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The Implication of the Trips and Intellectual Property Rights for the Access to Affordable Generic Drugs: A Case Study of Kenya

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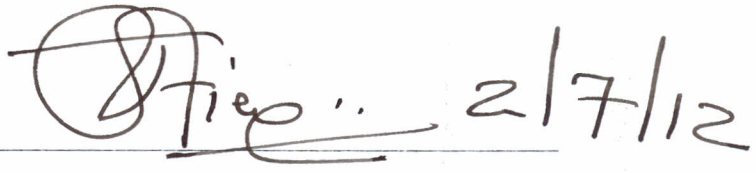
DECLARATION

I, SHADRACK M. MULANGA, do hereby declare that this is my original work and has not been submitted and is not currently being submitted for a degree in any other University.

SIGNED  .

SHADRACK M. MULANGA

This dissertation is submitted for examination with my approval as University Supervisor.

SIGNED 

PROF. JAMES OTIENO-ODEK

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DEDICATION

This work is dedicated to all sons and daughters of the world toiling to make the world a healthy place to live in. May their input bear fruit in their generation and generations to come. To you my children, Lydia, Kavata, UK, Caroline Museo, Tiagin, China and Sam Kyle, may God bless you abundantly. A merry lot, you form.

ACKNOWLEDGEMENT

The long journey that starts with a single step forward has finally come to an end. A research work that began in 2004 is finally coasting to fruition. Of giving thanks for helping me through this study, the inadequacy of language lets me down, and the range of helpers too wide for individual appreciation. I want to sincerely thank the late Dr. Andronico Oduogo Adede who taught and encouraged in me research on this topic, a task that would stand the test of time. May God rest his soul in eternal peace. Special acknowledgement goes to Prof James Otieno-Odek for painstakingly and tirelessly offering the most invaluable guidance. His patience and constructive criticism can only be compared with the finesse of an accomplished sculptor. Friends and colleagues at the Nyeri Municipal Council, and especially my Secretary, Jane, I am forever indebted to you.

ABSTRACT

The main purpose of this study is to examine the implication of TRIPs in intellectual property, particularly in regard to rights of access to affordable generic drugs in developing countries and emphasizing in the context of the Kenyan case study. TRIPs was aimed to assist in universalizing the standards of Intellectual Property Rights. It was also geared to frame the rules of the game of developing counties as par with the developed countries.

Secondary data collection method was applied in this study. This case study is based on the documentary survey whereby there was available data in the university library and internet sources. This study design was descriptive because it allows for prudent comparison of the research findings. The qualitative design chosen for this research is theory grounded, or natural inquiry. Grounded theory research unfolds and emerges empirically from data and is more responsive to contextual values rather than researcher values, but other design used in this study was exploratory and explanatory. The study examined on implications of TRIPs provisions for access to affordable generic drugs in Kenya. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialized countries and the multi-nationals pharmaceutical industry. While TRIPs does offer safeguards to remedy negative effects of patent protection or patent abuse, it is unclear whether and how countries can make use of the safe guards when patents increasingly present barriers to medicine access.

The study concludes that TRIPs was theoretically designed as a social policy tool to encourage innovation by establishing minimum standards for the protection of intellectual property including patents on pharmaceutical; however, these standards were developed based on Western European and North American property law by wealthy countries with little regard for the needs of developing countries. The study recommends that the decision of 31st August 2003 should be used in good faith to protect public health and not as an instrument to pursue industrial or commercial policy objectives .It should be appreciated that the decision would be defeated if products supplied thereunder were diverted from the markets for which they were intended and that it is important for member countries to seek to resolve any issues arising from the use and implementation of the decision expeditiously and amicably.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AIDS/HIV	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral Drugs
GATT	General Agreement on Tariffs and Trade
GSK	GlaxoSmithKline
IPR	Intellectual Property Rights
MMV	Medicines for Malaria Venture
NGOs	Non-Governmental Organizations
OECD	Organisation for Economic Cooperation and Development
PDPs	Product-Development Partnerships
PhRMA	The Pharmaceutical Research and Manufacturers of America
PI	Parallel Imports
R & D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WIPO	world Intellectual Property Organisation
WTO	World Trade Organisation

LIST OF STATUTES

South African Medicines and Medical Devices Regulated Authority Act

Industrial Property Act, Act No. 3 of 2001

The Constitution of Kenya (2010)

1.0 CHAPTER ONE

RESEARCH PROPOSAL

1.1 Research question

This study was to examine in details the implication of Trade Related Property Rights (TRIPs) particularly for the rights of access to generic drugs in developing countries and emphasizing in the context of the Kenyan Case study. The study would undertake to re-examine in details the implication of TRIPs, political and economic impact in relation to the availability of generic drugs in the developing countries and the political game played by multi-national pharmaceutical companies supported by their countries.

i. What were the TRIPs requirements with respect to patenting of pharmaceutical drugs?

ii. What is the implication of TRIPs, provisions for access to affordable generic drugs in Kenya?

iii. What were the challenges and barriers to the reforms necessary for enacting of the laws necessary for access to affordable generic drugs?

1.2 Background of the study

The Agreement on Trade Related Aspects of Intellectual Property(TRIPs) adopted at Marrakesh on 15th April, 1994 is to date the most significant milestone in the development of intellectual property rights regime in the 20th Century.

TRIPs was aimed to assist in universalising the standards of Intellectual Property Rights. It was also geared to frame the rules of the game of the developing countries to be with those of developed countries. Several factors prompted the industrialised nations to seek stronger protection for their innovations in all the countries. Among these were the continuous advancement in science, a new breakthrough in bio-technology, the growing participation of the private sector in the cost intensive research and development in the knowledge based pharmaceutical sector. Others were the relative strength demonstrated by the developing nations in adapting the results of the scientific innovations to the local environment. These and others

have prompted the industrialised nations to seek stronger protection for their innovations in all the countries.[1]

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) set global minimum standards for the protection of intellectual property, substantially increasing and expanding intellectual-property rights, and generated clear gains for the pharmaceutical industry of the developed world. [2]

The extent to which patent protection would be extended to pharmaceuticals has always been and continues to be an issue that stirs public debate and discussion.[3] Developing countries and Non-Governmental Organizations ("NGOs") argue that strict enforcement of pharmaceutical patent holders' rights has resulted in high prices, which render unaffordable to poor countries drugs critical to the treatment of epidemics.[4] The concern stems from the fact that the patent holders' rights exclude others from selling or making their exact or substantially similar patented products for the term of the patent.[5]

This period of exclusivity provides the patent holder with the power to control the selling price of the patented product.[6] Critics contend that pharmaceutical companies, as patent holders, have abused this right in order to reap tremendous profits, despite a staggering loss of human life.[7] In response, proponents of strong patent rights assert that patents were not the major barrier to

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[1] N. Lalitha, TRIPS and Pharmaceutical Industry: issues and Prospects , *Gujarat Institute of Development Research, Ahmedabad.*

[2] Peter Drahos, Developing Countries and Intellectual property Standard-setting, Study Paper 28, Commission on Intellectual Property Rights.

[3] Rosemary Sweeney, The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision, 9 PAC. RIM L. & POL'Y J. 445, 447 (2000).

[4] *See generally* Amol Sharma, *Fourth Ministerial Conference in Doha Developing Countries Seek Amendment to WTO Drug Patent Guidelines,* EARTII TIMES at http://www.earthtimes.org/nov/worldtradeorgfourthnov3_01.htm (last visited 20th October,2002).

[5] *See* JOHN H. JACKSON ET AL., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS: CASES, MATERIALS AND TEXT 844 (3d ed. 1995)

[6] *See id.* at 845.

[7] *See* Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries,* 3 TuL. J. TECH. & INTELL. PROP. 1, 3 (2001).

access to essential medicines; rather inaccessibility to critical medications results from inadequate infrastructure, absence of an effective drug distribution system, and poverty.[8]

Taking the example of sub-Saharan Africa, with the most affected region in the global AIDS epidemic, more than two thirds (68%) of all people HIV-positive live in this region. The situation has become one of the greatest public health challenges in the history of mankind.[9] This area of the world now contains more than seventy percent of the world's new AIDS cases.[10]

While the optimal way to address the AIDS/HIV crisis is to attack the root of the problem by reducing the rate of HIV infection,[11] the short-term solution lies with drug therapies that increase the life expectancy of those suffering from the disease.[12] The tragedy is that of the nearly 25 million people infected only about 25,000 people, at most, have access to life-prolonging medicines. [13]

The role that medicine plays in health care cannot be overemphasized: they can save lives and improve health. They promote trust, participation and utilization of health services. Medicines were a key component for a well-functioning health care system. In fact, medicines were one of the most cost-effective elements of modern health care. However, not all medicines represent value for money and often medicines were marketed with little concern for the real needs and priorities of the people, particularly in developing countries.

Availability of medicines at facility level is often considered a major factor influencing health seeking behaviour. Patients tend to equate medicine availability with quality of care leading to satisfaction with the health system. A well-functioning medicine supply system is a major contribution for making a health system operational and improves the responsiveness of the

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[8] See Amir Attaran & Lee Gillespie-White, Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?, 286 JAIA 1886, 1886.

[9] JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, AIDS EPIDEMIC UPDATE: DECEMBER 2010, accessible at http://data.unaids.org/pub/epislides/2007/2007_epiupdate_en.pdf (last visited 20th October, 20110.

[10] Id.

[11] Bess-Carolina Dolmo, Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example, 7 BUFF. HUM. RTs. L. REV. 137, 139

[12] Id.

[13] Id.

health system to the health care needs of the population. Medicines were thus a very important component of healthcare but need to be used rationally in order to be cost-effective.

Lack of access to medicines has become the enduring challenge for the globe. This characterization states that global inequities in access to medicines exist between rich and poor countries because of market inequalities and government failures as well as huge income differences. Multiple policies were required to address this global medicine gap.

At the beginning of the 21st century, very few people in the developing world had access to HIV treatment. This was in large part because of the very high prices of antiretroviral drugs (ARVs) and the international patents that stopped them from being manufactured at cheaper prices. However, in 2001 drug manufacturers in developing countries began to produce generic drugs under special terms in international trade law. In sub-Saharan Africa, countries including Kenya and South Africa passed bills that made it legal for them to purchase generic drugs from abroad. The vast reduction in price made possible by the manufacturing of generic drugs meant expansion of treatment on a global scale was possible.

Access to essential medicines has been substantially inhibited by patent protection. The development of anti-retroviral drugs is the primary reason for the increased life expectancy and improved quality of life for HIV-positive in developed countries. The use of anti-retroviral drugs has diminished the death rate of HIV-positive patients by seventy per cent in the United States and Europe.[14] The problem in countries such as those in sub-Saharan Africa is that anti-retroviral drugs were not available for the vast majority of HIV-positive people because they cannot afford the astronomical prices of the HIV drug therapies. The pharmaceutical companies that produce these drugs often charge high prices because they own patents for the drugs they develop. The patents essentially provide the patent holder with a legal monopoly for a finite number of years, usually upto twenty.[15]

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[14] Lynn Woods, Government AIDS Efforts Target Drug Makers 10 BUS. WITHOUT BORDERS 18(2000).

[15] Weissman, p. 23.

The most striking evidence is from sub-Saharan Africa where prices of patented antiretroviral medicines (ARVs) were maintained at the levels of the Developed Countries until large scale international pressure forced the big pharmaceutical companies to move toward approximating prices offered by generic producers in India and Brazil. Developed country-based pharmaceutical manufacturers have actively opposed introduction of generic ARVs in South Africa, Kenya, Uganda and elsewhere. The world political situation has most recently made it more difficult for the big pharmaceutical companies to aggressively attack sub- Saharan African plans to market generic versions of HIV-related medicines, but current political circumstances were not an appropriate basis upon which to base multilateral trade and IPRs policy. Moreover, the political pressure pertaining to actions in sub-Saharan Africa does not necessarily pertain in other parts of the world. Reliance on voluntary restraint by big pharmaceutical companies is not an adequate basis upon which to analyze and frame TRIPS Agreement rules.

The study would also determine the infamous decision referred to as the August Decision of 20th August, 2003 on the Article 31 of TRIPS. The campaign principle on the parallel importation and the campaign beyond price reduction and availability of affordable drugs in the Developing countries.

The challenge is on governments in developing countries in seeking to break the silence and walk the talk. The study would show that TRIPS, if properly implemented, in a flexible and supportive fashion with critical focus on Article 31 could provide a relatively relaxed avenue for the Developing countries to respond to conditions of extreme emergencies caused by HIV/AIDS pandemic.

1.3 Justification of the Study

Improving healthcare in the developing world presents a complex challenge to the global community. It can only be addressed if the significant barriers that stand in the way of improved access were tackled as a shared responsibility by all the stakeholders sectors of global society - governments, international agencies, charities, academic institutions, the pharmaceutical industry and others.

Admittedly, most of the decisions impacting on the access to affordable medicines in the poor and developing nations of the world were made by and in the developed nations by a process that frequently slips past the view of the generic companies that supply the poor nations with their essential medicines.

Developing countries, on the other hand, were not making full use of flexibilities built in to TRIPS to overcome patent barriers, such as compulsory licences and parallel imports.

The above therefore indicate that unless unless homage is paid to these potential strategic challenges , access to better and proper healthcwere is likely to continue to be a mirage, hence this study.

The study was further justified by the Constitutional fact that every person now has the right to the highest attainable standard of health[16] and this bolsters the realisability of another fundamental right-the right to life.[17]

1.4 Significance of the Study

Millions of people in developing countries do not have access to even the most basic healthcare services, including safe and effective medicines. This has led to a global healthcare crisis, in which diseases such as HIV/AIDS, tuberculosis (TB) and malaria were spreading in countries that have neither the resources nor the facilities to deal with them.

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[16] The Constitution of Kenya, Article 43(1).

[17] The Constitution of Kenya, Article 26(1).

Poverty is the single biggest barrier to improving healthcare in the developing world. In many countries people do not have enough food, access to a clean water supply, hospitals or clinics in which to receive treatment, and healthcare professionals to care for them.

Much of the discourse on this issue has revolved around the contribution intellectual property regimes, and in particular patents, have operated to diminish access to medicine by the poor people of the Developed Countries. The study therefore contributes to the discourse challenges of the developing world by suggesting an innovative, responsible and, above all, sustainable approach to enhancing access to medicine in the Developing Countries.

1.5 Purpose of the Study

This study focussed on the strategic challenges that the country faces in its efforts to comply with TRIPS and in enhancing access to medicine while at the same time nurturing an environment for social justice and development.

1.6 Objectives of the Study

The major objective of the study was to explore and analyse provisions on access to medicine in the TRIPS. Specifically, the study sought to:--

Explore the implications on the implementation of TRIPS Agreement on access to drugs for HIV/AIDS, malaria and tuberculosis in developing countries;

Identify the real barriers and suggest possible solutions to the access challenge in developing countries;

Examine the flexibilities and tools for ensuring access to medicine in Developing countries;

Examine the doctrine of exhaustion of patent rights and the question of political would in the massive campaign for enhanced access to medicine;

Consider the sustainability of continued implementation of TRIPs in the Developing Countries with respect to access to medicine.

1.7 Research Questions

i. To examine the provision s of TRIPs agreement on patents for pharmaceuticals drugs.

ii. To examine the real barriers and possible solutions to the challenges of access to medicine in Kenya.

iii. To examine /investigate how Kenya can leverage on the accessibility to provision of TRIPs on access to affordable drugs.

1.8 Research hypothesis

The TRIPs provision on patents for pharmaceutical drugs is not sufficient to enable Kenya access to affordable drugs.

1.9 Conceptual Framework

Millions of people worldwide still do not have access to essential medicines that were affordable and of good quality. Access to medicines easily translates to access to treatment. Improving access to quality treatment is currently the most important strategy to reduce disability and death from many diseases. More generally, ensuring access to effective treatment is a high priority issue for international public health. Access to essential medicines is part of the human right to health.

The poor lack access to medicines for many reasons, all of which must be addressed in a comprehensive manner. The most important is poverty, which means that neither the poor nor their governments can afford to purchase essential medicines or ensure their rational use in well-run health systems. Affordability is one core issue at the centre of debates about medicine use in international health.

The reasons for the lack of access to essential medicines were manifold, but in many cases the high prices of medicines were a barrier to needed treatments. Prohibitive medicine prices were often the result of strong intellectual property protection. The World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which provides 20 years' patent protection for pharmaceuticals, also includes safeguards such as compulsory licensing, to ensure that countries can override patents whenever they were a barrier to access to medicines.

The past years have clearly shown that the Doha Declaration must be actively implemented and defended if it is to have any force. There were however other major factors which deny access by the populations of low-income countries to effective medicines for the treatment of the diseases to which they were subject.

Poor infrastructure and unreliable medicine supply systems, waste and inefficiencies in managing logistics add to low availability of medicines. Most medicine research is carried out by global pharmaceutical companies, which exist to make profits for their shareholders. This means that they focus mainly on the diseases of developed countries, with the result that diseases prevalent in developing countries were largely neglected.

Many of the issues surrounding the accessibility of medicines in low income countries can only be addressed with concerted national and international action. This study therefore considers the issues of accessibility and availability of pharmaceuticals in international health, and describes the initiatives that have been taken to address them in Kenya.

Like most Developing Countries, Kenya's patent law affects access to drugs and medicine. The Industrial Property Act of 2001 states that an invention is patentable if it is new, involves and inventive step and is industrially applicable or is a new use.[18] An invention constitutes a solution to a specific solution to a specific problem in the field of technology and it may relate to products and processes.[19] There however was an exemption to patentable subject matter. Section 21(3)© of the Act excludes from patent protection methods for treatment of human or animal body, surgery, therapy as well as diagnostic methods practiced in relation thereto, except products for use in any such methods. The exception relating to products reinforces the notion that medicine and equipment use for human or animal treatment were patentable.[20]

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[18] Section 22 of the Industrial Property Act of 2001.

[19] Otieno-Odek J,(2005), Intellectual Property and Public Health: TRIPS Flexibilities and Access to Medicine in Kenya, Kenya Industrial Property Institute, Nairobi: Dalton Press, p.17.

[20] Otieno-Odek J, at 17.

Section 21(3)(e) permits the Minister for Health to exclude from patent protection public health related methods of use or of uses of any molecule or other substances whatsoever used for the prevention or treatment of any disease which has been designated a serious health hazard or as a life threatening disease.

Under Section 26 (b) inventions contrary to public health and safety were not patentable in Kenya.

1.10 Limitations of the Study

There were two limitations that need to be acknowledged and addressed regarding the study.

The time duration allocated for the study was short.

Data limitations in respect of the number of persons with access to generic drugs in Kenya were unavailable. Even secondary data available in this regard were largely based on estimates.

The exploratory nature of this study had its limitations. The study only covered Kenya, and as such, the results may not apply directly to all countries in this region, and indeed in the developing world in a similar predicament.

Because of the limited time and financial resources available, the surveys were of limited scale and scope, such that the survey results may not be fully representative of the views of the relevant stakeholders in the countries studied.

Overall, while the study was useful in gaining an understanding of the dynamics between the TRIPs and the question of access to medicine in the Developing Countries, it is clear that more detailed national level studies should be undertaken, if possible as an integral part of the implementation of TRIPs.

1.11 Delimitation of the Study

The study would rely only on the conventions and treaties on international intellectual property the already enacted legislation;

The researcher might use assistants to help in completing the research within the timelines provided.

1.12 Assumption of the Study

The study would be premised on three assumptions:

That the developing countries used and implemented TRIPS in a flexible and supportive manner;

That the flexibilities in TRIPS can facilitated access to affordable generic medicine in Developing countries.

1.20 Literature Review

TRIPs mandate a minimum set of intellectual property protection for patented pharmaceutical products. It raises questions about how new global standards for patent protection will affect innovation, Research and Development (R &D) investment, and product availability, especially for developing economies with significant innovative capacities in health R&D (such as Brazil, China, India and South Africa).[21]

Margweret Kyle and Anita McGahan[22] examined the relationship between patent protection for pharmaceuticals and investment in development of new drugs. Patent protection has increased around the world as a consequence of the TRIPS Agreement, which specifies minimum levels of intellectual property protection for members of the World Trade Organization. They echo the general argument that patents were critical for pharmaceutical research efforts, and so greater patent protection in developing and least-developed countries might result in greater effort by pharmaceutical firms to develop drugs that were especially needed in those countries. Since patents also have the potential to reduce access to treatments through higher prices, it is imperative to assess whether the benefits of increased incentives have materialized in research on diseases that particularly affect the poor. They find that patent protection is associated with increases in Research and Development (R&D) effort when adopted in high income countries. However, the introduction of patents in developing countries has not been followed by greater investment. Particularly for diseases that primarily affect the poorest countries, their results

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[21] ibid

[22] Margaret Kyle and Anita McGahan, Investment in Pharmaceuitcals Before and After TRIPS, National Bureau of Economic Research, 1050 Massachusetts Avenue Cambridge, MA 02138, U.S.A.

suggest that alternative mechanisms for inducing Research and Development (R&D) may be more appropriate than patents.[23]

As Adede argued, the motive of the developed countries has been to expand their commercial control of the world's biodiversity within the industrial sector, relying on the instruments such as TRIPS. There have thus been continued calls for the strengthening of the TRIPS Agreement and its implementation within WTO which they aptly characterize as a rule-based organization.[24]

The developing countries have on the other hand, preferred WIPO or the Convention on Biodiversity (CBD) as the forums for the implementation of the legal instruments dealing with issues of intellectual property rights and biodiversity issues embodies in the TRIPS Agreement. He stated that it is clear that they were reluctant ab initio to place IPRs on the agenda of the Uruguay Round. But they were sold the idea that including TRIPS on the agenda would enable them to gain concessions on other areas of negotiation of particular interest to them such as agriculture, textile and clothing, tropical products and safeguards which were so important for compulsory licensing and parallel importing. However, the subsequent negotiations which resulted in the controversial and aborted "millennium Round" convened in Seattle, Washington State in the USA in 1999, revealed that the developing countries had not realized the benefits arising from these areas, as they were promised under the Uruguay Round. As he observes, in this connection that: (a) increased access of developing countries exports to the rich countries markets has not occurred; (b) no gains have yet been realized from the supposed phasing out of textile quotas; (c) abuse or misuse of the anti-dumping measures against products from developing countries has not abated; and (d) the implementation of the Agriculture Agreement has not resulted in reducing the high protection of agriculture production of the rich countries.[25]

Vigorous debates in the developing world preceded the implementation of TRIPS, and it was timely to follow up on some of the questions raised in that debate. Would TRIPS lead to

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[23] ibid

[24] Adede,A.O., The Political Economy of the TRIPS Agreement: Origins and History of Negotiators, Nairobi, Kenya: Acts Press, African Centre for Technology Studies, 2001.

[25] Id.

monopolies on new drugs where, previously, imitation was possible? Would TRIPS encourage foreign investment for the health industry or create external constraints? Would TRIPS lessen interest, by developing country firms, in diseases of the poor where markets were uncertain, or would it motivate the development of innovative drugs against priority diseases in these countries? And would international product-development partnerships (PDPs) that were now generating a pipeline of drugs for poverty-related diseases find it easier to form partnerships with institutions and emerging suppliers in developing countries.[26]

The effect of stringent intellectual-property protection in the pharmaceutical market is contentious, focused in recent years on the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In January, 1995, the TRIPS agreement established global minimum standards for the protection of intellectual property, including a minimum 20 years' patent protection on pharmaceuticals. Compliance was postponed until 2005 for developing countries and 2016 for least developed countries. The agreement greatly expanded intellectual-property rights, including rules on the protection of test data for the effectiveness and safety of drugs. This change in intellectual-property rights generated clear gains for industry and the developed world, but the crucial question is whether it generated gains for developing countries in the form of increased exports.

For most developing countries, the domestic industry was small, usually focused on generic production and traditional medicines. These countries consequently have to pay high prices for imported medicines, and were affected by intellectual-property rights, especially TRIPS and TRIPS-plus standards. For most countries, developed and developing, the escalating cost of medicines—even those recognized as essential ,means that aspects of the pharmaceutical industry (especially in the context discussed here), trade, TRIPS, and TRIPS-plus were thus a major global concern at the moment. There were some exceptions—e.g., Brazil, Thailand, and India that have substantial capacity to produce generic medicines. For India, a thriving competitive domestic pharmaceutical industry has kept generic prices at amongst the lowest in the world, helped by not granting patents on medicines until 2005, when it was required to do so

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[26] ibid

by the WTO. Two-thirds of these drugs were now exported to the developed world, although potentially threatened by enhanced patent protection (likely to drive prices up unless voluntary or compulsory licences to continue production were granted), making the TRIPS and TRIPS-plus process essential.[27]

1.21 Strategies for Enhancing Access to Medicine

The question of whether TRIPS generates gains for developing countries, in the form of increased exports, is addressed by Richard D. Smith, Carlos Correa, *et al* in "Trade, TRIPS, and Pharmaceuticals."[28] It does so through consideration of the importance of pharmaceuticals in health-care trade, outlining the essential requirements, implications, and issues related to TRIPs, and TRIPs-plus, in which increased restrictions are imposed as part of bilateral free-trade agreements. To their minds, TRIPs has not generated substantial gains for Developing countries, but has further increased pharmaceutical trade in Developed countries. The unequal trade between developed and developing countries (ie, exporting and importing high-value patented drugs, respectively) raises the issue of access to medicines, which is exacerbated by TRIPs-plus provisions, although many countries have not even enacted provision for TRIPs flexibilities. Therefore their text focuses on options that are available to the health community for negotiation to their advantage under TRIPs, and within the presence of TRIPs-plus.

The text offers a practical approach which bolsters the argument that there is indeed an array of flexibilities options which a country can leverage to create self-sustaining productivity levels of drugs, hence enhancing access to medicine.

Accessing the implications of TRIPs for the development of new products to treat diseases of poverty is difficult. Technology transfer and innovation, in general, are strongly viewed as ways

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[27] ibid

[28] See Smith, R. Correa, et al, TRADE, TRIPS, AND PHARMACEUTICALS, Health Policy Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK.

to strengthen an economy; clearly, however, emerging pharmaceutical industries can do more than generate new knowledge, skilled labour, and markets.

These industries can address social objectives by developing health-related products to meet local needs. But will the emerging pharmaceutical industries in Brazil, China, India, and elsewhere become sources of new medicines for diseases that disproportionately affect low- and middle-income nations? Early evidence suggests the answer is no. Pharmaceutical firms in India are focusing globally, exploiting their strengths to develop or improve therapeutic drugs for well-characterized medical conditions that exist in robust global markets. For example, based on projected sales growth, Ranbaxy Laboratories aspires to increase its percentage of revenue from sales to member countries of the Organization for Economic Cooperation and Development (OECD) from 20% in 2000 to 70% in 2007 (presentation at investors conference in Murnbai, September 2004).[29]

1.22 The Political Economy for Enhancing Access to Medicine in Developing Countries

The public sector predominantly remained responsible for promoting the development of new technologies to meet local needs. For example, the government of India was addressing this task by promoting investment in drug development through several innovative schemes, such as increased R&D tax benefits and subsidies to support industry–university partnerships. In Kenya, the issue is being addressed by enacting the new laws to deal with accessibility to affordable drugs. The New Millennium Indian Technology Leadership Initiative, for example, supports local technology partnerships between publicly supported R&D institutes and industrial companies. Among health-related activities, the program supports the development of new targets, drug delivery systems, bio-enhancers, and therapeutics for latent mycobacterium tuberculosis to better manage India's high disease-burden of tuberculosis.

Equally important, the new global Intellectual Property (IP) standards have emerged just as public–private product- development partnerships (PDPs) were pioneering creative forms of IP management. PDPs use intellectual property as a negotiating tool for developing high-quality,

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[29] Ibid.

affordable therapeutics and vaccines for diseases of the poor. For example, the Medicines for Malaria Venture (MMV) have formed technology partnerships to develop an artemisinin-derived lead compound for malaria.

In explaining the success of the partnership, MMV points to its pragmatic approach to collaboration with the private sector, an approach made possible by the effective identification and management of intellectual property. Indeed, each PDP must adapt its IP strategies to the contributions of its public sector and industrial partners.

Nonetheless, PDPs share the common goal of constructing deals that both provide incentives to the private sector and meet the social objectives of the public sector. These deals were achieved through negotiated agreements on territorial markets, pricing structures for public and private markets, or field of use, among other areas.

In "TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of Paragraph 6 Waiver",[30] Jessica L. Greenbaum observed that lack of access to medication contributes to high death rates, particularly in sub-Saharan Africa. She highlights various factors which contribute to the lack of access to medication, and states that the largest barrier is the exorbitant cost of antiretroviral therapy. The high cost of medication is a result of both patent protection, which prevents the production of generic forms of anti-retrovirals to be sold at lower costs, and also the inability of many underdeveloped countries to manufacture their own medication. At the centre of her argument is the competing interests of patent holders and developing countries surround the issue of affordable access to medication. In 2003, the World Trade Organization (WTO) proposed a waiver to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), known as the "Paragraph 6 Waiver," in order to create flexibility for developing countries and to allow easier importation of cheap generic medication. She argued that it is now time to revisit the TRIPS agreement and determine how to guarantee global access to essential medications. In this respect, the suggestions that

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[30]Jessica L. Greenbaum ,"TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of Paragraph 6 Waiver", 25 J. CONTEMP. HEALTH L. & POL'Y 142 2008-2009.

would solve the problems overlooked by the WTO and allow for a more effective implementation of the "Paragraph 6 Waiver."[31]

Thousands of people die from AIDS every day in countries that do not have the resources to manufacture cheap generic medication. While the WTO has approved the use of compulsory licensing to manufacture and to import generic medications, only one country has attempted to use the Paragraph 6 Waiver in the five years since the WTO's announcement, she argues.

According to her, WTO's attempted at "striking a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions" is weighted in favor of the long term objective of protecting innovation and to the detriment of those people who desperately need existing inventions.

She argued that the problem is not beyond intractability. First, by ensuring that developing countries do not fear reprisal or sanctions, they would be encouraged to either seek out developed countries with manufacturing abilities or issue compulsory licenses to manufacture medications themselves. Next, the WTO can help potential exporting countries by creating model legislation that would allow them to issue compulsory licenses for the sole purpose of exporting cheap generic medications so that countries do not feel that the task of creating such legislation is not worth the trouble it could potentially cause. Finally, a "TRIPS" fund should be created that could be used for remuneration of patent holders to ensure that the pharmaceutical industry is adequately compensated, and to ensure the WTO's broader long-term goal of providing incentives for future inventors. All WTO member states and humanitarian organizations should contribute to this fund, she quips. If all of these goals were accomplished a true balance can be found between the long term benefits of protecting innovation and the short term benefits to be gained from new invention. Most importantly, millions of people suffering from AIDS would gain access to life saving medication.[32]

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[31] Id.

[32] Id.

Phillip Cullet attempts to establish the link between medical patents and the human right to health in "Patents and Medicine: The relationship between TRIPs and the Human Right to Health."[33] From a legal perspective, his discussion is focused on two main areas of law. First, the question of access to medicines is a central issue in any consideration of human right to health. His second is that debates on access to drugs were now strongly linked to the question of whether drugs can, and should be, patentable. He points out that while intellectual property law and human rights law have largely evolved independently, the links between the two bodies of law have become increasingly and obviously blurred, as a result of the broadening scope of patents in areas related to basic needs such as health and the attendant recent development in the health sector. TRIPs, according to him necessitated further consideration of the relationship between the right to health and patents on medicine, particularly for Developing Countries. He notes that while human rights documents have given some consideration to intellectual property in relation to human rights, there has been no similar effort in the field of intellectual property.[34]

According to Cullet, the notion introduced a complication from an international law point of view in the sense that TRIPs is being applied not in a vacuum, but in a context where the right to health is a well-established human right codified in one of the two main international human rights treaties.

To him the introduction of patents to drugs has provoked a significant outcry in a number of Developing Countries, where success to medicine is abysmally low. The justification offered for the existence of patents as incentive to innovation often do not appear convincing to patients in developing countries, who see that hardly any R& D was being invested in disease specific to those countries. In other cases, the cost of these drugs have been so high that as to render them affordable only Developing Countries.[35]

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[33] Phillip Cullet, "Patents and Medicine: The relationship between TRIPs and the Human Right to Health, available at < www.ielrc.org/about_cullet.php> (last accessed 20th October, 2011.

[34] Ibid.

[35] Ibid.

His central argument was that while states must endeavour as far as possible to reconcile their different international obligations, there seem to be some cases where the implementation of TRIPs directly implies a reduction in access to drugs and thus a step back in the implementation of the right to health. This appears to be unacceptable under the ESCR covenant and countries in this situation would be expected to give priority to their human rights obligations. This solution, which gave primacy to human rights, was unlikely to meet with the approval of all states and would probably not stand if it came for adjudication in a WTO context. It nevertheless seems adequate from a legal and ethical point of view.[36]

1.23 TRIPS and Public Health Safeguards

TRIPS also raised issues related to compulsory licensing and parallel trade. These public-health safeguards were provided under the TRIPS agreement and were reinforced by the Doha Ministerial Conference. In December 2005, the WTO Council permanently adopted a key policy on compulsory licenses that had existed as a waiver since 2003. The waiver had significantly improved the ability of developing countries without manufacturing capabilities to import patented drugs from sources other than the originator company.

The waiver would become a formal part of the agreement after WTO members ratify it. Production under compulsory licenses, however, presents some operational challenges. First, companies need to secure adequate know-how from the original manufacturer, or from elsewhere, to recreate products. Second, the products must reach markets that were large enough to enable compulsory licensees to recoup development and production costs. While compulsory licenses were potentially beneficial tools, developing countries can use other ways to help ensure that intellectual property does not create barriers to access. These included both conventional licensing arrangements and, notably, the enactment of laws to permit and regulate the government's use of patented inventions. Other options include the actions of patent courts to protect the public interest, the thoughtful management of genetic resources and traditional knowledge, and the judicious framing of competition law and policy.

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[36] Ibid.

In sum, the international IP standards mandated by TRIPS allow member nations considerable discretion to enact laws and provisions that both meet treaty obligations and support national innovation policies and development priorities.

1.24 Patent Rights and Access to Medicine in Kenya

The Industrial Property Act of 2001 has a direct bearing on access to medicine by virtue of the exclusive monopoly rights granted to the patent-holder. As Otieno-Odek observes, the patent-holder has the right to preclude any person from exploiting the patented invention.[37] He has the rights to conclude license contracts related to the invention. The law allows the patent owner to preclude any person from making, importing, offering for sale, selling and using the product.[38] He also reserves the right to preclude any person from stocking the product for purposes of offering it for sale or selling or using the product. When the patent relates to a process, the owner has the right to preclude any person from using the process or doing or producing any product obtained directly by means of the process.[39]

The patent-owner has additional protection and enforcement rights to the extent that he can obtain an injunction to restrain the sale or selling or likely performance of any prohibited act without his authorization and to claim damages or compensation from any person who infringes the patent.[40]

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[37] Otieno-Odek J,(2005), Intellectual Property and Public Health: TRIPS Flexibilities and Access to Medicine in Kenya, Kenya Industrial Property Institute, Nairobi: Dalton Press, p.17.

[38] Section 54(1)(a) of the Industrial Property Act, 2001.

[39] Section 54(b) of the Act.

[40] Section 55 of the Act.

1.30 Research Design and Methodology

1.31 Introduction

This study was conducted in Kenya. This chapter also presents how the data was gathered in order to find answers to the stated research questions. The study was largely descriptive, comparative and analytical.

1.32 Data Collection

When a thesis is written, the research can be based on primary or secondary data or both of them. Primary data is the data collected for the first time. Secondary data is information taken from other researchers.

Secondary data can often be easier or more realistic to use because of the accessibility of the already existing information.[41]

Yin[42] presents six different sources when carrying through case studies: documentation, archival records, interviews, direct observation, participant observations, and physical artifacts. These sources should be combined, which is referred to as triangulation.

Triangulation used in a case study gives the researcher an opportunity to discuss a broad range of historical, attitude-related and behavioral issues. This is done to increase objectivity since several sources were used as opposed to just a few.

To conduct the research and to find sufficient and describing data, the study was based on both secondary and primary data. The researcher wanted to collect information to be focused on the particular research questions, hence the suitability of be triangulation as a consolidated mode. To be able to find appropriate and describing data, secondary data would largely be used.

According to Yin,[43] interviews were the most important way of collecting data when conducting case studies. An interview is an interaction between an interviewer and a respondent, normally

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41 See for example, Saunders & Thornhill (2000).

42 Yin, R.K. (2003), Case Study Research: Design & Methods, 3rd Ed. Thousand Oaks, Sage Publications, Inc.

carried out through a telephone or by person.[44] When specific and in-depth data is needed, then interviews were the ultimate data collection methods. In this study, that kind of data was needed, making its use appropriate.

Semi-structured interviews were conducted to enable the interviewee develop his own ideas and to answer more specifically. The interviews were structured as a guide to help in finding answers to the research questions.

The interviews were conducted personally. During the interviews, the researcher took notes.

1.33 Sample Selection

The reasons for selecting firms in Nairobi can be described as what Saunders referred to as convenience sampling, which is a sampling that is easily available to find information from, at the same time also a sampling method that is normally utilized when working with case studies.

1.34 Data Analysis

Once the empirical data had been collected, analysis was done. The objectives and attempts with the analysis strove to answer the stated research questions. Yin[45] says that data analysis is a process where the researcher examines, tabulates tests, categorises, or combines the evidence to address initial prepositions of the study. Miles and Huberman[46] argue that either a with-in case analysis or a cross analysis were proper ways of analyzing case study data. Miles & Huberman also states that the analysis consists of three simultaneously different activities:

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43 Yin, R.K. (1994), Case Study Research: Design & Methods, 3rd Ed. Thousand Oaks, Sage Publications, Inc.

44 Widersheim-Paul, F. & Eriksson, L.T. (1997) *Att Utreda Forska och Rapportera*, Stockholm: Lieber Ekonomi.

45 Yin, R.K. (2003), Case Study Research: Design & Methods, 3rd Ed. Thousand Oaks, Sage Publications, Inc.

46 Miles, M.B., & Huberman, M.A. (1994), Qualitative Data Analysis,: An Expanded Source Book, Thousand Oaks: Sage.

Data Reduction- the process stage where data is focused, selected, abstracted, simplified and transformed. The purpose of this process is to organize the data so that conclusions can be verified and drawn.

Data Display- The segment where the data is concentrated and organized in a compressed way to make it simpler for conclusion drawing.

Conclusion Drawing and Verification- the phase where the researcher begins to make comments and clarify what things mean. This is done by noting regulations, patterns, explanations, configurations, casual flows and prepositions.[47]

The data collected was analyzed through the use of the three activities described by Miles and Huberman. The reduction was made through a comparison of the empirical data and the theories presented in the conceptualization or as what Yin is describing as a with-in case analysis. To make things easier, the process of linking theories to empirical data and draw conclusions was conducted in a way in which the different theories and data were matched and categorized. Finally, when the with-in case analysis and the cross section analysis were conducted, conclusions were drawn and presented.

1.36 Validity and Reliability

Validity is concerning to what extent the researcher measure what the researcher is supposed to measure, and reliability is about how reliable research methods were when conducting a study. This means that reliability tests if the same results were obtained if the same research is conducted again. Validity and reliability were two methods were two measurement instruments that exhibit a significant degree of trustworthiness and credibility the research has.[48] These twin concepts were employed in this study.

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47 *Ibid.* .

48 Yin, R.K. (2003), Case Study Research: Design & Methods, 3rd Ed. Thousand Oaks, Sage Publications, Inc.

1.37 Organization of the Study

Chapter one of this study covered the background to the problem and in this section the writer introduced the topic under investigation covering a global, regional and national overview. The other were as covered include the statement of the problem which described the background of the problem; the research question; objectives of the study; significance of the study; scope of the study and the conceptual framework. It also covered the research methodology and design components which included the research purpose; research approach; research strategy; sampling design; data collection methods; sampling selection and data analysis.

Chapter Two examined the effectiveness of the requirements of importing and exporting member countries under the Paragraph 6 Decision and the "Best Practices" guidelines suggested by the WTO in order to prevent diversion of pharmaceuticals. Additionally, remedies available to patent holders that were victims of diversion under International law were discussed.

Chapter Three analyzed TRIPs and the controversy over the scope of review of the provisions of Article 27(3)(b) of TRIPs in regards to access to medicine and public health. It also provided an array of flexibilities which Kenya can utilize to enhance access to affordable generic medicine.

Chapter Four explored the various arguments across the divide on patent protection, as well as the implications for Developing Countries.

Chapter Five played receptacle to a summary of the discussions, conclusion, recommendation and suggestion for further research.

2.0 CHAPTER TWO

PARAGRAPH 6 DECISION AND ITS IMPLICATIONS ON ACCESS TO GENERIC DRUGS IN DEVELOPING COUNTRIES

2.1 Introduction

This Chapter examined the effectiveness of the requirements of importing and exporting member countries under the Paragraph 6 Decision and the "Best Practices" guidelines suggested by the WTO in order to prevent diversion of pharmaceuticals. Additionally, remedies available to patent holders that were victims of diversion under International law were discussed.

On August 20, 2003 World Trade Organization (WTO) member governments broke their deadlock[49] over intellectual property protection and public health, resulting in an international agreement.[50]

The new agreement, titled "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," allows any member country producing pharmaceuticals under compulsory licenses[51] to export to other member countries;[52] a privilege expected to be

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[49] WTO Members could not come to an agreement regarding specific instruction of the Ministerial Conference to the Council for TRIPS, contained in paragraph 6 of the Declaration, to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face in making effective us of compulsory licensing under the TRIPS Agreement. *See* Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT'L L.J. 101, 108 (2003).

[50] *See* Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports, *at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last visited March 8, 2005) [hereinafter Patent Obstacle].

[51] Compulsory licensing permits a Member state to legally license a party, other than the patent holder, rights to produce and distribute the patented pharmaceutical, subject to certain conditions in times of public health crises. *See* Kelly A. Friedgen, Comment, *Rethinking The Struggle Between Health & Intellectual Property: A Proposed Framework for Dynamic, Rather than Absolute, Patent Protection of Essential Medicines*, 16 EMORY INT'L L. REV. 689, 699 (2002). Article 31 of the TRIPS Agreement requires issuance based upon individual case consideration, limited scope and duration, failed attempts to negotiate a voluntary license over a reasonable period of time, non-exclusive and non-assignable use, meeting the demand of predominately the domestic market, the payment of adequate remuneration to the patent holder, and subject to judicial review within the Member state. Agreement of Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, 33 I.L.M. 86-87.

used only in good faith in order to deal with public health crises such as HIV/AIDS, tuberculosis and malaria.[53] Developed countries, however, remain fearful that the decision might be abused by developing countries and that patent protection may be undermined.[54] Many pharmaceutical companies were particularly concerned with a potential increase in diversion[55] of pharmaceuticals produced in response to public health crises.[56] Diversion not only defeats the purpose of the WTO decision,[57] but threatens research and development into new therapies for AIDS and other diseases.[58] Paragraph 2(b) (ii) of the Paragraph 6 Decision attempts to address these valid concerns by requiring exporting countries to clearly identify pharmaceuticals being produced under compulsory license through special packaging, coloring and shaping of

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[52] *See* Patent Obstacle; *See also* Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003), available at http://www.wto.org/ (last visited March 8, 2005) [hereinafter Paragraph 6 Decision].

[53] *See* Patent Obstacle.

[54] *See HIV Drugs for Africa Diverted to Europe*, WASH. POST, Oct. 3, 2002 at A10; *See also* Naomi Klein, *Bush's AIDS Test*, The Nation, October 27, 2003, *available at*

http://www.thenation.com/docprint.mhtml?i=20031027&s=klein (Accessed 1st November, 2011).

[55] Diversion, also called "parallel trading" and "gray goods", is the exploitation of pricing differentials between different wholesale levels. *See* International Coalition Against Diversion, *Protecting Your Assets in the New Global Economy, at* http://home.pipline.com/~pvteye/ (last visited Jan. 18, 2004); *see also* Donald E. deKieffer, *Diversion, available at* http://www.dhlaw.de/eng/04_publi/documents/diversion.2000.PDF (explaining that diversion of IP protected goods is not grey market, but is actually theft or other criminal activity) (last visited March 8, 2005) [hereinafter deKieffer Diversion]. "Parallel imports, also called gray-market imports, are goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right." Keith E. Maskus, *Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries, available at* http://www.wipo.int/aboutip/ en/studies/pdf/ssa_maskus_pi.pdf (last visited March 25, 2005).

[56] Ibid.

[57] *See* WTO News, The General Council Chairperson's Statement, *at*

http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (last visited March 8, 2005) [hereinafter Chairperson's Statement].

[58] See Klein.

products.[59]Although some see TRIPS as accomplishing the goal of harmonization with a fair balancing among differing interests, others, mainly developing nations, refute this claim.[60] Some developing country Members of the WTO believe that implementation of their domestic public health policies were adversely affected by the limitation of access to essential medicines[61] needed during public health crises due to TRIPS provisions.[62] While it is true that other factors such as infrastructure and professional support play an important role in determining access to drugs, it is also true that the prices that result from the existence of patents ultimately determine how many people suffering from AIDS and other diseases may go untreated.[63]

The WTO attempted to address these concerns by writing flexibilities, such as compulsory licensing, into the TRIPS Agreement.[64] Article 30 of the Agreement allows governments to issue compulsory licenses to companies to make patented products or use patented processes under license without the consent of the patent owner, but only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.[65] Some governments, including the

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[59] TRIPS: Council for TRIPS Decision of 30 August 2003 WT/L/540, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, *at*

http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[60] *See* Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J. 57, 60 (2002).

[61] The World Health Organization defines essential drugs and medicines as "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford." *See* Friedgen, *supra* note 3, at 693 (citing World Health Organization, Expert Committee of Essential Drugs, *at* http://www.who.int.medicines/organization/par/edi/trs/trs895.shtml).(Acessed on 1st november, 20110.

[62] See Sun, p. 103.

[63] Carlos M. Correa, TRIPS and Access to Drugs: Toward a Solution for Developing Countries without Manufacturing Capacity, 17 EMORY INT'L L. REV. 389, 390-391 (2003).

[64] *See* Patent Obstacle, *supra* note 2. *See also* Friedgen.

[65] *See* Patent Obstacle.

African Group,[66] sought clarification of how these flexibilities would be interpreted, and how far their right to use them would be respected.[67]

The Doha Declaration on TRIPS and Public Health ("the Doha Declaration") addressed these divergent perspectives.[68] Members reached an agreement in principle, which acknowledged the need to assist developing countries in combating the three fatal pandemics of AIDS, malaria and tuberculosis.[69] While promoting both access to existing medicines and the creation of new medicines, ministers at the Doha Ministerial Conference focused on the importance of implementation and interpretation of the TRIPS Agreement in favor of public health.[70] The declaration provided that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health, and that it should be interpreted accordingly:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions, in the TRIPS Agreement, which provide flexibility for this purpose.[71]

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[66] This Group comprises all the African States who are members of the WTO.

[67] Id.

[68] James Thuo Gathii, The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties, 15 HARV. J.L. & TECH. 291 (2002).

[69] Jean Bizet (France), *The Trips Agreement and Public Health*, Presented at Cancun Session of The Parliamentary Conference on The WTO (Sept. 9-12, 2003), *at* http://www.ipu.org/splz-e/cancun/5b.pdf (last visited March 8, 2005).

[70] *See* Patent Obstacle.

[71] WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/21 (Nov. 14, 2001) at para. 4, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (last visited October 31st, 2011) [hereinafter Doha Declaration].

This declaration gave developing country Members the autonomy to make and implement domestic public health policies with respect to intellectual property protection.[72] It also clarified members' right to adopt an international principle of exhaustion of rights, including parallel importation.[73] And similarly, it confirmed the members' rights to grant compulsory licenses on the grounds determined by each member.[74] Furthermore, these countries were granted the power to determine what constitutes a national emergency.[75]

Known as the Paragraph 6 Problem, Ministers at Doha recognized, but failed to resolve one critical issue with compulsory licensing.[76] Such authorizations benefited developing countries which were further advanced, such as India, Thailand, Brazil and South Africa, who have laboratories and the scientific capabilities to produce the pharmaceuticals.[77] The Agreement, however, overlooked the poorest developing countries which do not possess the technical production ability, although they were often the countries most affected by the diseases targeted in the declaration.[78] Specifically, the Agreement did not directly address whether countries, which were unable to produce pharmaceuticals domestically, could import patented drugs made under compulsory licensing.[79] Article 31(f) of the TRIPS Agreement in fact required that

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[72] *See* Sun, at 102.

[73] Correa,at 392. *See also* Bizet, note 27.

[74] Correa, at 392.

[75] *See* Ansari, at 64.

[76] Doha Declaration, at paragraph 6 ("We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.")

[77] Cancun Session.

[78] Id.

[79] Sun at 103.

products under compulsory licensing would be "predominately for the supply of the domestic market."[80]

Failing to define the term "predominately" in this provision left the WTO members, who lacked the requisite manufacturing infrastructure, with the unmet need of generic drugs.[81] Ironically, these countries, which were suffering the most severely due to public health crises, found it complicated to contract with a more developed country that was willing to supply them with drugs made under compulsory licensing.[82] This difficulty was due to the fact that developing countries producing pharmaceuticals under compulsory licenses were aware that the WTO accepted the manufacture of medicines for local use, but it was against the marketing of generic medicines and by extension, its export outside the domestic market mainly because of opposition from the big pharmaceutical groups.[83]

There were, however, a few countries, such as India, that were willing to export pharmaceuticals to developing countries lacking infrastructure. Indian law does not provide patent protections for pharmaceutical products, therefore manufacturers were able to produce generic versions of US and EU patented pharmaceuticals at a fraction of the price without violating local patent law.[84] After 2005, however, when the TRIPS Agreement became fully operative, exporting countries were obligated to fully comply with the Agreement and would no longer be able to produce and export cheap generic copies of patented medicines.[85] Consequently, the limited source of affordable drugs would be lost and developing countries suffering from emergency public health

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[80] *See* Patent Obstacle.

[81] Id.

[82] Id. *See* also Sun, at 103.

[83] See Cancun Session.

[84] Correa, at 393.

[85] Id.

crises and unable to benefit from compulsory licensing would become entirely dependent upon expensive patented pharmaceuticals.[86] This is where Kenya now finds itself.

WTO Members entrusted the TRIPS Council with the task of finding a legal solution to this problem.[87] The council's challenge was to reach an agreement that, in theory, would grant certain countries the authority to manufacture and export to "countries which need them the most" the generic medicines used for "diseases of an epidemic proportion" on a case by case basis.[88] According to the Doha Declaration, the TRIPS council should have found a solution and reported it to the General Council before the end of 2002.[89] Unfortunately, determination of which medicines were covered by the agreement and which countries could benefit remained unresolved and the deadline was not met.[90]

2.2 The Contestation between Intellectual Property Rights and Human Rights

It was generally undisputed that the developing world is suffering from multiple infectious diseases that were responsible for over 300 million illnesses and almost six million deaths per year.[91] That the stakes involved were very high cannot be overemphasized. According to the World Health Organization (WHO), a third of the world population, approximately two billion people, do not have access to essential medicines.[92] The critical health situation of developing countries is due mainly to the AIDS epidemic which affects 42 million persons throughout the world, the majority of whom were in Africa, and 90% of whom have no medicines.[93] Although

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[86] Ibid.

[87] Cancun Session.

[88] Although the guidance was stated in vague terms laden with flexibility, the Council was advised that it should, at a minimum, guarantee the poorest countries access to generic products at an acceptable price and avert the risk of re-export to other countries. *Id.* at II (b) 14.

[89] Doha Declaration, at paragraph 6. *See also* Sun, at 102.

[90] Cancun Session.

[91] Friedgen, at 690.

[92] Cancun Session.

[93] Ibid.

treatment for these diseases exists and would likely have a profound effect on the morbidity and mortality rates, access to these essential medicines for combating HIV/AIDS, malaria and tuberculosis is greatly hindered by the existence of patents.[94]The magnitude of this problem justifies making available to those persons affected the pharmaceutical products which were currently out of their reach because of their market price.

This problem of access has therefore emerged as a global priority.[95] Human rights activists advocate easing or eliminating patent protections for certain drugs, on the basis that such protections violated international human rights to health.[96] With the global nature of the AIDS scourge, at the price set on the European market, treating these populations would cost €6 billion a year, a far cry from the €500 million which the developing countries were able to allocate each year to their health budgets.[97]

On the other side, representatives of the pharmaceutical industry vigorously defend and lobby for the international application of intellectual property rights.[98] The United States often stresses the importance of IP protection for research and development, arguing that intellectual property contributes to public health objectives globally.[99] The patent system embodies a compromise between competing short-term and long-term economic and social interests.[100]

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[94] Correa, at 390.

[95] Friedgen, at 690. See also Ellen 't Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha, 3 CHI. J. INT'L L. 27, 38 (2002).

[96] Friedgen, at 690.

[97] Cancun Session.

[98] Friedgen,, at 690.

[99] 't Hoen, *supra* note 55, at 38.

[100] *See* ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, *at* http://www.who.int/medicines/library/dap/aseantripsagreement.pdf (accessed 2nd November, 2011).

Along with a well-functioning regulatory structure and marketing system, it allows the private pharmaceutical industry to contribute to a socially driven public health sector by providing it with cost-effective new technologies, including pharmaceuticals.[101]

The commercial sector discovered and developed nearly all new drugs and vaccines, but this is expensive and risky.[102] The purpose of the US patent system is to encourage technological innovation by providing economic incentives to inventors.[103] Such incentives were necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in research and development.[104]

Incentives for innovation were lost when the patent monopoly was disturbed, thereby threatening the profit scheme.[105] The pharmaceutical industry was not particularly concerned with this threat in regards to developing countries, which lack infrastructure, because they hold no such patent monopoly in these countries and the critical need is recognized.[106] This is evident in the industries willingness to lead initiatives, which seek to respond to the needs of the poor and

suffering.[107] Such pharmaceutical industry-based ventures included drug donation and give-aways, drug discounting, and voluntary licensing of technology related to various diseases.[108]

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[101] Ibid.

[102] Ibid.

[103] Lawrence M. Sung, Ph.D., Intellectual Property Protection or Protectionism? Declaratory Judgment Used by Patent Owners Against Prospective Infringers, 42 AM. U.L. REV. 239, 244 (Fall, 1992). See also, John Miller, Comment, A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market, 13 ALB. L.J. SCI. & TECH. 555, 566-567 (2003).

[104] See ASEAN.

[105] *See* Miller, at 566-567.

[106] Friedgen, at 707.

[107] Ibid at 690.

[108] Ibid.

Diversion of the product into higher-priced markets capable of bearing the high costs, which was sought by the pharmaceutical companies, was the focal concern of the pharmaceutical industry.[109] This position is understandable in light of basic economic theory.[110]

Introducing a diverted product into a market where the product is already patent protected effectively destroys the patent holder's monopoly,[111] ultimately affecting the amount of research funds available and in turn the availability of essential medicines.[112]

2.3 What Constitutes Diversion?

Product diversion refers to products sold by a manufacturer that were distributed, in violation of a contract, law or regulation, into markets other than those originally intended.[113] With product diversion, third parties can undercut a company's price and reap huge profits.[114] This international scheme hinges on an industry practice in which manufacturers set up different pricing for the same products in accordance with each regions particular economic status.[115]

Diversion of pharmaceuticals produced under compulsory licenses would theoretically occur when drugs produced by country A[116] were exported to country B[117] under the Paragraph 6 Decision. The medicines intended for country B could be diverted in one of three ways; first,

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[109] Id at 707.

[110] Id.

[111] Friedgen, at 707.

[112] See ASEAN.

[113] Product Diversion Investigations, *at* http://www.njinvestigator.com/Product%20Diversion.htm (last visited March 8, 2005) [hereinafter Diversion].

[114] Id.

[115] Id.

[116] Typically a developing country, which has been granted a compulsory license in order to combat a local public health crisis, also called the "exporting member."

[117] A developing country that does not have the capability or infrastructure to produce the drug, also called the importing member.

country A could break the contract and export the drugs directly to country C[118] at prices substantially lower than the local market; second, in route to country B diverters could steal the pharmaceuticals and sell them in country C at a great profit; and finally, after the importation, country B, could decide that the financial income brought in from selling the drugs would be more essential to the greater public than the drugs and could chose to export into country C at a large profit.

The origin of diverted goods is not exclusive to pharmaceuticals produced under compulsory licenses. Diversion has long been a problem after the sale of goods directly from the patent holder into a foreign market or via donation of the pharmaceuticals into developing country in a public health crisis.[119]

2.4 The Paragraph 6 Decision

On August 30, 2003 at the Ministerial Conference in Cancun, with public health and intellectual property rights in mind, ministers settled the unanswered question of exportation/importation of products produced under compulsory licenses.[120] Although the United States initially aimed at limiting the availability of compulsory licenses to countries affected by HIV/AIDS, malaria and tuberculosis, the diplomatic battle came to an agreement, when the United States accepted text covering all diseases, as was originally mandated by the Declaration.[121]

The final agreement waives countries' obligations under Article 31[122] of the TRIPS agreement, by allowing any WTO member country to export pharmaceutical products made under compulsory licenses within the terms set out in the decision.[123] This solution was based on a

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[118] A country where the drug is already in the market, including the patent holder's country.

[119] International Coalition Against Diversion, *Protecting Your Assets in the New Global Economy*, *available at* http://home.pipline.com/~pvteye/ (last visited October 20th, 2011).

[120] *See* Patent Obstacle.

[121] Correa, at 393.

[122] See TRIPS.

[123] Patent Obstacle.

compromise developed by the Chair of the TRIPS Council and on a "Statement by the Chair" proposed by the United States as a condition to accept the deal and satisfy the U.S. pharmaceutical companies.[124] The Decision takes the form of an interim waiver that would last until the TRIPS Agreement is amended.[125]

Details in the decision explained exactly how compulsory licensing should be used to protect public health and how diversion can be prevented.

2.4.1 In Good Faith to Protect Public Health

Paragraph 1 (b) addressed the United States concern that low-cost producers in places such as India would smuggle medicines into rich markets and use their technologies to boost profits rather than for humanitarian reasons.[126] The provision defines "eligible importing member" as any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.[127] In the latter case any WTO Member may at any time notify the council that it would use the compulsory licensing system as an importer.[128]In order to justify such use, the Member must show that importation is necessary due to national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[129] By limiting importing members to countries with justifiable

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[126] See Scott Miller, WTO Drug Pact Lifts Trade Talks – Landmark Deal Provides Medicines to Poor Nations, available at http://www.usvtc.org/WTO/WTO%20Drug%20Pact%20Lifts%20Trade%20Talks.h tm; EU's Lamy Is Optimistic, WALL ST. J., Sept. 2, 2003, at A2.

[127] TRIPS: Council for TRIPS Decision of 30 August 2003 WT/L/540, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, *at* ttp://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[128] Id.

[129] Id. Exporting member is defined as a Member using the system set out in his Decision to product pharmaceutical products for, and export them to, an eligible importing member." *Id.* Section (b) also notes that some Members will not use the system in the Decision as importing Members and that some other Members have stated that, if they use

humanitarian needs other than commercial needs, the Decision does not allow for exploitation of compulsory licenses.

Paragraph 2 further limited the possibilities of exploitation by waiving the responsibilities of Article 31 of the TRIPS agreement, but setting out obligations of both exporting and importing members with respect to granting compulsory licenses to the extent necessary for the purposes of production of pharmaceuticals and their export.[130]

Specifically, the importing member must notify the Council providing them with details of product need, establishing that the requesting member has insufficient or no manufacturing capacities in the pharmaceutical sector for the products, and confirming that where a pharmaceutical product was patented in its territory, it granted or intended to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.[131] The Decision goes on to require that exporting Members produce only the amount of pharmaceuticals necessary to meet the needs of the importing Member and that all such products would be shipped in their entirety to the cited importing Member.[132]

Restricting the amount of product that the exporting Member can produce and export to the actual need of the importing countries is another attempt by the Council to ensure that compulsory licensing would only be used in good faith in order to ensure public health.

2.4.2 Preventing Diversion

The importing members under the Decision have the burden of ensuring that drugs imported into their country were not re-exported, or diverted, to other markets.[133] In order to make this

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the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency. *Id.*

[130] See Implementation.

[131] Id.

[132] Id.

[133] Id.

feasible, exporting member were required to produce products that can be clearly identified as being produced under the system set out in the Decision.[134] The Decision does not lay out any specific requirements but identifies methods such as special packaging, coloring or shaping of the products. This provision is, however, only required if such distinction is feasible and does not have a significant impact on price.[135] Paragraph 2 also requires that the exporting Member post on a Web site the quantities of pharmaceuticals being supplied to each destination, listing the distinguishing features of the products.[136]

Paragraph 4 of the Decision required that importing members must also "take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion, to prevent re-exportation of the products that have actually been imported into their territories under the system."

With the new Decision laid out it seems that the WTO has finally come to a conclusion that satisfies both the pharmaceutical industries and the developing country's desire for a more balanced set of regulations for the protection of international IP rights. It has yet to be seen, however, how the Decision would affect each side in practice.

2.5 Implementation of the Decision

With the Decision in place and paragraph 6 of the Doha Declaration now a reality the question remained, would developing countries have the capability to even take advantage of the new Decision? Multiple criticisms of the Decision quickly emerged after the agreement was reached.[137]

Some commentators believed that the United States, at the behest of the pharmaceutical lobby, was successful in pushing for so many conditions, that the deal has become far from workable.[138]

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[134] See Implementation.

[135] Id.

[136] Id.

[137] *See* Correa, at 398; Klein,; Scott Miller.

[138] Klein.

A coalition of Non-Government Organizations declared that the new deal was in fact just "a gift bound in red tape."[139] Even if countries wanted to import cheap generics they would first have to jump through multiple hoops to prove that they were truly in need, unable to afford patented drugs and incapable of producing the medicines domestically.[140] Furthermore, since the Agreement also put up extensive requirements for the exporting member to comply with, there is no guarantee that there would be a sufficient supply of drugs for the importing members to buy.[141]

It was also been suggested that, because the Decision takes the form of an interim waiver,[142] national laws must be aligned with the waiver in order for its benefits to be realized.[143] If such alignment is not realized, patent holders may succeed in initiating a complaint invoked under the provision in the national laws.[144] Revision or amendment of national laws may impede, if not prevent, the waiver from being used.

Others find the Decision favourable, but burdened with problems. The European Union's trade commissioner, Pascal Lamy, supports the decision but stated, "We all have to be very modest. We have solved about 10% of the problem of access to medicines by developing countries."[145] The problem that Lamy emphasizes is that even if life-saving drugs do become cheaper, they

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[139] Id.

[140] Id.

[141] Id.

[142] According to paragraph 11 of the Decision: This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on the Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

[143] Correa, at 398.

[144] *Id.* at 390.

[145] Miller.

would remain too costly for many people. And furthermore, most developing nations do not have the distribution system or the trained staff to get the medicines to the people in need.[146]

If it in fact is true that the recent Decision would not help solve the public health crises, who would benefit from the compulsory licensing and exportation of generic pharmaceuticals? It has been suggested that the generic producers would be the only entity seeing benefits from the Decision.[147] There stands the possibility that generic firms may use the Decision as a way to reach new markets.[148] Many analysts in fact agree that the Indian generic industry stands to gain the most from such exploitation of the new Decision.[149] South Africa's local generic drug manufacturers would also benefit from the loopholes in the Decision.[150]

WTO operative Pascal Lamy stated that finally the WTO has reached an even balance between human rights and intellectual property rights, however criticism from both sides of the fence seems to indicate that implementation of paragraph 6 of the Doha Declaration does not solve the majority of the problems.[151]

Patients in need of essential medicines may not receive any increased access and pharmaceutical companies relying on patent licensing may see the risk of diversion increase.

The pharmaceutical companies' hesitations about the Decision becomes more of a reality if in fact the Decision would only slightly affect public health issues and only benefit generic drug producers. If this proves to be the case, worries about the diversion of pharmaceuticals becomes a valid concern and forefront issue.

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[146] Id.

[147] Brand, Generics Reps Praise New WTO Drug Plan, Washington Drug Letter (Vol. 35, No. 36) (Sept. 15, 2003).

[148] Id.

[149] Id.

[150] All Africa, WTO Deal Paves Way for Cheaper Drugs, available at http://www.cdcnpin.org/PrevNews/2003/sept03/update091103.txt (last visited March 25, 2005).

[151] *See* Miller.

2.6 Conclusion

Although it has taken several years and continual negotiation, the WTO has come to a temporary agreement on how to balance human rights and intellectual property rights. Although it is exactly what the developing countries were pushing for, allowing the exportation of pharmaceuticals manufactured under compulsory licenses may not be the best solution to the critical public health issues many developing countries were facing. This exportation also exposes pharmaceutical companies to an increased threat of diversion, which would in turn lead to decreased profits and potentially a reduction in research and development of essential medicines.

The WTO Paragraph 6 Decision could be effective if combined with a pharmaceutical dispersion scheme, which would ensure that the essential medicines reached the patients that were in desperate need. Implementation of a dispersion plan would also greatly reduce the chance that diverters could intercept the shipments, therefore solving both of the current problems.

Unfortunately, implementation of such a plan would require large amounts of funding and personnel. Until this or another solution is realized the international community would have to make the best of the Decision

3.0 CHAPTER THREE

TRIPs AND THE PROBLEM OF ACCESS TO MEDICINE IN KENYA

3.1 Introduction

Governments in Developing countries that attempt to bring the price of medicines down have come under pressure from industrialized countries and the multinational pharmaceutical industry. While TRIPs does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

Public health advocates welcomed the Doha Declaration as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members' rights to use TRIPs safeguards. But the Doha Declaration did not solve all of the problems associated with intellectual property protection and public health. The recent failure at the WTO to resolve the outstanding issue to ensure production and export of generic medicine.

Expanding access to essential drugs and other basic public health supplies is a global priority and should be viewed within the context of the importance and recognition of the right to health for all.[152]

But the problem of access to medicines is not only limited to HIV/AIDS, TB, and malaria, although these diseases have attracted the most attention from international organizations, donors, and the general public. Millions of people, especially in the developing world, do not have access to existing medicines that are safe, effective, and relatively inexpensive, and that can save lives and prevent unnecessary suffering.

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[152] Statement by WHO to the United Nations Human Rights Commission, point 10 on the agenda, Economic, Political and Cultural
Rights, Geneva, 1 April 2003.

In many cases the high prices of drugs are a barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. The average cost of medicines is only one of the many reasons for lack of access; what is clear is that the debate surrounding the effects of patents on prices and access, and in the final analysis, the impact on public health, is one of the most contentious and difficult to resolve.[153]

The TRIPs requires WTO Member Governments to adopt and amend national laws to comply with the basic norms governing the protection of intellectual property. However, it also provides for the enactment of certain safeguards (for example, use of patents by governments; compulsory licensing; parallel imports; and other exceptions to exclusivity rights) that can void or limit the rights of patent holders under certain conditions. In fact, such measures have been introduced by developed countries in order to balance intellectual property rights with the public interest, encouraging competition, protecting consumers, and in the case of medicines, promoting access to affordable medicines by substituting expensive products with generics.

3.2 Developed Countries' Arguments for Stringent Patent Protection in Developing Countries

The first argument used by developed countries to emphasize the importance of the international recognition of patents within an international trade environment is that patent protection encourages participation in the pharmaceutical industry by providing financial incentives.[154] "Patents create more certainty of potential profits at the end of the research cycle and decrease the risk of investment."[155] Along those same profit- based lines, developed countries argue that

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[153] WHO Discussion Document: For the 110th Inter-Parliamentary Union Assembly, Mexico (19-23 April 2004).

[154] Sahar Asiz, Linking Intellectual Property Rights in Developing Countries with Research and Development,
Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry, 10
ILSA J. INT'L & COMP. L. 1, 5 (2003).

[155] Ibid at 4.

stringent international patent protection is crucial in allowing pharmaceutical companies to recoup their substantial research and development (R&D) costs.[156] The pharmaceutical industry, unlike other industries, devotes the majority of its resources to R&D.[157]

During the last twenty years, the U.S. pharmaceutical industry's percentage of sales allocated to R&D increased from 11.9 percent in 1980 to 18.5 percent in 2001.[158] Therefore, developed countries argue the most effective way to continue to provide financial incentives for pharmaceutical companies is to protect profit margins from being eroded by cheap generic drugs through internationally enforceable patent rights.[159]

Related to the first argument, the second major argument offered by developed countries to justify stringent international patent protection is strong patent protection fuels innovation.[160] Developed countries argue that by providing patents pharmaceutical companies will research and develop more drugs that will improve the overall global public health.[161] However, most of the developed countries' arguments justifying stringent patent protection do not explicitly revolve around their pharmaceutical companies' economic interests for obvious political reasons, but rather tend to emphasize the global benefits of stringent patent protection in general.[162] By providing pharmaceutical companies with a monopoly over the sale and distribution of their drugs for a fixed time period, developed countries argue that patents are supposed to create

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[156] Ibid at 5.

[157] Stephen Barnes, Note, Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa, 91 KY. L.J.
911,913(2003) at 914.

[158] Ibid

[159] Asiz, at 4.

[160] Ibid. At 5-6.

[161] Ibid. At 5.

[162] Ibid.

incentives for R&D activities in every country's private sectors.[163] This basically means that developing countries' ensuing concerns with high pharmaceutical prices and inaccessibility to essential medicines are countered with the developed country theory that too much access caused by weak patent protection will create more inaccessibility in the long run, resulting in the stagnancy of new drug discoveries.[164]

Third, developed countries argue that stringent patent protection is necessary to create an international trade environment.[165] Supporters of TRIPs argue that international law creating enforceable intellectual property rights are necessary to create an international economy and are a natural progression from the post-World War II economy.[166] Therefore, the inclusion of TRIPs as a WTO agreement is a requisite gradual move towards economic globalization.[167] "[T]he push for more secure and stable international trading systems, and the emergence of the hyper-connected international economy, have necessitated strict intellectual property protections."[168] The fourth argument offered by Developed countries for the importance of international patent law emphasizes the benefits available to developing countries through technology transfer and foreign direct investment.[169] "TRIPs . . . encourage technology sharing, which could lead to pharmaceutical companies (both generic and multi-national) sharing expertise, giving more Developing countries the capability to produce drugs for their own people."[170] Developed countries argue that the benefits from strong patent protection will not be limited to their own

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[163] Ibid.

[164] Ibid.

[165] Barnes, at 917.

[166] Ibid.

[167] Ibid.

[168] Matthew Kramer, Comment, The Bolar Amendment Abroad: Preserving the Integrity of American Patents
Overseas After the South African Medicines Act, 18 DICK. J. INT'L L. 553, 557 (2000).

[169] Asiz, at 6.

[170] Ibid.

rich and powerful pharmaceutical companies, but will assist local manufacturers in developing countries to establish their own R&D activities, which will be better suited to local needs.[171] In the international patent process, developing countries are supposed to benefit from the dissemination of knowledge required through patent disclosures, which can be used as inputs for more innovation.

> Therefore, IPRs [including patents] will support innovative behavior that adapts existing technologies to local needs of which the cumulative effect can ignite growth in knowledge and economic activity. The local firms will also have an equal opportunity to sell their products abroad in order to reap the higher profits currently enjoyed by western [multinational pharmaceutical enterprises] that own the majority of existing pharmaceutical patents.[172]

Developed countries argue stringent patent protection facilitates contracting between firms and increases technology transfer, thereby increasing the production of drugs and the efficiency of the R&D process for new drugs.[173] For example, technology transfer can occur through the shipment of advanced inputs to subsidiaries in local markets in developing countries.[174] In this way, pharmaceutical companies can theoretically indirectly share blueprints, product designs, and skilled producer services.[175]

Along these lines, developed countries argue that developing countries will benefit from international pharmaceutical patent law through foreign direct investment from wealthy member

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[171] Asiz, at 6.

[172] Asiz, at 6.

[173] Ibid.

[174] Ibid, at 7.

[175] Ibid.

countries to poor member countries with stable patent protection systems.[176] With strong international patent protection, pharmaceutical companies should be more willing to commit to "foreign direct investment, joint ventures, and licensing agreements in developing countries."[177]

Developed countries argue that as patent laws are strengthened in developing countries, foreign direct investment is likely to increase "in complex, but easily copied technologies" including pharmaceuticals.[178]

Without stringent patent protection not only will the providers of foreign direct investment hesitate to invest in these developing countries, but many pharmaceutical companies may refuse to export their drugs in order to protect their global profit margins.[179] Therefore, the thrust of the developed countries' argument is it is the developing world's responsibility to provide a business environment friendly to the needs of wealthy, multinational pharmaceutical companies in order to have access to essential medicines.[180]

3.3 Developing Countries' Arguments against Stringent Patent Protection in Developing Countries

Developing countries like Kenya argue that instead of patents being viewed as a fundamental or natural right, patent protection should instead merely represent a conscious governmental decision to maximize social welfare and patents should instead be viewed as governmental "grants,""licenses," or "privileges," which could then be conditioned or even refused rather than universally accepted.[181] Unfortunately for developing countries whether rightfully or wrongfully,

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[176] Asiz, at 6.

[177] Ibid, at 7.

[178] Ibid.

[179] Ibid.

[180] Ibid.

[181] Cann, at 783.

these intellectual "property" rights have been placed on a "moral plane" by powerful Developed countries.[182]Although, developed countries have strong arguments in favor of stringent patent protection, developing countries have even strong counter-arguments that patent protection should be more flexible in developing countries.

First, in response to developed countries' arguments that stringent international patent protection is needed to allow pharmaceutical companies to continue to operate, to create financial incentive for innovation, and to allow them to recoup their R&D costs, developing countries argue that it is unfair to deny access to essential medicines simply because poor developing countries do not have sufficient manufacturing capacity to produce or develop these essential medicines. In fact, "[o]nly a few developed countries (Belgium, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, UK, and United States) in the world have the sufficiently sophisticated pharmaceutical industry and significant research base necessary to conduct complex research and development activities."[183] Further, many monopolist drug companies receive tax benefits and foundation funds that help them finance their R&D costs.[184]
However, Developed countries have used this power to restrict access to developing countries and to place significant pressure on developing countries to strictly conform their domestic patent laws to TRIPs.[185]

Second, although developed countries argue that" [u]ltimately, the economic incentives derived from monopoly power of individual pharmaceuticals will benefit overall global welfare through the discovery of new drugs and therapies that cure debilitating, if not fatal, diseases."[186] In reality, only a few pharmaceutical companies (including GlaxoSmithKline and Novartis) have

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[182] Ibid. At 782-783

[183] Asiz,at 4

[184] Rajeev Dhavan, *The Patent Controversy,* The Hindu, Dec. 10, 2004, available at http://www.hindu.com/2004/12/10/stories/2004121002361000.htm (last visited Apr. 10, 2005).
[185] Asiz, at 4.

[186] Ibid. At 5.

increased their investment in infectious-disease research and even fewer (only GlaxoSmithKline) have increased their investment in vaccine development, hut only on a small scale.[187] Developed countries argue that one of the disadvantages arising out of weak patent protection in developing countries is corresponding a lack of focus by pharmaceutical companies on diseases and illnesses prevalent in developing countries. However, it is clear that without great financial incentives pharmaceutical companies will not focus on diseases and illnesses prevalent in developing countries.

Third, the developed country theory that stronger patent protection is essential to promote a stable international economy[188] has created a small group of powerful pharmaceutical multinational enterprises (MNEs) worldwide with significant influence in shaping domestic and international patent policies.[189] Unfortunately, it is primarily these pharmaceutical companies' business concerns that dictate developed countries' approaches to implementing patent rights on an international scale.[190] In reality, these patent rights give pharmaceutical companies monopolies over lifesaving medicines and allow the pharmaceutical company to restrict competition, limit access, and increase prices.

Finally, contrary to the developed countries argument that patent protection facilitates technology transfer and foreign direct investment, developing countries argue that the current system does not transfer technology or increase foreign direct investment. Developing countries argue contrary to the argument that the creation of stringent international patent protection will not provide developing countries with more access to up-to-date technologies through technology transfer, instead developing countries become isolated from new technologies and the

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[187] Michael Bailey, Big Pharma 's Tiny Gestures, European AIDS Treatment Group (EATG), May 19, 2004, available at http://www.eatg.org/modules.php?op=modload&name=News&fileartic1e&sid=244 (last visited October 12, 2011).

[188] Barnes, at 918.

[189] Asiz, at 4.

[190] Ibid.

only solution is for them to begin building their own technological knowledge from scratch.[191] This is a nearly impossible mission given their economic and infrastructural constraints.[192]

TRIPs should not have been included within the WTO/GATT Agreement.[193] Monopolies should have no place in an international free trade agreement.[194] Unfortunately, so far developed country governments have been more spirited in defending its pharmaceutical companies than developing countries (like India and South Africa) have been able to defend its poor who desperately need access to life sustaining drugs.[195]

3.4 Policy Instruments available under TRIPs

Although, the poor may still not have affordable access to essential medicines for reasons of low purchasing power and poor infrastructure, fortunately, there are several policy options open to the governments of WTO member countries under TRIPs to attenuate the adverse price increases associated with product patents.

3.4.1 Compulsory Licensing

Under a compulsory license, the right holder is forced to license his patented invention to a third party, decided by governments or courts, and obtain an 'adequate remuneration' in return. Indeed, several studies have found evidence that important patented inventions are generally not licensed voluntarily for financial considerations, particularly in the pharmaceutical sector.[196]

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[191] Ibid. At 6.

[192] Ibid.

[193] Dhavan.

[194] Ibid.

[195] Ibid.

[196] See, for instance, C.T. Taylor and Z.A. Silberston (1973) *"The Economics of the Patent System: A Study of the British Experience"*, Cambridge University Press, pp. 180-186.

Thus, non-voluntary licenses can be an important way for governments in developing countries to make patented inventions available at more competitive prices. The very existence of statutory provisions on compulsory licenses may, in fact, be adequate to encourage voluntary licenses.

There are no restrictions on the purposes for the grant of compulsory licenses or use by governments, although TRIPs Article 27.1 disallows discrimination in the enjoyment of patent rights between imported and locally produced products.[197] The conditions listed in TRIPs Article 31 have been called "strict safeguards". However, some of the crucial conditions are entirely dependent on the purposes and merits of such grant, as laid down in national laws. This gives considerable leeway to policy makers in developing countries to construct the grounds such that the conditions do not become restrictions. For example, if the purpose is to lower prices, it can be tackled by making the sale of patented inventions on unreasonable terms a ground for compulsory licenses.[198] Alternatively, an undertaking in the public or private sector could, in public interest, be authorized by government to manufacture a patented pharmaceutical product for sale to the public through government hospitals or health centers on a non-commercial basis. Indeed, the patent laws of several developed and developing countries contain such provisions, although only one, Canada, actually used this instrument extensively in the past for medicines.

However, in cases where the cooperation of the right holder has to be ensured to work the invention, voluntary licenses should be preferable. Also, many developing and least developed countries do not have a generic drug industry and thus, may have to rely on imports. TRIPs only conditions the grant of a compulsory license on predominant 'supply of the domestic market', thus allowing both entire imports and partial exports. Through inter-governmental cooperation amongst developing countries, those with generic industries and strong domestic demand can grant compulsory licenses for partial export to those without such an industrial base. However,

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[197] This is generally interpreted to mean that a compulsory license cannot be granted solely on the ground that the patented invention is not being manufactured locally.

[198] Watal, J. (2000.)(Pharmaceutical Prices and Welfare Losses: Policy options for India under the WTO TRIPs Agreement, World Economy.

extensive use of this policy instrument could adversely affect trade relations, and, in some cases, domestic innovation. Therefore, developing countries must incorporate the flexibility available in Article 31 into their patent laws, even while using this instrument sparingly in practice. In addition, they can also use competition policy instruments to ensure that patent licensing conditions are not unduly restrictive or beyond the scope of the patent rights or that the patent owner's behaviour is not anti-competitive. If remedies in such cases result in compulsory licenses, the TRIPs conditions are somewhat more lenient.

3.4.2 Parallel Imports

Generally speaking, IPRs are exhausted once the goods or services, which incorporate these rights, a.re put on the market. The controversy arises when goods, legitimately and consensually placed on the market in one country by the IPR owner, are imported into another country without the authorization of the IPR owner in that country.

Article 6 of TRIPs does not prohibit members from following their national laws on the question of parallel imports or exhaustion of IPRs as long as there is no discrimination amongst IPR owners on grounds of nationality. WTO members are explicitly prohibited from using the dispute settlement mechanism to address this issue. Given the fact that there are huge price variations in the prices of identical medicines across countries, some see this provision as a major policy option for developing countries to attenuate the ill effects of strong intellectual property protection, apart from eliminating unfair duplication of the rights of IPR holders. Others argue in favour of clearly prohibiting parallel trade in products protected by all IPRs, particularly pharmaceuticals, to protect the incentive to innovate.

They attribute price differences to many factors outside the control of pharmaceutical companies and argue that prices do not fall even with parallel imports.[199] However, such a prohibition

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[199] See Barfield, C.E, and M.E. Groombridge (1999): Parallel Trade in the Pharmaceutical Industry: Implications for
Innovation, Consumer Welfare and Health Policy, Fordham Intellectual Properly, Media & Entertainment Law

would require TRIPs to be amended. South Africa recently amended its Medicines Act to allow for parallel imports of medicines, leading to strong pressure from U.S and Europe based pharmaceutical companies, through diplomatic and legal channels, to amend its policies. However, with domestic and international sensitivities on finding rapid solutions to the AIDS problem in Africa, the USTR announced an agreement with South .Africa to respect TRIPs and the pharmaceutical companies were forced to hold their hand on this issue for the time being.[200] Similarly the Thai patent law allows the importation of patented products if the patentee has consented to the manufacture or sale of the product elsewhere. It is alleged that Thailand receives a relatively high level of parallel imports of pharmaceuticals from other parts of Asia.[201] Argentina too has, in its new patent law, specifically permitted international exhaustion. Brazil, however, has opted for national exhaustion of rights i.e. prohibition of parallel imports.

However, it has to be noted that consumers in developing countries from which parallel imports originate may experience a rise in prices or may face inadequate availability of the product subjected to parallel exports. However, this is a matter of empirical study and verification. Also, it is not clear, *a priori*, which countries would be parallel exporters and which parallel importers as this would differ with product and perhaps, over time.

3.4.3 Price Controls

Almost all countries in the world regulate prices of medicines, particularly of patented medicines, through review mechanisms or cost-reimbursement limitations or through administratively fixed cost-plus prices. This policy instrument is not prohibited by the TRIPS Agreement. India, for example, has established a cumbersome, and relatively inefficient, system

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Journal, Vol. X, No. 1, Autumn, pp.185-265.

[200] See www.cptech.org for a flavour of the debate on this issue. See also www.phrma.org/issues/intl/safrica.htnii for the US pharmaceutical's industry's stand on the issue.

[201] See www.phrma.org/issues/intl/thailand.html.

of administrative price controls.[202] However, the costs of effectively administering such a system may well outweigh the benefits. Reference pricing systems may lead to uniformly higher global prices and strictly enforced price regulation could lead to shortfalls in the availability of essential medicines.

3.4.4 Generic Drug Approvals and other Measures

Developing country members of the WTO should be aware that TRIPs does not, even under its provisions on test data, explicitly prohibit countries from permitting the regulatory approvals of generic drugs to occur before the patent term expires. Thus, generic drug companies can be ready to put out substitutes very soon after patent expiry. Also, TRIPS does not require patent term extensions granted now in many countries for pharmaceutical products to compensate for regulatory delays. Similarly, TRIPS does not require patents to be granted for human genes, new therapeutic uses of known substances nor on methods of medical treatment. New formulations and dosage and delivery forms of patented medicines need not be given fresh patents or other forms of market exclusivity, unlike in the case of many developed countries.

3.5 Domestic Pharmaceutical Protection and Developments in Developing Countries

3.5.1 Indian Pharmaceutical Patent Law and Recent Developments

A number of countries produce generic drugs including Canada, Brazil, South Africa, China, and Singapore, but the biggest producer is India.[203] Indian companies not only produce the finished tablet form of generic drugs, but they also produce cheaper versions of the raw ingredients and chemicals to export to major pharmaceutical companies to use in their brand name drugs.[204] A

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[202] Use of such a system could reduce prices by a maximum of about 40% from patent monopoly levels, if costs can be correctly determined. See Watal (2000).

[203] Michelle Nerrozi, The Battle over Life-Saving Pharmaceuticals: Are Developing Countries Being TRIP-ped by
Developed Countries? 47VILL. L.REV. 605, 615 (2002).
208 Ibid.
[204] Ibid.

number of developing countries also produce generic AIDS drugs including Brazil, which has a very large generic pharmaceutical industry that enables its government to provide free ARVs to everyone that needs them.[205] India also produces large volumes of ARVs for its own people and for export.[206] These thriving generic pharmaceutical industries in developing countries, especially India, have shown that the price fixed by pharmaceutical companies has nothing to do with the cost of production, but more to do with the power of these companies as [207]

> "On May 6, 1981, Indira Gandhi declared India's policy when she said her 'idea of a better world is one in which medical discoveries would be free from patent and there will he no profiteering from life and death."[208] India's policy quickly changed between 1987 and 1994 when the WTO treaty •was negotiated.[209] The Indian Parliamentary records reflected great concern with the "grave impact of the proposed patent...on the drug prices in the country' and warned that the 'primacy of public interests for the .right of patent holders should be ensured."[210]

India passed the First Patents Amendment Act in 1999, the Second Amendment Act in 2002, and the Third Amendment Bill of 2003, which did not contain any ameliorative amendments and which was passed without change or discussion due to the implicit threat of WTO retaliation for non-compliance.[211] From 1995 to 2004, many foreign pharmaceutical companies filed

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[205] Ibid.

[206] Nagelkerke N, et al. 2001; UNAIDS, Transnational Working Group, The Global Fund to Fight AIDS, Tuberculosis and Malaria (http://www.GlobalFundATM.org/) and; WHO Macroeconomics Commission, Draft Recommendations 2001.

[207] Ibid.

[208] Ibid.

[209] Ibid.

[210] See Boer.

[211] Ibid.

anticipatory claims against generic manufacturers under the WTO's "mail box" procedure,[212] which would become full-fledged patents on January 1, 2005.[213]

Until the end of 2004, India had no regulations on patenting, which is one of the reasons generic drug manufacturing became such a large-scale industry.[214] However, as India was mandated to meet the January 1, 2005 deadline to comply with the TRIPs regime, some of the cheap, generic anti-AIDS drugs India is famed for could be a thing of the past due to the new Indian patent laws that will come into force.[215] By rushing to comply with the TRIPs deadline, some argue that India has turned its own domestic law upside down and has given greater credence to WTO deadlines than to democracy.[216]

Fortunately, although most of the ARVs listed as essential treatments by the WHO did not become physically available until 1996 or later, they had been patented well before TRIPS was introduced in 1995, therefore they can continue to be produced by India legally.[217] For drugs patented after 1995, if the original drug producer had also filed for and had been granted a patent in India, as of January 1, 2005, all current production of that drug must stop and all future production would be illegal for 20 years. Developing countries, like India, are not influenced by the same sources or factors as developed countries (powerful pharmaceutical lobbyists and international trade) when creating national patent laws. Instead, India's patent laws have been influenced by protectionism.

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[212] Ibid.

[213] Ibid.

[214] Ibid.

[215] Ibid.

[216] See John A. Harrelson, TRIPs, Pharmaceutical Patents, and the NIV/AJDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion, 7 WIDENER L. SYMP. J. 174, 175 (2001).

[217] Margo A. Bagley, Legal Movements in Intellectual Property: TRIPs, Unilateral Action, Bilateral Agreements, and HIV/AIDS, 17 EMORY INT'L L. REV. 781, 786 (2003).

India adopted weak patent laws especially with respect to pharmaceuticals due to concerns about the future of India's pharmaceutical industry and domestic health concerns.[218]

In response to TRIPS, as well as to disputes with the U.S. and the WTO, the Indian government adopted the 1999 Patents Amendment Act to comply with WTO recommendations.[219] This Act sought to provide stronger patent protection for foreign pharmaceuticals and to create stronger domestic research capabilities.[220] For example, an Indian company (Ranbaxy Lab, Inc.) signed a $90 million dollar joint venture with Eli Lilly & Co. to collaborate for pharmaceutical research and development.[221] These Indian patent laws could allow the Indian pharmaceutical industry to modernize its pharmaceutical industry and compete with the developed world.[222]

3.5.2 South African Pharmaceutical Patent Law and Recent Developments

Unlike India's patent laws, which have been influenced by protectionism, South Africa's controversial patent laws have been influenced by the serious public health crisis in South Africa due to HIV-AIDS.[223] Therefore, in 1997, the South African Parliament passed the Medicines and Related Substances Control Act based on its public health crisis.[224] The Minister of Health was allowed to use the tools within this Act to override patent protections including parallel importing and compulsory licensing to provide access to pharmaceuticals.[225]

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[218] Jessica L. Greenbaum, Trips and Public Health: Solutions for Ensuring Global Access to Essential Aids Medication in the Wake of the Paragraph 6 Waiver 25 J. CONTEMP. HEALTH L. & POL'Y 142 2008-2009.
[219] Ibid.

[220] Ibid.

[221] Ibid.

[222] Ibid.

[223] Nitya Nanda & Ritu Lodha, Access to Essential Medicines and Affordable Drugs: Making Essential Medicines Affordable to the Poor, 20 WTS. INT'L L.J. 581, 581 (2002).
[224] Ibid.

[225] Ibid.

The Act allowed the South African government to use compulsory licensing provided the drug was initially marketed by the patentee or with the patentee's consent and the drug does not have other restrictions.[226] In fact, the patent holder rights would be overruled if those patent rights prevented South African companies from domestically developing effective versions of the medicines.[227]

However, in April 2001, the South African Parliament passed the South African Medicines and Medical Devices Regulated Authority Act (SAMMDRA).[228] Since SAMMDRA was passed, the South African government has not attempted to grant any compulsory licenses and therefore, the international community has lifted its intense pressure to strictly comply with TRIPs.[229] Recently, some progress in solving the lack of access concerns of South Africa have been made due to reductions in drug prices and withdrawal of litigation.[230] For example, the pharmaceutical industry dropped its court case against South Africa and the U.S. government dropped its WTO dispute settlement proceeding against Brazil.[231]

3.6 Conclusion

TRIPs requires the availability of product and process patents for pharmaceuticals virtually from 1995, dramatically changing patent laws in Developing countries that earlier allowed such exclusions. This change will, almost certainly, lead to higher prices up to about 200-300% for patented medicines, including for important diseases such as HIV/AIDS, in countries where such patents are valid. Policy instruments available under TRIPs such as compulsory licenses or

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[226] Ibid.

[227] Ibid.

[228] Ibid.

[229] Ibid.

[230] See Lisa C. Pavento, Jamie L. Greene & John K. McDonald, International Patent Protection for HIV Related Therapies: Patent Attorney's Perspective, 17 EMORY TNT'L L. REV. 919, 921 (2003).

[231] Ibid.

government use, parallel imports and price controls could attenuate such adverse effects on the affordable access to medicines considered essential. None of these instruments is without certain disadvantages and must be used with care. Finally, despite pressures from certain quarters, Developing countries need not go beyond what TRIPs requires. Paragraph 6 Decision, already discussed, is a step in the right direction.

4.0 CHAPTER FOUR

THE PROBLEM OF ACCESS TO AFFORDABLE GENERIC MEDICINE IN KENYA

4.1 Introduction

This Chapter discusses the challenges the country has in its quest to avail affordable generic medicine to its citizenry. It also discusses the flexibilities that the country can leverage to enhance access to medicine.

Kenya enjoys the membership of the WTO, and virtue of Article 2(5) of the Constitution, international law forms part of the law of Kenya. Further, Article 29(60) states that any treaty or convention ratified by Kenya forms part of the law of Kenya. TRIPs affect access to medicine through its patent provisions and the provisions relating to pharmaceutical products.

The Kenya patent law is largely hosted by the industrial property Act of 2001, which provides that an invention is patentable if it is new, involves an inventive step and is industrially applicable or is a new use.[232] The Act defines an invention as a solution to a specific problem in the field of technology and it may relate to a product or process. The effect of this definition is that it permits the grant of patent rights to investors of drugs and other medicinal products and processes.

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[232] Section 22 of the Industrial Property Act, 2001.

The definition of patentable subject matter is however subject to exclusions in section 21(3) (c) of the Act which excludes from patent protection methods for treatment of human or animal body, surgery or therapy as well as diagnostic methods practiced in relation thereto, except products for use in any such methods. The exception relating to products reinforces the notion that medicine and equipment used for human or animal treatment are patentable.

Section 21(3) (e) permits the Minister for Health to exclude from patent protection public health related methods of use or uses of any molecule or other substances whatsoever used for the prevention or treatment of any disease which has been designated serious health hazard or as a life-threatening disease.

The provisions of section 26(b) on non-patentable inventions also have a bearing on access to medicine. The provision stipulates that inventions contrary to public health shall not be patentable in Kenya.

4.2 Exclusive Patent Rights and Access to Medicine in Kenya

The Industrial Property Act directly affects access to medicine by virtue of the exclusive monopoly rights granted to the patent holder. The patent holder has the right to preclude any person from exploiting the patented invention. He has the right to conclude license contracts relating to the invention. More specifically, the patent owner has the right to preclude any person from making, importing, offering for sale, selling and using the product.[233] When the patent relates to a process, the owner has the right to preclude any person from using the process or doing or producing any product obtained directly by means of the process.[234]

The patent owner has additional protection and enforcement rights to the extent that he can obtain an injunction to restrain the sale or selling or likely performance of any prohibited act

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[233] Section 54 (1)(a)of the Act.

[234] Section 54 1(b) of the Act.

without his authorization and to claim damages or compensation from any person who infringes the patent.[235]

4.3 Kenya's Patent Law and Exceptional Provisions

Section 54(2) of the Industrial Property Act, 2001 contains a bolar provision. It states that the rights conferred on the owner of the patent shall not apply to acts by third parties necessary to obtain approval or registration of a product from the Kenya Industrial Property Institute for the purposes of commercializing the product after the expiry of the patent.[236]

4.4 Flexibility and Tools for Enhancing Access to Medicine in Kenya

There exist a number of flexibilities which can be utilized to enhance access to medicine in Kenya.

4.4.1 Compulsory Licensing

When a product is patented, competitive bidding is not a viable option to reduce prices because, unless a patent is made ineffective, there is no competition. Compulsory licences may be an important cost-containment measure in that situation. The granting of such licences creates competition by one or more compulsory licensees, which in turn may force prices down. At the same time, the patent holder (and/or any voluntary licensees) can continue with commercial exploitation of the patent, and will receive compensation (generally in the form of a royalty) from the compulsory licensee/s.[237]

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[235] Section 55 of the Act.

[236] Section 54(2) of the Act.

[237] Correa C. *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. Geneva, South Centre, 2000, p. 93-94.

Article 31 of the WTO TRIPS Agreement expressly allows the granting of compulsory licences. The Agreement contains no limits on the grounds under which such licences can be granted. Members' right to determine such grounds has been confirmed by the Doha Declaration on the TRIPs Agreement and Public Health (November 2001). Article 31 makes particular, but not exhaustive, reference to cases of national emergency or extreme urgency, dependency of patents, licences for governmental non-commercial use, and licences to remedy anti-competitive practices. National laws can, however, provide for the granting of such licences whenever the title holder refuses to grant a voluntary licence "on reasonable commercial terms" (Article 31 (b)) and for other reasons, such as public health or broad public interest considerations. The Agreement permits compulsory licences to authorize licensees to exercise any of the rights conferred by a patent, including production or importation.

In Kenya, section 58(5) of the Industrial Property Act stipulates that the rights of the patent shall be limited by the provisions on compulsory licenses for reasons of public interest or based on the interdependence of patents and by provisions on state exploitation of patented inventions.

Section 72 of the Act regulates the grant of compulsory licences. At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period expires last, any person may apply to the Tribunal for a licence to exploit the patented invention on the ground that a market for the patented invention is not being supplied on reasonable terms in Kenya.

This however will not be granted if the tribunal is satisfied that circumstances exist which either justify the market for the patent invention not to be supplied or is not being supplied on reasonable terms in Kenya.

Section 74 sets out preconditions for the grant of compulsory licenses. A compulsory licence shall not be granted unless for grant of the person requesting the licence-

a) satisfies the Tribunal that he has asked the owner of the patent for a contractual licence but has been unable to obtain the licence on reasonable commercial terms and within a reasonable time; and
b) offers guarantees satisfactory to the Tribunal to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to his request.

However there is also a provision that the requirement under subsection (a) shall be waived in the case of a national emergency or other circumstances of extreme urgency, provided the owner of the patent shall be so notified as soon as is reasonably practicable.

Under section 75 of the Industrial Property Act, in considering a request for a compulsory licence, the Tribunal is required to decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant taking into account any terms agreed by the parties, proceed to fix the terms which shall be deemed to constitute a valid contract between the parties and shall be governed by the provisions of contractual licences.

In fixing the terms of the compulsory licence, the Tribunal ensures that the compulsory licence:-

a) is limited, in scope and duration, to the purpose for which it was authorized, and in the case of semi-conductor technology, shall only be for public noncommercial use or to remedy a practice determined after a judicial or administrative process to be anti-competitive;
b) is limited predominantly for the supply of the domestic market;
c) does not entitle the licensee to grant further licences, without the consent of the owner of the patent;
d) is non-exclusive; and

e) provides for the payment to the owner of the patent of remuneration which is equitable with due regard to all the circumstances of the case, including the economic value of the licence.[238]

A representative of the Institute and of the Government shall have the right to appear and be heard at the hearing of an application for a compulsory licence, before the Tribunal. [239]

4.4.2 Freedom to Operate

In terms of Intellectual Property (IP), Freedom to Operate (FTO) is an evaluation of whether one infringes the patent, design or trademark rights of another entity. This is normally signed between patent rights holder authorizing each other to use their respective patented technology. Under this, the party is free to conduct research and develop a defined number of therapeutic and diagnostic anti-body based products. [240]The net effect is that it helps avoid expensive litigation, uncertainty and risky affairs.

The FTO obviates a situation where a country is planning to develop and launch new products, hut there are existing extensive patenting and where commercialization of the product may be blocked by a competitor who holds a patent for a technology incorporated within that product.

4.4.3 Parallel Importation

Parallel Imports (P1), also called gray-market imports, are goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right. This owner is typically a licensed local dealer. For example, it is permissible for a trading firm to purchase quantities of prescription drugs in Spain and import them into Kenya •without the approval of the local distributor owning licensed patent rights. The ability of a right-

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[238] See Section 75 of the Act.

[239] Section 75(3) of the Act.

[240] Otieno-Odek, p. 19.

holder to exclude P1 legally from a particular market is exigent upon the importing nation's treatment of exhaustion of intellectual property rights (IPR).

Regulation of P1 in the pharmaceuticals area has become a critical issue in the global trading system. Advocates of strong international patent rights for new medicines support a global policy of banning P1, arguing that if such trade were widely allowed it would reduce profits in the research-intensive pharmaceutical sector and ultimately slow down innovation of new drugs. Moreover, P1 could make it difficult for health authorities in different countries to sustain differential price controls and regulatory regimes. However, public-health authorities in many countries argue that it is important to be able to purchase drugs from the cheapest sources possible, requiring an open regime of PT. Whether or not such imports actually occur, the threat that they might come in could force distributors to charge lower prices. It is evident that policymakers in developing countries especially would place a higher weight on affordability of medicines than on promoting R&D abroad.

Patents provide inventors of new products and technologies the legal right to exclude rivals from making, selling, and distributing those inventions. Trademarks provide their owners the right to prevent rivals from using identical or confusingly similar identifying marks and trade names on their goods. A country's law concerning the territorial exhaustion of these rights is an important component of how it regulates and limits their use. Under national exhaustion, exclusive rights end upon first sale within a country but IPR owners may exclude parallel imports from other countries.

Under international exhaustion, rights are exhausted upon first sale anywhere and parallel imports cannot be excluded. A third possibility is regional exhaustion, under which rights end upon original sale within a group of countries, thereby allowing parallel trade among them, but are not ended by first sale outside the region.

A policy of national exhaustion amounts to a government-enforced territorial restriction on international distribution. Countries following this regime choose to isolate their markets from

unauthorized foreign competition in legitimate goods traded under recognized IPR protection. Thus, original manufacturers retain complete authority to distribute goods and services themselves or through dealers, including the right to exclude P1 through border controls. In contrast, countries permitting P1 are not territorially segmented and do not recognize any right to exclude imports of goods in circulation abroad.

Because IPR are recognized on a territorial basis, each nation has established its own policy covering parallel imports. Section 58(2) of the Industrial Property Act plays receptacle to parallel importation. It states that the rights under a patent shall not extend to acts in respect of articles which have been out on the market in Kenya or in any other country or imported into Kenya.[241] The Industrial Property Regulation 37 provides that the limitations on the rights under a patent extend to acts in respect of articles that are imported from a country where the articles were legitimately put on the market.[242]

4.4.4 Voluntary Contractual Licensing

Voluntary licensing arrangements between a patent holder and another party in a country, or serving the country's market, may afford opportunities for significant cost- containment. As with negotiated discounts, the benefits of voluntary licensing arrangements depend crucially on the terms of the licence. For voluntary licences, the capacity of the licensee is also critical.

Patent holders may at their discretion, license to other parties, on an exclusive or non- exclusive basis, the right to manufacture, import, and/or distribute a pharmaceutical product. Depending on the terms of the licence, the licensee may act entirely or effectively as an agent of the patent holder; or the licensee may be free to set the terms of sale and distribution within a prescribed market or markets, contingent on payment of a royalty. Either option, or arrangements in between, may allow for substantial price reductions. However, terms in a voluntary licence may set price ranges, or include other terms, that maintain prices at or near the same level as those

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[241] Section 58(2) of the Act.
[242] The Industrial Property Regulation 37.

offered by the patent holder. Or terms may limit how many patients or which categories of patients are eligible to benefit from the lower prices provided by the licensee. Again, such matters turn on the terms of the licence contract. Voluntary licensing arrangements, at the discretion of the patent holder, are usually made for strategic reasons (e.g. market entry) rather than as price gestures and they may not entail any price reduction at all.

In Kenya, the owner of a patent has the right to issue a contractual licence with respect to all the exclusive rights exercisable over that patent. When a licence has been issued, the licensee is entitled to make, import, and offer for sale, sell, use the product or stock the same for purposes of sale without limitation as to time, in the whole of Kenya and in any field of use of the invention.[243] A licensee is precluded from granting permission to a third person without the consent of the licensor if the license is not exclusive.[244]

4.4.5 To protect people rights to health

Access to affordable quality generic medications has transformed treatment of diseases like HIV. With new science and increased treatment, the next generation can be on free of HIV, and continue to have access of affordable generic HIV medicine here in Kenya and around the world.

Unfortunately this is not an assumption we can take for granted and Kenya and its partners must take up the challenge of assuring that low cost quality HIV medications are available to all who need them.

By the end of 2011 the "Dohas Declaration will be marking 10th anniversary on the Trips and public Health" (Trips is an acronym for the World trade origination agreement that governs intellectual property for all WTO member states).

The Doha Declaration protects the rights of low and middle income countries to provide health medications to address public health needs such as HIV, TB and Malaria.

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[243] Section 64 of the Industrial Property Act, 2001.

[244] Section 54(2) and Section 65 of the industrial Property Act, 2001.

Many new medications are providing to be powerful with fewer side effects. A supply of new drugs is important for diseases like HIV where either older medication is more toxic or the disease becomes resistant to a regime and patients need new drugs to fight the disease.

In the last five years several new classes of HIV medications have been brought to the market. However during this same time frame, India and South Africa, the major producers of generic HIV medications for low and middle income countries, have enacted laws in accordance with the Trips agreement that allow pharmaceutical firms to patent drugs in these states.

Kenya has already taken steps to follow the direction given by the Doha Declaration to ensure that Kenyans have the medications they need. Kenya's has shown great leadership by introducing for public health in the industrial property Act. These will prove to be vital for Kenyans growing pharmaceutical industry which has now begun to manufacture generic HIV medication.

Despite the Doha Declaration access to generic medications is still under significance threat because of the increase in patenting. This means that first many countries need to be ready to use the full flexibilities in the Trips agreement to enable continued access to low cost medicines.

Second Kenya and East Africa community are drafting laws that confuse counterfeits with quality assures generic medications (LDC) like Uganda have the opportunity to extend the period of time during which they can freely produces generic medications, but no LDC has yet applied to the WTO to take advantage of this extension.

4.4.6 Life Saving Generic Drugs

Generic competition is the most powerful tool to bring down prices and when patients are in need, the ability to provide effective and affordable generic medicines can mean the difference between life and death.

To protect its people right to health, Kenya should review and reform all laws, policies or trade agreements that may reveres or threaten the gains made in accordance with the Doha Declaration.

Particularly important in the short term will be the outcome of the constitutional case brought by people living with HIV, against certain provisions in the anti-counterfeit legislation on the basis they may limit access to access to life saving generic drugs Kenya can also more fully use its rights under the TRIPs agreement to access generic medications.

Kenya should also support LDCs in the EAC to apply for an extension that would allow these countries produce generic medications that can benefit patients in the region.
Also to ensuring legal rules are in place, she should also support the medicines patent pool, which seeks to obtain public health focused voluntary agreements from pharmaceutical companies to allow generic competition of HIV medicines.

Kenya can win fight against HIV and other diseases but will need the best tools for now and in the future. Protection of quality and affordable generic medications must be paramount so Kenya can meet the challenge of ensuring that the next generations is HIV free.

5.0 CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

This chapter seeks to state the findings and synthesize the discussions in the preceding chapte in a way that may be useful in facilitating better access to generic medicine in Kenya.

TRIPs created a common set of international intellectual property rules establishing minimu levels of patent protection that all countries within the WTO must give to other memb countries.[245] Potential competitors are prohibited from producing and marketing cheap generi of these pharmaceutical products for a twenty-year period.[246] Thereby giving the pharmaceutic patent holder a monopoly based on the exclusive marketing rights on its patented product for least those twenty years.[247]

The WTO's Dispute Settlement Board enforces TRIPs to ensure member country compliance.[2 All member country governments must comply with TRIPs by introducing these stringent pate laws domestically or face severe penalties from the WTO.[249] Although this may seem like a easy task, most Developing countries do not have strong domestic patent laws, therefore TRI

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[245] Bonita de Boer, TRIPs, AIDS, and Generic Drugs, AVERT.ORG, Jan. 19, 2005, available a http://www.avert.org/generic.htm (last visited Apr. 10, 2005).

[246] Cut the Cost - Patent Injustice: How World Trade Rules Threaten the Health of Poor People, Oxfam Briefing Report, Feb. 2001, available at http://www.oxfarn.org.uk/whatwe do/issues/health/downloads/patentiniustice.pdf (last visited Apr. 10, 2005).

[247] Id at 5.

[248] Id at 18

[249] Id. at 18

provides an extremely high standard of patent protection[250] If a member country fails to meet its obligations under TRIPs, the burden of proof is on the defending country.[251]

If the defending country fails to meet its burden, the WTO's Dispute Settlement Board most often allows the prosecuting country to impose trade sanctions.[252] By restricting the right of governments to allow the production, marketing, and import of low-cost copies of patented medicines (called generic drugs), the WTO's rules will restrict competition, increase prices, and further reduce the already limited access of poor people to vital medicines.[253]

TRIPs was theoretically designed as a social policy tool to encourage innovation by establishing minimum standards for the protection of intellectual property including patents on pharmaceuticals; however, these standards were developed based on Western European and North American property law by wealthy countries with little regard for the needs of developing countries.[254] The major selling point for the issuance of patents is in theory by "providing limited exclusivity to the 'inventors' of products. Innovation will be promoted and society as a whole will benefit from the availability of new and improved products."[255] In reality, the twenty-year global patent protection system has created an extremely profitable and powerful group of multinational pharmaceutical companies that by law are allowed to deny access to life-saving medicines.[256]

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[250] Barnes, 919-934.

[251] *Cut the Cost, supat 18.*

[252] Ibid.

[253] Ibid at 3.

[254] Ibid at 2.

[255] Ibid.

[256] TRIPs Agreement, preamble.

The discourses within the Developing countries, Kenya included, are almost unanimous on the position that TRIPs agreement is almost nightmare for almost everyone. Intellectual property can be the backbone of the development in every nation but its protection and implementation as the Developing countries has incorporated in TRIPs agreement really needs a very strong infrastructure. To the poor people of the Least Developed and even for the Developing countries where most of the people are illiterate, this rings true. Due to lack of technical capacity and infrastructure, TRIPs really seems to be frightening and terrifying tools to the Least Developed Countries.

It is doubtlessly accepted that strong patent regime ensures the technological and economic development as well by encouraging the inventors to dig for more invention for the industrial application. it is also well accepted that implementation of such a strong patent regime needs very high level of economic, industrial and legal infrastructure. Implementing strong patent regime in a very early stage of industrialization and poverty alleviation gives negative impact to the industrial development and poverty alleviation process.

The Decision of 30th August 2003 creates a new layer of rights applicable to exporting and importing member countries. The obligation of an exporting member country under Article 31 (f) of the TRIPs Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purpose of production of a pharmaceutical product (s) and its export to an eligible importing member. The implication is that production predominantly for the domestic market is waived. Before this waiver can take effect, three conditions must be fulfilled.

a) The eligible importing member must have made a notification to the TRIPs Council specifying the names and expected quantities of the products needed;
b) The eligible importing country confirms that it has established it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in questions and
c) The eligible importing country confirms that where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPs Agreement.

Further, it can be internalized that the Decision of 30th August 2003 addresses the issues of regional economic groupings in developing countries. Paragraph 6 of the decision stipulates that where a developing or least developed country WTO member is party to a regional trade agreement within the meaning of Article XXIV of GATT... and at least half of the current membership of which is made up of countries presently on the UN list of least-developed countries, the obligation of that member under Article 31 (f) of the TRIPs Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the problem in question.

This will not prejudice the territorial nature of the patent rights in question. The development of systems providing for the grant of regional patents applicable to the above members should be encouraged. In Kenya, as in other Third World Countries, few of the victims of poverty-related diseases have heard of the WTO. In a country with sovereignty underpinning most of its Constitutional provisions, fewer still have had an opportunity to engage in debate over the implications of its rules for their welfare. Yet world trade laws have profound implications in its welfare-and nowhere more so than in the area of patents and public health. Governments in all developing countries are currently implementing sweeping changes in order to bring national legislation in line with WTO obligations stipulated by TRIPs.

Motivation for effecting this is partially attributable to the threats of trade sanctions against Developing countries initiated by developed countries, acting on behalf of corporations, including pharmaceutical companies, which stand to gain significant increases in their profits as a result of the new patent regime being strictly enforced in developing countries.[257]

AIDS continues to claim a significant portion of the population in Developing countries. Contrast this with the situation in Developed countries. The development of antiretroviral drugs

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[257] Cut the Cost, at 18.

is the primary reason for the increased life expectancy and improved quality of life for HIV-positive people in the developed world.

Since the adoption of TRIPs in 1994, slight improvements have been made in the global pharmaceutical patent system through the participation of the member countries in the WTO, the recognition by governments of the importance of the public health of its citizens and global public health, and the gradual flexibility of pharmaceutical companies in finding a solution to the HIV-AIDS crisis.

TRIPs should be amended or reformed to consider the needs of developing countries. The implicit and explicit exceptions contained in TRIPs Article 8, 27, 30, 31, and 73, the Doha Declaration, and the Decision have all attempted to clarify the power of individual countries to protect the public health of their citizens in reality, these safeguards are not enough. The arguments developed countries offer for the imposition of stringent patent protection in developing countries do not outweigh the potential harm created by allowing pharmaceutical companies to have monopolies that limit access to essential medicines. Pharmaceutical companies, generic drug manufacturers, and governments all have a duty to improve the access of developing countries to drugs including combination and second-line generic drugs.

Some possible solutions to improve access to drugs in developing countries are allowing generic competition, creating a tiered pricing mechanism to reduce prices, and providing political support for utilizing the public health safeguards contained in TRIPs. Unfortunately, AIDS and other infectious diseases are only some of the numerous problems facing developing countries today. Developing countries also lack the infrastructure and public health systems necessary to implement widespread disease treatment programs. Developed and Developing countries should work together to develop an international pharmaceutical patent system that truly promotes global public health by providing equal access to all.

5.2 Recommendations

The current system of global pharmaceutical patent protection under TRIPs needs to be amended or revised to consider more specifically the needs of Developing countries. Some examples of possible solutions and considerations to improve access include reducing the prices and increasing the access to pharmaceuticals in developing countries;[258] recognizing the importance and value of generic competition in international trade;[259] and, creating a systematic tiered pricing mechanism for pharmaceuticals.

In granting patent protection, emphasis should be placed on inventive step and novelty as well as limiting the duration and scope of patent protection in Developing countries.

Domestic patent laws should be created or amended to make full use of the flexibilities (Public Health Safeguards) in TRIPs by emphasizing public health over patent rights. This would have the added positive effect of preventing the systematic dismantling of the Doha Declaration). It is also high time the Developing countries without the ability to manufacture were permitted to more easily be able to import them.

Recently, Developing countries have gained considerable power in the world of internationa.l trade. "The World Trade Organization's ministerial conferences have demonstrated a considerable willingness on the part of developing countries to build alliances among themselves as a way of countering the [influence] of the rich [developed] countries during trade negotiations."[260] The inequalities created within the WTO agreements gave an overwhelming amount of power to rich Developed countries.[261] Developing countries must remedy the

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[258] Mohga Kamal Smith, Generic Competition Price and Access to Medicines- The Case of Antiretroviral in Uganda, Oxfam Briefing Paper, vol. 26, June 2002, available http://www.oxfam.org.uklwhatwedo/issues/health/downloads/bp26generic.pdf (last visited Apr. 10, 2005).

[259] Ibid.

[260] Adriano Compolina Soares, G20, G90, and G33: Challenges for Building a New Politics, Terraviva (Yale Global Policy Forum), Jan.23, 2005, available at (last visited October. 10, 2011).

[261] Ibid.

unfairness found in these WTO trade agreements by adopting stronger negotiating postures within the WTO trade talks.[262] Developed countries like the U.S. and the E.U. have to be prevented from imposing their individually created "agreements" on other less powerful members.[263]

Therefore, Developing countries should build solid alliances among themselves focused on specific negotiating proposals in order to be effective in trade talks.[264] Although, it seems impossible for Developing countries to counter the intense political and financial power of big Developed countries, they are gaining some power within the WTO. This new, strong posture of Developing countries has gradually emerged from the WTO Seattle Ministerial Conference demonstrations and from the WTO Doha Ministerial Conference proposals offered by Developing countries on access to medications, which led to the Doha Declaration.[265]

While considerable progress has been made in including Developing countries like Brazil and India in the decision-making nucleus of the WTO, a series of new challenges have emerged from this new Developing country power dynamic.[266] Although the involvement of Developing countries in the decision-making process is a clear improvement, the exclusion of the others is unacceptable.[267] It is crucial not to create a WTO decision-making process, where the decisions are primarily made in small group alliances, whether developed or developing countries.[268] Encouraging these small alliances between member countries ultimately encourages the exclusion of certain other member countries. Therefore, it is important to keep the decision-

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[262] Ibid.

[263] Ibid.

[264] Ibid.

[265] Ibid.

[266] Soares, at 2.

[267] Ibid.

[268] Ibid.

making process open to all member countries to create an international trade system based on democratic form and transparency.[269]

In order for the Developing country power dynamics emerging from the WTO Cancun Ministerial Conference to be transformed into an opportunity for fairer international trade rules and an opportunity for Developing countries to succeed in counterbalancing the dominance of the Developed countries, the dialogue within and between the groups of Developing countries must continue to be deepened.[270] More particularly, it is essential that governments, and the partners in civil society and the private sector actively evaluate the flexibility that the TRIPs Agreement affords to promote access to affordable generic medicines in their countries. Countries may need to amend their patent legislation in order to take advantage of flexibilities such as the 2016 transition period, and the Paragraph 6 Waivers.

The right to health is now a Constitutional right in Kenya, and the State is under an obligation to ensure that it is achieved. Kenya should review and reform all laws, policies or trade agreements that may reverse or threaten the gains made in accordance with the Doha Declaration.

There, however needs to be certain considerations in the short term, key of which would be the outcome of the Constitutional case brought by people living with HIV/ AIDS against certain provisions of the Anti-Counterfeit Act,2008.[271]

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[269] Ibid

[270] Ibid

[271] In **Patricia Asero Ochieng & Others v the Attorney General**, Petition No, 409 of 2010, the Petitioners were infected with HIV virus and had been on the first line of generic antiretroviral drugs. They petitioned the High Court to challenge the new Anti-Counterfeit Act,2008 on the basis that it violates the right to health. The Petitioners, three people living with HIV, argued that the law confuses generic and fake medicine. This could cause a health crisis as generics constitute 90 percent of medicines used in Kenya. The application and enforcement of the Act stands to severely limit access to essential drugs and medication necessary for the treatment of HIV and AIDS and other opportunistic infections. The matter is still sub judice and so, the discourse in regards to it is severely restricted.

The contention by the Petitioners in this case was that the statute could potentially limit access to life-saving generic drugs in Kenya. The outcome of the suit is likely to affect the degree or extent of compliance with TRIPs.

Secondly, Kenya should also support Least Developed Countries in the East African Communities to apply for an extension that would permit these countries produce generic medication that can benefit patients in Kenya.

One other area where specific focus should be trained is the medicines Patent Pool, which seeks to obtain public health-focused voluntary agreements from pharmaceutical companies to allow generic competition of HIV medicines.

What Kenya must do to be eligible to use the solution proposed by Decision of 30th August 2003.

There are several steps that Kenya as a developing country must undertake before it can be eligible to use the Decision of 30th August, 2003 as an importer or exporter of pharmaceutical products. These are:

a) Notify the TRIPs Council of its intentions to use the system as an importer either in whole or in a limited way; and
b) Notify the TRIPs Council of its intention to use the system as an exporter; and
c) Establish that it has no manufacturing capacity in the pharmaceutical sector for the product it intends to import or
d) If Kenya has some manufacturing capacity it must make a determination that the existing capacity is insufficient to meet its needs; and
e) Ensure that countries it intends to export pharmaceutical products are either least developed countries or members of a regional trade agreement with at least half of the members being LCDs and
f) That Kenya will grant compulsory licence issued as an exporting or importing member and

g) The countries to which Kenya intends to export the pharmaceutical product must have notified the TRIPs Council of their intention to use the system and also confirms that it will grant or intends to grant a compulsory licence in accordance with Article 31 of the TRIPs Agreement, if pharmaceutical product is patented in its territory.

Further, it can be recommended that the Decision of 31st August 2003 should be used in good faith to protect public health and not as an instrument to pursue industrial or commercial policy objectives. It should be appreciated that the Decision would be defeated if products supplied thereunder are diverted from the markets for which they are intended and that it is important for members countries to seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably. This should include information on how the member in question should establish that it has insufficient or no more manufacturing capacities in their pharmaceutical sector and all the information gathered in the implementation of the decision should be brought to the attention of the TRIPs Council.

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