IMPLEMENTING PARALLEL IMPORTATION AND LICENSING MECHANISMS TO INCREASE ACCESS TO MEDICINES IN KENYA

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ABSTRACT

This dissertation presents the results of an empirical investigation Kenya's experience in implementing the mechanisms of parallel importation and licensing to increase access to medicines in the country. Three interconnected research questions are addressed: are the mechanisms of parallel importation and licensing in fact being used in Kenya; what factors have promoted the use or non use of these mechanisms; and what has been the impact of the use of the mechanisms, if any, on the intellectual property rights holders in the country.

The research that informs this thesis was conducted using a multi-method approach. The overarching research strategy was however that of semi-structured interviews with representatives of key actors in the pharmaceutical industry in Kenya. The findings revealed that whereas there is significant use of parallel importation mechanism, there is very limited use of voluntary licensing and in fact, there has not been any use of the involuntary licensing mechanisms at all.

Based on the research findings, it appears that in Kenya, use of parallel importation has flourished more than licensing mechanisms because, save for legislative action and creation of a policy framework, the former does not require further significant action on the part of the Government. Licensing mechanisms on the other hand require action in terms of for example providing incentives targeted towards lowering the cost of manufacture.

I therefore argue that where the government's active intervention beyond mere legislative action is required, the mechanism is not as successfully implemented as is the case where none or minimal involvement of the government is required. I suggest that for effective

implementation of the mechanisms of parallel importation and licensing, creating an enabling legislative and policy framework is merely the critical first step. This framework needs to be further followed up with more deliberate intervention on the part of the government so as to ensure successful implementation of the mechanisms.

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1.0 INTRODUCTION

In the last decade or so, extension of patent protection to pharmaceutical products has evoked debate and controversy. This has stemmed primarily from the perception that pharmaceutical patents have a negative impact on access to human medicines. On its part, this perception has been fuelled by the dilemma presented by the modern day reality that whereas life-saving medicines for most diseases do exist, the poor, particularly in the developing world, continue to die needlessly since they cannot access these medicines.

Admittedly, patents are not the only barrier. Other significant barriers to access include poor health care infrastructure, lack of political will to direct attention and resources towards improving access, high tariffs and most importantly, low purchasing power on the part of the affected patients.[1] Further, other forms of intellectual property rights such as trademarks and data protection may also impede access to medicines. Yet, the patent system has dominated the debate on access to medicine both at the international level as well as in Kenya.

The patent system has been particularly implicated for varying reasons, chief among them being the very nature of a patent right. Patent rights are exclusive rights which enable the holder to prevent others from making, using, selling or importing the invention for the duration of the patent right. Being exclusive rights, they are therefore a form of a monopoly grant which enables the rights holder to control the output, and, within the limits set by demand, the price of the patented products.[2] The ability to control prices has therefore been

[1] International Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*: *A Report Prepared for the WIPO*, 53 (2000), available at http://www.wipo.int/export/sites/www/aboutip/en/studies/pdf/iipi_hiv.pdf, (last visited Apr. 23, 2009)
[2] EDITH PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM, 2 (1951).

cited as a significant barrier to access to medicines, particularly where, as is usually the case, access is inhibited by the high cost of the medicines.

There have been two dimensions to the debate on patents and access to medicines: (a) where treatment has already been developed, the debate revolves around strategies for transferring the medicines to poor countries and patients in need; and (b) where treatment does not (yet) exist, particularly in the case of the so-called "neglected diseases," the debate has been on how to direct research and development investment to these diseases.[3] Consequently, the debate on a lasting solution to the problem of access to medicines has centred on the need to construct a patent regime that balances the short term objective of allowing people to use the existing medicines with the long term objective of providing incentives for future innovations.

Though pertinent, the second dimension mentioned above is not addressed in this paper. Instead, the paper focuses on access to existing medicines within the framework of the current international patent regime. This regime is established by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).[4] Subsequent to the Agreement's entry into force in 1995, there were concerns that the regime established was so stringent that it affected the ability of patients in poor countries to access vital medicines. Consequently, attempts were thereafter made to ameliorate the negative effects of the TRIPS Agreement.

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[3] See, United Kingdom's Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights And Development*, 30-31 (2002), available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (last visited Apr. 22, 2009).

[4] The Agreement constitutes Annex 1C of the Agreement establishing the World Trade Organization. The Agreement was adopted as part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations in Marrakech, Morocco on 15 April, 1994. See Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15,1994, 33 I.L.M. 81 (1994) [hereafter TRIPS].

These attempts culminated with the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) of 2001 through which the WTO member countries affirmed the existence of mechanisms which can be built into a country's domestic patent laws for purposes of improving access to medicines. Chief among these are parallel importation and licensing mechanisms. Following the Doha Declaration, many developing countries, including Kenya, have enacted domestic patent laws which are not only TRIPS Agreement compliant but which also incorporate the available mechanisms for improving access. This notwithstanding, as shall be seen in Chapter three of this paper, access to medicine in several developing countries such as Kenya remains a challenge.

Limited access to existing medicines raises two critical issues. Firstly, whether the patent regime is, in fact, a significant barrier to accessing medicines. Since the patent sting has been somewhat ameliorated by the availability of various mechanisms to improve access, could the continued access problems point to the fact that the patent system was never the culprit in the first place? Secondly, whether there are factors that have constrained the effective implementation of the available mechanisms for improving access. If the problem lies at the implementation level, identification of the possible constraints and their subsequent remedying should therefore substantially improve access to medicines.

The first issue is beyond the scope of this paper. The research which informs this paper therefore specifically set out to inquire into the second issue. Using Kenya as a case study, the research aimed to establish: whether parallel importation and licensing mechanisms, the two most important mechanisms for improving access, are in fact being used in Kenya; the

factors that have influenced the use or non use of these mechanisms; and the impact that the use of the mechanisms, if any, has had on the intellectual property rights owners in Kenya.

Data was obtained through a multi-method approach but the overarching research strategy was that of semi-structured interviews with persons representing key stakeholders in the pharmaceutical industry in Kenya. Thereafter, the data was analyzed and specific findings made. The study established that there is significant use of the parallel importation mechanism in the country. Regarding licensing, whereas there is some minimal voluntary licensing, there has been no use of involuntary licensing at all. Most importantly, parallel importation and the limited voluntary licensing that is taking place, are confronted by a myriad of constraints which almost erode the benefits of these mechanisms.

The objective of this paper is therefore to present a detailed description of the Kenya's experience in implementing parallel importation and licensing mechanisms from the perspectives of representatives of key stakeholders in the pharmaceutical industry who were interviewed for the study.

I argue that where government's active intervention beyond mere legislative action is required, a particular mechanism is not as successfully implemented as is the case where none or minimal involvement of the government is required. In Kenya, parallel importation has therefore flourished more than licensing mechanisms because, save for legislative action and creation of a policy framework, the former does not require further significant action on the part of the Government. Licensing mechanisms on the other hand require action such as providing incentives targeted towards lowering the cost of manufacture. Successful

implementation of the licensing mechanism therefore requires much more deliberate and active intervention on the part of the government.

There is the possibility that the absence of active and deliberate action by the government to implement both mechanisms effectively may have resulted from a lack of awareness of the specific ways in which to intervene. Knowledge of the country's experience in implementing these mechanisms may therefore shed some light on what needs to be remedied so as to make the mechanisms deliver the desired result of improved access. This paper aims to make a contribution in this regard. The paper is divided into five Chapters. Chapter one comprises of the Introduction. Chapter two sets out the essential conceptual and analytical framework. Chapter three introduces the Kenyan context while Chapter four presents the research and its findings. Finally, Chapter five makes appropriate conclusions and recommendations.

2.0 CONCEPTUAL AND ANALYTICAL FRAMEWORK

The aim of this Chapter is to establish the framework of analysis that will be employed in the subsequent Chapters of the paper. Firstly, a conceptual understanding of 'access to medicine' as employed in the paper, is set out. Following this, a brief overview of the global debate on the problem of access to medicine is given. Lastly, the available mechanisms for improving access to medicine are introduced but with more emphasis on parallel importation and licensing-- the two mechanisms which are the focus of this paper.

2.1. The Concept of Access to Medicine

It has been acknowledged that in the context of the debate on access to medicines, very often the term "access" is employed in a manner that confounds and obscures problems that are fundamentally different in nature.[5] Therefore, whereas the grand project of developing a conceptual definition of the term 'access to medicine' is beyond the scope of this paper, it is nevertheless necessary, at the very outset, to clarify the understanding of the term as employed in the paper. Such clarification will, in turn, aid in establishing the paper's proper scope of analysis.

Fundamentally, there is a dearth of literature which is specifically devoted to the advancement of a conceptual understanding of this term. Further, the limited literature that exists[6] has approached the subject, not from the perspective of intellectual property law, but

[5] See World Health Organization, Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*: *Report of the Commission on Intellectual Property Rights*, 11 (2006), available at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf (last visited Jan. 25, 2009).

[6] See for Example, Phillipe Cullet, *Human Rights and Intellectual Property Protection in the TRIPS Era*, 29 HUM. RTS. Q. (2007) 403-430; and Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT'L L.J., 325.

from a human rights (to health) perspective.[7] Consequently, in this paper, the term access to medicines is similarly conceptualized from a human right to health paradigm.

The core provision of the right to health in International Human Rights law is set out in article 12 of the International Covenant on Economic Social and Cultural Rights ("ICESCR"). This article recognizes the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It further states that "steps to be taken by the state Parties to the present covenant to achieve the full realization of this right shall include those necessary for …the prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "the creation of conditions which would assure to all medical service and medical attention in the event of sickness." Access to medicine is therefore a critical component of the right to health both as a treatment for epidemic and endemic diseases and as part of medical attention in the event of any kind of sickness.[8] In addition to the ECESCR, the right to health as a basic human right is further recognized in numerous other international instruments.[9]

[7] The links between intellectual property rights and human rights is exemplified in the science and technology related provisions contained in Article 27 of the Universal Declaration of Human Rights. The specific link between intellectual property rights and the realization of human right to health however became more apparent in the last decade, within the context of the HIV/AIDS epidemic that plagued many developing countries. Since most of the required medicines are protected by patent rights, there was a possible direct link identified between patents, the price of medicines and access to medicines. The identified link in turn fuelled the need to conceptualize access to medicines from the perspective of the human right to health. See Cullet, *Id*. at 414.
[8] See Yamin, *supra* note 6, at 337.
[9] See for example art. 25 (1) of the Universal Declaration of Human Rights; art. 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965; arts. 11 (1) (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979; and art. 24 of the Convention on the Rights of the Child of 1989. In addition, there are several regional human rights instruments which also recognize this right as well. For a detailed discussion of these instruments, see BRIGIT C.A. TOEBES, THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERTNATIONAL LAW (1999).

Significantly though, it was not until the year 2000 that the normative content of the human right to health was elaborated. In its General Comment No. 14 on the "Right to the Highest Attainable Standard of Health" the United Nations Committee on Economic, Social and Cultural Rights[10] explained that access to health related goods and services (defined to include essential medicines) comprises three elements: (a) *physical accessibility* in the sense that goods and services should be within safe physical reach of all sections of the population; (b) *economic accessibility* in the sense that the goods and services must be affordable; and (c) *informational accessibility* which calls for the right to seek, receive and impart information and ideas concerning health issues including pricing and treatments.[11]

For purposes of this paper, the concept of access to medicines is thus broadly understood to include the three components of physical, economic as well as informational access. However, the study upon which this paper is based restricted its inquiry to the physical and economic aspects of access. Consequently, as used in this paper, the term 'access to medicines' will be more specifically understood to refer to the physical and economic elements of access which, simply put, refer to accessibility and affordability of medicines.

[10] This is a body of independent experts that monitors implementation of the ICESCR by the state parties. It was established in 1985. The Committee publishes its interpretation of the ICESCR known as General Comment. For more details see http://www.unhcr.org/english/bodies/cescr/.

[11] U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14: The Right to the Highest Attainable Standard of Health*, 20th Sess. 12 U.N.Doc E/C.12/2000/4 (2000). Although the General Comments of the Committee do not have legally binding effect, they are considered authoritative guidance on clarifying the contents of rights and obligations enshrined in the ICESCR.

2.2 The International Patent Regime and the Problem of Access to Medicines: The Global Debate Revisited

2.2.1 The Patent System and its Justifications

Although there are many dimensions to the problem of access to medicine,[12] the debate on access to medicine has focused more on the impact of the expansion of patent protection to pharmaceutical products. An understanding of the nature of patent rights, the patent system and the latter's justifications therefore helps to explain why the patent system has been particularly implicated.

A patent[13] right is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.[14] The right is best thought of, not as an affirmative right, but as a right to exclude or a veto which enables the holder to prevent others from making, using, selling or importing the invention for the duration of the patent right.[15]

Being an exclusive right, a patent is therefore a form of a monopoly grant which enables those who hold rights under it to control the output, and, within the limits set by demand, the

[12] The other dimensions include poor health care infrastructure in these countries, international pricing mechanisms, high tariffs and most importantly, low purchasing power on the part of the affected. See International Intellectual Property Institute, *supra* note 1.

[13] The term "Patent" is a short for "letters patent," derived from the Latin term '*literae patentes*,' meaning 'open letters.' Letters patent were originally issued by the Sovereign and addressed "to all whom these presents shall come" reciting a grant of some dignity, office, franchise, or other privilege that has been given by the sovereign to the patentee. See CRAIG ALLEN NARD, THE LAW OF PATENTS, 1 (2008).

[14] It is also noteworthy that patent rights fall within the broader family of rights usually referred to as Intellectual Property Rights (IPRs). IPRs are private property rights which are the products of the conferment on legal persons by society, through its legal systems, of the rights to exclude others from the use and enjoyment of creations of human intellect. See Patricia Kameri-Mbote, *Patents and Development*, in LAW AND DEVELOPMENT IN THE THIRD WORLD, 412, 212 (Yash Vyas et al. eds., 1994).

[15] Richard Gold & Timothy Caulfield, *Patents and Human Rights*, Paper prepared for Justice Canada, (2003), available at http://www.cipp.mcgill.ca/data/publications/00000006.pdf, (last visited Feb. 3, 2009).

price of the patented products.[16] In the context of access to patented medicine, it has for example been argued that the producer of a patented drug may attempt to earn a monopoly profit by charging higher prices than would otherwise be the case.[17] This core conception of a patent right reveals a great deal about why patents are the most basic, the most valuable, and, to others, potentially the most dangerous of all Intellectual Property Rights.[18]

Intellectual property regimes, unlike private property regimes created in respect of tangible property, deal with information goods. Specifically, the use, diffusion, and production of information are at the core of the patent system.[19] Unlike tangible property, though, information goods bear two main characteristics. They are non-rivalrous[20] and non-excludable.[21] The two characteristics in turn lead to a free-rider problem in the sense that persons other than the creator of the information could exploit the information without sufficiently contributing to its creation.

Consequently, economists argue that in the absence of appropriate incentives, information will therefore tend to be under produced or not produced at all. They further argue that creation of private property rights over information is one of the ways[22] that governments could intervene so as to induce the production of information goods.[23] The patent system is one such private property rights regime.

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[16] See Penrose, *supra* note 2, at 2.
[17] See United Kingdom's Commission on Intellectual Property Rights, *supra* note 3, at 31.
[18] WILLIAM R. CORNISH, INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADE MARKS AND ALLIED RIGHTS, 7 (1999).
[19] Nard, *supra* note 13, at 26.
[20] In the sense that many people can benefit from it without interfering with the pleasure that others get from the same piece of information. See i*d.* at 27.
[21] In the sense that once disclosed, it is extremely difficult to exclude others from using the information. See *id.*
[22] Other ways include government subsidies, rewards, prizes and government financing of research projects. See *id.*
[23] *Id.*

There are other more specific justifications which have been offered in support of the patents system. According to Penrose[24] the four main justifications are: (a) *the natural rights* argument which posits that a man has a natural property right to his own ideas and that this right should be recognized by the grant of an exclusive right; (b) the *reward* argument which suggests that society is obligated to reward inventors with an exclusive privilege in the form of a patent since they render useful services to the society; (c) *incentive to disclose secrets* argument which proffers that patents are granted in exchange for a disclosure of the invention and in the absence thereof, the invention would be kept as a secret to the detriment of the society; and (d) *the utilitarian argument* whose upshot is that there would be no inventions, or at least, inventions would be delayed in the absence of patents since firms, wary of copying by competitors, would be unwilling to incur the heavy cost of research and development which is necessary for the creation of these inventions.

To each of these justifications, a corresponding counter-argument has been advanced. It has for example been argued that: (a) the *natural right* argument fails to take account of the fact that the same idea is very commonly generated independently in the minds of different persons and it cannot therefore be held to be the property of one and not the others; (b)the *reward* argument fails to recognize that most patented inventions are economically irrelevant since they remain unexploited, never reach the market and therefore, the owners never extract monopoly income (reward) from the invention, and that patent protection represents disproportionate reward for the inventor's contribution to the society, especially because there are other alternative rewards; (c) the *incentive to disclose secrets* argument is not credible since it is nearly impossible to keep important inventions secret for very long and

[24] Penrose, *supra* note 2, at 20.

most importantly, patents are applied for only when secrecy is impossible; and (d) the *incentive to encourage inventions* argument, is rendered weak by the fact that the claim that since economists have been unable to determine empirically whether the economic benefits of the patent system outweigh its costs, arguing that patents are essential for technological innovation is more of a truism than a proven fact.[25]

In sum, whereas it cannot be argued that the patent system lacks any sort of justification, it is however not as obviously or easily justified as many people think.[26] Since it is almost impossible to offer a completely acceptable rationale of the patent system, the patent system should not therefore, of itself, be excused as an acceptable barrier to access to medicines.

2.2.2 The debate on the International Patent Regime and Access to Medicines

Historically, the relationship between the international patent regime and medicines has been controversial. The controversy has its root in the divergence on the scope of patent protection that has always existed between technologically advanced countries and those in the process of industrialisation.[27] Whereas countries falling in the former category seek to have maximum protection of patent rights, those in the latter category often limit the scope of protection granted to patent right owners, usually foreigners, as part of the countries'

[25] For a detailed discussion of the justifications and criticism thereto, see R. S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and the Experimental Use,* (2000) 56 CHI.L.RE., 1025; E. C. Hettinger, *Justifying Intellectual Property* (1989) 18 Philosophy and Public Affairs Journal, 33-52, at 48; and NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, 2 (2nd ed. 2005); and Penrose, *supra* note 2, at 32-33.
[26] See Hettinger, *Id*. at 52.
[27] Correa and Yusuf argue that the divergence has existed in relation to all forms of Intellectual Property Rights but it has been particularly pronounced in the pharmaceutical field. *See* CARLOS M. CORREA & ABDULQAWI YUSUF, INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT, 4 (1998).

'catching up' strategy.[28] In deed, the mechanisms of parallel importation involuntary licensing are some of the most important strategies for limiting the scope of patent protection.

Perhaps in recognition of this divergence, the Paris Convention for the Protection of Industrial Property,[29] which was the first major international treaty on the protection of industrial property, left countries with the freedom to legislate in the industrial sectors that they considered appropriate for granting intellectual property protection. As a result, medicine was an area that many countries generally excluded from patentability.[30] Where some protection was given, until the mid 1970s, the general trend in both developed and developing countries was to extend protection to pharmaceutical processes and not products.[31]

All this changed in 1995 with the entry into force of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).[32] The Agreement, being the most comprehensive international Agreement on intellectual property ever established, was designed to strengthen and harmonize the protection of intellectual property rights

[28] The rationale has been that when a country's technological capacity is weak and its enterprises are not able to take significant advantages of the incentive provided by intellectual property protection, the benefits granted by such protection may be outweighed by the disadvantage of not being able to rapidly acquire and adapt foreign technology without reference to its creator or to import new products and processes from alternative cheaper sources. See, Correa and Yusuf, *Id.* at 5.

[29] The Convention was signed in Paris, France on March 20, 1883.

[30] Pedro Roffe, Christoph Spennemann and Johanna Von Braun, *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 9, 9 (Pedro Roffe et al., eds., 2006).

[31] Several European countries including France, Germany and Switzerland offered what is now standard protection only in the 1960s and 1970s. A study undertaken by WIPO in 1988 for the negotiating group that was dealing with TRIPS in the Uruguay Round revealed that out of the 98 state parties to the Paris Convention, 49 excluded pharmaceutical products from protection. See David M. Mills, *Patents and Exploitation of Technology Transferred to Developing Countries (in Particular Those of Africa)*, (1985) 24 Industrial Property, 120.

[32] See TRIPS, *supra* note 4.

worldwide. This goal was achieved by establishing a common set of minimum standards for all countries, in relation to not only patents, but also the six other separate areas of intellectual property that are covered by the Agreement.[33] Regarding patent protection, the most important standard may be said to be the requirement that patent protection must be provided for 'products as well as processes' and 'in all fields of technology.'[34]

To be sure therefore, in relation to patent protection for pharmaceuticals, under the TRIPS Agreement, countries no longer have the options available under the Paris Convention. All WTO member countries which have ratified the TRIPS Agreement and whose Intellectual Property laws do not meet the minimum standards that it establishes, have had to revise their laws to bring them into compliance with the Agreement.[35]

After the TRIPS Agreement came into force, there were concerns that the Agreement was adversely affecting the ability of patients in poor countries to access medicines. In the late 1990s, these concerns were validated by the increased inability by these patients to access the medicines needed to manage especially HIV/AIDS. These concerns provoked a global debate on TRIPS Agreement and access to medicines which pitted the pharmaceutical companies supported by the developed countries against the poor countries supported by civil society organizations.[36]

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[33] The other aspects of intellectual property rights provided for under the Agreement are copyright, trademarks, geographical indications, industrial designs and layout-designs (topographies) of integrated circuits. The Agreement also makes provision for protection of undisclosed information, control of anti-competitive practices in contractual licences and matters relating to enforcement of intellectual property rights.

[34] See TRIPS, *supra* note 4, art. 27.

[35] The deadlines set for countries to comply with the TRIPS Agreement were however staggered so as to take account of the different levels of economic development. Developed countries had one year following the Agreement's entry into force, developing countries had four years while Least Developed Countries now have until the year 2016. See TRIPS, *supra* note 4, art. 65.

[36] The international debate on the implications of the TRIPS Agreement for access to medicines came to the international attention in 1997 when President Nelson Mandela signed the South African Medicines and Related

The debate revolved around several issues but the notable one was the fact that whereas the TRIPS Agreement sets out minimum standards of protection to be applied by all members of the WTO, it does not create a uniform law. It gives members particularly in the field of patents, certain degrees of freedom to legislate at national levels. Yet, the poor countries were not confident that they could exploit this freedom to meet their public health challenges. Consequently the debate raised the issue of the scope and interpretation of the policy flexibilities embodied in TRIPS Agreement which could be used to improve availability and access to patented medicines.[37]

Ultimately, at the fourth session of the WTO Ministerial Conference,[38] WTO members made attempts to integrate the TRIPS Agreement into part[39] of the international action to address the public health problems. This was achieved through the passage of the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).[40] The Declaration clarified that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and further that "the Agreement can and should be

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substances Control Amendment Act (Act No. 90 of 1997) into law. The Act sought to create a legal framework for improving access to medicines through, among others, parallel importation and compulsory licensing mechanisms. The Act was met with attempts by the United States Government to force its revision and the subsequent filing of a legal challenge against the law by the South African Pharmaceutical manufacturers Association. Although the legal action was later withdrawn, the case was ground breaking in fostering international debate and civil society activism in the public health implications of the TRIPS Agreement. See PATRICK K. OSEWE *ET AL*., IMPROVING ACCESS TO HIV/AIDS MEDICINES IN AFRICA: TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS FLEXIBILITIE, 2 (2008).

[37] SISULE F. MUSUNGU ET. AL., UTILIZING TRIPS FLEXIBILITIES FOR THE PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS, 10 (2004).

[38] This was held in Doha Qatar on 14 November 2001.

[39] I say "part" because, as already acknowledged in sub-part 2.2.1 above, patents are not the only barriers to access to medicine and strategies to improve access to medicine therefore go beyond changes in patent policy.

[40] See World Trade Organization, Ministerial Declaration of 20 November 2001, WT/MIN (01)/DEC/2, 41 I.L.M. 755 (2002) [hereafter Doha Declaration].

interpreted and implemented in a manner supportive of WTO Member's right to protect public health and, in particular, to promote access to medicines for all."[41]

Following the Doha Declaration, countries now have opportunity to develop appropriate TRIPS-compliant national strategies so as to attain public health policy goals. One of the major policy goals in the pharmaceutical sector is to ensure regular access to essential drugs, at a reasonable cost, so as to meet the real health needs of all the people.[42]

2.3 Patent Related Mechanisms For Improving Access To Medicine

2.3.1 General Overview

In implementing the TRIPS Agreement, members (of the WTO) can, in particular, adopt certain measures that mitigate the impact of exclusive rights, promote competition and thereby facilitate access to medicines. Such measures are usually referred to as 'TRIPS flexibilities.'[43] There is a broad range of these flexibilities.[44] The mechanisms of parallel importation and licensing have however been hailed as the most important TRIPS

[41] Doha Declaration, *Id.*, para. 4.
[42] K. Balasubramaniam, *Access to Medicines and Public Policy safeguards under TRIPS*, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY, 139 (Christophe Bellmann et al., eds. 2003).
[43] They are termed 'flexibilities' because they derive from a flexible as opposed to a strict interpretation of the TRIPS Agreement.
[44] Other flexibilities include: (a) measures aimed at promoting socio-economic welfare and technological development under art. 7 TRIPS; (b) measures necessary for the protection of public health and nutrition under art. 8.1 TRIPS; (c)measures relating to control of anti-competitive practices, abuse of intellectual property rights by rights holders or resort by them to practices that unreasonably restrain trade or adversely affect the international transfer of technology under art. 8.2 of the TRIPS; (d) the freedom to define the broad parameters of a patentable invention under art. 27 TRIPS; (e) the possibility of establishing exceptions to the exclusive rights such as early working exceptions which allow generic firms to initiate and obtain marketing approval of a patented drug before the expiration of the respective patent under art. 30 TRIPS; and (f) freedom to determine how to protect test data relating to the quality, safety, efficacy as well as information on composition and physical and chemical characteristics of the product under article 39 TRIPS. Limited protection would facilitate entry of generic competition so as to lower prices and increase availability of medicines.

flexibilities as well as the most commonly used in Africa.[45] For this reason, they are the main focus of this paper. In the following section I address each of the mechanisms in turn.

2.3.2 Parallel Importation

Parallel importation arises as a consequence of a doctrine known variously as the 'first sale' doctrine or the 'exhaustion of rights' doctrine. [46] The doctrine holds that upon the first authorized sale of the physical item, the intellectual property owner is adequately remunerated and consequently, some or all of the intellectual property owner's exclusionary rights are 'exhausted' as applied to that physical item.[47]

Exhaustion of rights in turn leads to the phenomenon of parallel imports, or grey marketing, which occurs when an item validly marketed under the intellectual property regime in country A is imported into country B against the wishes of B's corresponding intellectual property holder.[48] Parallel imports are therefore 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 or licensed local dealer.[49] Whereas the phenomenon of parallel importation arises in

[45] Osewe et al., *supra* note 36, at 22.
[46] This doctrine addresses a conundrum in intellectual property law which arises when an intellectual property rights holder sells products or services embodying intellectual property, as is usually the case in the vast majority of consumer transactions, to a purchaser without including an express license of the intellectual property rights as part of the sale transaction. In the absence of an express license, the scope of the purchaser's permission to exploit the purchased item may be unclear. See GRAEME B. DINWOODIE AND MARK D. JANIS, TRADEMARKS AND UNFAIR COMPETITION: LAW AND POLICY, 695 (2007).
[47] Once exhausted, intellectual property rights can no longer be enforced by the person owning the rights.
[48] Alexander J, Stack, *TRIPS Patent Exhaustion and Parallel Imports*, 1 JWIP 657, 666 (2005).
[49] Keith E. Maskus, *Parallel Imports*, 23 The World Economy, 1269, 1271 (2000). See also N. Gallus, *The Mystery of Pharmaceutical Parallel Trade and Developing Countries* 7 JWIP 169, 177 (2004).

relation to all forms of intellectual property rights, parallel importation of pharmaceutical products would however mainly concern patent and trademarks rights holders.[50]

Significantly, the disparity between markets of the price at which goods are sold is the economic driver for parallel import activity. There are two main explanations for this disparity. Firstly from the practice of intellectual property rights holders to establish separated international market. It is therefore argued that parallel importation interferes with a right-holders ability to establish separated market thereby eroding their potential profits from international sales. Secondly, national price regulations established to achieve particular social objectives also accounts for the disparity. In this regard, it could be argued that parallel importation defeats the purpose of price regulation as distributors in more regulated (lower price) markets ship medicines to less regulated (higher price) markets.[51] Parallel importation will therefore arise where international price differences exceed the cost of transporting and selling goods across boarders.[52]

The benefit of parallel importation, according to Maskus, is that it expands the competition facing the original manufacturers and therefore benefits consumers through lower prices. On the other hand, the disadvantages are firstly that it wastes resources through cross hauling of

[50] Under the trademark law, issues arise since the imported goods are genuine trademarked goods - genuine in the sense that the mark was applied to the goods, and the goods put in the market, by or under authority of the mark owner. On the other hand, from a patent perspective, issues arise since the imported goods may embody patented technology. See: Dinwoodie and Janis, *supra* note 46, at 696; and Nard, *supra* note 13, at 602.
[51] See Matyn Hann, *Trade Mark Rights and Parallel Imports in Europe*, 1 JWIP 621, 631 (1998).
[52] Maskus, *supra* note 49, at 1274.

goods between countries.[53] Secondly, it is argued that permitting Parallel importation encourages consumer deception and trade in counterfeit and pirated goods.[54]

Crucially, the TRIPS Agreement avoids mandating worldwide norms on the legality of parallel importation thereby rendering parallel importation entirely an issue for domestic legal concern.[55] A country can opt for either a system of national, international or regional exhaustion. A system of national exhaustion prohibits parallel trade[56] while that of international exhaustion allows parallel trade.[57] Under regional exhaustion, rights end upon sale within a group of countries thereby allowing parallel trade among them but the rights are not exhausted by first sale outside the region.[58] Countries seeking to increase access to medicines would therefore opt for international exhaustion thereby making it possible for importation of drugs from wherever in the world the drugs are sold cheaper than in their own country.

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[53] *Id.*

[54] Maskus argues that whereas the former disadvantage seems tenable, the latter disadvantage is irrelevant in the strict sense of assessing the impacts of parallel importation. Counterfeiting and piracy are trade in unauthorized versions of products. Consumer deception would therefore only occur if lower-quality parallel imports were marketed as legitimate versions of higher quality products. This is not usually the case with parallel importation which trades in genuine goods. In either case, custom authorities should be empowered to act against trade in counterfeit goods without restricting genuine parallel importation. See *Id*. at 1274.

[55] Article 6 of the TRIPS Agreement provides that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

[56] Since right are only exhausted upon a first sale within the country. Parallel imports from other countries are therefore excluded.

[57] Since the rights are exhausted upon the first sale anywhere in the world. Parallel importation cannot therefore be precluded under this regime.

[58] Maskus, *supra* note 49, at 1270. The European Union is an Example of a Jurisdiction that employs regional exhaustion.

2.3.3 Licensing Mechanisms

A. Voluntary Licensing

The TRIPS Agreement does not provide a detailed framework for this mode of licensing. Article 28(2) of TRIPS which provides that patent owners shall have the right to "assign or transfer by succession, the patent and to conclude licensing contracts" is the only place where voluntary licensing is referenced in the Agreement. In the absence of an elaborate framework, presumably, the onus is on individual countries to lay out a legislative and policy framework which best serves the voluntary licensing need's of the country.

B. Involuntary Licensing

Article 31 of the TRIPS Agreement recognizes two modes of involuntary licensing: compulsory; and government use. Below is a description of each mechanism.

i) Compulsory Licensing

A compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.[59] Through compulsory licensing, a competent government authority can therefore license the use of an invention to a third party or government agency without the consent of the patent holder.[60]

Article 31 establishes a set of standards which must be respected when a country chooses to allow compulsory licensing under its national laws. The most important of these are the requirement of evidence of an unsuccessful prior request for a voluntary license (except in

[59] Giana Julian-Arnold, *International Compulsory Licensing: the Rationales and the Reality*, 33 IDEA 349 (1993).
[60] *Id.*

cases of national emergencies),[61] payment of adequate remuneration to the right holder;[62] and the requirement that authorization should be predominantly for the supply of the domestic market.[63]

ii) **Government Use Licensing**

Government use licensing is viewed as an eminent domain taking of a license under the patent, and thus not an infringement of the patent.[64] Invoking the government use right, a government can assign to its agency or department, or to a private company (as a contractor or subcontractor), the right to locally manufacture a patented product, without the patent holder's permission.[65] This form of licensing is recognized in the reference, in article 31, to the concept of 'public non-commercial use' and 'patents used by or for the government.'

Government use licensing or public use of patents, though somewhat similar to compulsory license, is nonetheless more direct and less restrictive method of authorising involuntary use of a patent.[66] under the TRIPS regime, the advantage of pursuing government use licensing as opposed to compulsory licensing is that there is no requirement to obtain the patent holder's permission or to hold prior negotiations for a voluntary license with the patent

[61] See TRIPS, *supra* note 4, art. 31(b).
[62] See TRIPS, *supra* note 4, art. 31(h).
[63] See TRIPS, *supra* note 4, art. 31(f). Other pertinent requirements are the need to consider each application for a compulsory license on its own merits limiting of the scope and duration of use to the purpose for which it was authorized; non-exclusivity of the license granted; non-assignability of use except with part of the enterprise or goodwill which enjoys the use.
[64] SISULE F. MUSUNGU & CECILIA OH, THE USE OF FLEXIBILITIES BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 35 (2006).
[65] Government use is a form of involuntary licensing which is recognized in many jurisdictions. Under 28 United States Code s. 1498 for example, the US government can use patents or authorize third parties to use patents for virtually any public use, without negotiation. Patent owners in US have no rights for injunctive relief, and may only seek compensation, not as a tort, but as an eminent domain taking. Other countries that have similar provisions include United Kingdom, Australia, Italy, Germany, New Zealand, Phillipines, Malaysia and Singapore. See James Love, *Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 74, 75 (Peter Drahos & Ruth Mayne, eds., 2002).
[66] See *id.* at 76.

holder, or to inform the patent holder prior to government use of the patent. For this reason, this authorization can be fast-tracked without usual negotiations. The required conditions are that adequate compensation be paid to the patent holder[67] and further that the manufacture be for public, non-commercial purpose. Government use option is especially advantageous if it is part of national policy for the government to provide the medicines free or at a subsidized (thus non-commercial) rate to patients.

2.4 *Constraints to Effective Implementation of the Mechanisms*

The Doha Declaration, in its Paragraph 6, recognized the reality that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector would face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. The Declaration therefore went on to provide the mandate for the establishment of legal machinery to enable such countries to obtain imports from other countries which are able and willing to assist them without impediment from the relevant patent holders.[68]

In addition, existing literature has alluded to other challenges that developing countries may encounter in their attempts to implement licensing mechanisms. The cited challenges include: relatively small markets which deny local manufactures the needed economies of scale in individual countries coupled with low purchasing power on the part of the

[67] See TRIPS, *supra* note 4, art. 31(h).
[68] The legal framework to facilitate this was initially embodied in a waiver known as the decision of 30 August 2003. The Waiver will be rendered permanent in the form of an Amendment to the TRIPS Agreement, Known as Article 31*bis*, whose ratification is currently under consideration by many governments. See: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), Do WT/L/540; and WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement, WT/L/641, 8 Dec. 2005, with Attachment 'Protocol Amending the TRIPS Agreement' (with Annex setting out Article 31*bis*).

population; [69] lack of well-defined, clear and simple administrative procedures necessary for efficient and coordinated decision-making which is necessary for implementation;[70] absence of awareness and will to implement the mechanisms on the part of political leaders;[71] and high cost of active pharmaceutical ingredients.

With specific reference to local production of HIV /AIDS Malaria and Tuberculosis, an additional major challenge which has been cited is the high cost of bioequivalence tests for each product, required for prequalification by the World Health Organization (WHO) which in turn leads to inability to supply the drugs to the specific governments under the Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund), the United States' President's Emergency Plan for Aids Relief (PEPFAR) and other similar international donor programs.[72]

Concluding Summary

Following the Doha Declaration, existence of mechanisms which taken together, permit countries to create very simple and easy to administer systems for permitting increasing access to medicines is no longer in doubt. In the absence of implementation constraints, the

[69] Osewe *et al*., *supra* note 36 at 25.
[70] I*d.*
[71] Robert Lewis-Lettington & Peter Munyi, *Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study*, 11 (2004) available at http://www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf, (last visited Mar. 19, 2009).
[72] The Global Fund is an international global public/private partnership established in 2002. It is dedicated to attracting and disbursing resources to prevent and treat HIV/AIDS, malaria and Tuberculosis. Kenya is one of the fund's beneficiaries. On the other hand, PEPFAR was established in 2003 to combat HIV/AIDS by providing funds intended to, among others, supply anti retroviral therapies in affected nations. Kenya is similarly one of PEPFAR's beneficiaries. Where locally manufactured medicines are not pre-qualified by the World Health Organization, the beneficiary governments cannot use funds from these donors to purchase medicines from local manufacturers. Although governments can use their own budgetary allocations to purchase the medicines, since a significant amount of financing for the purchase of the medicines comes from these donors, this factor has rendered local production unsustainable in the medium to long term. See Osewe *et al*., *supra* note 36, at 25.

available mechanisms for improving access to medicines should lessen the potential damaging impact of the TRIPS Agreement and the patent regime that it establishes. In the end however, it is the specific national laws and implementation thereof which will determine the extent to which these mechanisms serve to improve access to medicines.

3.0 THE KENYAN CONTEXT: RELEVANT SECTOR PROFILES AND LEGISLATIVE AND POLICY FRAMEWORKS

This Chapter presents background information on Kenya which will inform the analysis, discussion and conclusions in chapters four and five. I begin by giving a brief synopsis of the social-economic status of the country and also the health and pharmaceutical sector profiles. The last section contains a discussion of the legislative framework for patent protection in Kenya and legal framework for the licensing and parallel importation mechanisms.

3.1 Socio-Economic and Health Sector Profiles

Kenya is a developing country located within the East African region. The country's population, currently estimated at 37 million, is predominantly poor with an estimated 56% thereof living below the poverty line.[73] In deed, the country was ranked at position 148 out of 177 countries in the 2007/2008 Human Development Report,[74] published by the United Nations Development Program. However, amidst the pervasive poverty, Kenya, like most other developing and least developed countries, is faced with the challenge of how to increase access to medicines for her population.

The country is plagued by various disease pandemics. HIV/AIDS, tuberculosis, malaria and other equally lethal and debilitating but preventable and treatable diseases continue to ravage

[73] International Monetary Fund, Kenya Poverty Reduction Strategy Paper, IMF Country Report No. 05/11, 9 (2005) available at http://imf.org/external/pubs/ft/scr/2005/cr0511.pdf, (last visited Mar. 9, 2009).
[74] The Human Development Report publishes the human development index (HDI) which looks beyond GDP to a broader definition of well-being. The HDI provides a composite measure of three dimensions of human development: living a long and healthy life (measured by life expectancy), being educated (measured by adult literacy and enrolment at the primary, secondary and tertiary level) and having a decent standard of living (measured by purchasing power parity and income). The data on Kenya is available at http://hdrstats.undp.org/countries/data_sheets/cty_ds_KEN. html, (last visited Mar. 10, 2009).

the country. HIV/AIDS was for example declared a national disaster in 1999[75] and the number of people living with HIV/AIDS is currently estimated at 1,500,000.[76] On its part, malaria is one of the leading contributors to morbidity and mortality in the country, accounting for 34,000 deaths annually in children below five years of age. Regarding tuberculosis, in 2005, Kenya was ranked at position 10 out of 22 high burden countries for tuberculosis in the world.[77] The need to avail medicine to the affected population is therefore most urgent.

Yet, access to health services in general-- of which medicine is merely but one of the components-- still remain a challenge in the country. Health services in Kenya are delivered through a network of facilities organized in a pyramidal pattern. The network starts from dispensaries and health centers at the bottom, through to sub-district hospitals, district hospitals, and provincial general hospitals and, at the apex, two national hospitals.[78] Facilities become more sophisticated in terms of diagnostic, therapeutic, and rehabilitative services as one advances from the lower to the upper levels.

There are about 5,945 health care facilities in Kenya, of which the public sector controls and runs about 52% while the private sector, the mission organizations and the Ministry of Local

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[75] James Otieno Odek, *Towards TRIPS Compliance: Kenya's Legislative Reforms*, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 277, 279 (Christophe Bellmann et al., eds. 2003). According to Odek, the reason for this declaration was so as to make HIV/AIDS a national emergency within the meaning of Article 31 of the TRIPS Agreement. Under this article, exploitation of a patent without the prior authorization of the right holder must be preceded by prior efforts to obtain authorization from the right holder on reasonable commercial terms. This requirement may however be waived by a Member in the case of a national emergency.

[76] See World Health Organization et al., the *Epidemiological Fact Sheet on HIV and AIDS: Core Data on Epidemiology and Response* in Kenya 4 (2008) available at http://www.who.int/globalatlas/predefinedReports/EFS2008/full/EFS2008_KE.pdf, (last visited Apr. 20, 2009).

[77] World Health Organization, *Global Tuberculosis Control Report* 24 (2007) available at http://www.who.int/tb/publications/global_report/2007/pdf/full.pdf, (last visited Apr. 22, 2009).

[78] These are Kenyatta National Hospital and Moi Teaching and Referral Hospital.

Government run the remaining 48%.[79] Further, the health care professionals are not sufficient to meet the health care needs of the population. According to the latest available statistics, in 2007, there were a total of 6,271 doctors, 931 dentists, and 2,775 pharmacists registered in Kenya. This translates to 17 doctors, 3 dentists and 7 pharmacists for every 100,000 people respectively. [80]

Further complicating the issue of access to health services in general and medicines in particular, is the fact that there is a major burden placed on households in relation to health care spending. The most recent National Health Accounts data indicate that in 2006/07 financial year, households' contributions amounted to 51% of health financing, while government was the second largest contributor at 30%.[81] Donors and international NGOs accounted for a further 16% of the resources envelope with the remaining 3% coming from private companies, local NGOs and other unspecified sources. [82]

The stated poverty levels, disease pandemics and the grim statistics notwithstanding, the key policy objective of the country's ministry of health is to 'create an enabling environment for the provision of sustainable quality healthcare that is acceptable, affordable and accessible to

[79] Ministry of Health (Kenya), *Public Expenditure Tracking Survey 2007*, 9 (2007) available at http://www.hcf-kenya.org/publications/files/Final%20Public%20Expenditure%20Tracking%20Survey%20%20Report%202007.pdf, (last visited Apr. 12, 2009).
[80] Kenya National Bureau of Statistics, *Kenya Facts and Figures*, available at http://www.cbs.go.ke/knbsinformation/pdf/kff2008.pdf, (last visited Mar. 20, 2009).
[81] In the 2006/07 financial year, the per capita public expenditure on health stood at USD 9.47**.** This is below the World Health Organization (WHO) recommended level of USD 34 per capita (of which a minimum of US$ 2.5 should be on essential medicines) needed to provide a minimum package of health care services. See the World Health Organization, *Microeconomics and Health: Investing in Health for Economic Development, A Report of the Commission on Macro-Economics and Health*, 11(2001) available at http://whqlibdoc.who.int/publications/2001/924154550X.pdf, (last visited Mar. 20, 2009).
[82] Public Expenditure Tracking Survey 2007, *supra* note 79, at 9.

all Kenyans.'[83] Access to medicines is emphasized as a core component of this goal. Most significantly though, access to medicines still remains an unattained dream for most Kenyans. To give but one example, out of the estimated 1,500,000 HIV/AIDS patients in the country, 430, 000 adults require Antiretroviral Therapy (ART) but only 172,000 (a mere 40%) are currently receiving ART. [84] Further, out of the 100,000 children who are infected, 23,000 require ATR but only 13,000 (56.5%) are receiving it. This is notwithstanding the fact that since 2005, ART has been free for patients attending the pubic hospitals although the patients bear the cost of medical support services such as laboratory testing.

Donor funding however underwrites the largest portion of HIV/AIDS expenditure in Kenya. For example, during the financial year 2007/2008, the Government allocation for HIV/AIDS expenditure was a paltry USD 7.7. Million. On the other hand, the United State's President's Emergency Plan for Aids Relief (PEPFAR) committed a total of USD 367 Million in 2007.[85] Donor funding may however not be a sustainable strategy for increasing access to medicines in the long term. Effective implementation of other strategies such as parallel importation and licensing mechanisms may therefore be critical for sustaining improved access.

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[83] See Ministry of Health (Kenya), *National Health Sector Strategic Plan for 2005-201*,2 (2004) (Unpublished Manuscript on file with the author).

[84] National AIDS Control Council, Office of the President, Kenya, *United Nations General Assembly Special Session on HIV and Aids (UNGASS) 2008 Country Report for Kenya*, 26 (2008) available at http://data.unaids.org/pub/Report/2008/kenya_2008_country_progress_report_en.pdf, (last visited Apr. 16, 2009).

[85] In deed, in 2007, PEPFAR supported 110, 000 patients who are on ART and contributed to the support of another 44,000 patients. Further support for ART treatment in the country was received from the World Bank, United Kingdom's Department for International Development (DFID), and the Swedish International Development Cooperation Agency (Sida). See *Id.* at 46.

3.2 The Pharmaceutical Sector Profile

3.2.1 General Overview

The pharmaceutical industry in Kenya is still in the infancy stage. However, outside South Africa, Kenya has the most developed pharmaceutical industry in sub-Saharan Africa. In this regard, Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA)[86] region, supplying about 50% of the region's market.[87] In deed, out of the COMESA region's 50 most recognized pharmaceutical manufacturers, more than two thirds of them are based in Kenya.[88] These include local manufacturing companies, large multinational corporations, subsidiaries, joint ventures as well as Indian Generic manufacturers.

There are thirty three indigenous companies registered as pharmaceutical manufacturers in Kenya, but only about a third of them are engaged in the actual manufacture of medicines. [89] Local pharmaceutical manufacturing companies have very limited production capacity and engage in minimal research and development activity. Instead, the companies are primarily engaged in compounding and packaging medicines, repacking formulated drugs and processing bulk drugs into doses using predominantly imported active ingredients and excipients.[90] The bulk of locally manufactured preparations are therefore non-sterile, over-the counter products.[91] For these reason, local pharmaceutical companies are therefore not able to meet the current and probably near future pharmaceutical needs of the country.[92]

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[86] This is a regional body consisting of the following twenty member countries: Kenya, Angola, Burundi , Comoros, D.R. Congo, Djibouti, Egypt, Eritrea, Ethiopia, Libya, Madagascar, Malawi, Mauritius, Rwanda, Seychelles, Sudan, Swaziland, Uganda, Zambia and Zimbabwe.

[87] Export Processing Zone Authority (Kenya), *Kenya's Pharmaceutical Industry Report*, 2 (2005), available at http://www.epzakenya.com/UserFiles/File/Pharmaceutical.pdf (last visited Apr. 24, 2009).

[88] *Id.*

[89] *Id.*

[90] Pharmaceutical excipients are substances other than the pharmacologically active drug ingredients which are included in the manufacturing process or are contained in a finished pharmaceutical product dosage form. They include Binders, disintegrants ,fillers, lubricants, glidants (flow enhancers), compression aids, colours sweeteners, preservatives, suspensing/dispersing agents, film formers/coatings and flavours.

[91] Kenya's Pharmaceutical Industry Report, *supra* note 87, at 4.

[92] Lettington and Munyi, *Supra* note 71, at 13.

3.2.2 Legislative Framework for Regulating the Pharmaceutical Sector

Regulation of the sector falls within the mandate of the Pharmacy and Poisons Board (the Board), which is established under the Pharmacy and Poisons Act.[93] The Board's broader mandate is to regulate the practice of pharmacy as well as the manufacture and trade in drugs and poisons. The Board comprises of eight members who are appointed by the Minster for Health[94] to represent various stakeholders in the pharmaceutical industry in Kenya.[95] The Director of Medical Services (DMS)[96] chairs the Board while the Chief Pharmacist (CP) in the Ministry of Health is the Board's Registrar. Senior officials of the Ministry of Health, including the Minister, DMS and CP therefore wield immense influence over the Board.

The Registrar of the Board is responsible for registering persons authorized to practice the profession of pharmacy in Kenya.[97] In this regard, no person other than a registered pharmaceutical practitioner can carry on, either on his own behalf, or on behalf of another, the business of a pharmacist.[98] The Board is also responsible for ensuring that the registered practitioners adhere to professional conduct in the course of their practice.[99]

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[93] Pharmacy and Poisons Act, Cap. 244 (Kenya).
[94] They serve for a renewable three years term. The appointing Minister is also empowered to revoke the appointment of any member who, in the view of the Minister, appears to have failed to carry out his functions under the Act. See *Id.* at s. 3.
[95] The members include: the Director of Medical Services who sits are the Chairman; the Chief Pharmacist; the Director of Veterinary Services or a veterinary surgeon, nominated by him; four Pharmacists appointed by the Minister from a panel of names submitted by the Pharmaceutical Society of Kenya of whom to represent the civil service, community pharmacy, the pharmaceutical industry and the Department of Pharmacy of the University of Nairobi; one pharmaceutical technologist appointed by the Minister from a panel of names submitted to him by the Kenya Pharmaceutical Society.
[96] This is a senior official in the Ministry of Health.
[97] There are two categories of these practitioners: pharmacists and pharmaceutical technologists. The former are holders of at least a Bachelor of Pharmacy Degree while the latter are holders of at least a Diploma in Pharmacy. See Pharmacy and Poisons Act *supra* note 93, s. 8(1).
[98] A body corporate can however carry on the business of a pharmacist so long as the business is under the management of a superintendent who is a registered pharmacist who should also be a member of the board of directors of the body corporate. See *id,.* s. 19 (1).
[99] See *Id.*, s. 12.

In relation to regulation of importation of medicines into Kenya, the Minister for Health, in consultation with the Board, is empowered to make rules under which medicines may be imported into the country.[100] In 2006, the Minister, acting through the Board, developed specific guidelines for parallel importation of patented medicines into Kenya. These guidelines are however yet to be gazetted and as such, they have not yet come into force. Consequently, the Board continues to regulates parallel importation as it would any other importation of medicine into the country. In this regard, all imports –parallel imports included-- must be authorized by the Board through issuance of import permits prior to importation.

The Board is also responsible for regulating the manufacture of medicine in Kenya. Manufacturers are required to apply for the licensing of the manufacturing premises and also to have the method of manufacture approved by the Board. [101] Most importantly, every person who is granted a manufacturing license is required to comply with the international standards on good manufacturing practices (GMP) which are enforced locally by the Board.[102]

3.2.3 Pharmaceutical Distribution system in Kenya

Kenya's drug market is currently estimated at over Kenya Shillings 14 billion (equivalent of US$ 185 million).[103] The market for pharmaceutical products in general is therefore even

[100] *Id*., s. 44 (1).
[101] *Id.*, s. 35. A (1).
[102] *Id*., s. 35.B.
[103] See Steve Mbogo, "Why we are losing the war against fake drugs" Business Daily, May 2, 2008 available at http://www.bdafrica.com/index.php?option=com_content&task=view&id=7372&Itemid=5822 (last visited Mar. 18, 2009).

larger. An efficient distribution system is therefore necessary to get the products to the end user.

In Kenya, the management of the pharmaceutical supply system varies according to the sector. In the public sector, essential medicines[104] and other pharmaceutical products for use by dispensaries, district as well as provincial hospitals are procured, stored and distributed by Kenya Medical Supplies Agency (KEMSA) on behalf of the Ministry of Health. These hospitals can however still procure essential medicines and medical supplies using user fees especially for products which are not available through KEMSA or items for special needs. The two national referral hospitals[105] procure their supplies independently.[106] KEMSA in turn supplies the public hospitals on the basis of a quarterly kit ('push') supply system. There are however initiatives aimed at changing the supply system to a monthly demand-based ('pull') system.

In the private not-for-profit sector pharmaceutical products are procured, stored and distributed by Missions for Essential Medicines (MEDS) and other not-for-profit agencies on behalf of faith-based and other health facilities. In the private for-profit sector, supply of medicines is managed by commercial agencies such as wholesalers and distributors, on the basis of market supply and demand.[107] Further, the various private not for profit organizations, bilateral and multilateral agencies[108] also operate their own parallel

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[104] As defined by the Kenya Essential Drugs List (KEDL) which is periodically updated by the Ministry of Health.
[105] Kenyatta National Hospital and Moi Teaching and Referral Hospital.
[106] See Ministry of Medical Services (Kenya), *The Kenya National Pharmaceutical Policy*, 21 (2008), at www.hac**kenya**.org/index.php?option=com_docman&task=doc_download&gid=5863&Itemid=254, (last visited Mar. 28 2009).
[107] *Id*., at 23.
[108] Notable International Agencies involved in pharmaceutical distribution in Kenya include United Nations Population Fund (UNFPA), United States Agency for International Development (USAID) and United Nations Children's Fund (UNICEF). See *id.* at 23.

distribution systems. As a result, supply of medicines in Kenya is uncoordinated and often duplicative and wasteful.[109]

3.3 The Legislative Framework for Patent Protection of Pharmaceuticals (1933 to date)

Patent laws, like most other laws in Kenya are of colonial heritage. On becoming a British colony in the year 1897, the substance of the British common law, doctrines of equity and statutes of general application in Britain were extended to the Kenyan colony. In this regard, the patent system of the United Kingdom was introduced in Kenya through the Kenya Patent Registration Ordinance (1933). This Ordinance became the Patents Registration Act (PRA)[110] upon the country gaining independence in 1963.

Under the PRA, only a person who was a grantee of a patent in the United Kingdom (UK) or a person deriving his right from such a grantee by assignment or any other operation of the law could apply to have his patent registered in Kenya.[111] As such, the Act merely provided for a re-registration system which was dependent upon patent registration in the UK. To obtain patent protection in the Kenya, an applicant had to first obtain a patent grant in UK. A certified copy of the letters patent granted by the UK Patent Office would then be submitted to the Registrar of patents in Kenya for re-registration within three years from the date of the UK grant. There was no requirement for further examination prior to registration in Kenya.[112]

[109] Ministry of Medical Services, supra note 106.
[110] Patent Registration Act, Cap. 508 (Kenya).
[111] Id., s. 4.
[112] *Id*., s. 6.

The certificate of registration conferred on the applicant privileges and rights as though the patent had been granted in the UK with an extension to Kenya.[113] The patent would remain in force only as long as the patent remained in force in the UK.

The re-registration system was in place until 1989 when an independent patent regime was created in the country through the enactment of the Intellectual Property Act of 1989.[114] The Act was passed following recommendations of the National Council for Science and Technology, Legal and Patents Committee (the "Committee") which had been formed to appraise the effectiveness of the patent regime in the country.[115] The committee found the existing regime to be inadequate[116] and thus recommended that an independent patent system be established.[117]

The 1989 Act had the following objectives: to promote inventive and innovative activity; to facilitate the acquisition of technology through the grant and regulation of patents, utility models and industrial designs; to provide for screening of technology transfer Agreements and licenses; to provide information to the public in Kenya; and to repeal the previous patent law which was based on re-registration of UK patents.

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[113] *Id.*, s. 7.
[114] Intellectual Property Act, (1989) Cap. 509 (Kenya).
[115] James Otieno Odek, *The Kenya Patent Law: Promoting Local Inventiveness or Protecting Foreign Patentees?* 38 Journal of African Law 79, 80 (1994).
[116] According to the Committee's findings, the dependent system had the following shortcomings: it was costly for the local residents; it provided insufficient patent information; it failed to enhance the acquisition and transfer of appropriate technology to Kenya; it allowed grant of patents in Kenya without examination as to substance; it denied revenue to the country by way of patent fees; and it did not ensure that patent licenses did not contain contractual clauses that inhibit the acquisition and transfer of technology. According to the Committee's findings, the dependent system had the following shortcomings: it was costly for the local residents; it provided insufficient patent information; it failed to enhance the acquisition and transfer of appropriate technology to Kenya; it allowed grant of patents in Kenya without examination as to substance; it denied revenue to the country by way of patent fees; and it did not ensure that patent licenses did not contain contractual clauses that inhibit the acquisition and transfer of technology.
[117] Odek, *supra* note 115, at 81.

Having been enacted pursuant to a process of extensive inquiry into the form of patent laws that would best suit the country's economic as well as social needs, the Act was perceived as being sufficient to address the specific needs of the country at the time. [118] In relation to access to medicine however, whereas compulsory licensing was allowed, it is noteworthy that parallel importation was prohibited under the 1989 Act.

As a developing country member of WTO, Kenya was obligated to revise its intellectual property laws so as to bring them into compliance with the TRIPS Agreement within four years of the Agreement's entry into force. To fulfill this obligation, the 1989 Act was opened up for a review debate in 1999. The review debate therefore coincided with the global debate on the TRIPS Agreement and its impacts on access to medicines. Consequently, the core issue dominating the review debate in Kenya was not only the need to comply with the TRIPS Agreement but also the need to incorporate available mechanisms for improving access to medicines in the revised law.

Following extensive debate and active lobbying by a caucus of the civil society known as the Kenya Coalition for Access to Essential Medicines (KCAEM),[119] the Industrial Property Act (IPA)[120] which reflects the current position of patent law in the country was eventually passed in 2001 and subsequently came into force on 1st May, 2002. In line with the TRIPS Agreement, the IPA provides for protection of products as well as processes in any field of

[118] James Otieno Odek, *Towards Trips Compliance: Kenya's legislative Reforms* in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY*, 277 (in C. Bellmann, et al., Eds, 2003).
[119] The members included Action Aid, the Association of People Living with Aids in Kenya(TAPWAK), Health Action International (Hai Africa), Women Fighting Aids in Kenya (WOFAK), International Federation of Women Lawyers Kenya (FIDA), CARE International, Medecins Sans Frontieres (MSF), Pharmaciens Sans Frontieres (PSF), Kenya Medical Association and Campaigners for Free Society.
[120] Industrial Property Act, Act No. 3 of 2001 (Kenya) [hereafter IPA].

technology[121] and for a term if twenty years from the date of application.[122] Medicines, being pharmaceutical products are therefore offered patent protection in Kenya.

3.4 Legal Framework for Improving Access to Medicines in Kenya

Since the IPA was enacted pursuant to active lobbying on the issue of access to medicines, it incorporated most important TRIPS Flexibilities. Among the flexibilities included are: (a) exclusion of public health related methods of use or use of any molecule used for the treatment or prevention of any disease designated by the Minister for Health as a serious health hazard or life threatening;[123] (b) acts necessary to obtain approval or registration of a product for purposes of commercializing it after expiry of the patent - the so called 'Bolar' exception;[124] and (c) acts done for scientific research.[125] Most significantly, the Act does in fact make provision for parallel importation and licensing mechanisms. Since these mechanisms are the main focus of this paper, they are discussed in more detail hereunder.

3.4.1 Licensing Mechanisms

A. Voluntary Licensing

Under the IPA, voluntary licenses are referred to as contractual licenses. These licenses are important in two respects: in relation to involuntary licensing; and as substantive mechanisms in their own right for improving access to medicine. Regarding the former, it is a requirement that before a compulsory license is sought, the applicant must have made unsuccessful attempts to obtain a voluntary license. With regard to the latter, the IPA sets out an elaborate

[121] *Id*., s. 21.
[122] *Id*., s. 60.
[123] *Id.,* s. 21(3)(e).
[124] *Id*., s. 54(2).
[125] *Id*., s. 58 (1).

framework for regulating voluntary licensing all with the view of ensuring that the licensing terms are not prohibitive.

Regarding licensing as a substantive mechanism, the IPA makes provision for the form of license contracts;[126] the rights of the parties;[127] registration requirements;[128] and prohibited terms.[129] The last two points are important for subsequent analysis in this paper and therefore require further elaboration. All voluntary licenses must be submitted to the Kenya Industrial Property Institute (KIPI)[130] for registration. KIPI has authority to refuse registration and thereby invalidate any license contract if it is not satisfied with some or all of the terms and conditions of the voluntary license. Section 69 IPA sets out thirty three terms and conditions which cannot be included in a voluntary license.[131] The Managing Director of KIPI therefore has a very wide discretion and can refuse registration where she is of the opinion that any clause in a license contract imposes unjustified restrictions on the licensee.

B. Involuntary Licensing

The IPA makes provision for compulsory as well as government use licensing. With regard to compulsory licensing, the enabling regime is established under sections 72 to 79 (both inclusive) of the Act. There are only two grounds on which a compulsory license application can be made: if a market for the patented invention is not being supplied on reasonable terms

[126] These must be in writing. See Id., s. 67.
[127] See *id.*, ss. 64 and 65.
[128] *Id.*, s. 68(1).
[129] *Id.*, s. 69.
[130] This is the relevant Patent Office in Kenya.
[131] Examples of these conditions include: royalty rate which is disproportionate to the value of the technology; restricting sources of raw material; limits on the volume of production; restrictions on exportation of the products manufactured under license and restricting use of technology other than that licensed. See IPA, *supra* note 120, s. 69 for a full list of the prohibited terms and conditions.

in Kenya;[132] and based on interdependence of patents.[133] Where patented medicine is not being sold in Kenya at a reasonable price, an application for a compulsory license to manufacture medicines locally may, therefore arguably be made on the basis of the former ground.[134]

To be successful on either ground, the applicant must demonstrate evidence of an unsuccessful prior request for a voluntary license on reasonable commercial terms and within a reasonable time.[135] The applicant must also offer satisfactory guarantees to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which have given rise to his request.[136] These two prerequisites are however waived in case of a national emergency or other circumstances of extreme urgency but even in these instances, the owner of the patent is to be notified as soon as is reasonably practical.[137]

[132] A compulsory licence shall however not be granted on this grounds if the owner of the patent demonstrates that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or being supplied on reasonable terms in Kenya. Further, an application under this ground can only be made after expiry of four years from the filing date of an application or three years from the date of grant of the application (whichever period last expires).

[133] Under IPA, where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the latter patent may apply for a compulsory license with respect to the earlier patent to the extent necessary for the working of his invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent. see IPA, *supra* note 120, s. 73 (1).

[134] An application based on the first ground can however only be made after expiry of four years from the date of application or three years from the date of grant of a patent, whichever period last expires while an application of the latter ground can be made at any time. This means therefore that there is a guaranteed minimum period of patent protection in Kenya during which a patent may not be the subject of attack on the ground that the local market is not being supplied on reasonable terms. This may have implications to newly patented medicine. See IPA, *supra* note 120, ss. 71(1) and 73(1).

[135] *Id.*, s.74 (1) (a).

[136] *Id.*, s.74(1) (b).

[137] *Id.*, s.74(2).

Applications for a compulsory license are made to the Industrial Property Tribunal[138] which is established under the IPA. When granting a compulsory license, the Tribunal is required to set the terms and conditions of the license, which constitute a valid contract between the parties.[139] In setting the terms, the Tribunal must ensure that the compulsory license: a) is limited in scope and duration, to the purpose for which it was authorized; (b) is limited predominantly for the supply of the domestic market;[140] (c) does not entitle the licensee to grant further licenses without the consent of the owner of the license; and, (d) provides for the payment to the owner of the patent remuneration which is equitable with due regard to all the circumstances of the case, including the economic value of the license.[141]

On its part, government use licensing is provided for under section 80 of the IPA which provides that a government use order can only be made where: a) the public interest, in particular, national security, nutrition, health, environmental conservation or the development of other vital sector of the economy so requires; or b) where the managing director of KIPI determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive.[142]

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[138] The Tribunal is established under s. 113 (1) IPA. It consists of: a chairman who must be a lawyer who has been or is qualified to be a judge of the High court of Kenya; two lawyers with at least seven years of experience and; two other members with industrial, scientific or technological expertise. All five members are appointed by the Minister of Trade and Industry.

[139] See IPA *supra* note 120, s. 75(1).

[140] This provision, being a replica of article 31(f) of TRIPS, limits the capacity of Kenya to fully exploit the advantage availed through the WTO decision on the implementation of paragraph 6 of the Doha Declaration made on 30th August 2003, now the proposed article 31 *bis* amendment to the TRIPS Agreement. This allows countries which are unable to make effective use of compulsory licensing due to insufficient manufacturing capacity to import generic medicines from a generic producer through a waiver of the restriction on exports in Article 31(f). See TRIPS, supra note 4, art. 31(f).

[141] IPA, *supra* note 120, s. 74(3) IPA.

[142] Id., s. 80 (1).

Significantly, a government use order can only be made pursuant to an application. In other word, a government official cannot act on his own volition and grant the use order. Once the application has been made by for example a local manufacturer, there are two avenues open to the responsible minister to follow in exercising his power to grant the order. He may, under section 80(1), consult with KIPI and the owner of the patent before granting the order. If this avenue is opted for, adequate compensation is to be paid to the patent owner. Adequacy is defined in terms of equity with due regard to all the circumstances of the case and in particular, the economic value of the patent.[143] It may therefore be argued that this avenue is similar to compulsory licensing. Alternatively, the minister may, under section 80(1A) IPA, issue a Government use order without notice to the patent holder or any other notifiable party.[144] An order made in this manner shall not require the payment of compensation to the owner of the patent, a license holder or any other interested party.[145]

Whereas the conditions for involuntary licensing generally mirror the conditions set out under Article 31 of the TRIPS Agreement, there are some slight differences. Remuneration under the TRIPS Agreement is for example required to be "adequate" while the IPA requires that it be "equitable". Whether the two are necessarily the same is debatable. It has been argued that adequacy as dictated by TRIPS can only be assessed with the interests of the patent rights owner in mind. On the other hand, by invoking equity, the IPA redefines the requirement of adequacy to imply justice dictated by reason, conscience, and a natural sense of what is fair to all, in this case, the patent right owner, the applicant and the consumers.[146]

[143] Id., s. 80 (4).
[144] This would include KIPI and the patent owner's licensees.
[145] See IPA, *supra* note 120, s. 80 (1B).
[146] Jame Otieno Odek, *supra* note 115, at 100.

3.4.2 Parallel importation

As already noted above, parallel importation was prohibited under the 1989 Act but is now allowed under the IPA.[147] Section 58(1) of the IPA specifically provides that the right of a patentee to preclude any person from importing patented products does not extend to "acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya." This provision is understood as allowing international exhaustion because once the patented product has been put in the market anywhere in the world, the product can be freely imported into Kenya. Clause 37 of the Industrial Property Regulations (2002)[148] further clarifies that the limitation on the rights under a patent in section 58(1) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market. So long as the goods have been placed in the foreign market by the proprietor of the right or with his consent, the rights are exhausted and the goods can be imported into Kenya.

However, whereas the IPA is unambiguous in its language sanctioning parallel importation in Kenya, the Trademarks Act[149] is silent on the issue. As already seen in Part 1 above, parallel importation of pharmaceutical products would raise concern under both patent as well as trademark laws. Consequently, as a result of absence of any express provisions dealing with parallel importation in the Trademarks Act - either outlawing or allowing it - there have been

[147] Parallel importation was one of the key lobbying points for civil society organizations and international NGOs during the review of the 1989 Act since it was perceived to have high potential for providing immediate tangible results in improving access to medicines. The fact that parallel importation did not depend upon any bureaucratic procedures or discretionary decision-making was perceived as a major element of this potential. See Letington & Munyi, *supra* note 71, at 11.
[148] These are regulations made by the Minister in charge of Trade and Industry in exercise of the powers conferred by section 119 of the Industrial Property Act. Under the section, the Minister may make such regulations as are necessary to implement the Act.
[149] The Trademarks Act, Cap. 506 (Kenya).

attempts to seek to proscribe parallel importation on the basis that it violates the Trademarks Act.

The case of ***Lords Healthcare Limited v Salama Pharmaceuticals Limited***[150] is illustrative. The plaintiff in this case (Lords) was an importer and distributor of pharmaceutical products in Kenya. Among its range of pharmaceutical products was an inhaler used for the treatment of asthmatic patients, known as Budercort-200. According to the evidence adduced before the court, Budercort-200 is manufactured in India by Cipla Limited. Cipla Limited and Lords had entered into an agreement whereby Lords would be the sole distributing agent of its products in Kenya. Consequently, Lords had registered the trade mark consisting of the word "Budecort' in Kenya.

Lords had been awarded successive tenders to supply the product to Kenyatta National Hospital[151] as well as other government institutions over a period of four years. In May 2006, Lords however unsuccessfully bid for the supply of the inhalers to Kenyatta National Hospital. Subsequently, Lords discovered that the defendant had won the tender and had therefore been supplying the product, under the trademark Budecort-200 to this and other institutions. Lords therefore sued seeking an injunction to restrain the defendant from infringing its registered trademark. In its defense, the defendant argued that parallel importation was legal under the IPA and it could not therefore be accused of trademark infringement.

[150] High Court of Kenya, Nairobi (Milimani Commercial Courts), Civil Suit No. 334 of 2007.
[151] This is the largest public hospital in Kenya.

Ruling on the application for an interlocutory injunction, the court held that 'the alleged infringement by the defendant being anchored on the existence of the plaintiff's exclusive rights, and the existence of the exclusive rights being doubtful, no prima facie case had been established.' The suit is yet to proceed to full trial and it is not clear what the court's decision on the substantive issue of infringement will be. What is clear is however is that there is need to clarify the legality of parallel importation from the perspective of trademark law, either legislatively or through judicial interpretation. The need for this becomes even more urgent in light of the fact that there have been three attempts made so far to amend the IPA so as to outlaw parallel importation in Kenya.[152]

Concluding Summary

In her effort to enable her citizen deal with the many pandemics that afflict them, Kenya is undoubtedly confronting the challenge of how to increase access to medicines. Although a legislative as well as policy framework for facilitating increased access has been created, its efficacy in delivering the promise of increased access to medicines will however depend on implementation. The next Chapter analyzes the specific experience of Kenya in implementing parallel importation and licensing mechanisms.

[152] The initial attempt was made through the Statute Law Miscellaneous Amendments Act, 2002 which entered into force on 4th June, 2002 but the amendment was subsequently reversed in August 2002. Subsequent attempts were made in 2005 and 2007 but neither was successful since the proposed Amendment Bills were never passed by Parliament.

4.0 THE KENYAN EXPERIENCE IN IMPLEMENTING PARALLEL IMPORTATION AND LICENSING MECHANISMS: THE EMPIRICAL FINDINGS AND ANALYSIS

This Chapter is dedicated to discussing the current study. I start by setting out the methodology adopted and the rationale for the same. I then move on to present the data collected including analysis and discussion thereof. The aim is to lay the foundation for appropriate conclusions and recommendations in the final chapter of the paper.

4.1 Methodology of Research

The study upon which this paper is based was designed as an exploratory as well as a descriptive one. From an exploratory approach, the study sought to identify key hypothesis and variables for future research. Regarding the descriptive component, since the time devoted to the study was short; the aim was not to build a thorough, detailed thick description of the phenomenon under study. Instead, it broadly aimed at revealing some preliminary insights on the use of parallel importation and licensing mechanisms to improve access to medicines in Kenya. The ultimate aim was to reveal subtleties of implementing these mechanisms from the perspectives of key stakeholders which may thereafter be explored by future researchers.

The data analyzed in this paper came from both public and private sources, as well as interviews conducted by the author. The main fieldwork for the study was conducted between December 22, 2008 and January 6, 2009. In total, I conducted 20 interviews. The interviewees included: parallel importers of pharmaceutical products; local manufacturers of pharmaceutical products; Multinational Pharmaceutical Companies (MTCs) with a presence

in Kenya; representatives of Regulatory Agencies; representatives of pool procurement Agencies;[153] and a local expert on the pharmaceutical industry. A detailed list of all interviewees is contained in Appendix A while Table 1 summarizes the distribution of interviews by key categories.[154]

Table 1: Distribution of Interviewees by relevant categories

Category	**No. of Interviewees**
Representatives of Regulatory Agencies	3
Formal Parallel Importers	5
Informal Parallel Importers	1
Representatives of Pool Procurement Agencies	2
Local Manufacturing Companies	4
Representatives of Multinational Pharmaceutical Companies	4
Other Informants/Experts on the Pharmaceutical Industry in Kenya	1
Total Interviewees	**20**

The Interview questions were designed as semi-structured and open ended. The Interview protocols are presented in Appendices B and C. All the interviews were conducted in Nairobi, the capital city of Kenya. The choice of this city was influenced by the fact that this is the city where most of the pharmaceutical companies are located and further that all the relevant regulatory Agencies are also located there. I only had time and resources to interview a small number of people. Consequently, I decided to use the snowball sampling approach to identify the key informants. I had previously interacted with players in the Kenyan pharmaceutical industry in workshops and seminars on Intellectual Property law.

[153] There are two Pool procurement Agencies in Kenya. These Agencies procure pharmaceutical products in bulk and distribute them to Hospitals and other institutions in the country. The two Agencies are: Kenya Medical Supplies Agency (KEMSA) which is a Government Agency that procures pharmaceutical products on behalf of public (Government) hospitals; and Missions for Essential Drugs and Supplies (MEDS) Kenya which is a private Agency that procures drugs for use by hospitals owned by Christian (church) based Organizations.
[154] Each of the categories was considered important in order to present a holistic perspective of the Kenyan pharmaceutical industry.

From these interactions, I had established valuable contacts that greatly facilitated the interviews. Most of the interviewees were therefore very cooperative and they gave candid responses regarding their experiences and perceptions as relates to the study.

In order to attain its descriptive goal, the study adopted a qualitative approach. I opted for this approach in order to be able to describe the experiences and perceptions of the interviewees in great detail. I therefore found that a qualitative approach was best suited for revealing as much information as possible so as to fully understand what is happening on the ground. The greatest weakness of qualitative studies is that they are not generalizable in the probabilistic sense.[155] The findings of the study are therefore not generalizable. Additionally, given the small number of interviews conducted and the non-random manner of sampling, the findings are also not definitive from a statistical standpoint. They nevertheless offer valuable insights regarding the experience of implementing parallel importation and licensing mechanisms to improve access to medicine in Kenya.

In the following sections, I report the findings of the study in detail. Due to the fact that most of the interviewees requested for and were therefore promised confidentiality, in this paper, the interviewees are referred to by capital letters ("Interviewee A," "Interviewee B" etc).

[155] CATHERINE MARSHALL AND GLETCHEN B. ROSSMAN, DESIGNING QUALITATIVE RESEARCH, 42 (2006).

4.2 USE OF PARALLEL IMPORTATION MECHANISM

4.2.1 Is there parallel importation of pharmaceutical products in Kenya?

As already explained in Chapter 3, parallel importation has been given legal recognition under the IPA, thus, it is legal in Kenya.[156] Yet, the mere fact that an activity is legal does not, of itself, guarantee that the activity will take place in the society. It was with this in mind that this study deliberately set out to establish whether parallel importation of pharmaceutical products was in fact taking place in Kenya. The study confirmed that in deed, parallel importation is taking place in the country.

All interviewees' unanimous view was that parallel importation commenced immediately upon the coming into force of the IPA in the year 2002 and has been increasing steadily since then. As previously stated in Chapter 3, the incorporation of the mechanisms of parallel importation and involuntary licensing into law was preceded by extensive lobbying by various stakeholders who were calling for increased access to medicines in Kenya.[157] These stakeholders already appreciated how the mechanism of parallel importation worked and most importantly, its potential benefits in improving access to medicines.[158] Therefore it is not surprising that importation commenced immediately upon the entry into force of the relevant law.[159]

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[156] Although, as stated in sub-part 3.4.2 above, the Kenyan Trade Marks Act neither allows nor prohibits parallel importation. The silence in the Trade Marks Act has created a legal ambiguity which has presented enormous challenges for parallel importers in Kenya. These challenges are discussed more substantively under subsection 4.1 here below.

[157] See sub-part 3.3 above.

[158] In the sense that immediately upon the enactment of the enabling law, they would be able to shop around the world for the cheapest medicines and import it into Kenya.

[159] It is reported that the fist parallel importation of medicines in Kenya occurred in early June 2002. This was a symbolic shipment of anti-retroviral drugs by MSF from India. See lettington and Munyi, *supra* note 71, at 17.

4.2.2. How much of the market for pharmaceutical products is supplied by parallel importers?

It is not clear how much of the Kenyan market for pharmaceutical products is being supplied by parallel importers. Interviewee C is a parallel importer as well as a high ranked official of Kenya Pharmaceutical Distributors Association.[160] According to him parallel importers were supplying about 40% of the market until the month of April, 2008.[161] The market share however started declining due to a combination of factors, the most significant of which is difficulty in obtaining import permits from the regulator, the Pharmacy and Poisons Board.[162] In his view, as at the time of the interview in December, 2008, parallel importers commanded a market share of between 30% and 35%. The plausibility of this figure was confirmed to me by Interviewees F and H who are both representatives of Multinational Pharmaceutical Companies (MTCs) with a presence in Kenya.[163]

Therefore, parallel importation of pharmaceutical products is not only taking place in the country, but it also appears to be significant. As stated in Part 2, the Kenyan market for medicines is currently estimated at over Kenya Shillings 14 billion (equivalent of US$ 185 million). The market for pharmaceutical products in general[164] is therefore significantly higher than this. Even going by a most conservative figure of 20%, the market for drugs which is supplied by parallel importers would be worth US$ 37 Million.

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[160] This is an Association of Parallel Importers in Kenya.
[161] This figure is collaborated by media reports which similarly claim that parallel importers supply about 40% of the market. See for example Mbogo, *supra* note 31.
[162] These are discussed in detail under subsection 4 of this chapter.
[163] I asked the interviewees whether it was plausible for the parallel importers to claim that they have, at the peak, supplied 40% of the market. Interviewee F, a representative of Sanofi Aventis remarked: "it is possible that they are supplying 40% of the market. The figure is not exaggerated." Interviewee H, a representative of GlaxoSmithKline (GSK) however put their possible, market share at between 20-30 percent.
[164] Comprising of medicines as well as other pharmaceutical products such as vaccines, surgical equipments etc.

4.2.3. Who are the Parallel Importers, what do they import and from Where?

A. The Importers

From the various interviews, I was able to identify specific institutions and individuals who engage in parallel importation of pharmaceutical products in Kenya. These include: registered pharmaceutical distributors and retailers;[165] Non Governmental Organizations; large private as well as public institutions which buy pharmaceutical products in bulk; local distributors appointed by MTCs to market the latter's products in Kenya; individual marketers employed by MTCs; and the so called "brief case importers" who are ordinary business men who have no professional training in pharmacy and therefore fall outside the regulatory ambit of the Pharmacy and Poisons Board.[166]

There were some unexpected findings regarding the identity of parallel importers. Firstly, although a number of interviewees confirmed that Non Governmental Organizations do in fact engage in parallel importation, it emerged that Missions for Essential Drugs and Supplies (MEDS) Kenya, is not one of the importing NGOs.[167] Interviewee O, a representative from MEDS confirmed to me that although previously they obtained some of their supplies through parallel importation, they no longer do so. This was surprising since MEDS was instrumental in lobbying for the incorporation of TRIPS flexibilities in the Kenyan law. In

[165] See sub-part 3.2.2 of Chapter three for a discussion of discuss the pharmaceutical sector in Kenya and in particular, the difference between retailers and distributors.
[166] These traders are termed "briefcase importers" because they bring in the drugs in briefcases. They travel to their source countries as tourists or visitors with empty briefcases or suitcases and on their way back into the country, they bring the products in their briefcases or suitcases.
[167] MEDS is a private pool procurement Agency which procures drugs for use by hospitals owned by Christian (church) based Organizations.

fact, MEDS was the first institution to bring in a consignment of parallel imported drugs immediately after the IPA came into force.[168]

The interview with the MEDS representative was conducted at MEDS' offices in Nairobi. While I was at the office, I noticed many stickers for United States Agency for International Developments (USAID) on the furniture. I therefore hypothesized, although the MEDS representative declined to confirm this, that MEDS was receiving funding from USAID to procure pharmaceutical products for its members. Their ability to procure the products through parallel importation with funding received from such donors may therefore be curtailed. I would however require better data to confirm this hypothesis.

Secondly, it was surprising to establish that local distributors as well as employees of MTCs were themselves engaging in parallel importation. This finding was surprising because parallel imports offer direct competition to the products placed in the market by local patent right holders (MTCs in this case). Their employees and agents are therefore engaged in activity which definitely undermines the MTCs' interests. As explained to me by Interviewee K from GlaxoSmithKline (GSK):

> The Med Reps (Medical Representatives) of MTCs and local distributors are the ones who are parallel importing (the pharmaceutical products). Local agents are also involved in parallel importing and counterfeiting. They have the necessary channels to push the drugs… The Med Reps do this just to make some extra cash...The distributors do this especially when the negotiated profit margin is not adequate. The MTCs and the Board (Pharmacy and Poisons Board) will never know since everything is very well camouflaged.

[168] See *supra* note 119. MEDS was a member of KCAEM, a caucus of civil society groups which had actively lobbied for legalization of parallel importation in Kenya.

This position was confirmed by Interviewee E from AstraZeneca (a MTC). According to her, the company suspected that their own sales team was parallel importing the company's drugs but so far, they have had no evidence to confirm this.

That informal (briefcase) importers are engaged in parallel importation of pharmaceutical products was however not surprising given the fact that the environment within which parallel importation is taking place in the country appears to be inadequately regulated. Persons who either do not qualify to apply for import permits from the Board, or who qualify but cannot apply for various reasons[169] would fall in this broad category of informal importers. Interviewee G who claimed to be a retired informal importer was however very quick to distinguish his business from parallel importation. In his words:

> I would call what I was doing smuggling because I never used to apply for permits from the Board (Pharmacy and Poisons Board). Most of my colleagues in business also never used to apply for permits. The Board would never give me a permit since am not a registered pharmacist. I only applied for a permit once when my drugs were impounded at the Namanga boarder point[170] and even then I had to bribe a registered pharmacist to apply for the permit on my behalf.

It seems therefore that parallel importers of pharmaceutical products in Kenya fall under two broad categories: (a) those who make efforts to comply with the laid down procedures for importing pharmaceutical products into the country;[171] and (b) those who do not bother to obtain the relevant authorization before importing the products into the country.[172]

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[169] According to the interviewees, most informal importers are not registered pharmacists and they would therefore not qualify to apply for the necessary authorization to import. Although the marketers employed by MTCs as well as the dealers may be registered pharmacists, they would also not be willing to obtain the required documentation so as to conceal their import activities from their employers and principals respectively.
[170] The town of Namanga is at the boarder of Kenya and Tanzania.
[171] Falling in this category are: registered pharmacists; Non Governmental Organizations; and large private as well as public institutions which buy pharmaceutical product s in bulk.
[172] Falling in this category are individual marketers employed by MTCs; local distributors of Multinational Pharmaceutical companies; and the informal (briefcase) importers.

Yet, it is not entirely accurate to talk of legal procedures in relation to parallel importation in Kenya. As already stated in Chapter three, there is no specific regulatory framework for parallel importation of pharmaceutical products into the country.[173] In the absence of specific regulations on parallel importation, the Pharmacy and Poisons Board treats parallel imports as they would any other form of import and has therefore been regulating them as such. Compliance with legal requirements should therefore be understood in this sense.

B. The Products

The imported products are dictated by economic considerations of demand, supply and profit margin. In the words of Interviewee C, a parallel importer, "parallel importation in Kenya is fuelled by demand…whatever moves fast (meaning in high demand) will be imported." This factor was elaborated by interviewee I, another parallel importer who stated that since the importers are very keen on profits, they mostly import drugs for chronic diseases such as diabetes, cancer and high blood pressure where they rely on per unit cost to maximize their profits. They also import drugs for acute diseases such as antibiotics where they rely on volumes of sale to make their profit. Further, the products could be either drugs, other pharmaceutical consumables (such as injections) as well as pharmaceutical equipment. Interviewee P a representative of a local pharmaceutical company for example confirmed that her company imports drugs, injections and surgical equipment.

In sum both, drugs as well as other pharmaceutical consumables and equipments, are imported into the country based on demand. Importantly, the imported products could be on or off- patent. Since Kenya is an important market for multinational pharmaceutical

[173] The framework for regulating importation of drugs in Kenya is discussed in greater details in sub part 3.2.2 of Chapter three. As noted, whereas preparation of the Guidelines for parallel importation of medicines into Kenya were finalized in September 2006, these Guidelines are yet to enter into force.

companies, they usually register their patents in Kenya. Appendix E presents the patents status of selected essential medicines in Kenya.

Market dynamics however compel the importers to be very strategic in identifying the products to import into the country. Products which are not in high demand are therefore unlikely to be parallel imported. This is a critical shortcoming that the mechanism of parallel importation has in improving overall access to pharmaceutical products in the country. It is noteworthy that medicines for Anti Retroviral Treatment (ART) are not parallel imported. This is because, as noted in Chapter 3, since the year 2005, ART has been availed by the Government in public hospitals for free.

C. The Source of Imports

The interviewees cited various sources of parallel imports. These include: neighboring countries of Tanzania, Uganda, Burundi, and Rwanda; Egypt; United Arab Emirates, particularly Dubai; China; and India.

Interviewees repeatedly stated that the neighboring countries are a major source of the imported products. This is because, compared to Kenya, pharmaceutical products are generally cheaper in the neighboring countries. Various reasons were given for this disparity in prices among similarly situated African countries. These include market segmentation by MTCs operating in the region and the consequent treatment of Kenya as a prime market; differences in currency value in the East African region;[174] and absence of a regulatory

[174] Currently one Kenya shilling is equal to: 17 Tanzanian Shillings; and 26 Ugandan Shillings. According to Interviewee C, "the Ugandan and Tanzanian currency is not as strong as the Kenyan shilling and so with a few Kenya shillings, one is able to buy a lot of drugs. Since MTCs treat Kenya as a prime market and therefore sell

framework for pharmaceuticals in Rwanda and Burundi which means that drugs are cheaper in these countries.[175]

Regarding price differential, Interviewee H (from GSK) for example admitted that GSK segments its East African Market. In her words:

> GSK products are generally expensive in Kenya compared with Uganda and Tanzania. Kenya is the headquarters of the East African Market. Drugs are therefore first registered in Kenya and thereafter in Uganda and Tanzania. Each Government however has its own specifications. The packs are therefore different depending on the Ministry of health specifications for each country. So you end up with the same product retailing at different prices in each country. Kenyan prices are usually the highest.

According to Interviewee I (a parallel importer), UAE Dubai is also a major source of Parallel imports. It is however mainly a conduit for products originating from Egypt. In his words:

> Drugs are very cheap in Egypt. Egypt is however a complicated source because the government prohibits and stops export to non-Arab countries. They do not mind if the drugs are destined to Arab countries. So we use our agents located in Dubai who source the drugs from Egypt on our behalf.

4.2.4. What are the factors that promote parallel importation of pharmaceutical products in Kenya?

As already noted, there appears to be a significant amount of parallel importation of pharmaceutical products taking place in Kenya. Various factors have combined with the legalization of parallel importation to stimulate and encourage this activity. I now turn to these factors as identified to me by the interviewees.

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their drugs more expensively, cost of drugs in Kenya is higher than in Uganda and Tanzania. Parallel importers therefore go to neighbouring countries to buy the same drugs at cheaper rates."

[175] This factor was given to me by Interviewee C. Interview with Interviewee C, a parallel importer, (Dec. 22 2008).

A. Potential Profits as a consequence of price differences

As already noted in sub-part 3.2 of this Chapter, parallel importers are generally driven by economic factors. Further the price of drugs in Kenya is generally higher than other markets. To emphasize the difference in Kenyan prices for medicines and the prices in source countries, during the interview with Interviewee I (a parallel importer) he pulled out products from the shelves in his chemist at random and indicated to me the Recommended Retail Price (RPP) in his source market (Egypt) and the corresponding RPP in Kenya. It is to be noted that these are identical products manufactured by the same Company (Originator) but sold at different prices in Kenya and Egypt. Table 2 contains a summary of the prices.

Table 2. Price Comparison of randomly selected pharmaceutical products sold at a pharmacy outlet in Nairobi.

Drug	**Originator**	**Description**	**RRP in Kenya**	**RRP in Egypt**	**Percentage in price difference**
Casodex	Astra Zeneca	Cancer drug	803/- per 50 mg tablet	308/-	61.6%
Augmentin	GSK	Antibiotic	165/- per tablet	36/- per tablet	78.2%
Leukeran	GSK	Cancer drug	112/- per 2 mg tablet	1.50/- per 2 mg tablet	98.6%
Zovirax	GSK	Herpes*	2,985/- per 5% pack	144/- per 5% pack	95.1%
Zinnat	GSK	Antibiotic	266/- per tablet	54/- per tablet	79.7%

Source: The prices were given to me by Interviewee I during the interview which was held at his pharmacy located in the central business District of Nairobi city.

Notes: 1: Originator refers to the Manufacturer who is usually also the Patent Holder
2. The RPP is quoted in Kenya Shillings. At the time of calculation, one US Dollar was equal to Kenya Shillings 80/-.
3. The Egyptian RPP was originally quoted in Egyptian Pound (EGP). The Respondent converted the prices to Kenya Shillings using the then prevailing exchange rate. One EGP was equal to Kenya Shillings 14/- .
* Herpes is a viral condition which is very common with HIV/AIDS patients. This drug is not supplied by the Government as part of the free HIV/AIDS treatment program and patients therefore have to pay for it from their own resources.

Where there is a huge price differential and the cost of importing the drugs (in terms of transportation; insurance; taxes etc) is low, the profit margin of the importers can be substantial. Although the parallel importers themselves were hesitant to confirm their profit margins, some interviewees thought that it was quite significant.[176] Price differential and the potential for profits that it portends is therefore an important factor that fuels parallel importation in Kenya.

B. Desire to improve access

Another factor that was mentioned, albeit not as frequently as would be expected, was the desire to make medicines more affordable to the consuming public. This was particularly emphasized by the parallel importers. Other interviewees who are not importers themselves were however very skeptical that any parallel importer operating in the private sector would be motivated by anything other than the desire to make profit. Interviewee B, an expert who has conducted many consultancies on the Kenyan pharmaceutical field put it this way:

> Parallel importers are only interested in profits. They could not care less about access to medicine. How come that they are only importing drugs for high blood pressure, cancer, diabetes and antibiotics? Parallel importation by the private sector has no larger goals like access to medicine. This is pure business.

As evidence of the fact that parallel importers are not interested in improving access medicines, representatives of MTCs argued that in certain instances parallel imported products sells for just as much or are merely slightly cheaper than what the MTCs supply locally. In response to this, Interviewee I, a parallel importer, stated:

[176] According to Interviewee H (GSK), where GSK products are supplied to local distributors who in turn supply to the retailers, the latter's profit margin is usually around 30%. In her view, given the huge price differences between Kenyan prices and prices at source markets, the profit margin for parallel imports on the other hand could be even higher than 100%, especially where the importers sell directly to the consumers. Interview with Interviewee H from GSK (Dec. 22, 2008)

> It is true that local prices of branded medicine are used as benchmarks for parallel imported drugs. It is also true that parallel imports sometimes sell for the same amount as the medicine sold locally by MTCs. But this only happens when there is no sufficient competition. It is not parallel importation itself that brings down the cost but the element of competition that it introduces. If there is only one parallel importer bringing in a certain drug, he is likely to sell it for as much as he wants so long as he is slightly cheaper than the local brand. When more than one importer brings in the same drug, they are forced to reduce prices to the minimum that they can bear.

It would appear therefore that for parallel importation to have any meaningful impact on access to medicines, there is need to have as many importers as possible importing the medicine at issue. According to Interviewee G, a retired informal importer, parallel importation has helped to bring down prices because of the competition created by the trade. He observed that:

> Kenyan consumers are sensitized and they will not buy expensive medicine if there is an option for cheaper medicine. They walk from chemist to chemist with the prescription and only buy what is cheapest. Most chemist owners are both retailers as well as wholesalers. They are able to sell drugs to consumers on whole sale prices especially after parallel importing the drugs. This is what brings down the prices. Competition helps to bring down the cost of medicine.

In deed, most interviewees acknowledged that even though access to medicine is not a motivator for most parallel importers in the private sector, access has improved as a consequence of parallel importation. In view of this, it appears that parallel importation is duly playing a part in improving overall access to pharmaceutical products in the country, whether directly or indirectly.

4.2.5. What are the challenges faced by parallel importers of pharmaceutical products in Kenya?

A. Ambiguous Legal Framework

As already intimated in Chapter 3, parallel importation is expressly authorized under the IPA. The Trademarks Act on the other hand is silent on the issue. Further the Pharmacy and Poisons Act which is the specific piece of legislation that regulates the pharmaceutical industry in the country has not been amended to make provision for parallel importation. Additionally, the rules which were specifically targeted to regulating parallel importation (the parallel Importation Guidelines) though finalized as far back as the year 2006, they are however yet to be gazetted and operationalized.

The ambiguity created by these legal gaps has therefore been exploited to frustrate parallel importation in the country. The use of the Trademarks Act to frustrate parallel importation was specifically emphasized by Interviewee I a representative of Salama Pharmaceuticals Limited, the defendant in the trademark case discussed in Chapter 3 above.[177] It appears therefore that for effective implementation of parallel importation in Kenya, the regulatory framework needs to be streamlined through harmonization of the relevant laws.

B. Association of parallel importation with trade in counterfeits products

The legal ambiguity has been further compounded by attempts to equate parallel imports with counterfeits. Like is the case in many jurisdictions, trade in counterfeit goods is illegal in Kenya. Lumping parallel imports together with counterfeit goods would therefore have the effect of rendering parallel importation illegal as well. This seems to be a strategy which has

[177] See *Lords Healthcare Limited v. Salama Pharmaceuticals Limited*, *supra* note 150.

been deliberately employed by those who oppose parallel importation so as to frustrate the importers. Many interviewees commented on this issue. An example is Interviewee G, a parallel importer who for example observed that:

> In recent times there has been crackdown on parallel importers due to counterfeits. People do not understand that Parallel imports are different from counterfeits. People have been commissioning the manufacture of counterfeit malaria drugs in China. These are mistaken for parallel imports merely because they are imported into the country.

It emerged also that even most professional pharmacists do not understand the difference between parallel imports and counterfeits and they therefore equate parallel imports with counterfeits.[178] The ensuing confusion poses constraint to trade in parallel imports since it discourages pharmacists from stocking parallel imports for fear of prosecution by the Pharmacy and Poisons Board.

C. Shifting policy based on changes in office holders

The ambiguity of the legal framework has also meant that the policy on parallel importation in Kenya has changed with each change of the holders of the involved offices. The key officials are the Minister for Health, the Permanent secretary in the same Ministry and the Director of Medical Services (DMS) all of whom wield immense influence over the Pharmacy and Poisons Board. Without a clear legal and policy framework, parallel importation in Kenya appears to be based on the whims and caprices of these office holders. This grim picture was more vividly presented by Interviewee I, a parallel importer as follows:

> The future of Parallel importation looks very bleak. Nyikal (this was the former DMS) was very supportive. When he left, Kimani (the current DMS) came in….he was immediately lobbied by MTCs and now he is supporting them (MTCs). The minister also

[178] Interview with Interviewee K, a pharmacist (Jan. 3, 2009)

> supports them. The Board is not doing its work. It is not independent. It is pocketed by the Minister for Health, Permanent Secretary of the Ministry of health and the DMS. Every time there is a new person in office, all gains are lost.

Similar sentiments were expressed by Interviewee G, another parallel importer who observed that, "it was much better when Mrs. Ngilu (the former Minister) was the Minister for Health. The system was transparent. With the change of guard (appointment of Anyang Nyong'o who is the current Minister for Health) things have changed." The need to establish a clear legislative and policy framework is therefore most urgent if parallel importation is to thrive in the country.

4.2.6 But has parallel importation of pharmaceutical products had any negative consequences?

Most interviewees alluded to the safety concerns raised by parallel importation which is taking place in the absence of an adequate regulatory and policy framework. Four key concerns were particularly emphasized. Firstly, there is the real possibility of counterfeit products finding their way into the country disguised as parallel imports. This possibility was confirmed by Interviewee C, a parallel importer who was however very quick to implicate briefcase parallel importers as the ones responsible for counterfeits. In his view, if parallel importation was adequately regulated, this would ward off counterfeiters.

Secondly, safety issues arise due to difficulty of recalling products by manufacturers in the event of an adverse occurrence. Interviewee B, an expert in the pharmaceutical industry stressed that pharmaceutical products should not be imported without the knowledge of the manufacturer. If so imported, should the need to recall the products arise, it would be hard for the manufacturer to trace and recall the products. Unsuspecting consumers would

therefore continue consuming products which have already been recalled for one reason or the other thereby exposing themselves to health risks.

Thirdly, there are safety issues raised by the inappropriate means of transportation and storage which is used by the importers. Interviewee H, a MTC representative, for example claimed that delicate products such as injectables, suspensions and vaccines which require refrigeration, are imported in containers which arrive in Kenya by sea in containers which are not equipped with the appropriate refrigeration system. In her view, such drugs should be stored in low temperatures. Consequently, if they are exposed to high temperatures, their active ingredients deteriorate and the drugs' efficacy is compromised.

It however seems that the parallel importers who are trained pharmacists do appreciate this safety concern. Interviewee I, a parallel importer for example responded to this particular concern in the following terms:

> For very delicate drugs, we bring them with planes especially built for transporting goods at specific temperatures. The drugs are packed in boxes with cold packs which contain ice. The cold packs can preserve the temperatures for 24 hours even without refrigeration. We also use them [the cold packs] for transporting the drugs from Nairobi to other parts of Kenya. I understand the seriousness of safety requirements.[179]

Briefcase operators who are not trained professionals or who, though trained, may nevertheless not have the financial capacity to invest in the required transport conditions cannot however be vouched for. They may not be as careful as this respondent.

Lastly, safety concerns are also raised by the mismatch between the climatic conditions in Kenya and the conditions in the source countries. Interviewee E from AstraZeneca (a MTC)

[179] This interview was conducted at the premises of the respondent [a chemist located in up town Nairobi. The respondent showed me a cold pack which was brought from a cold room located within the premises. I therefore found his assertion to be credible.

emphasized that pharmaceutical products are manufactured to the specification of a particular region, with due regard being had to the stability of the product under the specific climatic conditions. In her view, some of the drugs that parallel importers bring into the country are not suited for the tropical climatic conditions. By the time the drugs reach the end user, their efficacy could therefore be greatly compromised.

Arguably, whereas parallel importation plays a role in improving access to medicine from the economic as well as physical perspectives, it could undermine access to medicine from other perspectives such as efficacy and safety. Availability and affordability of medicine would not mean much if the medicine is not efficacious and safe for the end consumers.

4.2.7 How have the Multinational Pharmaceutical Companies (MTCs) responded to Parallel Importation?

MTCS have responded to parallel importation in various ways. These range from ignoring parallel importers; complaining about the trade; changing their market strategies; and active opposition (fighting parallel importation).

The MTCs who have ignored parallel importers are those who feel that parallel importation is not as big a business in Kenya as has been claimed. Interviewee L from Roche for example stated that, “MTCs have ignored parallel importers… they are more concerned with counterfeits… parallel importers are small players… they cannot supply the whole market…they are merely a passing cloud.” The same interviewee further claimed that parallel importation is not a big problem for Roche’s business in Kenya and the trade does not therefore bother them at all. It therefore appears that where a MTC’s products have not

been directly targeted by parallel importers, the MTC's response tended to be to ignore the trade.

The MTCs who appeared to complain were those whose products were being parallel imported. In this category were also those who were skeptical about the benefits of parallel importation. Interviewee E from AstraZeneca for example complained that, "MTCs are supplying the market fully. We have never ran out of drugs. There has never been a supply crisis. On the other hand, parallel importation is not consistent. They (parallel importers) bring only what will sell… parallel importation is very seasonal and also sporadic." This compliant does not seem to appreciate the fact that the parallel importers identify a need in the market and then swiftly move to meet such need.

To emphasize the perceived notion on the part of MTCs that parallel importation is not necessary in Kenya, Interviewee F from Sanofi Aventis insisted that:

> Parallel importation has more disadvantages than advantages. It is only acceptable under certain circumstances. Only when the drug is not available locally…on the grounds of insufficiency. But this is not usually a problem because most companies have built in mechanisms to supply the market. They have annual budgets and plans. They have a sense of what the needs are…mechanism of special import is already there under Cap 244 and so you don't need parallel importation.

The complaining MTCs also felt that parallel importers were free riding on the MTC's local investment in promoting the products. Interviewee F from Sanofi Aventis further stated that, "MTCs put together a marketing team. They invest in for example cars and promotional material for marketers. They have a promotional budget as well as labor costs. The field is

therefore not level and MTCs will be forced to pull out. The consequences will be job losses and other economic consequences."[180]

In response to parallel importation, most MTCs in Kenya have also been compelled to change their marketing strategies. Interviewee E from AstraZeneca told me:

> We are loosing almost 50% of sales on our cancer drugs. They (parallel importers) are selling our drugs at almost half price. We have therefore been forced to change our marketing strategy. Doctors are required to keep patient profiles. They also get a free pack for every 6 packs bought…We know when a container has arrived in the country because our drugs do not move and our sales fall. We then do serious marketing by bonusing (giving extra units of the product). The regional Head office in South Africa is upset. They do not think we should do hard core selling. Bonuses increase our costs since we have to buy the samples. We are however trying to save the long term relationship with the patients so we have to do this.

It seems therefore that parallel importation has forced MTCs to employ marketing strategies that they would otherwise not use if parallel importation was not permitted in Kenya.

Lastly, most MTCs have responded to parallel importation by mounting active opposition to the trade. According to Matyn Hann, parallel imports are a bit like car theft. If it is going to happen, little can be done to prevent it. He further opines that often the best that can be done is to make the parallel importer's life so difficult that he turns his attention to other products.[181] Perhaps in appreciation of this fact, MTCs have employed several strategies to fight parallel importation in Kenya, including, according to some interviewees, seeking to have parallel importation outlawed.[182]

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[180] Maskus has however argued that parallel importation does not necessarily constitute inefficient free riding. This would be for example the case where a manufacturer engages in the promotional activities itself, thereby internalizing their benefits for all authorized distributors. Where the local distributors of MTCs do not meet the cost of marketing the products in Kenya, the free riding complaint may not be valid. See Maskus, *supra* note 49, at 1280.

[181] Hann, *supra* note 51, at 628.

[182] Interviewee C was of the view that it is the MTCs who have been behind the three failed attempts to have the law amended to outlaw parallel importation in Kenya. For details of these attempts, see *supra* note 152.

Further, the parallel importers interviewed also felt that the MTCs are the ones behind the campaign to have parallel imports labeled counterfeits. They also felt that MTCs have lobbied the government to frustrate parallel importation under this guise. This combative strategy was presented by Interviewee I, a parallel importer, in the following terms

> The Board was initially very supportive but the MTCs have been persistent in fighting them (the Board members) even to the point of being accused of collaborating with counterfeiters. Parallel imports are being fought with the guise of fighting counterfeits. If an official of the Board issues an import permit to a parallel importer, they are accused of assisting counterfeiters. They (Board Members) are now afraid of signing the permits since this will be used against them… that they are the ones facilitating import of counterfeits in Kenya. The MTCs are dealing directly with the Permanent Secretary in the Ministry of Health; the Minister etc. They tell them that Parallel importers are bringing counterfeits and the Board should not issue permits. The Board members are actually scared and intimidated. It is now very difficult to get permits. Copies of the permits are taken by MTCs to the Minister and the officials are accused of supporting counterfeits. Now they are so scared. Nobody wants to sign a permit.

Active opposition appears to have yielded results. As noted above, the market supplied by parallel importers has declined from 40% to around 30%.

4.3 Use of Licensing Mechanisms

4.3.1 Is there use of Licensing Mechanisms in Kenya?

As discussed in Chapter 3, the Industrial Property Act (IPA) requires that all voluntary licenses issued by patent holders should be registered in the patents register which is maintained by the patent office, Kenya Industrial Property Institute (KIPI).[183] Similarly whenever the Industrial Property Tribunal grants a compulsory license, the Tribunal is required to instruct the Managing Director of KIPI to record the grant in the patent

[183] Under the IPA, all license contracts (voluntary licenses) should be submitted to the Institute (KIPI) for registration in the patent register. See IPA, *supra* note 120, s. 68(1).

register.[184] There is however no registration requirement for Government Use Orders. A perusal of the patent register would therefore reveal the number of issued licenses and also other vital details of these licenses.[185]

A perusal of this register revealed that no compulsory license or government use license has been registered thereon. This is consistent with the fact that no such license has been cited in existing literature. Interviewee M from KIPI indeed confirmed to me that no compulsory license or Government use order has been issued in Kenya so far.

There were however a total of six voluntary licenses entered in the register between the year 1997 (year of the earliest registration) and 2008 (year of the most recent registration). The registered licenses have been issued in various fields of technology. Only two of the licenses have been issued in the pharmaceutical field. Table 3 contains details of the two licenses issued in the pharmaceutical field. Details of the four licenses issued in other fields of technology are provided in Appendix D.

[184] See *id.*, s. 78.
[185] See *id.*, s. 46(2). The patent register is a public document and any person may inspect the register at any time during working hours

Table 3: Voluntary Licenses issued in the Pharmaceutical filed of Technology as registered with KIPI

Date of License	Licensor	Licensee	Licensed Invention or Formulation	License Fee	Exclusive or Non-exclusive	Geographical scope of License.
26/10/2004	Boehringer Ingelheim International	Cosmos Ltd.	Nevirapine*: including its salts and sad crystal forms.	5% of net sales	Non-exclusive	East African Community.
1/1/2000	Pharmavet Ltd	Cosmos Ltd	Poultry, Veterinary And Human Formulations.	4% of net sales	Exclusive	Kenya, Uganda, Tanzania, Ethiopia, Eritrea, Yemen, PTA countries, and countries in Eastern and Southern Africa.

Source: KIPI's register of Voluntary Licenses
Note*: Nevirapine is an antiretroviral drug for managing HIV/AIDS.

Interviewee M from KIPI however pointed out that there may be other voluntary licenses issued to local companies but which have not registered with KIPI. The veracity of this claim is confirmed for example by the fact that despite Cosmos Limited having been also licensed by GSK to manufacture antiretrovirals in Kenya, this license has not been registered with KIPI. In 2004, GSK licensed Cosmos to manufacture medicines containing the active agents zidovudine and lamivudine. Interviewee J who is a senior manager at Cosmos Limited confirmed the existence of this license to me.

The fact that this often quoted license is not registered with KIPI is therefore telling of the fact that there could be more voluntary licenses issued in the country. Establishing the actual number of voluntary licenses issued would therefore require further research employing a different methodology from that employed in this study. In sum, whereas no involuntary license has been issued in Kenya so far, there is some voluntary licensing activity in the

country. The precise extent of this activity is however difficult to establish with absolute certainty due to limited compliance with the requirement to register the licenses with KIPI.

4.3.2 What Factors have Promoted use of Voluntary Licensing?

As noted above, only a limited number of voluntary licenses have been issued so far. Further, the known licenses have all been issued to one company, Cosmos Limited. Consequently, the discussion under this head only draws from the experience of this company.

Interviewee J from Cosmos Limited cited the desire to supply pharmaceutical products at an affordable price thereby increasing access to medicine in the country as the main factor that motivated the company to seek voluntary licenses. Regarding the licenses to manufacture antiretroviral drugs for example, he stated that:

> At the time we applied for the licenses, there were close to 2 million people reported to be HIV positive in Kenya and the number was increasing. Less than 0.5% of them were accessing the branded medicine. Even now the access is still not 100%. Cosmos is the leading local pharmaceutical manufacturer in East and Central Africa. We knew we had capacity to manufacture the drugs locally. Availing the product (the antiretroviral drugs) at an affordable price was our greatest motivation.

Although this is a for profit private sector company, it seems that the desire to increase access to medicine is a major factor which has propelled the company to seek licenses for local manufacture of pharmaceutical products. However, since most private companies are usually profit-minded, the desire to make profits, though not cited by the interviewee, cannot also be ruled out.

4.3.3 What factors constrain use of voluntary and involuntary licensing mechanisms in Kenya ?

Given the limited amount of voluntary licensing and absence of involuntary licensing, the discussion under this head will focus on both forms of licensing. I will discuss each of the factors reported by the interviewees in turn.

A. Insufficient manufacturing capacity

It appears from the interviews that only about three local manufacturing companies possess sufficient manufacturing capacity. This figure was obtained from Interviewee L from Roche (a MTC). She informed me that some time ago, Roche was keen to license the manufacture of one of its products to local companies. After assessing the manufacturing capacity of local companies, only three of them were found to possess the requisite capacity to manufacture Roche's product. In the interviewee's words:

> During the height of the HIV/AIDS crisis, Roche was trying to do technology transfer to empower them (local companies) with capacity to produce Saquinavir (an antiretroviral drug by Roche). We approached a number of companies to assess their capacities to produce the drug. Three companies had sufficient capacity but the cost of production turned out to be high and the companies did not pursue the licenses.

Many other interviewees reported insufficient manufacturing capacity as the most significant factor which has constrained licensing activities in the Kenyan pharmaceutical industry.

B. High cost of production

It is clear from the above excerpt from the interview with Interviewee L that even where companies possess sufficient manufacturing capacity, the high cost of production of pharmaceutical products operates as a disincentive to companies which may desire to take out licenses. Interviewee M, the Managing Director of a local generic manufacturing

company which has never sought a voluntary license to manufacture on-patent drugs observed that the most expensive elements are usually the cost of raw materials such as active ingredients and excipients.[186]

In his view, whereas manufacturers of generic products are also faced with the same challenge, license fees would increase the cost of manufacturing on-patent drugs thereby rendering it less viable, when compared with generic products. Without incentives specifically targeted towards lowering the cost of local production in general, it seems that licensing mechanism will not be a viable strategy for increasing access to pharmaceutical products in Kenya.

C. Small market size

The small size of the Kenyan market for pharmaceutical products was also cited as a major constraint to local manufacture of the products under license. Undoubtedly, the small size of the market is an impediment to local manufacture of generic medicines as well. However, as already explained above, license fees increase the cost of manufacturing on-patent drugs. To recoup the cost, manufacturers have to increase the price per unit or in the alternative, sell high quantities of the products and rely on economies of scale. With a small market, the latter option is not available.

On this issue, Interviewee M, a representative of a local generic manufacturing company observed that, “the Kenyan market is too small. If there was a population of 200 million people, then it would make economic sense to manufacture under license.” In deed, Interviewee J from Cosmos Limited confirmed that when the company was negotiating its

[186] See *supra* note 90 for a definition of excipients.

voluntary licenses, they insisted on an expanded market to include not only Kenya but also other neighboring countries.[187] Without the ability to supply these other countries, the license would not, in his view, have made any economic sense.

D. Stringent Licensing Preconditions

Local companies are required to meet certain stringent preconditions before they can be licensed by the MTCs. This was cited as a key constraint to voluntary licensing. To elaborate on the scope of these preconditions, Interviewee J from Cosmos Limited stated:

> In the license there will be terms and conditions on what you can or cannot do. The active ingredient must for example be the same or at least therapeutically bioequivalent. When it comes to excipients for example starch, cellulite, gum etc, these you can vary. You can for example use the best binder available, of course depending on costs… cGMP (Current Good Manufacturing Practices) is a very stringent criteria for licensors. They must match the licensors. They (the licensors) always insist on certain minimum requirements before licensing.

Given the low levels of manufacturing technological capacity in the sector, the local companies' ability to comply with especially the cGMP is in doubt. cGMP are international quality assurance standards[188] which are enforced locally by the Pharmacy and Poisons Board. They were repeatedly cited as the most stringent of these preconditions and thus, one of the key constraints to voluntary licensing. Interviewee M from a local generic manufacturing company which has never sought a license elaborated on the reason why local companies find it difficult to comply with cGMP:

> Complying with cGMP standards is a very expensive exercise. It needs high investment. Companies are trying to comply but it is very difficult. Most local companies will never attain these standards. The high cost of cGMP compliance in turn leads to high cost of locally manufactured drugs since the cost has to be passed

[187] See Table 3 above.
[188] See Roy Widdus, *Product Development Partnerships on 'Neglected Diseases': Intellectual Property and Improving Access to Pharmaceuticals for HIV/AIDS, Tuberculosis and Malaria*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES, 234 (Pedro Roffe *et al*., eds., 2006).

> on to the consumer. Besides, unless you want to supply the drugs to the government, why bother?

Interviewee B, a local expert on the pharmaceutical industry further observed that:

> If local companies follow cGMP, the cost of production in Kenya will be very high. It therefore does not make business sense to go into local manufacture if one intends to comply with the cGMP standards. I recently conducted a study. Out of the 30 or so registered pharmaceutical companies in Kenya, only three met the cGMP standards. About six others had potential but for the rest, there is no hope.

Without any hope of most of the companies adopting GMPs, it seems that voluntary licensing in Kenya will remain significantly constrained.

E. Inability to supply the Government due to lack of WHO prequalification

Failure to comply with cGMP in turn leads to inability to supply the government in those instances where the government is seeking to purchase products using funds obtained from multilateral and bilateral donors such as the Global Fund to fight AIDS, Tuberculosis and Malaria[189] and United State President's Emergency Plan for AIDS Relief (PEPFAR)[190]. All medicines supplied under these funding schemes must be pre-qualified by the World Health Organization.

To be so pre-qualified, the manufacturers must comply with the WTO's version of cGMP. Interviewees B, a local expert and J (from Cosmos Limited) confirmed to me that no local pharmaceutical company has been WTO pre-qualified. This means that even the antiretroviral drugs manufactured by Cosmos Limited under license can only be supplied to the government in the instances where the government is using its own budgetary allocation

[189] This is an international global public/private partnership established in 2002. It is dedicated to attracting and disbursing resources to prevent and treat HIV/AIDS, malaria and Tuberculosis. Kenya is one of the fund's beneficiaries.
[190] See supra note 72 for a description of PEPFAR.

to make the purchases. This reduces the amount of locally manufactured drugs purchased by the government, thereby further eroding the viability of local production of medicines under license.

Concluding Summary

Although implementation of both mechanisms through use appears to be significantly constrained in Kenya, the mechanism of parallel importation appears to have thrived more than licensing mechanisms. In the Concluding Chapter, I suggest a possible explanation for this outcome.

5. CONCLUSION AND RECOMMENDATIONS

This study set out to establish whether the mechanisms of parallel importation and licensing are in use in Kenya, the factors that influence the use or non-use of these mechanisms and the ways in which use of the mechanisms, if any, has impacted the patent right holders in the country. The overall objective was to inquire into the experience that Kenya has had in implementing these mechanisms for purposes of improving access to medicines.

As is clear from the discussion in Chapter four, although the mechanisms are in use, parallel importation appears to have thrived more than licensing. Regarding licensing, whereas there is some limited voluntary licensing, not a single involuntary license has been issued so far. Both the extensive use of parallel importation and the limited use of voluntary licensing appear to be promoted by the desire to increase access to medicines as well as by the pursuit of profits. Most fundamentally, there still remain significant challenges to the effective implementation of both mechanisms as highlighted in Chapter four of the paper. Kenya's experience therefore reveals the immense difficulties that similarly situated countries would face in implementing these mechanisms.

To achieve the desired goal of increasing access to medicines, the mechanisms of parallel importation and licensing must not only be incorporated into the domestic law but also implemented through use. Kenya has taken the initial step of incorporating these mechanisms into the patent law. In relation to parallel importation, there is also some attempt at developing policy guidelines. Other relevant laws such as Trademarks Act and the Pharmacy and Poisons Act have however not been amended to make provision for this trade. As seen in Chapters three and four, parallel importation is driven by the factors of demand, supply and

potential for profit making. Save for adequate legislative action and policy guidelines, parallel importation may therefore require, arguably, minimal further involvement on the part of the government for it to thrive. Though constrained, parallel importation is therefore still taking place in Kenya.

On the other hand, in relation to licensing mechanisms, whether voluntary or involuntary, the constraints revealed in Chapter four indicate that legislative action alone is not sufficient for the use of these mechanisms to thrive. Other incentives are also necessary. Examples include: (a) in relation to the constrain posed by the small market size for example, there may be need for the government to pursue efforts towards regional market integration so as to increase size of the market to be served by local manufacturers; (b) regarding high production costs, incentives such as a favorable tax regime for imported raw materials and other factors of production would be required so as to render local production of on-patent drugs under license viable; and (c) in relation to cGMPs and WHO prequalification, subsidies or soft loans may be offered to companies to help them make the necessary investments.

The overall conclusion drawn from this study is therefore that for effective implementation of the mechanisms, creating an enabling legislative and policy framework is merely the critical first step. This framework needs to be not only adequate but also followed up with more deliberate intervention on the part of the government. Due to the limited scope of this study, it is however not possible to make well informed suggestions on the specific ways in which the government could intervene. Further research in this regard is therefore called for to assess the viability of the available incentive options.

APPENDIX A: LIST OF INTERVIEWEES

No.	Designation	Institution	Category
1.	Interviewee A	KIPI	Regulator
2.	Interviewee B	PharmaQ Limited	Expert
3.	Interviewee C	KPDA	Parallel importer
4.	Interviewee D	Njimia Pharmaceuticals Ltd	Parallel Importer
5.	Interviewee E	AstraZeneca	MTC
6.	Interviewee F	Sanofi Aventis	MTC
7.	Interviewee G	- *	Informal parallel Importer
8.	Interviewee H	GlaxoSmithKline	MTC
9.	Interviewee I	Salama Pharmaceuticals Limited	Parallel Importer
10.	Interviewee J	Cosmos Limited	Local Manufacturer
11.	Interviewee K	Surgipham Pharmaceuticals	Parallel Importer
12.	Interviewee L	Roche	MTC
13.	Interviewee M	Biodeal Pharmaceuticals Ltd	Local Manufacturer
14.	Interviewee N	KIPI	Regulator
15.	Interviewee O	Kenya Medical Supplies Agency	Public Pool Procurement Agency
16.	Interviewee P	Mission For Essential Medicines	Private Pool Procurement Agency
17.	Interviewee Q	Elys Chemicals Limited	Local Manufacturer
18.	Interviewee R	Pharmacy and Poisons Board	Regulator
19.	Interviewee S	Universal Pharmaceutical Co.	Local Manufacturer
20	Interviewee T	Omaera Pharmaceuticals	Parallel Importer

Note: * This interviewee was not affiliated to any institution.

The Designations were allocated chronologically. Interviewee A was therefore the first respondent to be interviewed while Interviewee T was the last to be interviewed.

APPENDIX B: INTERVIEW PROTOCOL FOR PARALLEL IMPORTERS AND LOCAL MANUFACTURERS

PART I: COMPANY INFORMATION

1. How long has the company been in operation

2. What is your company involved in: manufacture only; distribution only; manufacture and distribution; other?

3. For manufacturing companies, how would you describe the sufficiency of manufacturing capacity of your company

PART II: AWARENESS OF PARALLEL IMPORTATION AND INVOLUNTARY LICENSING MECHANISMS

4. Are you aware that pharmaceutical companies are allowed to import patented drugs into Kenya from countries where they are sold cheaply and to sell them in Kenya in competition with the drugs sold by the patent right owner?

5. If yes, is there a general awareness of this information within the company?

6. Are you aware that local pharmaceutical companies in Kenya can apply to the Government for a license to manufacture a patented drug without obtaining permission from the patent right owner?

7. If yes, is there general awareness of this information within the company

PART III: USE OF THE MECHANISMS OF PARALLEL IMPORTATION AND INVOLUNTARY LICENSING

A. INVOLUNTARY LICENSING

8. Does your company supply drugs to the government?

9. Has your company ever applied to the government for a license to manufacture a drug without the consent of the patent right owner?

10. If yes, how many times?

11. If yes, what are the factors that made you decide apply for the license

12. If no, what are the factors that best explain the reason why the company has not applied for such a license

B. PARALLEL IMPORTATION

13. Does your company import drugs into Kenya from other cheaper sources even when the drug is already being distributed and marketed in Kenya by the patent right owner?

14. If yes, please indicate the main types of drugs that are usually imported

15. If yes how would you describe the importation trend in your company in the last 6 years: Increasing; decreasing; or not changing

16. If yes, please indicate the factors that motivate the company to engage in the importation of drugs

17. If no, please indicate the factors which have de-motivated the company from importing drugs into Kenya from cheaper sources

PART III GOOD MANUFACTURING PRACTICES AND WHO PRE-QUALIFICATION

(The questions in this section are only applicable to manufacturing companies)

18. Is your manufacturing process certified as a "Good Manufacturing Process"

19. Are your drugs WHO pre-qualified?

APPENDIX C: INTERVIEW PROTOCOL FOR GOVERNMENT AGENCIES AND POOL PROCUREMENT AGENCIES

I KENYA INDUSTRIAL PROPERTY INSTITUTE (KIPI):
COMPULSORY LICENSING

- How many compulsory licenses have been registered with KIPI
- How many voluntary licenses have been registered with KIPI
- is there sufficient or insufficient use of the mechanisms of compulsory licensing in Kenya
- What factors have influenced the use or non-use of the mechanism
- Is there need to encourage use of this mechanism
- How can the use of this mechanism be encouraged?
- Any other relevant information

II MINSIRTY OF HEALTH
GOVERNEMENT USE ORDER

- How many applications have been made for this order
- Cosmos Pharmaceutical Company applied for a Government use Order in they year 2003 which was withdrawn after a voluntary license was successfully negotiated with the patent holder. Is there a deliberate government policy to encourage use of voluntary licenses instead of making government use orders or compulsory licenses
- Has this mechanism been sufficiently used?
- Is there need to encourage use of this mechanism
- What factors have influenced the use or non-use of the mechanism
- How can the use of this mechanism be encouraged
- Any other relevant information

II POOL PROCUREMENT AGENCIES

1. **KEMPSA**- Public Agency which procures drugs for public hospitals
2. **MEDS**- Private Agency which procures drugs for use by hospitals owned by Christian (church) based Organizations

PARLLEL IMORTAITON

- Does the Agency obtain drugs through parallel importation
- What is the frequency of use of the mechanism
- What is the trend of use (increasing, decreasing, stagnant)
- What are the factors that influence use or non-use of the mechanism
- Is there need to encourage use of the mechanism
- How can use of the mechanism be encouraged
- Any other relevant information

APPENDIX D: LICENSES ENTERED IN THE PATENT REGISTER BUT WHICH WERE NOT ISSUED IN THE PHARMACEUTICAL FIELD OF TECHNOLOGY

NO.	Date of License	Licensor	Licensee	Licensed invention/ Formulation	Royalty Rate	Exclusive or non-exclusive	Geographical scope of License.
1	25/7/2008	Corn Products International.	Corn Products Kenya Ltd	Starch-hemicellulose adhesive for high speed corrugating.	3% of the net sales of the licensee.	Non exclusive	Kenya.
2	2/1/87	Establishment International TEAL	A.I. Records Kenya Ltd.	phonographic disc records , cassettes and cartridges (master recordings)	100% of the net sales.	exclusive	Kenya, Uganda and Tanzania.
3	3/4/97	Colgate Palmolive Co. USA.	Colgate Palmolive East Africa	Cockroach Repellant Toothbrush.	4% of gross sales	exclusive	Kenya, Comoros, Djibouti, Ethiopia, Lesotho, Malawi, Mauritius, Somalia, Swaziland, TZ, UD.
4	26/8/96	BAT England	BAT Kenya	Trademarks in Connection with the manufacture of brands of cigarettes and other tobacco products	USD 1 per thousand units sold.	Non-exclusive	Somalia, Rwanda and any other country which may be added to the agreement.

Source: Kenya Industrial Property Institute's Licenses Register.

APPENDIX E: PATENT STATUS OF SOME ESSENTIAL DRUGS IN KENYA

Generic Name	Kenya Patent Number	Protection of:	Filing Date in Kenya	Expiry Date in Kenya	Patent Status in Kenya
Acyclovir	KE3002	Basic Substance	02/09/79	02/09/95	expired
	AP 160	new Composition and use	10/08/88	10/08/08	expired
azithromycin	AP44	new form	15/06/88	15/06/08	expired
	AP566	new dosage form	06/04/95	06/04/15	in force
ceftriaxone	KE3268	substance patent	29/03/83	30/05/99	expired
ciprofloxacin	KE3545	basic substance	19/06/85	21/08/01	expired
fluconazole	KE3771	basic substance	29/09/87	22/04/02	expired
	KE3867	new process	16/02/84	16/02/04	expired

Source: Robert Lewis-Lettington & Peter Munyi, *Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study*, (2004) available at http://www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf.

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