost of ARVs has risen significantly since 2013, see Angela Oketch (n 83).
157 UNAIDS Country Factsheet Ibid (n 82).
Question 5: Do government agencies have efficient mechanisms for expedient registration of new essential medicines and efficient procurement systems to ensure speedy purchase and distribution of these essential medicines?

New medicines introduced in Kenya are required to obtain PPB marketing authorization. Submission of test data to regulatory agencies is also required to obtain marketing authorization for novel pharmaceutical products. The PPB then undertakes an autonomous evaluation of the quality, safety and efficacy of medicines. The PPB through the Experts Committee on Clinical Trials has a time frame of up to 30 days within which to review an application for registration of medicines and provide a response to the applicant.

According to Respondent X:

“Clinical trials in Kenya are not mandatory for new medicines provided the applicant submits test data even though it has already been submitted in a foreign jurisdiction. However, for most patented products, test data is not readily available as it is considered proprietary or confidential given the amount of time and effort invested in generating it. It may also be subject to intellectual property protection.”

The Clinical Trials Guidelines in Kenya do not mention the requirement to disclose test data to regulatory authorities such as PPB for example, in cases of national emergencies for example procurement of essential medicines to treat a widespread communicable disease in Kenya particularly ARVs. Clinical trials and bioequivalence tests may take on average from 3 years. This protracted period may lead to many deaths especially in cases where treatment is needed promptly in emergency situations such as nationwide epidemics.

According to respondent Y:

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159 Test data is subject to protection in various jurisdictions. Test data is generated by the patent holder or originator company of the medicine through various tests and clinical trials. TRIPS requires protection of test data but provides leeway for WTO member States to determine the form and scope of protection. See WHO, WIPO, WTO (n 41).

160 PPB (n 150).

161 ibid.
“The supply of essential medicines to LDCs in Africa faces some challenges, the major ones being, first, insufficient forecasting by Governments hence inadequate medication is supplied. Second, governments may lack the funds hence payment for the medicines may take time and this can delay delivery of medicines to these countries especially in emergency situations.”

This response corroborates evidence to the effect that most developing countries including Kenya rely on external funding which may be curtailed for one reason or other which affects access to essential medicines.

Question 6: What are the major hurdles you face when dealing with the medicines regulatory agency in Kenya?

The dominant view among the respondents in the generic manufacturing industry was that the PPB lacks sufficient capacity in terms of adequate personnel to deal with the high demand for registration of generic products. However, according to respondent Q who mainly deals with innovator patented products stated that:

“PPB has a fast-track process where new medicines can be registered within 6 to 18 months provided all requisite procedures are followed.”

The clinical trials guidelines however do not document this fast track process for registration of medicines. In fact, the Guidelines do not contain a timeframe within which the registration process is completed. This lack of proper documentation on approval timelines may result in unreasonable delays for no substantive reason which poses a serious threat to generics entry in the Kenyan Market.

3.3 Conclusion

This chapter has examined how TRIPS has been incorporated into Kenya’s law which is a first step in becoming TRIPS compliant. While Kenya can be considered TRIPS compliant, more
needs to be done in terms of going beyond the enactment of a relevant legal framework to actual implementation to ensure full utilization of TRIPS flexibilities. The Chapter has also examined institutional challenges faced by various institutions tasked with the implementation of Trips flexibilities and the conclusions from the various interviews can be summarized as follows:

First, the institutions discussed in this chapter lack adequate staff skilled in dealing with modern technologies which may lead to delays in registration and approval processes of essential medicines.

Second, the institutions also lack access to emerging technologies and access to information that links patents to medicines which can compromise the quality of patents granted in Kenya and eventually delay generic entry.

Third, the institutions lack properly automated online systems containing crucial information which should be publicly accessible for the benefit of generic manufacturers and lack streamlined business systems to expedite approval applications.

Fourth, Kenya lacks adequate manufacturing capacity and relies heavily on external donors to funds its HIV/AIDS Program. In addition, the incentives for local production of medicines are inadequate to spur substantial growth of the pharmaceutical industry.

Finally, there is lack of coherent and supportive policy frameworks to guide the implementation of the current TRIPS legislative framework to secure increased access to essential medicines. Further, the ambiguities identified in the law can lead to uncertainty in interpretation and implementation of TRIPS flexibilities.

The next chapter examines India’s legislative framework as a best practice model to determine factors attributed to the exponential growth of India’s generic manufacturing industry.
CHAPTER FOUR: IMPLEMENTATION OF TRIPS FLEXIBILITIES IN INDIA’S LEGISLATIVE FRAMEWORK

4.0 Introduction

The introduction of penicillin in the 1940s marked the beginning of the ‘therapeutic revolution’ in the world’s pharmaceutical industry. This revolution is defined as the unprecedented growth in the discovery and development of medicines to manage communicable and non-communicable diseases. India has played a major role in this therapeutic revolution. India accounts for “about 3.1 – 3.6 per cent of the global pharmaceutical industry in value terms and contributes the second largest share of pharmaceutical and biotech workforce in the world and as at March 2018, the Indian pharmaceutical market grew at 9.5 per cent year-on-year.”\(^{162}\) India has therefore become the go-to market for cheaper quality generic medicines.

This chapter delves into a historical overview of India’s Patent regime to determine factors attributed to the growth of India’s generic manufacturing industry. There were numerous amendments\(^{163}\) to India’s Patent law however this paper will focus primarily on legislative changes touching on the TRIPS flexibilities which promote access to essential medicines namely, transition periods, patentability criteria, Bolar exception, parallel importation, government use and compulsory licensing. Access to generic medicines at affordable cost in India has been largely attributed to proper implementation of these TRIPS flexibilities which has revolutionized India’s patent regime. This has in effect, positioned India as a lead distributor of essential medicines to the world at large.

\(^{162}\) India Brand Equity Foundation, ‘India Pharmaceuticals Industry Analysis’ (IBEF, April 2018) \(<https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>\) accessed on 10 October 2018

4.1 The History of the Patent Regime in India

4.1.1 Transition Periods

Prior to independence from British colonial rule, India’s government relied on the colonial Designs and Patents Act of 1911. After independence in 1947, India enacted the first Patent law over two decades later in 1970. In the interim, the government was focused on encouraging MNCs to invest in India such that by 1970 when the Patents Act was enacted, 80% of the local pharmaceutical industry was controlled by foreign owned entities.164 In fact between 1947 and 1970, “approximately 99% of all pharmaceutical products under patent in India were held by foreign companies and domestic Indian drug prices were among the highest in the world.”165 This situation meant that India was unable to provide essential medicines to its populace due to non-availability and unaffordability of medicines.

The Government of India established two committees166 to review the 1970 Patents Act in a bid to encourage the advancement of India’s domestic pharmaceutical industry. Following recommendations from the Committees, the Indian Government through a series of policy changes, abolished product patents167 related to food, pharmaceuticals and chemicals and instituted process patents and the duration of protection for process patents restricted to 7 years. The rationale for abolishing product patents was that India’s government realized that nearly “80% to 90% of Indian patents were foreign owned and a large percentage of these patents were not worked in India.”168 The Indian government also realized that the high costs of patented medicines will have a negative effect on their obtainability and affordability to its citizens. The Committees for example recommended that compulsory licensing is introduced

166 Gopakumar. G. Nair, (n 21), The Tek Chand Patents Enquiry Committee (1948-50) and the Ayyangar Committee (1959) whose recommendations formed the basis for the 1970 amendments to the Patent Law.
167 This necessitated deletion of s 5, Patents Act 1970.
and the ‘license of right’ which enabled anyone to use an invention on grounds of public interest without worrying about infringement suits. MNCs opposed changes to the Patents Act arguing that patents are essential in promoting innovation and dissemination of technological knowledge that domestic pharmaceutical companies can later use to boost their own manufacturing capacity.

The grant of patent over process related inventions lowered the patentability standard and allowed the local generic industry to copy and produce the patented drug using reverse engineering techniques using a different production process. This also allowed generic manufacturers to produce in large quantities, patented medicines and trade at a lower cost since the costs related to the research and development of the new medicine were avoided. However, given the high cost accrued from research and development as well as introducing new medicines to market, this move did not serve India well in attracting foreign investors looking to recoup costs of investment.

During the 70s, India’s national pharmaceutical industry took the initiative in carrying out process development studies geared at generating generic equivalents to inventors’ products. According to Greene, “these policy changes ended India’s dependence on expensive foreign medicines, fostered the development of a competitive pharmaceutical industry and guaranteed the Indian public access to inexpensive medicines.” This is because the reverse engineered medicines differed from the original medicine, through the production process employed, therefore, essential medicines could be copied and manufactured at a much cheaper price.

The 1970 Patents Act effectively weakened the Patent system but encouraged the growth of domestic pharmaceutical companies as a result of the generic versions produced and in effect,

169 Gopakumar. G. Nair, (n 21).
171 William Greene (n 165).
increased local capacity to produce pharmaceutical products. This growth trend continued steadily until 1995 when India joined WTO. In fact, according to Nair, “between 1970 to 1995, the share of the national sector of the pharmaceutical industry recorded a growth from 15% to nearly 18% and India became nearly self-sufficient in the manufacture of medicines and substantially large manufacturer and exporter of bulk medicines or active ingredients.” 172

Since the enactment of the 1970 Patents Act, competition between generic manufacturers drove down the cost of generic medicines drastically over the years.

When India joined WTO in 1995, it had to comply with TRIPS requirements of establishing minimum standards for IPRs by amending its domestic laws. India had, as a developing country, a transition period of 10 years up to 2005 in which to implement a new patent regime in compliance with TRIPS specifications. Between 1995 to 2005, India’s Patent laws, underwent a 2-stage process to ensure compliance with TRIPS specifications. First, India amended its Patent Act in 1999 to provide that from 1995, applications for pharmaceutical inventions would be accepted and put away in a ‘mailbox’, to be examined in 2005173 when India was due to comply with TRIPS obligations. This action was in response to a case filed under the WTO dispute resolution system by the United States (US) based on claims that India violated articles 70.8 and 70.9 of TRIPS. These articles provide that “where a Member does not grant patent protection for pharmaceutical products on the date of signing TRIPS, then such a member must implement a system for filing patent applications for such products.”174 The WTO Appellate Body held that India had to give retrospective effect to it’s Patents (Amendment) Act of 1999 from 1995, the date that India was supposed to have set up a sound ‘mailbox’ mechanism consistent with TRIPS specifications.175

172 Gopakumar G. Nair (n 21)
173 ibid.
174 See WTO Dispute Settlement: India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (Complaint by the United States) DS 50 Adoption date 16 January 1998 <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm> accessed on 16 June 2018
175 TRIPS articles 70.8 and 70.9
Under the ‘mailbox’ system, generic manufactures can use medicines which have not been granted patent protection but whose application is pending examination in the ‘mailbox’. This means that once patent protection is granted then a compulsory licensing scenario is automatically created. Generic manufactures feared that this provision would cause medicines currently in production to go off the market and lead to unprecedented price surges of generic medicines. However, these fears were assuaged following clarification in the Patents (Amendment) Act of 2005 that the patent holder’s right begins from the date of grant of patent instead of the date of the application. In addition, the “patent holder is only entitled to receive reasonable royalties.” The Act did not define what this reasonable royalty rate is. Therefore, in case of any dispute regarding royalty payment, parties would have to negotiate a ‘reasonable royalty’ rate. It is therefore left to disputing parties to agree for example based on current market rates or comparing with the royalty rates in other jurisdictions.

India also introduced the Patents (Amendment) Act of 2002, which extended “patent protection terms from 7 years to twenty years to ensure that India’s Patent law complies with TRIPS minimum standards for IP protection.”

Kenya as a developing country had a grace period of 5 years to implement TRIPS compliant provisions in its domestic legislation. This meant that by 1 January 2000, Kenya’s should have been consistent with TRIPS. Kenya had an option to delay patent protection for pharmaceutical products until 1 January 2005 since Kenya did not provide for patent protection of pharmaceutical products on 1 January 1995, the date that TRIPS entered into force. Kenya did not however delay recognition of product patent and therefore failed to utilize the full 10-year

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177 The Patents Act 2005 art11A (7)

transition period and instead introduced patent protection under the Industrial Property Act (IPA) in 2001.

4.1.2 The Patentability Criteria

Foreign owned MNCs in India were disgruntled and opposed the amendment to the Patents (Amendment) Act of 2005,\(^{179}\) which only “afforded patent protection to pharmaceutical products that constituted new chemical substances or enhanced the therapeutic efficacy of known substances.”\(^{180}\) Norvatis, a Swiss company challenged the amendment following an unsuccessful patent application on its cancer medicine *Glivec* in the India Patent Office. The patent application was rejected on grounds that the medicine was a mere superficial enhancement that it therefore lacked “novelty and inventiveness” in line with section 3(d). Norvatis had filed a patent over *Glivec* around the world, in about 40 countries. Norvatis then sought patent protection for *Glivec* in India in accordance with the “mailbox” obligation which was later rejected on grounds that the *Glivec* patent application is “an unpatentable modification of an existing substance, *imatinib*.\(^{181}\) Norvatis opposed this move by suing the Indian government claiming that section 3(d) of the Patents (Amendment) Act of 2005 was vague and in violation of TRIPS. The case eventually moved to the Indian supreme court which upheld previous court judgements and stated that *Glivec* failed to uphold the standard set out in section 3(d) since it was simply a modification of an existing patent. The Court disallowed the argument that Norvatis’s patent application on *imatinib* was novel, on grounds that slight changes made to the chemical composition in *imatinib*, an existing pharmaceutical product, defeats the purpose of patent protection. In addition, Norvatis had failed to prove *Glivec’s*

\(^{179}\) Patents (Amendment) Act of 2005 s 3(d) provides that “inventions are not 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. It further states that for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

\(^{180}\) Novartis AG v. Union of India (UOI) and Ors.; Natco Pharma Ltd. v. UOI & Ors.; M/S Cancer Patients Aid Association v. UOI & Ors., Civil Appeal No. 2706-2716 of 2013.

\(^{181}\) ibid.
enhanced efficacy. The Court’s ruling has been critiqued for failing to address the actual meaning of term “enhanced efficacy.” Initially, section 3(d) of the 1970 Patents Act omitted from the ambit of inventions, “the mere discovery of new property or new use for a known substance” while the amended section 3 (d) expanded the scope of exclusion by emphasizing that patent protection over existing substances would only be applicable in cases of enhanced efficacy of such substances. Proponents of the 2005 Patents (Amendment) Act particularly international civil society groups and public health advocates have praised this move arguing that it provides accessibility to generic medicines to millions of patients since MNCs can no longer extend patent protection period as a result of slight modifications made to existing patents.

Basheer, in critiquing the Court’s decision, observes that the phrasing of section 3(d) was borrowed from “the term ‘generic medicinal product’ as defined under a European Directive dealing with drug safety regulation.”\(^{182}\) He argued that since the wording was directly transferred from a medicine regulatory regime, it focuses more on clinical trials to collect information on drug efficacy which usually occurs after a patent has been granted.\(^{183}\) The practice by MNCs is to file a patent application upon discovery of new medicine therefore he argues that this articulation of what constitutes an invention does not fit into the universally accepted practice as provided under TRIPS.

The 2005 Patents (Amendment) Act effectively narrowed the scope of the patentable subject matter by limiting the definition of novelty to the efficacious nature of the invention. However, given that one of the standards of patentability under TRIPS is that an invention should be industrially applicable\(^ {184}\), it may be inferred that India parliament intended to enact a law in

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\(^{183}\) Ibid.

\(^{184}\) Article 27 TRIPS.
compliance with TRIPS such that inventions have actual and beneficial use to society. From a public health perspective, increased therapeutic efficacy in existing medicine may signify the difference between life and death for example it can be argued that in cases where the invention is a chemical that allows faster absorption of an existing medicine in the human body, then the invention would qualify for patent protection. On the flip side, the only way to evaluate efficacy is through actual use of the invention which means that the inventor must proof that the invention is efficacious possibly through a series of clinical trials. This high standard in the patentability criteria effectively curbed ‘evergreening’ as anticipated by the Indian government. ‘Evergreening’, is “an abusive patenting practice in the pharmaceutical industry aimed at filing and then obtaining separate patents relating to different aspects of the same medicine.” The effect of section 3(d) was to curtail the practice by MNCs of extending patent applications by making minimal changes over existing medicines. According to Basheer, the 2005 Patents (Amendment) Act attempts to “balance out competing interests of a variety of stakeholders, including domestic generic medicine producers, foreign multinational pharmaceutical companies and civil society groups concerned with access to medicines.” This in his view, has been the primary cause for the lack of clarity in the law.

Kenya’s definition of an invention is inclusive rather than exclusive like in India’s case where the 2005 Patents (Amendment) Act describing what does not constitute an invention. India’s 2005 Patents (Amendment) Act expressly disregards “discoveries of an existing substance unless they result in the enhanced usefulness of a product.” This means that derivatives from a patented substance cannot be patented in India unless such derivatives have some new use. The Indian Act also excludes frivolous claims which are obvious and contrary to natural laws from classification as inventions.

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186 Shamnad Basheer (n 168).
187 Patents (Amendment) Act of 2005 s 3(d).
188 ibid s 3(a).
Novartis alleged that section 3(d) contravened TRIPS despite the flexibility afforded to members States in enacting domestic legislation in line with their public health interests. TRIPS however, does not expound of the terms “inventive step” and instead leaves it open for members states to provide the limits to patentability based on their domestic needs. To counter evergreening in India, proof that the invention has new use is required. This means that India has placed emphasis on the industrial applicability criteria in terms of gauging the usefulness of the invention.

The Novartis case demonstrates the public health issues the Indian Court had to grapple with particularly the effects of patents in restricting access to generic medicines. The decision has been criticized as likely to lead to a decrease in foreign investment by MNCs in India’s pharmaceutical industry and further the courts dicta only made the patentability standard less clear since the term enhanced “enhanced efficacy” was not defined. This lack of clarity was occasioned by India’s government attempt to balance competing interests that is, the need to safeguard public health vis-à-vis the need to respect patent holder’s exclusive rights.

4.1.3 Compulsory Licensing and Government Use

India’s 1970 Patent Act and subsequent amendments to the Act, contained 19 amendments sections on compulsory licences.189 These changes were as a result of India signing TRIPS and thereby agreeing to adhere to the minimum standard of intellectual property protection.

India’s 1970 Patents Act provided for compulsory licensing which permitted anyone to freely practice an invention, “where at any time after the expiration of three years from the patent... the patented invention is not available to the public without fear of any infringement suit.”190

However, the compulsory licence provision has been criticized due to the duration of time (3 years) that generic manufactures must wait for, following the grant of a patent, to apply for a

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190 Patents Act, No. 39 of 1970 art 84 (1).
compulsory license instead of a much shorter duration given the lifesaving nature of essential medicines. The Patents (Amendment) Act of 2005 stipulates conditions for granting compulsory licenses as follows:

\[ \begin{align*}
\text{a.} & \quad \text{“Reasonable requirements of the public with respect to the patented invention have not been satisfied, or; } \\
\text{b.} & \quad \text{that the patented invention is not available to the public at a reasonably affordable price, or; } \\
\text{c.} & \quad \text{that the patented invention is not worked in the territory of India”}.^{191}
\end{align*} \]

The three-year duration appears to be reasonable because it gives the government time to evaluate the patents holder’s fulfillment of the above-mentioned conditions. The patentee’s “right to oppose the grant of a compulsory license through the Indian Appellate Board”\(^{192}\) and each party can lodge counter arguments. The opposition process may take an adversarial turn and may be protracted leading to a delay in availability of essential medicines to the detriment of patients.

There are separate conditions for granting compulsory licenses in cases of national emergencies, circumstances of extreme urgency or in cases of public non-commercial use. The question then is what constitutes an emergency? Is the HIV/AIDS pandemic affecting nearly 2.1 Million people\(^{193}\) in India an emergency or a case of extreme urgency? The 2005 Patents (Amendment) Act answers this question by providing that the government has the discretion to declare through a gazette notice, following an application for compulsory license, that cases of emergency or extreme urgency may include public health crises, relating to HIV/AIDS, tuberculosis, malaria or other epidemics. \(^{194}\) This provision \emph{prima facie} indicates foresight and

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191 Patents (Amendment) Act of 2005 s 84.
192 ibid s 117A (2).
193 According to the World Health Organization only “18.2 million people out of an estimated 36.7 million people living with HIV had access to treatment at the end of June 2016” <http://www.who.int/hiv/mediacentre/news/India-treat-all/en/> accessed on 16 June 2018
194 Patents (Amendment) Act of 2005 s 92 (3).
commitment by the Indian government in ensuring that the right of access to health as a basic human right takes precedence over the exclusive rights of the patentee.

The Indian Patents (Amendment) Act of 2005 provides that a “compulsory licence can be granted for the export of patented pharmaceutical products.”\textsuperscript{195} In Kenya, the compulsory licence granted by the Tribunal under the IPA, “is limited predominantly to the supply of the domestic market.”\textsuperscript{196} This provision does not comply with the Doha Declaration Decision taken in 2003 which allows for export of pharmaceutical products under compulsory licensing to address public health problems. Initially, TRIPS only allowed compulsory licensing for supply in a “domestic market of the country where the licence is issued.”\textsuperscript{197} This put LMICs in a difficult position due to lack of capacity to manufacture generic medicines and also because the countries that manufacture generic medicines cannot export them to LMICs. On 30 August 2003, the General Council of the WTO approved a decision on “implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” and this decision was intended to be the solution to the difficulties faced by LMICs lacking sufficient pharmaceutical manufacturing capacity “in making effective use of compulsory licensing under the TRIPS Agreement.”\textsuperscript{198} The meeting culminated in the proposed amendment to TRIPS article 31 via an additional article 31\textit{bis} which allows exporting countries to issue compulsory licenses for domestic use as well as for export purposes hence in effect allowing export of medicines to LMICs. This new article 31\textit{bis} aims at surmounting the lack of manufacturing capacity hurdle in LMICs by creating an additional form of compulsory licence, “one that is especially tailored for the export of medicines to LMICs – in effect, a 'trade related' compulsory licence.”\textsuperscript{199} The Constitution of Kenya 2010 provides that “general rules of international law and any treaty or

\textsuperscript{195} Section 90 (1)(vii) India Patents (Amendment) Act 2005.
\textsuperscript{196} s 75(2)(b) IPA
\textsuperscript{197} Article 31 TRIPS
\textsuperscript{199}World Trade Organization, TRIPS and public health <https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> accessed on 25 June 2018
convention ratified by Kenya forms part of the laws of Kenya.\textsuperscript{206} This consistency between the Act and the Doha Declaration indicates that Kenya is in breach of its international obligations if a strict interpretation of the Constitution is applied.

It is interesting to note that since the enactment of the 2005 Patents (Amendment) Act, the number of compulsory licenses issued over pharmaceutical patents have been few and far between. It has been argued that the Government of India seems to be concerned with the interest of MNCs over the populace right to health.\textsuperscript{201} Closer scrutiny of the statistics of compulsory licenses issued by WTO members since 2001 Doha Declaration, reveals that the numbers are in fact not that high. There was the assumption that there would be increased instances where WTO members in LMICs would issue compulsory licenses over essential medicines following the enactment of the 2005 Patents Act. Studies show that there have been “24 verified compulsory licensing episodes in 17 nations, mostly upper-middle-income countries, that occurred between January 1995 and June 2011.”\textsuperscript{202} Majority of these incidents resulted in lower prices of pharmaceutical products. “Sixteen of the compulsory licensing episodes involved medicines for HIV/AIDS, four involved medicines for other communicable diseases, and four involved medicines for non-communicable diseases such as cancer.”\textsuperscript{203} The reasons for this low uptake rate are varied. The conditions for compulsory licenses issued by exporting countries are quite stringent and burdensome for example manufactured products must be specially packaged in colour, shape and labeling prior to exportation to the eligible importing member State.\textsuperscript{204} Another reason according to Janodia et. al, “is that certain countries threatened to issue compulsory license to negotiate for lower prices of medicines for government procurement but did not issue compulsory license as they felt the threat of trade

\textsuperscript{206} Constitution of Kenya 2010, art 2(5) and (6).
\textsuperscript{201} The Economic and Political Weekly observes that ‘it is essentially the de facto precedence that the government accords to the rights of the patent holder over the basic human right to health.’ Compulsory Licensing of Pharmaceutical Patents. (2010). Economic and Political Weekly, 45(39), 8-9 <http://www.jstor.org/stable/25742108> accessed on 10 June 2018.
\textsuperscript{203} Ibid.
\textsuperscript{204} Art 2(b) Doha Ministerial Declaration (n 74).
sanctions from certain advanced jurisdiction.” Other LMICs lack the political and economic clout to oppose developing countries. In addition, the procedure for claiming compulsory license is often protracted and complex bearing in mind that the Patent holder is likely to oppose the grant of such a licence through available administrative and judicial avenues.

The most outstanding case is the compulsory licence granted to Natco, an Indian pharmaceutical company based on a high court order in 2012, over Nexavar, a kidney and liver cancer medicine. Nexavar, owned by German drug company Bayer. Natco marketed Nexavar under the generic name, Sorafenib tosylate. The case is the first of its kind in India since the 2005 Patents (Amendment) Act. Natco had applied for a compulsory licence as per section 84 of the Patents Act after a futile attempt at obtaining a voluntary licence from Bayer to manufacture and sell the medicine. The Controller General of Patents (Controller) whose role includes the issuance of compulsory licenses under the Act in extreme and/or urgent situations, found that “the three conditions under which a compulsory license can be granted had been satisfied.”

According to Srinivasan, India is one of the few countries where issuing compulsory licence for local manufacture is meaningful, because Indian industry has the capacity to back it up by actually manufacturing the medicines so licensed. This case has been hailed as a win for cancer patients in accessing affordable generic medicines. Bayer’s patented anticancer medicine Nexavar was “exorbitantly priced in India at Rs 2.8 lakhs (about USD 4500 a month) and was only available to 2% of the patient population while Natco offered the medicine marketed under the brand name Sorafen at Rs 8,800 lakhs (about USD 150) a month.”

The Supreme Court of India upheld the High Court’s position and found that Bayer had failed to work the patent to a reasonable extent meaning that the supply of Nexavar

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206 NATCO Pharma Limited v Bayer Corporation, Compulsory Licence Application No.1 of 2011 before Controller of patents Mumbai <http://www.ipindia.nic.in/writereaddata/Portal/News/358_1_compulsory_License_12032012.pdf> accessed on 11 October 2018
208 ibid
compared to the demand from a significant number of cancer patients was low due to unaffordability. This case demonstrates that LMICs can use TRIPS flexibilities for public health purposes. This case also demonstrates that compulsory licensing can be used as a tool to curb monopoly rights by the patent holder. A dominant market position drives up the cost of essential medicines because the patent holder is primarily focused on recouping costs of research and developing the drugs and increasing profit margins.

The decision in the *Nexavar Natco* case encouraged generic manufacturers to obtain compulsory licenses for the manufacture of generic substitutes. In another case, BDR Pharmaceuticals Pvt. Ltd, an Indian pharmaceutical company, applied for the grant of a compulsory licence, for cancer medicine *Sprycel* owned by American company, Bristol-Myers Squibb. BDR had requested for a voluntary license from Bristol however Bristol insisted that grant of the licence was conditional upon fulfillment of certain conditions related to quality assurance. BDR argued that this response was a rejection of the request for a voluntary licence and filed for a compulsory licence. BDR also contended that Bristol’s response was an indication that negotiations for the voluntary license would be protracted indefinitely. The 2005 India’s Patents (Amendment) Act provides that the Controller will determine “as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.” The Controller in deciding the matter, noted that the 2005 Patents (Amendment) Act defines a ‘reasonable period’ as less than 6 months. The Controller held that BDR’s decision to apply for a compulsory licence without reasonably engaging Bristol was irregular since no “significant effort made to obtain a voluntary licence on reasonable terms.” Therefore, BDR’s application was rejected. This case demonstrates that India’s

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210 India Patents (Amendment) Act 2005 s 84(6)(iv).

211 ibid.
patent office is not biased in granting compulsory licenses to domestic manufacturers but instead examines if due process has been followed.

Kenya has barely utilized compulsory licensing to import cheaper generic medicines or pharmaceutical ingredients. Rwanda for example, in 2007, become the first country in Africa to use compulsory licensing, by notifying WTO of its intent to import generic medicine, a triple combination AIDS therapy drug, from Canada. Rwanda “informed WTO that it intends to import 260,000 packs of the medicine over two years.”\(^\text{212}\) The notification was to the effect that any patents related to the medicine granted anywhere in the world would not be recognized in Rwanda. This low participation from African LMICs is possibly due to political pressure from developed nations, for example the threat to cut funding for development projects or because patent protection over the essential medicine is not in force in the importing LMICs so there is no need to issue a compulsory licence.

### 4.1.4 Parallel importation

Under India’s 2002 Patents (Amendment) Act, parallel imports of patented products into India were subject to the patent holders consent.\(^\text{213}\) Analyzed closely, this provision did not address exhaustion doctrine per se given that the patent holders exclusive rights come into play by pegging importation of grey products on the patent holders consent. However, an amendment to Patents Act in 2005 explicitly changed this position by stipulating that:

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<https://www.wto.org/english/news_e/news07_e/canada_notification_oct_e.doc> accessed 11 October 2018

\(^\text{213}\) Section 107(b) of the Patents (Amendment) Act of 2002 states that “importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the products shall not be considered as an infringement of patent rights.”
This provision eliminated the need to obtain the patent holder’s consent meaning that purchase of medicines from authorized distributors in India even where the medicines are patented cannot be considered patent infringement. Opponents have argued that this diminishes the patent holder’s incentive to continue innovating because of increased competition from cheaper imported products. Pharmaceutical companies may not invest in research and development in new products in the face of such legislation. On the hand, the proviso secures easier and affordable access to life-saving medicines.

Article 58(2) of Kenya’s IPA on parallel importation is drafted vaguely. Use of the words “by the owner of the patent or with his express consent” seems to imply that the patentee’s consent is required. This goes against the essence of the exhaustion or first sale doctrine. The patentee’s consent is only required at the point of first sale. In the case of Beecham Group Ltd v International Products Ltd and Bristol, the defendant argued that since the plaintiff had authorized the sale under a licence and royalties paid, then its rights had been extinguished. The Court held that there had been infringement since the patentee had not itself sold the goods therefore the distributor in Kenya was not authorized to sell the drug.

This parallel importation provision in India complies with TRIPs in that it provides leeway for member States to implement homegrown measures by interpreting TRIPS in accordance with their public health objectives. Parallel importation encourages competition between domestic producers and generic medicines importers.

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214 Patents (Amendment) Act 2005, s107 A(b).
4.1.5 Bolar Exception

Initially, the Indian Patents Act of 2002, was amended to exclude from infringement “the act of making, using or selling a patented invention” for the purpose of obtaining information to be submitted to a regulatory authority.216 The exception is particularly useful for generic medicine manufacturers who may need to perform bioequivalence tests to ensure that the generic medicine is approved for marketing as soon as the patent protection over medicines expires.

The 2005 Patents (Amendment) Act further supports this Bolar exception by providing under section 47 (3) that grant of patents is subject to certain conditions:

47(3) “any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.”

This means that the patentee exclusive rights are limited in cases where the use is for educational and research purposes. This provides an opportunity for generic manufactures to reverse engineer patented products under the guise of research to generate derivatives thereby avoid reinventing the wheel simultaneously, cutting costs involved in research and development.

In Bayer Corporation vs Union of India, Bayer Corporation owned a patent known as ‘Sorafenib Tosylate’ prescribed for cancer treatment. Natco, an Indian pharmaceutical company had been granted a compulsory licence for the use and sale of the medicines in India. Natco proceeded to also manufacture the medicine for export outside India for clinical studies and trials. Bayer objected arguing that exportation contravened section 107 of the Patents Act.

216 Ibid (n 233) s 107A.
The main issue that the Court considered is whether section 107A envisaged export of a patented product for purposes of conducting bio-equivalence tests for obtaining regulatory approvals in the importer country. Section 107A read as follows:

107A. “(a) any act of making, constructing, using or selling a patented invention solely for uses reasonable relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;

(b) importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product, shall not considered as an infringement of patent rights.”

The Court held that India’s Patents Act made provision for the Bolar exception and recognized that India is a WTO member. India had ratified TRIPS which led to amendment of the 1970 Patents act (vide Patents (Amendment) Act of 2002) introducing exception to exclusive patentee rights therefore it had to comply with this TRIPS flexibility. The Court found that a “purposive interpretation of section 107A of the Act” permitted exportation of information to another country other than India to obtain regulatory approvals so as not to allow exploitation of the patent beyond the 20 years of exclusivity granted to the patent holder.

The wording of section 54(2) in Kenya’s IPA is inclusive and provides that the exclusive rights of the patentee do not extend to acts related to obtaining regulatory approval. This can be interpreted to mean that ‘acts’ can include exportation of patented products for purposes of obtaining regulatory approvals.

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218 Ibid.
Failure to grant the early working exception can lead to a delay in the entry of generic medicines into the market. This would stifle competition and prolong the patentee’s monopoly in the market.

According to Chaudhuri, the Bolar exception is very important for “generic entry because it permits generic entry soon after the patents expire and hence allowing consumers to benefit from competition and lower prices without delay.”\(^{219}\) Patents are granted for a limited duration and issued based on full disclosure for working of the patent to allow researchers and scientists to carry out further research. The Bolar exception therefore strikes at the heart of limiting a patent holder’s exclusive patent rights however it does not conflict with the patent holder’s right to exploit the patent.

4.1.6 Analysis of India’s Patent Regime

India has an exceptionally large consumer base, cheap labour, the capacity to adopt and manufacture generic medicines using spill over technology and a conducive environment for proliferation of generic pharmaceutical industry which is largely attributed to its imitative capabilities through reverse engineering processes. It may be argued that to some extent India has chosen market freeloading by believing that it’s the only option to offer affordable drugs in the marketplace. For example, by excluding incremental modification to already existing patents from the patent protection scope and adopting rigid patentability criteria has boosted the generic industry’s access to technologies and knowhow from expired of patents but it has lowered India’s potential to attract investments from MNCs. The argument has been that the Indian pharmaceutical industry has perfected its technological and production capabilities, which were strengthened during the transition periods granted under TRIPS to LMICs which delayed implementation of patent protection over pharmaceutical products.

Critics have argued that the current Indian patent regime has been built through a flurry of amendments that were ill-conceived as wording was borrowed blindly from various legislative instruments without any foresight to India’s needs. For example, according to Basheer, the term ‘pharmaceutical substance’ is defined in the 2005 Patents (Amendment) Act but is not thereafter mentioned in the entire Act\(^\text{220}\), an act which, as he concludes amounts to shoddy drafting.

Proponents on the other hand, have argued that LMICs like Kenya need to borrow a leaf from India in terms of adopting effective legislative mechanisms geared towards attaining public health objectives. Proponents also argue that the current Patent law in India will not be a hurdle to HIV/AIDS battle due to compulsory licensing procedures which allow India to grant compulsory license in cases of public health emergencies such as disease outbreaks. India continues to hold its title as pharmacy of the world due to significant export of generic medicines to LMICs.

### 4.2 Conclusion

This chapter examined India, as a best practice model in the implementation of the TRIPS flexibilities related to access to essential medicines within the legal framework and identified gaps in Kenya’s legislative framework. Strategic implementation of TRIPS flexibilities is not merely about establishing a relevant legislative framework, but it also involves a proactive regulatory and administrative structure, growing domestic capacity to manufacture generic medicines and actively pursuing trade related measures to achieve public health objectives. The next chapter concludes the study and provide recommendations.

\(^{220}\) Basheer Shamnad (n 168).
CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

This study now concludes with a summary of findings and offers recommendations. Recommendations are mainly directed at the Kenyan government and pharmaceutical companies established in Kenya.

5.1 Summary of Findings

5.1.1 Kenya

The Constitution of Kenya seeks to balance competing interests between societal right to health through access to affordable medicines and the promotion of individual IPRs as TRIPS endeavours to do.

TRIPS flexibilities that promote access to medicines are concluded as follows: -

Compulsory licensing mechanism in Kenya is primarily for the supply of products in the local market. This not only curtails Kenya’s capacity to grow its domestic capacity by supplying medicines to neighbouring LCDs but also means that under international law, Kenya is in breach of the 2003 Doha Decision on export of pharmaceutical products under a compulsory licence.

Pharmaceutical companies are generally not aware of TRIPS flexibilities as plausible options. Most pharmaceutical companies in Kenya also lack the manufacturing capacity to take on production of off-patent medicines. In addition, information of expired patents linked to essential medicines has not been made publicly available, preferably online. Information pertinent to the production of essential medicines is not easily accessible, which hinders prompt manufacture and procurement of essential medicines.

Parallel importation is clearly provided for under Kenya’s laws, however, as enumerated in the Patricia Asero case, the current legal framework does not clearly address the ambiguities related to generic medicines which are interpreted to be counterfeit or substandard goods.
Caselaw has proved beneficial in clarifying the difference between the two and in declaring parts of the Anti-Counterfeit Act as unconstitutional. Policy guidelines from PPB are lacking.

Kenya introduced the Bolar exception via an amendment in 2017. However, the inconsistencies within the IPA need to be addressed so not to cause a legal quagmire. Use of patented medicines to obtain regulatory approval should not require the patentee consent. Findings indicate that pharmaceutical companies in Kenya are generally unaware of this exception and have not taken up this TRIPS flexibility as a public health option mainly due to the lack of production capacity of essential medicines.

On the patentability criteria, Kenya provides for the basic standards or criteria for patent protection as prescribed under TRIPS. The IPA is not purposeful in addressing public health issues as compared to India for example the India Patents (Amendment) Act 2005 anticipates public health matters by providing that circumstances such as national emergencies warrant issuance of a compulsory licence including events such as HIV/AIDS epidemic.

Institutional challenges faced by government agencies implementing TRIPS flexibilities include lack of awareness on TRIPS flexibilities, inadequate manpower which leads to delay in approval processes such as in PPBs case for importation of generic medicines, deficiency of requisite technical skills to allow effective patent examination and lack of access to prior art information in KIPIs case which compromises adherence to the patentability criteria.

5.1.2 India

This study has provided an overview of the Indian legal framework of TRIPS Flexibilities that promote access to essential medicines and is the basis for a comparative study with Kenya. India’s patent history is important in understanding what standards were used to achieve India’s status as one of the largest generic medicines producers in the world.
This section concludes the role of the TRIPS flexibilities that promote access to essential medicines as implemented in India as follows:

The most prominent feature under India’s patentability criteria, is that it effectively eliminates patent protection over known substances which may be submitted for protection under the guise of ‘new uses’. The requirement to demonstrate efficacy of derivatives of known substances raises the patentability criteria bar such that frivolous patent applications which do not meet the inventiveness and industrial applicability criteria are rejected. This protects citizens right to health thus making essential medicines accessible because patentees cannot seek patent protection to retain market monopoly after the expiry of existing patents.

India’s case law on compulsory licensing is an indication of India’s commitment to curbing patent monopoly which is, to some extent detrimental to the right to health. The judgments delivered in these cases have encourage LMICs to proactively adopt measures that secure access to essential medicines. Such measures are supported by the 30 August 2003 Doha decision which permits LMICs to use the compulsory licensing mechanism to import patented products from countries with a strong production capacity such as India. In any event, MNCs are not likely to seek patent protection for their products in LMICs due to the high costs of patented medicines which would be unaffordable to many people living in LMICs. The detail and specificity with which India’s laws are drafted is remarkable in that the legal framework is quite favourable to the public health sector. For example, voluntary licence negotiation cannot be subject to delay tactics since a reasonable 6-month negotiation period is prescribed under the law.

Parallel importation in India’s case demonstrates the need to reach an equitable balance between the patentee interests and those of patients in need of life-saving medicines. Availability of essential medicines should not be curtailed by the patentee hence the amendment to the Patents Act eliminated the need to obtain consent for importation of a
patented product. This is line with TRIPS in the sense that the delicate balance is maintained between individual interests by providing incentives for inventors through protection of IPRs and societal interests by permitting access to essential medicines which is one of the objectives of the Doha Declaration.

India’s laws on the Bolar exception as discussed in chapter 4 seem to have been drafted with generic medicine manufacturers in mind by providing that information derived from the use of a patented product can be exported to obtain regulatory approvals in foreign jurisdictions. India has certain advantages such as cheap labour, available market, domestic manufacturing capabilities and supportive legislation that have made implementation of the Bolar exception particularly successful.

5.2 Recommendations

First, paragraph 6 of the Doha Declaration Decision is a trade-related mechanism which would have benefited Kenya which is building its domestic capacity. In one instance, a Bangladeshi medicines manufacturer has commenced the building of a medicines plant in Kenya with investment costs of up to USD 75 million. The medicines plant is expected to cater for domestic demands as well as exports to the USD 400 million COMESA population. As seen in India’s case, the capacity to manufacture cheaper medicines for local consumption and for export to neighboring LCDs with inadequate manufacturing capacity using TRIPS flexibilities such as the compulsory licensing mechanism, will allow Kenya to tap into economies of scale. Kenya could be said to have good potential to expand its manufacturing capacity because of the considerable presence of pharmaceutical manufacturing companies already established in the

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221 Douglas Weru (n127)
country compared to other EAC countries. EAC countries have in total 66 pharmaceutical firms with Kenya leading with 40 firms.\textsuperscript{222}

Second, clear policy or guidelines should be formulated to guide the implementation of TRIPS flexibilities. KIPI should have guidelines for examination of pharmaceutical patent applications to ensure it can access a variety of patent databases to guarantee quality patents examination. The PPB should finalize its draft framework for regulation of parallel imports of medicinal substances which is important to address gaps such as the definition of generic medicines, timelines for importation of medicines in emergency situations and approval processes for generic medicines. Policy guidelines will allow proper implementation of the legislative framework regarding parallel imports and will assist in clarifying ambiguities in the law occasioned by poor drafting.

Third, the Medicines Patent Pool\textsuperscript{223} concept whereby patentees submit their patents to form a pool available to 3\textsuperscript{rd} parties such as generic drug manufacturers on a non-exclusive basis can be beneficial to access essential medicines at reasonable cost. Use of MPP will allow Kenya to have access to patentee’s to negotiate freedom to operate licenses. Since MPPs creation in 2010, about 20 sublicensing agreements have been executed with generic suppliers and product developers for essential medicines ranging from ARVs to tuberculosis treatments with more than 4.7 billion tablets supplied to 131 countries.\textsuperscript{224} A good illustration is the voluntary licence issued by GlaxoSmithKline on its patent owned ARV, \textit{Dolutegravir} sold under the brand name \textit{Tivicay} to the MPP for the benefit of LMICs like Kenya.\textsuperscript{225} This arrangement has increased access to this life-saving ARV. Some LDCs access the medicine under a royalty-free basis


\textsuperscript{223} Medicines Patent Pool is a “United Nations-backed public health organization working to increase access to HIV, hepatitis C and tuberculosis treatments in LMICs,” see https://medicinespatentpool.org/ accessed on 2 October 2018.


while a certain percentage of LMICs can access the drug under a tiered royalty licence arrangement.

Fourth, there are technologies that are publicly available that provide efficient access to patent information and link that information to medicines. For example, “Patent Information Initiative for Medicines (Pat-INFORMED)” is an initiative stemming from a public-private partnership between WIPO and IFPMA, a global association of research based pharmaceutical companies. The initiative seeks to provide key linkage between patent information and essential medicines that may not have otherwise been readily available to bodies such as KIPI, which does not subscribe to private 3rd party databases. Patent information on essential medicines is crucial information that can assist Kenya in obtaining appropriate TRIPS flexibility tools.

Fifth, Kenya’s government should invest in capacity building in science, technology and innovation to build skilled manpower to grow its pharmaceutical industry. India success as a leading generic medicines producer is largely attributed to its skilled workforce that utilizes reverse engineering technics. Product development partnerships as seen in the case of the Uganda-India partnership are useful in supporting access to new health technologies which are transferred through capacity building of government agencies such as KIPI and PPB by countries with medicine production expertise.

Sixth, to address the institutional challenge of lack of access to modern technologies and skills for dealing with such technologies, there is need to streamline and automate business processes in KIPI to ensure that the public has uninhibited access to medicine patent information. In addition, KIPI can also access specialized databases, for example, the Access to Specialized

226 WIPO launched the Access to Specialized Patent Information Program (ASPI) in 2010 to support developing countries in accessing patent information free of charge or at low cost as part of the overall objective of facilitating access to specialized patent databases. WIPO also offers training in the use of these databases accessed 17 October 2018.

227 Patent Information Initiative for Medicines (Pat-INFORMED), provides information on key patents for small-molecule products and covers therapeutic areas such as HIV/AIDS, as well as products covered under the WHO Essential Medicines List, see testimonials section, accessed on 2 October 2018.
Patent Information (ASPI) program initiative by WIPO which facilitates access by national patent offices to patent data at little or no cost.\(^\text{228}\) This will diversify the patent databases containing prior art which KIPI has access to. This will ensure that Kenya can comfortably comply with the TRIPS patentability criteria.

Seventh, KIPI and PPB should hire additional specialized staff to deal with the challenge of lack of adequate staff and aggressively build the capacity of existing staff for example through engaging in partnerships with India to hire their specialized staff to work with and train staff in government institutions in order to benefit from technologies in India’s generic pharmaceutical industry.

Finally, given that Kenya does not manufacture but instead imports active pharmaceutical ingredients, the government should provide adequate tax reliefs and incentives such as subsidizing infrastructural costs to lower the cost of manufacturing medicines and grow the capacity of local generic pharmaceutical industries. As seen in Kenya’s case, raw materials supplied to Pharmaceutical manufacturers in the manufacture of medicines are zero-rated. The government should also incentivize research and development especially in public universities. Universities can be research hubs, publicly funded to address access to medicines challenge by pioneering research in diseases largely ignored by for profit private R&D pharmaceutical companies.

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QUESTIONNAIRE

1. In substantive examination of applications for pharmaceutical patents related to essential medicines, what are the main challenges you face?

2. What are the main challenges facing access to essential medicines such as ARVs in Kenya?

3. What is the number of expired pharmaceutical patents related to essential medicines in Kenya? Have generic manufacturers taken up the production of generic substitutes following the expiry of these patents?

4. How many compulsory licensing applications related to essential medicines have been made since the inception of the Industrial Property Act (IPA) in 2001?

5. Do government agencies have efficient mechanisms for expedient registration of new essential medicines and efficient procurement systems to ensure speedy purchase and distribution of these essential medicines?

6. What are the major hurdles you face when dealing with the medicines regulatory agency in Kenya?