

**UTILIZING THE WTO-TRIPS FLEXIBILITIES ON PUBLIC HEALTH AT A
REGIONAL LEVEL: A CRITICAL REVIEW OF THE EAST AFRICAN COMMUNITY
FRAMEWORK**

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Declaration

I declare that this Mini-Dissertation which is hereby submitted for the award of Legum Magister (LL.M) in International Trade and Investment Law in Africa at the International Development Law Unit, Centre for Human Rights, Faculty of Law, University of Pretoria, is my original work and it has not been previously submitted for the award of a degree at this or any other tertiary institution.

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28 April 2014

Abstract

The East African Community (EAC) states recently adopted a policy on utilising the WTO-TRIPS flexibilities on public health. The policy spells out a number of flexibilities and the minimum standards thereof to be enacted in domestic legislation. This study critically reviews this policy. In doing this, the study notes that the EAC member states, like most developing states, have very low per capita income levels. The people are too poor to afford expensive medicines. At the same time, these countries are faced with peculiar, region-specific diseases, the so-called ‘African diseases.’ Already, these diseases have been neglected by foreign pharmaceuticals reluctant to invest in developing medicines for poor markets. There are no established pharmaceuticals in the EAC states.

It is against this background that this research makes an argument against the aforementioned policy. It will be demonstrated that the policy is biased towards ensuring access to medicines through price-reduction, at the expense of patent protection. This approach is inappropriate because: first, given the absence of market incentives to invest in developing medicines for African diseases, the policy will only worsen the already bad situation since it undermines the strongest alternative incentive (patent protection); and second, such a policy will not only discourage foreign pharmaceuticals further but also suppress domestic pharmaceutical activity, which is undoubtedly necessary in view of the growing neglect of African diseases by foreign pharmaceuticals.

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List of Acronyms

| | |
|-------|--|
| ARIPO | African Regional Intellectual Property Office |
| BIRPI | United International Bureaux for the Protection of Intellectual Property |
| CAPs | Collective Action Problems |
| EAC | East African Community |
| INN | International Non-proprietary Name |
| IP | Intellectual Property |
| IPRs | Intellectual Property Rights |
| LDCs | Least Developed Countries |
| MRAs | Medical Regulatory Authorities |
| NE | Nash Equilibrium |
| TRIPS | Agreement on Trade Related Aspects of Intellectual property |
| UNDP | United Nations Development Programme |
| WIPO | World Intellectual Property Organisation |
| WTO | World Trade Organisation |

Directory of Cases

Asahi Kasei Kogyo [1991] RPC 485

Canada – Patent Protection of Pharmaceutical Products WT/DS114/R 17 March 2000

Valensi v British Radio [1973] R.P.C. 337

WTO Appellate Body Report, United States-Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (12 October 1998)

List of Treaties and Instruments

Berne Convention for the Protection of Literary and Artistic Works 1886 (revised Paris 1971)

Decision on the General Council on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health WT/L/540 and Corr.1 1 September 2003

Doha Declaration on the TRIPS Agreement and Public Health WT/MIN (01)/DEC/2 20 November 2001

Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, legal instruments—results of the Uruguay round volume 1, 33 I.L.M. 1125 (1994)

Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Industrial Property Organization (adopted on 10 December 1982)

Paris Convention for the Protection of Industrial Property 1883 (revised, Stockholm 1967)

The Decision of the Council for TRIPS of 27 June 2002 on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for certain Obligations with Respect to Pharmaceutical Products IP/C/25 1 July 2002

The East African Community Health Protocol on Public Health Related WTO-TRIPS Flexibilities

The Patent Cooperation Treaty (19 June 1970) 1160 UNTS

The Patent Law Treaty (1 June 2000) 2340 UNTS

The Protocol on the Establishment of the East African Community Common Market

The Regional Intellectual Property Policy on the Utilisation of Public Health-related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation

Treaty Establishing the East African Community (30 November 1999) 2144 UNTS 255

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CHAPTER ONE

1.1 Introduction

Tensions often arise between the need to protect intellectual property rights (IPRs) on the one hand, and on the other, the need to ensure that users of the commodities in which IPRs are embedded access them on the market affordably.¹ This is because the protection of IPRs leads to monopolization which results into higher market prices because there is no competition.² Undeniably, in no other area are these tensions more evident than in the relationship between patents and access to medicines.³ It is no wonder therefore that in August 2000, the United Nations Commission on the Promotion and Protection of Human Rights adopted a resolution declaring that ‘there are apparent conflicts between the TRIPS regime, on the one hand, and human rights (including the right to health) on the other.’⁴ The problem is particularly acute in developing countries which are not only plagued with high levels of poverty but also myriad of diseases.⁵

There have been attempts to ensure that patents do not block access to medicines. The most notable of these are the ‘WTO-TRIPS flexibilities.’⁶ The East African Community (EAC) countries recently adopted a policy (hereafter, the Policy) as a regional roadmap to guide EAC

¹ M Boldrin & DK Levine ‘Does intellectual monopoly help innovation?’ (2009) 5:3 *Review of Law and Economics* 991.

² L Forman ‘Trade rules, intellectual property, and the right to health’ (2007) *Ethics and International Affairs* 337 339.

³ LR Helfer & GW Austin *Human rights and intellectual property mapping the global interface* (2014) 90; Duncan Matthews ‘Intellectual property rights, human rights and the right to health’ in W Grosheide (ed) *Intellectual property rights and human rights: A paradox* (2009) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1414900 (accessed 10 December 2013).

⁴ Quoted in S Sterckx ‘Patents and access to drugs in developing countries: An ethical analysis’ (2004) 4 *Developing World Bioethics* 59; P Cullet ‘Patents and medicines: The relationship between TRIPS and the human right to health’ (2003) 1 *International Affairs* 79 160.

⁵ CF Wu ‘Transnational pharmaceutical corporations’ legal and moral human rights responsibilities in relation to access to medicines’ (2012) 7 *Asian Journal of WTO & International Health Law & Policy* 77 79; A Grover *et al* ‘Pharmaceutical companies and global lack of access to medicines: Strengthening accountability under the right to health’ (2012) *Journal of Law, Medicine & Ethics* 234; S Lucyk ‘Patents, politics and public health: Access to essential medicines under the TRIPS Agreement’ (2006) 38 *Ottawa Law Review* 193.

⁶ AG Watson ‘International intellectual property rights: Do TRIPS’ flexibilities permit sufficient access to affordable HIV/AIDS medicines in developing countries?’ (2009) 32 *Boston College International & Comparative Law Review* 143.

member states in utilizing the WTO-TRIPS flexibilities.⁷ The overall objective of the Policy is stated as being:

...to guide the EAC Partner States on how their national intellectual property legislation must be adjusted in order to enable them to fully utilise the Public Health-related WTO-TRIPS Flexibilities. It provides a comprehensive ‘road map’ of how the latter can facilitate optimization of the populations’ access to health and other health-related products. It further identifies the lowest common denominator of intellectual property legislation that can be approximated across all the EAC Partner States.⁸

This research is a critical review of the Policy. The various instruments encompassed in the Policy are assessed in terms of their potential effectiveness in striking the delicate yet necessary balance between protecting patents and ensuring access to medicines in the EAC member countries. Importantly, access to medicines is understood not only to mean the medicines are financially affordable, but also that the medicines are physically available.⁹ This understanding is crucial because there is the real risk of policy makers crafting policies biased towards ensuring financial affordability of the medicines without securing their physical availability. This study will demonstrate that the Policy suffers from this shortfall.

There are some preliminary points to note. The first is that patents are one of the main forms of intellectual property.¹⁰ As it will be shown in subsequent parts, patent protection is considered necessary for a number of reasons. Key among them is that patent protection encourages new inventions.¹¹ Patent protection, it is also argued, encourages inventors to disclose their inventions.¹² Individuals, it is said, will be more willing to invest in inventive research and disclose their inventions if they are guaranteed that the inventions will be protected until they recoup their research investments. The logic is that when people gain from their research and inventions, they would have the incentive to conduct further research, invent more and

⁷The Regional Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (hereafter the Policy) <http://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf> (accessed 10 October 2013).

⁸ The Policy (n 7 above) para 2.3.

⁹ H Adila *et al Health and democracy* (2007) 436.

¹⁰ Sterckx (n 4 above) 59.

¹¹ SK Sell ‘TRIPS-plus free trade agreements and access to medicines’ (2007) 28 *Liverpool Law Review* 41 43.

¹² F Machlup & E Penrose ‘The patent controversy in the nineteenth century’ (1950) 10 *Journal of Economic History* 1 25.

disclose.¹³ Therefore, the protection of the rights of patent holders would ensure access to medicines in the sense of the physical availability of the medicines. This, as will emerge later, is the utilitarian justification of patents.¹⁴

This argument for patent protection is almost unassailable. This is until other consequences of patent protection are considered in their own right. One of these consequences is central to this research: the contention that patents also hinder access to medicines. The argument is that patents have the effect of raising the prices of drugs as patent holders effectively have a monopoly in the market.¹⁵ There is no competition at least for the term of the patent and this translates into higher prices.¹⁶ Even then, it is crucial to appreciate that patents are not the only hindrance to access to medicines because ‘even cheap generic drugs may not be affordable for people below the poverty line.’¹⁷ What is not in doubt is that patent protection enables the patent-holder to limit the supply of medicines in the market. In terms of the law of demand and supply, limited supply leads to higher prices. This is especially true for medicines whose demand, in economic terms, is inelastic.¹⁸ The demand for commodities is inelastic if it remains constant despite price increases. The demand is inelastic because the commodities are necessities.

This situation creates a difficulty. Governments have to ensure their citizens can afford essential medicines while patents need to be protected. If patents are not protected, innovation would be stifled. There would be no more (new) medicines. The tension between these is thus obvious. Indeed, there ‘...is a significant tension between the pharmaceutical industry’s aim to recoup its investments and governments’ interest to contain the cost of healthcare.’¹⁹ The WTO-TRIPS flexibilities were the response to this tension. These, generally speaking, are an attempt to make the ‘patent system more health friendly.’²⁰ It is incumbent upon states to fashion legal regimes

¹³ J Watal ‘Access to essential medicines in developing countries: Does the WTO TRIPS Agreement hinder it?’ (2000) *Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, MA, USA* 3.

¹⁴ See chapter two below.

¹⁵ JA Harrelson ‘TRIPS, pharmaceutical patents, and the HIV/AIDS crisis: Finding the proper balance between intellectual property rights and compassion’ (2001) 7 *Widener Law Symposium Journal* 175 187; Watal (n 17 above) 2.

¹⁶ Forman (n 2 above).

¹⁷ Cullet (n 4 above) 143.

¹⁸ Adila *et al* (n 9 above) 440.

¹⁹ Cullet (n 4 above) 142.

²⁰ As above.

that would serve the dual purpose of ensuring access to essential medicines while protecting the rights of patent-holders. The overarching argument in this study, however, is that the Policy evinces a bias towards ensuring financial affordability of medicines at the expense of patent protection.

From the outset, it is critical to appreciate the rather unique place of developing and least developed countries (LDCs) like the EAC member states. This uniqueness lies first, in the fact that these countries, as mentioned above, are the most devastated by both disease and poverty.²¹ This means that while there is a greater need for medicines, the population can hardly afford.²² This scenario would seem to justify the adoption of a policy biased towards availing medicines at a reduced cost. However, the second facet of the unique place of these countries militates against such a strategy. This facet is that these countries lack the capacity to manufacture medicines.²³ Most of the pharmaceutical companies supplying medicines to these countries are foreign based, mainly western.²⁴ Already, these pharmaceuticals, due to commercial considerations, neglect investing in developing medicines for diseases rampant in developing countries.

1.2 Statement of the problem

The problem that this research highlights is that the Policy does not strike the necessary balance between patent protection and ensuring access to medicines. The Policy as currently spelt leans heavily towards enhancing access to medicines through price reduction at the expense of patent protection. This is notwithstanding the fact that patent protection is necessary to spur invention and therefore, secure the availability of medicines.

The handicap of the Policy as shall be demonstrated in this study is that some of the policy tools, while perhaps bearing the potential to make medicines affordable, will yet hinder further research and invention which is necessary to ensure availability of medicines. The problem is aggravated by the fact that pharmaceuticals, due to commercial considerations, have already ignored investing in developing medicines for diseases predominant in African countries.

²¹ Wu (n 5 above).

²² Forman (n 2 above).

²³ C Tuosto 'The TRIPS Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences' (2004) 26:12 *European Intellectual Property Review* 542 543.

²⁴ T Aplin & J Davies *Intellectual property law: text, cases, and materials* (2013) 551.

1.3 Research questions

This research seeks to answer the following five questions:

1. What is the rationale for the protection of patents and what is the international framework for their protection?
2. What are the WTO-TRIPS flexibilities and what is their justification?
3. How does the EAC Policy exploit the WTO-TRIPS flexibilities?
4. What are the identifiable shortcomings in the EAC Policy?
5. In what ways can the EAC Policy be made more effective in promoting the utility of the WTO-TRIPS flexibilities and access to medicines?

1.4 Thesis statement

The central argument in this study is that the Policy does not strike a balance between patent protection and ensuring access to medicines. These two competing needs are mutually reinforcing: Protecting patents is necessary to foster research and ensure availability of medicines, thereby promoting access to the medicines. The Policy does not achieve this crucial balance because it is biased towards reducing the prices of medicine at the expense of patent protection. There is therefore need to review and reconstruct the Policy.

1.5 Justification

This research is important in two main ways. First, it is important for those in the academia with interest in the wider field of patent protection and access to essential medicines. Those with interest in the utilization of the WTO-TRIPS flexibilities generally and from a regional angle may also find this study beneficial. The study aims to provide an insight that would add to the existing knowledge-base in this field and hopefully motivate further research.

Second, this research should be useful to policy makers. In particular, policy makers interested in utilizing the WTO-TRIPS flexibilities, either generally or at a regional level, may find it helpful. As a critical review of the Policy, this research identifies shortcomings that need to be addressed. It also proposes ways through which these shortcomings might be addressed. Policy makers could therefore draw useful lessons that could be used to reshape the Policy and similar frameworks, to make them more effective.

1.6 Preliminary literature review

Many authors have over the years written much about the interplay between patents and access to medicines. There are many views on the relationship between these two just as there are many authors. However, this investigation is distinct and novel in the sense that it is a specific review of the EAC Policy. The existing literature is extensively reviewed to lay the basis for a critical review of the Policy. The study agrees with the views espoused by some of the literature. It also diverges from the points of view that others have posited. Arguments are given to justify the concurrence or divergence.

For purposes of this review, the literature is considered from a number of angles. The first set of literature considers the theory of patent protection. This is the literature that explains the various justifications for patent protection. The second set is concerned with the international framework for patent protection. Essentially, this is the literature that reviews the WTO-TRIPS Agreement and the related instruments. The next set of literature to be reviewed is that on the relationship between patent protection and access to essential medicines. This will be succeeded by literature that considers the various mechanisms that have been put in place to ensure that patents do not hinder access to essential medicines, that is, the WTO-TRIPS flexibilities. The last set to be reviewed will be what constitutes the EAC framework on IP protection and access to essential medicines.

Why is it necessary to protect patents? There seems to be a point of consensus on the answer to this question. This point is that while the justification of patents broadly follows John Locke's natural rights theory or Jeremy Bentham's utilitarianism argument, neither of the theories is impeccable.²⁵ John Locke and his followers, like Hegel, espouse the notion that patent protection is justifiable because persons have a natural right to the fruits of their labour.²⁶ While Hegel modifies the trajectory taken by Locke by justifying IPRs on the basis of personality, the common denominator in their arguments is that focus is on the natural rights of the person.²⁷ Sigrid Sterckx aptly captures the logic of the naturalists when he states that patents are protected

²⁵ n 24 above, 24.

²⁶ J Locke *The second treatise on government* (1690); J Hughes 'The philosophy of intellectual property' (1988-89) 77 *Georgetown Law Journal* 287 330.

²⁷ As above.

because ‘man has a natural right to his ideas and consequently that society is obliged to enforce that right.’²⁸

Then there are those of the utilitarianism theory. Their thrust is that the protection of IPRs is an incentive for further research and innovation. Susan Sell notes that ‘[t]he rationale for intellectual property rights is that they provide incentives for the creation and dissemination of innovation. Without the compensation made possible by intellectual property rights, public goods will be underprovided.’²⁹ This is the opinion of Philip Cullet and Carlos Correa as well.³⁰ Sterckx explains this justification as being two-limbed: that patents give the incentive to invent and the incentive to disclose an invention.³¹ Utilitarianism has been widely considered as the most persuasive philosophy of IPRs protection.³²

What this study will share with the authors above is that patent protection not only incentivises inventions but that it also *ipso facto* ensures the physical availability (supply) of the invented commodities on the market.

TRIPS is undoubtedly the first most comprehensive international instrument on IPRs protection. Zinatul Zainol *et al*, retrace the origins of TRIPS and consider the various arguments explaining the birth of TRIPS.³³ This is the tangent that Bryan Mercurio and Alexander Watson also take. Additionally however, Mercurio correctly observes that:

...TRIPS establishes minimum international standards and attempts to strike a balance between the short-term objective of providing access to life-saving medicines and the long-term objective of encouraging and providing incentives to the pharmaceutical industry for the development of new medicines.³⁴

Alexander Watson also highlights the general tension over TRIPS. The tension is between developed countries who argue that in fact TRIPS is too lenient in the protection of IPRs; and developing countries who consider TRIPS as an imposition of Western values (in the context of

²⁸ Sterckx (n 4 above) 62.

²⁹ Sell (n 11 above) 43.

³⁰ Cullet (n 4 above) 140; CM Correa ‘Pharmaceutical innovation, incremental patenting and compulsory licensing’ (2011) 41 *South Centre Research Paper* 2.

³¹ Sterckx (n 4 above) 66.

³² As above.

³³ ZA Zainol *et al* ‘Pharmaceutical patents and access to essential medicines in sub-Saharan Africa’ (2011) 10 *African Journal of Biotechnology* 12376 12377.

³⁴ B Mercurio ‘TRIPS, patents, and access to life-saving drugs in the developing world’ (2004) 8:2 *Marquette Intellectual Property Law Review* 211 217.

the fact in most developing countries, knowledge was in fact shared freely).³⁵ The argument in this research is that TRIPS, if properly used, could be a boon for developing countries.

Existing literature reveals two divergent views on the relationship between patents and access to medicines. There are those who argue that patents increase the cost of, thereby hindering access, to essential medicines. The writings of Ellen F M't Hoen; Tenu Avafia and Savita Mullapudi Narasimhan; Germán Velásquez and Phillip Cullet are just but a sample of those that advance this view.³⁶ The common thread that runs through these writings is that patents increase the cost of medicines and hinder access by that very fact.

Others argue that there is no empirical evidence that the existence of patents hinders access to medicines. They in fact argue that there are many other factors that affect access to medicines. These, they call, non-patent factors.³⁷ The writings that bring to the fore these arguments include those by Zainol *et al* and Susan K Sell.³⁸ Jayashree Watal also notes that '[t]here are few reliable estimates of differences in prices of medicines in developing countries, on account of patents alone.'³⁹ It is argued that even drugs that are off-patent or '...cheap generic drugs may not be affordable for people below the poverty line.'⁴⁰

This study cannot compensate for the lack of credible research on the actual relationship between patents and the price of medicines. Rather, the discussion will proceed from non-contested facts: that patents create a monopoly, that in monopoly prices are usually higher than in competitive markets; that patent protection has the potential of encouraging research and invention; that research and invention are the way to ensure availability of medicines and lastly, that generic

³⁵ Watson (n 6 above) 149.

³⁶ EF M'T Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' (2002) 3 *Chicago Journal for International Law* 42; T Avafia & SM Narasimhan 'The TRIPS Agreement and access to ARVs' (2006) *United Nations Development Programme* 3; Germán Velásquez 'The right to health and medicines: The case of recent negotiations on the global strategy on public health, innovation and intellectual property' (2011) 2 *South Centre Research Paper* 6; Cullet (n 4 above) 143.

³⁷ Zainol *et al* (n 33 above) 12377.

³⁸ As above; Sell (n 11 above) 45.

³⁹ Watal (n 13 above) 3.

⁴⁰ Cullet (n 4 above) 143.

drugs increase competition and thereby lower the price of medicines.⁴¹ Indeed, despite the divergent views highlighted above, a review of the literature on both sides reveals the modal argument that patent protection encourages research and invention and that generic drugs lead to lower prices of medicines because of competition.

The WTO-TRIPS flexibilities encompass a number of policy instruments that states may use to strike a balance between patent protection and access to medicines. This investigation will critically review the writings on policy tools like transition periods, patentability criteria, test data protection, compulsory licensing, and parallel importation, among others. The arguments on the use of each of the policy tools will be evaluated. Useful literature in this regard will include the writings of Robert Bird who ponders the use of compulsory licensing,⁴² and Duncan Matthews who explores whether the Paragraph 6 of the Doha Declaration on TRIPS and Public Health could be a solution to the problem of access to medicines.⁴³ The writings of Tanya Aplin and Jenniffer Davies; Lionel Bently and Brad Sherman; Alexandra G Watson; Carlos M Correa and Sara M Ford will also be very useful.⁴⁴ This literature will be helpful in evaluating the Policy as it discusses the tools espoused in the Policy. In order to lay a proper basis for a proper critical analysis of the Policy against the existing body of knowledge, the extant system shall first be discussed. In this regard, there will be a review of the relevant national legislation in the various member states, the EAC Health Protocol and the Policy itself. It is after this that shortcomings will be identified and recommendations on the way forward will also be made.

1.7 Research methodology

This will entirely be a desk-top research. It will be conducted largely by way of document review and analysis. This will involve assessments of the literature available on the topic. Such literature shall include published books, journal and newspaper articles, reports and legal instruments. The internet will be resourceful as a source of some of this literature. Therefore, both primary and secondary sources will be used. Some of the primary sources include the legal instruments such

⁴¹ Watal (n 13 above) 3; FM Scherer 'The pharmaceutical industry' in AL Culyer & JP Newhouse (eds) 1 *Handbook of health economics* (2000) 1322 1324.

⁴² RC Bird, 'Developing nations and the compulsory license: Maximizing access to essential medicines while minimizing investment side effects' (2009) *Journal of Law, Medicine & Ethics* 209.

⁴³ D Matthews 'Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health: A solution to the access to essential medicines problem?' (2004) 7:1 *Journal of International Economic Law* 82.

⁴⁴ Watson (n 6 above) 149; Correa (n 30 above) 21; SM Ford 'Compulsory licensing provisions under the TRIPS Agreement: Balancing pills and patents' (2000) 15 *American University International Law Review* 945.

as domestic legislation and international legal instruments. The secondary sources shall include, as indicated above, published books, journal articles and reports. The reliance on primary and secondary sources is informed by the analytical nature of this research and the availability of a pool of materials that are relevant to the topic.

1.8 Overview of chapters

This paper has a total of six chapters. Chapter one is the introductory chapter. It introduces the subject of discussion and explains the background to this study. This chapter also states the research problem and formulates research questions to be used in understanding and answering the stated problem. The thesis statement and the justification for this research are also outlined in this chapter. A preliminary review of the literature to be used is also done in chapter one, which concludes with an explanation of the research methodology.

Chapter two is a discussion of the theoretical approaches used for this study. This chapter also evaluates various justifications for patent protection. The third chapter revisits the international regime for patent protection and access to medicines. It also delves into an analysis of the relationship between patents and access to medicines, before discussing the WTO-TRIPS flexibilities and the related Doha Declaration on TRIPS and Public Health.

The fourth chapter entails an overview of the EAC framework for patent protection and access to medicines. It considers the current national laws, the EAC Protocol on Public Health and the Policy. The key provisions of each of these ingredients of the EAC framework are highlighted. Importantly, in this chapter, the tools in the Policy are singled out for an overview.

Chapter five is a critical analysis of the Policy. In this chapter, a consideration is made of each of the tools in the Policy. The feasibility of each of the tools in the context of the EAC member states is critically evaluated. This chapter lays the ground for the conclusion and recommendations that are made in chapter six.

CHAPTER TWO

THE THEORETICAL FRAMEWORK

2.1 Introduction

This chapter has two parts. The first part sets out the theoretical approaches upon which the arguments in this study are premised. These are the Utilitarian and the Game theories. The rationale for using both of these theories will be explained. The second part evaluates the theories that have been used to justify patent protection. This part will consider the natural/moral rights theories and the utilitarian justifications for patent protection.

2.2 Theoretical approaches to the study

This study utilises the Utilitarian theory and the Game theory. The fusion of these theories creates a fitting and reinforcing model for the arguments in this research. The rationale for using each of the theories is set out below.

The idea behind utilitarianism has been explained in chapter one. Its basic precept is that laws are socially justified if they bring the greatest benefit to the greatest number of people.¹ This has been indicated to be one of the justifications of patents. In the broader context of this study, utilitarianism is used not just as the *raison d'être* for patents but also for any framework that seeks to utilise the WTO-TRIPS flexibilities. The application of utilitarianism to the present discussion has a major implication: that the Policy ought to bring the greatest benefit to the greatest number of people. What would be the greatest benefit and the greatest number of people in these circumstances?

The greatest benefit, without a doubt, is accessibility to medicines for the EAC population. The greatness of this benefit is what is at issue. The drafters of the Policy seem to consider the greatest benefit as lying in ensuring access through financial affordability. This study argues, however, that the benefit would be the greatest if regard is had to access in its two senses:

¹ Eg T Aplin & J Davies *Intellectual property: text, cases, and materials* (2013) 11.

ensuring financial affordability and securing the physical availability of medicines.² This would benefit the greatest number of people. This is because the Policy seeks to benefit only one side of the coin – that of the consumers of medicines. It blatantly undermines the interests of an equally important side – inventors – as epitomised by pharmaceutical companies. As utilitarianism requires that laws should be of the greatest benefit to the greatest number of people, a policy that secures access only in one sense and benefits only one half of the stakeholders clearly fails the test. There is need to strike a balance in order to achieve the greatest benefit for the greatest number of people. This is where the Game theory comes in.

In the Game theory, the law can be a tool for maximizing social wealth – it can be used to fashion a solution that will enable the players to maximise their social wealth. It is imperative to unpack the Game theory and its underlying assumptions. Game theory is ‘a formal, mathematical discipline which studies situations of competition and cooperation between several involved parties.’³ The parties in the ‘game’ are also called ‘players.’ Each player seeks to maximize utility from the common environment.⁴ There is an assumption that each player acts rationally and that the actions of each player are guided by what they expect other players to do in the common environment.⁵ The basic solution in the Game theory is the Nash Equilibrium (NE).⁶ This is the point at which no player has an incentive to deviate as it is the optimal given the behaviour of other players. However, sometimes, the NE raises problems. These are the Common Action Problems (CAPs). CAPs occur, for instance, where the NE is not pareto-optimal. In such situations, the law can be used to solve the CAPs.⁷ This work fits in the Game theory as follows:

The players in this game are the states and patent holders (pharmaceuticals). Both players have a common interest in patents. For the state, patents are necessary for disclosure and encouragement of research and invention, and therefore ensure availability of medicines for their citizenry. For patent holders, patents are necessary to enable them recoup the costs of research and investment and to reward them for their inventions. However, a strong patent regime would lead to higher

² H Adila *et al Health & Democracy* (2007) 436.

³ H Peters *The Game theory: a multi-leveled approach* (2008) 1.

⁴ Eg DG Baird *et al Game theory and the law* (1998).

⁵ n 4 above, 19.

⁶ As above.

⁷ n 4 above, 31.

prices of medicines – this would negate the state’s interests in the common environment because citizens would not be able to afford the medicines. A weak patent regime, on the other hand, will undermine the interests of patent holders. This may discourage further research into inventing medicines. There is need for some flexibility.

So, where is the NE? The extant NE for the EAC member states is the EAC framework. The framework is proposed as the point of equilibrium between the interests of the states and those of patent holders. This paper argues that this NE is not appropriate. It is not pareto-optimal. It is besieged with CAPs. It does not represent a state of pareto-efficiency. The argument is that the balance is tilted towards ensuring affordability of medicines at the expense of their availability. The Policy serves the interests of the state at the expense of patent holders. Patent holders may have the incentive to deviate (by not researching, inventing or disclosing). The law should therefore be used – through amendment or otherwise – to attain a better NE where the interests of both the states and patent holders shall be efficiently addressed. In such a situation, the states would ensure that prices are within reach for their citizenry. Patent holders would also be incentivised to research and invent thereby ensuring that medicines are available on the market. This will be perfectly in line with the utilitarianism – it would lead to the attainment of the greatest benefit for the greatest number of people.

2.3 The justification for patent protection

Justifying patents has been an old subject of intense debate.⁸ It is no wonder therefore that there are several theories on why patents (should) exist. It should be recalled that the justification for patents is not peculiar from the rationale for other forms of IPRs. Arguably, however, there are particular aspects of the justifications that would be more or less relevant to patents than to other forms of IPRs. While several theories abound to justify patents, this work focuses on the two main arguments: the natural/moral rights arguments and the utilitarian theory.⁹ The other arguments can, arguably, be subsumed by these two.

⁸ F Machlup & E Penrose ‘The patent controversy in the nineteenth century’ (1950) 10 *Journal of Economic History* 1.

⁹ For more arguments, see eg Aplin & Davies (n 1 above) 2-24; L Bently & B Sherman *Intellectual property law* (2009) 3.

2.3.1 The natural rights theory

The foundation of this theory is that ‘man has a natural right to his ideas and consequently that society is obliged to enforce that right.’¹⁰ This theory is generally considered from two perspectives: John Locke’s labour theory (Locke’s theory) and the Hegel’s personality theory (Hegel’s theory). Locke’s theory focuses on property understood largely in the sense of land – tangible property as opposed to intangible (intellectual) property.¹¹ However, pundits apply the tenets of the theory to IPRs as well.¹²

Locke’s view is that the world was given to all men by God in common (the commons) and that each man is endowed with reason to use the world to the best advantage of life and convenience.¹³ The logic of the argument is that people become entitled to something as their property upon mixing their labour with the commons – property rights are thus a reward for someone’s labour.¹⁴ In that sense therefore, one’s intellectual labour entitles him to IPRs if that labour results in intangible creations (IP).¹⁵ Hettinger captures the essence of the Locke’s view in these terms:

Perhaps the most powerful intuition supporting property rights is that people are entitled to the fruits of their labor. What a person produces with her own intelligence, effort, and perseverance ought to belong to her and to no one else. “Why is it mine? Well, it's mine because I made it, that's why. It wouldn't have existed but for me.”¹⁶

There have been objections to the Locke’s theory. One of them is that there are myriad other ways through which labour could be rewarded instead of property rights. These include fees, awards, praise, gratitude and public financial support.¹⁷ The other objection pertains to the important question of what exactly is the intellectual commons?¹⁸ For real property, it is easy to

¹⁰ S Sterckx ‘Patents and access to drugs in developing countries: An ethical analysis’ (2004) 4 *Developing World Bioethics* 59 62.

¹¹ J Locke *The second treatise on government* (1690); Daniel Attas ‘Lockean justifications of intellectual property’ in A Gosseries *et al* (eds) *Intellectual property and theories of justice* (2010) 29.

¹² Aplin & Davies (n 1 above) 4; Sterckx (n 10 above).

¹³ Locke (n 11 above); W Fisher ‘Theories of intellectual property’ in SR Munzer (ed) *New essays in the legal and political theory of property* (2001) 143-154.

¹⁴ LC Becker ‘Deserving to own intellectual property’ (1992-1993) 68 *Chicago-Kent Law Review* 623; JW Child ‘The moral foundations of intangible property’ (1990) 73 *The Monist* 578.

¹⁵ Aplin & Davies (n 1 above) 6.

¹⁶ EC Hettinger ‘Justifying intellectual property’ (1989) 18 *Philosophy and public affairs* 36.

¹⁷ Hettinger (n 16 above) 41.

¹⁸ Fisher (n 13 above) 186.

ascertain what forms part of the commons. It is a Herculean task to attempt the same for IP. What, for instance, in existing ideas, languages, cultures and facts can be said to be the commons?¹⁹

But why is it relevant to ascertain what constitutes the commons for IP labourers? The relevance lies in the fact that Locke's theory has provisos: there must be 'enough and as good left in common for others' and that one must not take more than one can use.²⁰ To leave 'enough and as good' for others and 'not to take more than one can use' presupposes that one has an understanding of what constitutes the commons.

Let us juxtapose the first proviso with patents. The nature of patents is such that 'enough and as good', whatever it is, cannot be left in common for others. This is because patents grant the inventor exclusive use of the invention.²¹ The first inventor obtains the patent and excludes all others so that 'enough and as good' is not left in common for others.

The third criticism of the Locke's theory is that since IP is a social product, it is difficult to attribute it solely to one's labour – much of it could as well have been influenced by previous creations.²² This one deserves elaboration.

The long and short of this criticism is that IP is a social product in two senses. First, in the case of patents for instance, the inventor is largely influenced by society's previous creations. Inventions are often improvements on earlier discoveries. This criticism is particularly real in the case of pharmaceutical products and the debate on the protection of traditional knowledge. The contention is that there has been '...appropriation and conversion of biologically or genetically unique information from indigenous cultures to private intellectual property, largely for the benefit of western pharmaceutical and seed companies.'²³

¹⁹ Aplin & Davies (n 1 above) 6.

²⁰ SV Shiffrin 'Lockean arguments for private intellectual property' in SR Munzer (ed) *New essays in the legal and political theory of property* (2001) 143.

²¹ Hettinger (n 16 above) 44.

²² J Rawls *A theory of justice* (1971) 310; Aplin & Davies (n 1 above) 6.

²³ LA Whitt 'Part one, interdisciplinary perspective: indigenous peoples, intellectual property and the new imperial science' (1998) 23 *Oklahoma City University Law Review* 215.

There is a second sense. This has to do with attributing intellectual products to one's labour and therefore entitling the labourer to the market price as the reward.²⁴ The argument is that the market price too, is a social product. It is not a creation of the labourer. The price is influenced by factors like the demand for the invention, the availability of substitutes and government policy, for which the labourer is not responsible. Hettinger pursues this argument to arrive at two conclusions: first, that the labourer is not entitled to the market price because it is not a product of the labourer's labour and second, even if the labourer was to be so entitled, the entitlement cannot be to the full market value because 'intellectual products result from the labor of many people besides the latest contributor, and they have claims on the market value as well.'²⁵ The plausibility of Hettinger's criticism is difficult to deny. The debate on indigenous knowledge alluded to above is evidence of the practical realities.

This argument, in both senses, illustrates the imprecisions of using labour to designate entitlement to IP and to the market price that the intellectual product attracts.²⁶ There is the related question of proportionality between one's labour and the reward that the product of that labour attracts.²⁷ In this regard, it is postulated that rewards may be more or less than what one actually deserves in return for his labour.²⁸ The logic is simple: some inventions take far much more effort than others yet the reward, for instance the patent period (at least 20 years under TRIPS), is the same irrespective of the differences in labour.²⁹

These deficiencies in Locke's theory lead to Hegel's theory as the most powerful alternative.³⁰ Hegel theorises that property 'provides a unique or especially suitable mechanism for self-actualization, for personal expression, and for dignity and recognition as an individual person.'³¹ According to Hegel, a person needs some control over resources in the external environment. This control is attained through property rights. Hegel argues that IP needs not be justified by analogy to physical property and that IPRs are the way of 'materializing' the intangible property

²⁴ Hettinger (n 16 above) 38.

²⁵ n 16 above, 39.

²⁶ Aplin & Davies (n 1 above) 6.

²⁷ Hettinger (n 16 above) 43; Rawls (n 22 above) 10.

²⁸ J Rachels 'What people deserve' in J Arthur & W Shaw (eds) *Justice and economic distribution* (1978) 150.

²⁹ TRIPS art 33.

³⁰ J Hughes 'The philosophy of intellectual property' (1988-89) 77 *Georgetown Law Journal* 287.

³¹ As above.

that IP is.³² In sum, Hegel's theory considers IP as a person's expression of personhood the control of which that person is entitled to through IPRs.

This theory too has attracted objections. One of them is that the meaning of personality is difficult to discern. For instance, does it mean reputation, self-expression or self-presentation?³³ The other objection has been that not all forms of IP are reflective of one's personality. Literary works like novels and other writings, for instance, may speak much about one's personality. The same cannot obviously be said of computer software and inventions.³⁴

2.3.2 The utilitarian theory

This theory hinges on Jeremy Bentham's argument that laws are socially justified if they bring the greatest happiness, or benefit, to the greatest number of people. The utilitarian theory has attracted greater support and is considered more convincing in justifying IPRs.³⁵ But what are the specifics of utilitarianism?

Utilitarianism, in respect of patents, is two-limbed. First, protecting patents creates an incentive to invent. The logic is that without 'the copyright, patent, and trade secret property protections, adequate incentives for the creation of a socially optimal output of intellectual products would not exist.'³⁶ The second limb is that patents are an incentive to disclose.³⁷ Patents, it is argued, encourage the disclosure of useful discoveries which would otherwise remain undisclosed.

Let us consider the first limb of utilitarianism – that patents are an incentive for invention. There are several suppositions that underlie this justification. One of them is that inventions need capital for research and development. Consequently, and this is the other supposition, inventors would only invest in research and development if they are assured of recovering and profiting from their investment.³⁸ This is why patents give the inventor monopoly over the invention, until, presumably, the investment is recovered. Lord Oliver of Aylmerton concurs:

³² As above.

³³ M Spence 'Justifying copyright' in D Mclean & K Schubert (eds) *Dear images: art, copyright and culture* (2002) 399.

³⁴ Hughes (n 30 above) 340.

³⁵ Hettinger (n 16 above) 47; Sterckx (n 10 above) 66.

³⁶ n 16 above, 48.

³⁷ D Davies 'The early history of the patent specification' (1935) 50 *Law Quarterly Review* 86.

³⁸ Machlup & Penrose (n 8 above) 10; Hettinger (n 16 above) 48.

The underlying purpose of the patent system is the encouragement of improvements and innovation. In return for making known his improvement to the public the inventor receives the benefit of a period of monopoly during which he becomes entitled to prevent others from performing his invention except by his licence.³⁹

This supposition has been resisted. One criticism is that not all inventions are a result of research. The other is that not all inventors expect to be rewarded for their inventions.⁴⁰ Indeed, it is a matter of practical reality that some discoveries result from a stroke of genius without major research input. However, that is not true of most inventions. This is particularly the case with the subject of this research – pharmaceutical products – which usually require significant research and experimentation to develop.⁴¹ The second criticism – that not all inventors expect to be rewarded for their work, is not as strong. This is because patents are not imposed. The inventor who desires to patent an invention applies for the patent.

Patents, in so far as they are regarded as incentives for further inventions, are considered to operate paradoxically.⁴² In the first order, there is a restriction on the availability of the invented commodity through monopolization. In the second order, the restriction operates to secure availability of inventions because the guarantee of temporary monopoly encourages inventors to invent more.⁴³ The encouragement should of course be broadly understood to apply not just to the instant patent holders but to potential inventors. The economist Joan Robinson articulates this paradox:

A patent is a device to prevent the diffusion of new methods before the original inventor has recovered profit adequate to induce the requisite investment. The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse...⁴⁴

The fact that patents create a monopoly and restrict the availability of commodities has been cited as a disadvantage. Some pundits argue that if the goal is to motivate further inventions,

³⁹ *Asahi Kasei Kogyo* [1991] RPC 485 523.

⁴⁰ Hettinger (n 16 above) 43.

⁴¹ JA Harrelson ‘TRIPS, pharmaceutical patents, and the HIV/AIDS crisis: Finding the proper balance between intellectual property rights and compassion’ (2001) 7 *Widener Law Symposium Journal* 184; GK Foster ‘Opposing forces in a revolution in international patent protection: The US and India in the Uruguay Round and its aftermath’ (1998) 3 *University of California Journal of International Law and Foreign Affairs* 297.

⁴² Hettinger (n 16 above) 48.

⁴³ As above; RT Rapp & RP Rozek ‘Benefits and costs of intellectual property protection in developing countries’ (1990) *Journal of World Trade* 86.

⁴⁴ Quoted in Hettinger (n 16 above) 48 (citing Dorothy Nelkin *Science as Intellectual Property* (1984)).

there are other ways through which this can be achieved without restricting availability, such as giving financial rewards to inventors and providing government funding for research.⁴⁵ These alternatives, albeit attractive, cannot survive close scrutiny. The argument for financial rewards for instance, seems to assume, incorrectly, that the cost of such rewards would be proportionate to the cost of the invention and that it would be less than the cost of a patent. The same would be the case for government funding.

Government funding for research activities may likely prove unsustainable. In the case of pharmaceuticals for example, breakthroughs are often made after years of costly yet frequently unsuccessful experiments.⁴⁶ It would not be economically justifiable for governments to fund such research as an alternative to patents. Undoubtedly, LDCs would especially be disadvantaged. This does not mean that governments should not fund research. The contention simply is that government funding should not supplant patents.

Other commentators against patents say the advantage inventors obtain for being the first in the market is enough to recoup their research investment.⁴⁷ Again, this contention cannot stand scrutiny. To begin with, it obviously cannot be true that being the first in the market will automatically give one an advantage. The demand for a product is always the key determinant. Demand is influenced by different factors – in the case of medicines, demand in a particular market may arise only following a disease outbreak. Importantly, in view of the rapidity of modern technology, it would not take competitors long to introduce an imitation in the market, thereby eliminating any lead-time advantage.⁴⁸

The foregoing paragraphs argue that the availability of patents encourages research and invention. But what would the unavailability of patents do? The absence of patents will discourage investment in research and development of new inventions. Hettinger writes:

⁴⁵ Z Lazzarini 'Making access to pharmaceuticals a reality: Legal options under TRIPS and the case of Brazil' (2003) 6 *Yale Human Rights & Development Law Journal* 103 112; Aplin & Davies (n 1 above) 13; Hettinger (n 16 above) 49.

⁴⁶ P Cullet 'Patents and medicines: The relationship between TRIPS and the human right to health' (2003) 1 *International Affairs* 79 141; HE Bale Jr 'The conflicts between parallel trade and product access and innovation: The case of pharmaceuticals' (1998) 1 *Journal of International Economic Law* 637.

⁴⁷ Machlup & Penrose (n 8 above) 18.

⁴⁸ Cullet (n 46 above) 141.

If competitors could simply...take one another's inventions..., there would be no incentive to spend the vast amounts of time, energy, and money necessary to develop these products... It would be in each firm's self-interest to let others develop products, and then mimic the result. No one would engage in original development, and consequently no new...inventions...would be developed.⁴⁹

Susan Sell similarly notes that '[t]he rationale for intellectual property rights is that they provide incentives for the creation and dissemination of innovation. Without the compensation made possible by intellectual property rights, public goods will be underprovided.'⁵⁰

Let us now consider the second limb of the utilitarian argument – that patents are an incentive to disclose. Patents are often regarded as contracts; in fact there is the contract theory to explain patents.⁵¹ The inventor discloses the discovery to the government in return for a patent. Why is disclosure important? For one, disclosure is important for public safety because a disclosed invention can be inspected.⁵² There is another significant reason: disclosure ensures the government has a database for research and future manufacturing.⁵³ Without patents, inventors would have no incentive to disclose their discoveries. Governments would be deprived of crucial scientific and technical information.

The utilitarian theory is the 'strongest and most widely appealed to justification for intellectual property.'⁵⁴ Unlike the natural rights approaches which focus on the rights of the inventor or creator, utilitarianism has its eyes on the users of intellectual products.⁵⁵ It considers IPRs, for example patents, merely as a means to the end; the end being availing commodities in the market for the users. This research adopts the utilitarian approach. In fact, as the next section reveals, international law making on IPRs is demonstrably informed by utilitarian undertones.

⁴⁹ Hettinger (n 16 above) 48.

⁵⁰ SK Sell 'TRIPS-plus free trade agreements and access to medicines' (2007) 28 *Liverpool Law Review* 43.

⁵¹ DI Bainbridge *Intellectual property* (2012) 18.

⁵² n 51 above, 18 & 395.

⁵³ Bently & Sherman (n 9 above) 340.

⁵⁴ Hettinger (n 16 above) 47.

⁵⁵ n 16 above, 48.

2.4 Conclusion

This chapter has set out the theoretical approaches upon which the arguments in this study are premised. These approaches are the Utilitarian and the Game theories. It has been explained that the precept behind utilitarianism is that laws are socially justifiable if they bring the greatest benefit to the greatest number of people. Applying this to patents and access to medicines, it has been argued that an appropriate regime would be one that balances between patent protection and access to medicines. The Game theory, it has been explained above, illustrates how the law can be used to maximise social welfare by balancing between competing needs. The second part has evaluated the justifications for patent protection. It has been illustrated that utilitarianism is the widely accepted justification. Importantly, international law-making on patent protection is demonstrably informed by utilitarianism. The next chapter discusses the international framework for patent protection and access to medicines.

CHAPTER THREE

THE INTERNATIONAL REGIME FOR PATENT PROTECTION AND ACCESS TO MEDICINES

3.1 Introduction

This chapter describes the existing international patent protection regime. The discussion of the international patent protection regime leads to the next part of the chapter, which examines the relationship between patent protection and access to medicines. This part forms the basis for an analysis of the Doha Declaration on TRIPS and Public Health. The Declaration, as the instrument that has been understood to affirm flexibilities in TRIPS, is critically assessed in terms of its legal status within the WTO framework and in terms of the nature of the commitments it creates. Although there are several other international treaties relevant to patent protection, this chapter shall be limited to the Paris Convention and TRIPS because they are of immediate relevance to this study.¹

3.2 The international framework for patent protection

The development of an international system for IPRs protection dates back to the late 19th Century. This period was characterised by the emergence of bilateral and multilateral treaties on the protection of IPRs.² The emergence of these treaties is said to have been a response to the increasing globalisation of trade.³ The most notable ones to emerge at this time were the Paris Convention for the Protection of Industrial Property 1883 and the Berne Convention for the Protection of Literary and Artistic Works 1886.⁴ The Paris Convention applies to inventions, trademarks and industrial designs. The Berne Convention deals with copyright.

The other aspect of the development of the international system was the creation of international bodies to administer the treaties. The United International Bureaux for the Protection of

¹ Eg the Patent Cooperation Treaty (19 June 1970) 1160 UNTS; the Patent Law Treaty (1 June 2000) 2340 UNTS.

² T Aplin & J Davies *Intellectual property: text, cases, and materials* (2013) 24.

³ As above.

⁴ Paris Convention for the Protection of Industrial Property 1883 (revised, Stockholm 1967); Berne Convention for the Protection of Literary and Artistic Works 1886 (revised Paris 1971).

Intellectual Property (BIRPI) was the body that administered the Paris and Berne Conventions.⁵ It was succeeded by the World Intellectual Property Organisation (WIPO) in 1967.⁶ In 1994, the Uruguay Round negotiations culminated in the establishment of the World Trade Organisation (WTO) and the adoption of TRIPS.⁷

3.2.1 The Paris Convention for the protection of industrial property (1883)

As indicated above, this Convention was signed in 1883 and applies to industrial property. Industrial property was the nomenclature developed to include patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations or origin and unfair competition.⁸ The Convention is administered by WIPO and has 175 party states – the Union countries.⁹

The Paris Convention outlines two principles, to wit, national treatment and priority.¹⁰ National treatment requires Union countries to accord the same protection for industrial property, to their nationals and nationals of other Union countries.

The principle of priority has the effect that once a patent application is filed in one of the Union countries, the applicant enjoys, for the purpose of filing in other Union countries, a 12-month period of priority calculated from the date of filing the first application.¹¹ This means patentability requirements such as novelty and inventive step will be benchmarked against prior art as it stood at the time of the first filing.¹²

The Paris Convention also provides for compulsory licencing to prevent abuses that may result from the exercise the monopoly rights that accrue to patents. Such abuses include failure to work or insufficient working of the patent.¹³

⁵ Aplin & Davies (n 2 above) 25.

⁶ As above.

⁷ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, legal instruments—results of the Uruguay round volume 1, 33 ILM 1125 (1994).

⁸ Paris Convention art 1(2).

⁹ http://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=2 (accessed 14 March 2014).

¹⁰ Paris Convention art 2.

¹¹ Paris Convention art 4A (1) & 4C (1)-(2).

¹² Aplin & Davies (n 2 above) 547.

¹³ Paris Convention art 5(2) A.

3.2.2 The TRIPS Agreement

TRIPS has been characterised as ‘the most comprehensive treaty dealing with intellectual property rights...’¹⁴ The reasons for this are that first, it at once covers many aspects of IP such as copyright, trademarks and patents and second, it incorporates a number of international Conventions covering different aspects of IP, including the Paris and Berne Conventions.¹⁵ For present purposes, there are certain matters of note about TRIPS.

One of them is that TRIPS establishes minimum standards of IP protection.¹⁶ This attribute is in other terms described as the establishment ‘substantive minima.’¹⁷ The idea of substantive minima is not entirely novel – it has been a defining feature of the development of the international IP system (the Paris and Berne Conventions both establish minimum standards).¹⁸ However, while that is the case, there are two important facts to note.

First, under the Paris Convention, a country was allowed to define its own substantive minima which would apply equally to nationals and non-nationals (from Union countries).¹⁹ TRIPS, on the other hand, establishes uniform minimums. Second, the internationalisation of IP has seen the upward growth of the standards. One of the substantive minima that TRIPS prescribes, for instance, in respect of patents, is that the term of a patent must be at least 20 years.²⁰

There is a second matter of note. This is that TRIPS embraces the principle of national treatment which requires states to give the same protection to the IPRs of nationals and foreigners in their territory.²¹ This principle, like substantive minima, has also characterised the development of the international IP system.²² Undoubtedly, national treatment is an acknowledgement of the

¹⁴ C Tuosto ‘The TRIPs Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences’ (2004) *European Intellectual Property Review* 542.

¹⁵ TRIPS art 2(1).

¹⁶ n 15 above, arts 27-34.

¹⁷ GB Dinwoodie ‘The architecture of the international intellectual property system’ (2002) 77 *Chicago-Kent Law Review* 993.

¹⁸ n 17 above, 995.

¹⁹ Paris Convention art 2.

²⁰ n 15 above, art 33.

²¹ n 15 above, art 3.

²² Dinwoodie (n 17 above) 995.

territoriality of IPRs. Because TRIPS is a WTO Agreement, disputes thereunder are to be referred to the WTO dispute settlement system.²³

The adoption of TRIPS brought to the fore certain challenges. In relation to pharmaceuticals, a hot debate was born between developed and developing countries.²⁴ Developing countries argued that a stronger patent regime in the area of pharmaceuticals made it very difficult to address the health needs of their populations.²⁵ The particulars of this debate are pursued further below.

3.3 TRIPS and public health

3.3.1 Patents and access to medicines

One of the areas in which there has been heated debate over TRIPS, is the interface between patent protection and access to medicines.²⁶ It has been explained above that the extant justification for patent protection largely follows the utilitarian approach.²⁷ The logic, as explained above, is that patent protection enables inventors to recoup their investments in research and development and that way, society benefits because inventions are incentivised.²⁸

Arguably, there are obvious reasons why this debate has been between developed and developing countries. First, TRIPS was considered, from the outset, as a developed countries' concept.²⁹ There has been contention that TRIPS benefits only developed countries.³⁰ It is reported that during the Uruguay Round negotiations, developing countries agreed to TRIPS in reciprocation for developed countries' concessions in the agricultural negotiations.³¹ The second reason somewhat buttresses the foregoing reason. This is that developed countries, being home to most of IP, advocate for stronger patent regimes at the behest of the pharmaceutical companies in their

²³ n 15 above, art 64.

²⁴ L Lalitha 'Doha Declaration and public health issues' (2008) 13 *Journal of Intellectual Property Rights* 401.

²⁵ ZA Zainol *et al* 'Pharmaceutical patents and access to essential medicines in sub-Saharan Africa' (2011) 10 *African Journal of Biotechnology* 12376.

²⁶ BC Mercurio 'TRIPS, patents, and access to life-saving drugs in the developing world' (2004) 10:2 *Marquette Intellectual Property Law Review* 211.

²⁷ Part 2.3.2 above.

²⁸ M Boldrin & DK Levine 'Does intellectual monopoly help innovation?' (2009) 5:3 *Review of Law and Economics* 991.

²⁹ N Bass 'Implications of the TRIPS agreement for developing countries: Pharmaceutical patent law in Brazil and South Africa in the 21st Century' (2002) 34 *George Washington International Law Review* 191 205.

³⁰ P Drahos & J Braithwaite *Information feudalism: Who owns the knowledge economy?* (2002) 10.

³¹ R Gutowski 'The marriage of intellectual property and international trade in the TRIPS Agreement: Strange bedfellows or a match made in heaven?' (1999) 47 *Buffalo Law Review* 754.

countries.³² Developing countries, on the other hand, have opposed a strong patent regime in order to address the public health needs of their population.³³

This debate ultimately found itself in the interpretation of TRIPS: Developing countries read the Agreement as having flexibilities for addressing public health needs; developed countries rejected such an interpretation, insisting that the only flexibility in TRIPS concerned the longer implementation periods allowed to developing countries and LDCs.³⁴ This debate on the extent of TRIPS flexibilities led to the Doha Declaration on TRIPS and Public Health.

3.3.2 Doha Declaration on TRIPS and public health

The Declaration was the resolution of divergent interpretations of TRIPS by developed and developing countries. Developing countries had opined that TRIPS allowed states to take measures aimed at addressing the public health needs of their populations.³⁵ In advancing their argument, developing countries were of the view that TRIPS should be interpreted on the basis of Articles 7 and 8, which, generally, recognise the adoption of measures to facilitate, *inter alia*, addressing public health and nutrition needs.³⁶

Developed countries countered with the argument that TRIPS already strikes a balance between patent protection and access to medicines because imposing stronger standards of protection is crucial to incentivise invention. In any event, developed countries argued, TRIPS already accommodated the needs of developing countries by allowing them longer transitional periods.³⁷ A further argument was that public health matters should not just be tied to patents because there was need for a ‘comprehensive approach that addressed other policy matters such medical

³² n 31 above, 754; CAP Braga *et al* ‘Intellectual property rights and economic development’ in KE Maskus (ed) *The WTO, intellectual property rights and the knowledge economy* (2004) 245.

³³ E George ‘The human right to health and HIV/AIDS: South Africa and South-South cooperation to reframe global intellectual property principles and promote access to essential medicines’ (2011) 18:1 *Indiana Journal of Global Legal Studies* 167 175.

³⁴ AG Watson ‘International intellectual property rights: Do TRIPS’ flexibilities permit sufficient access to affordable HIV/AIDS medicines in developing countries?’ (2009) 32 *Boston College International & Comparative Law Review* 143 146.

³⁵ JT Gathii ‘The legal status of the Doha Declaration on TRIPS and public health under the Vienna Convention on the law of treaties’ (2002) 15 *Harvard Journal of Law & Technology* 292.

³⁶ TRIPS (n 15 above) art 7 & 8.

³⁷ Gathii (n 35 above).

infrastructure, doctors, nurses, and initiatives by multilateral institutions such as the World Health Organization.³⁸

Against this backdrop, a raft of proposals was considered which climaxed in the adoption of the Declaration at the Doha Ministerial meeting in Qatar in November 2001. The Declaration largely mirrors the position of developing countries.³⁹ The essence of the Declaration as captured at paragraph five is reproduced below:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.⁴⁰

Paragraph six of the Declaration also deserves mention. This paragraph recognised that 'WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS and consequently instructed the Council for TRIPS to find an expeditious solution to the problem and report to the General Council before the end of 2002.⁴¹ It was not until August 2003 that a solution was reported to the General Council. This solution, widely known as the 30 August 2003 Decision, allows WTO members to issue compulsory licences for purposes of exporting to countries with no or insufficient manufacturing capacity.⁴² It essentially waives the requirement that compulsory licences should be issued for the manufacture of generic drugs predominantly for the domestic market.⁴³ There are pre-conditions to be met – there must be fair compensation for the compulsory licence; the drugs must be of the quantity needed to address public health needs; the drugs must be exported in their entirety and reasonable measures must be taken to prevent re-

³⁸ n 35 above, 298.

³⁹ P Drahos 'Developing countries and international intellectual property standard setting' (2002) 5:5 *Journal of World Intellectual Property* 781.

⁴⁰ Doha Declaration para 5.

⁴¹ Doha Declaration para 6.

⁴² The 30 August 2003 Decision.

⁴³ D Matthews 'Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health: A solution to the access to essential medicines problem?' (2004) 7(1) *Journal of International Economic Law* 82.

exportation.⁴⁴ In 2005, WTO members agreed to incorporate the 30 August 2003 Decision in TRIPS by amendment.⁴⁵

Before considering the import of the Declaration, it is useful to reflect on the 30 August 2003 Decision (the ‘Paragraph 6 system’). The Decision was obviously a thoughtful way of trying to give potency to compulsory licences for countries without manufacturing capacity. However, there are practical challenges which perhaps explain why the Decision has been used only once hitherto.⁴⁶ Chief among these challenges is that it is highly unlikely that developed countries, in which most pharmaceuticals are located, will issue compulsory licences against their companies in order to assist developing countries with no manufacturing capabilities.⁴⁷ One only has to recall the endeavours made by developed countries to strengthen the protection of intellectual property (primarily in the interest of their companies).

It is not here suggested that the Paragraph 6 system is completely unworkable. Situations are imaginable of pharmaceuticals giving up patents (likely one nearing its end) to allow for the manufacture of generic drugs on acceptable terms. Indeed, the incentive of guaranteed economic benefits by manufacturing and exporting under the Paragraph 6 system may encourage its use. The elaborate and time-consuming WTO procedures before the Paragraph 6 system can be used, however, are another major handicap.⁴⁸

3.3.3 The legal place of the Declaration

The importance of ascertaining the legal place of the Declaration need not be overemphasized. It is sufficient to state that the legal place of the Declaration determines the nature of the legal commitments it creates and the extent to which such obligations are implementable.

The WTO panels and the Appellate Body have not had occasion yet to decide on the legal place of the Declaration. However, academic literature abounds as to the possible status of the

⁴⁴ n 43 above.

⁴⁵ http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm (accessed 15 March 2014).

⁴⁶ http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm (accessed 15 March 2014).

⁴⁷ A Attaran ‘The Doha Declaration on the TRIPS agreement and public health, access to pharmaceuticals, and options under WTO law’ (2002) 12 *Fordham Intellectual Property, Media & Entertainment Law Journal* 859 869.

⁴⁸ L Forman ‘Trade rules, intellectual property, and the right to health’ (2007) *Ethics and International Affairs* 350; Zainol *et al* (n 25 above) 12383.

Declaration within the sphere of WTO law.⁴⁹ It has been argued, for instance, that the Declaration is a subsequent agreement regarding the interpretation of TRIPS (in terms of the Vienna Convention on the Law of Treaties).⁵⁰ It has also been argued that the Declaration could be considered as evidence of subsequent practice establishing the understanding of WTO members regarding the interpretation of TRIPS.⁵¹ Other pundits view the Declaration as a mere political statement.⁵² This view proceeds that the Declaration was a mere ‘...implicit reciprocation by the West to developing country governments for their implementation of TRIPS and their acquiescence to a new round of WTO talks.’⁵³ This perception is very easy to disagree with.

First, the heated context and process through which the Declaration was developed neuter the view that it is a mere political statement.⁵⁴ Second, the Declaration was adopted by the consensus of all WTO members. Drawing from the practice elsewhere, for example from the United Nations General Assembly declarations, the Declaration could easily be considered as customary international law.⁵⁵ This is because the Declaration was agreed upon by states on a wide scale – all WTO members. Therefore, ‘[e]ven if a country concluded that the Declaration is not legally binding, it still constitutes soft law with substantial hortatory authority that puts political pressure on governments and international institutions to comply.’⁵⁶

The other two possibilities therefore remain more plausible. The Declaration may be regarded as evidence of subsequent practice of states regarding the interpretation of TRIPS. This Declaration, read together with subsequent states’ behavior which conforms to the purpose of the Declaration, lends credence to this view.⁵⁷

Perhaps the most persuasive view, however, is that of the Declaration as a subsequent agreement on the interpretation of TRIPS. The Declaration is a compromise that was reached by states after

⁴⁹ SP Kumar ‘European border measures and trade in generic pharmaceuticals: Issues of TRIPS, Doha Declaration and public health’ (2009) 15:6 *International Trade Law & Regulation* 176.

⁵⁰ Matthews (n 43 above) 82; Gathii (n 35 above) 299.

⁵¹ Gathii (n 35 above) 299.

⁵² JJ Schott ‘Comment on the Doha Ministerial’ (2002) 5 *Journal of International Economic Law* 195.

⁵³ Gathii (n 35 above) 315.

⁵⁴ P Rott ‘The Doha Declaration - good news for public health?’ (2003) *Intellectual Property Quarterly* 2.

⁵⁵ J Dugard *International law: A South African Perspective* (2012) 30.

⁵⁶ Gathii (n 35 above) 314.

⁵⁷ n 35 above, 310.

negotiations on the interpretation of TRIPS. It is directive on how TRIPS should be interpreted.⁵⁸ Of significance is the fact that previous declarations that have undergone the same WTO process have been considered by the WTO Appellate Body as subsequent agreements on the interpretation of the respective treaties.⁵⁹

It is not for this study to provide authority on the actual legal status of the Declaration, although the argument here is that the Declaration can fit as a subsequent agreement on the interpretation of TRIPS. However, despite the absence of clear authority on the Declaration's legal status, there is a least common multiple that runs through all the foregoing three arguments – that the Declaration, at the minimum, creates legal rights and obligations. Even those who argue the Declaration is a mere political statement cannot counter the view that the Declaration could easily qualify as customary international law owing to its universal endorsement by all WTO member states.⁶⁰ In any case, states proceeding to utilize the TRIPS flexibilities could only be doing so if the Declaration creates legal rights and obligations.

It is appropriate, at this stage, to note that while the Declaration creates legal commitments, the nature of these commitments is clearly spelt out.⁶¹ In using the Declaration to utilize TRIPS flexibilities, the undertones of balancing between protection and access that motivate the Declaration ought to be borne in mind. Failure to do this poses two main risks: first, a bias for one will have practical consequences (of either limiting supply or inhibiting access) and second, a bias for access at the expense of protection may be a violation of TRIPS.

3.4 Conclusion

This chapter has described the international regime for patent protection. The climax of the regime thus far, TRIPS, has been considered. The tensions that emerged with the dawn of TRIPS, particularly between protection and access, have been brought to the fore. Narrowing these tensions to patent protection and access to medicines, this chapter has explained the lead-up to the adoption of the Doha Declaration on TRIPS and Public Health as an attempt to strike a balance between patent protection and access to medicines, by affirming an interpretation of

⁵⁸ Rott (n 54 above) 2.

⁵⁹ Eg WTO Appellate Body Report, *United States-Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (12 October 1998) para 50.

⁶⁰ Gathii (n 35 above) 314.

⁶¹ Both in the Doha Declaration and the 30 August 2003 Decision.

TRIPS that permits certain flexibilities. This chapter has also attempted a critical analysis of the legal status of this Declaration because that has a bearing on the nature of the commitments it creates. At the end, it has been concluded that whatever view one holds of the status of the Declaration, it clearly creates legal commitments. It has been argued that since the Declaration affirms an interpretation of TRIPS that balances between protection and access, the use of the TRIPS flexibilities must be motivated by the same balance. This chapter has laid the basis for a discussion of the EAC framework on patent protection and public health.

CHAPTER FOUR

THE EAC LEGAL FRAMEWORK FOR PATENT PROTECTION AND ACCESS TO MEDICINES

4.1 Introduction

This chapter is a discussion of the legal framework for patents and access to medicines in the East African Community (EAC) region. It aims to lay the basis for a critical analysis of the Policy – the mainstay of this study. The chapter begins with an overview of the applicable national patent laws in each of the EAC member states. The next part focuses on the regional framework in place, which consists of the Policy and the accompanying EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities (the Protocol). This chapter will identify the policy tools enshrined in the Policy. At the conclusion, the characteristic features of the existing EAC framework on patents and access to medicines, both nationally and regionally, would have been clearly set out.

4.2 Intellectual property laws and public health in the EAC

The EAC is ‘the regional intergovernmental organisation of the Republics of Burundi, Kenya, Rwanda, the United Republic of Tanzania, and the Republic of Uganda.’¹ After an initial collapse in 1977, the EAC was revived in 2000, and expanded its membership from three states when the republics of Burundi and Rwanda joined in 2007.²

The founding legal document of the EAC is the EAC Treaty (the Treaty).³ The Treaty spells out the objectives of the EAC. One of the objectives is to ‘to develop policies and programmes aimed at widening and deepening co-operation among the Partner States in political, economic ...and legal and judicial affairs, for their mutual benefit.’⁴ The Treaty lays out the stages of

¹ http://www.eac.int/index.php?option=com_content&view=article&id=1:welcome-to-eac&catid=34:body-text-area&Itemid=53 (accessed 2 April 2014).

² JV Mwapachu ‘EAC: past, present and future’ (2010) www.firstmagazine.com/downloads/specialist/publication/detail.480.ashx (accessed 2 April 2014).

³ Treaty Establishing the East African Community (adopted 30 November 1999, entered into force 7 July 2000) 2144 UNTS 255 (the Treaty).

⁴ n 3 above) art 5(1).

integration to be followed in order to attain this objective. The EAC is to commence as a Customs Union, then a Common Market before becoming a Monetary Union and ultimately, a Political Federation.⁵ Presently, the EAC is a Common Market and negotiations towards a Monetary Union are underway.⁶

The Treaty lists diverse areas of cooperation in which collaboration is necessary to attain the objectives of the EAC.⁷ These areas relate to diverse spheres, with the broader aim of strengthening economic, political and social integration in the region. As far as cooperation on IP is concerned, the EAC Common Market Protocol envisages cooperation in areas necessary for the effective functioning of the Common Market and maximising the benefits to be obtained.⁸ Cooperation in IP is specifically provided for in the Common Market Protocol.⁹ It is on this basis that the Policy and the accompanying Protocol have been developed.

It is important to note that while the EAC has a Legislative Assembly with powers to make laws, its competencies are clearly defined and that other spheres are left for domestic legislatures.¹⁰ Thus, as earlier noted, the Policy just provides the minimum guidelines to be enacted in national legislation by the individual states.¹¹ The following section is a general overview of the existing patent laws in the EAC member states.

4.2.1 The national laws

As indicated above, each of the five EAC member states maintains its own regime of patent law. This section identifies the key features of the existing national patent regimes that will be relevant for latter discussions. It will be pointed out, for instance, that some of the instruments proposed in the Policy already exist in some of the national patent laws but are never utilised. The reasons for this non-use will be explained in the next chapter.

⁵ n 3 above, art 5(2).

⁶ http://www.eac.int/index.php?option=com_content&id=44&Itemid=54&limitstart=1 (accessed 2 April 2014).

⁷ The Treaty (n 3 above) caps 11-27.

⁸ The Protocol on the Establishment of the East African Community Common Market (the Common Market Protocol) art 2.

⁹ The Common Market Protocol (n 8 above) arts 5(3) k & 43.

¹⁰ The Treaty (n 3 above) art 48.

¹¹ The Regional Intellectual Property Policy on the Utilisation of Public Health-related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (the Policy) para 2.3.

Burundi

The existing law is the Law no 1/13 of 2009 relating to Industrial Property in Burundi.¹² The regulations to implement this law are yet to be enacted, although in practice the Industrial Property Director already applies the law.¹³ Burundi is a party to TRIPS and the Paris Convention.¹⁴ As a LDC, Burundi has taken advantage of the 2016 transition period to exclude pharmaceuticals from patentability.¹⁵

The law stipulates the requirements for patentability and the procedure for making patent applications. It outlines what constitutes patentable subject matter and what cannot be patented.¹⁶ This law allows for pre-grant opposition procedures by filing a Notice of Opposition.¹⁷ It also makes provision for the withdrawal of the patent for non-working or under compulsory licensing.¹⁸

Kenya

Kenya is a party to TRIPS.¹⁹ The law relating to patents is the Industrial Property Act.²⁰ The Act rolls out the procedure for applying for patents, the requirements for patentability and what constitutes patentable subject matter.²¹ In contrast to the Burundi law, the Act does not allow pre-grant opposition; any opposition has to be post-grant.²²

Unlike all the other EAC member states, Kenya is classified as a developing country.²³ The implication of this in respect of pharmaceutical patents is that Kenya cannot make use of the

¹² Law 1/13 of 2009 relating to Industrial Property in Burundi (Law 1/13 of 2009).

¹³ Adams & Adams *Practical Guide to Intellectual Property in Africa* (2012) 78.

¹⁴ http://www.wto.org/english/thewto_e/countries_e/burundi_e.htm (accessed 2 April 2014); http://www.wipo.int/treaties/en/remarks.jsp?cnty_id=189C (accessed 2 April 2014).

¹⁵ Law 1/13 of 2009 (n 12 above) arts 17 & 381.

¹⁶ Law 1/13 of 2009 (n 12 above) arts 3-7; 17-18; 19-27.

¹⁷ Law 1/13 of 2009 (n 12 above) art 48.

¹⁸ Law 1/13 of 2009 (n 12 above) art 78-102.

¹⁹ http://www.wto.org/english/thewto_e/countries_e/kenya_e.htm (accessed 2 April 2014); http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax_a.pdf (accessed 2 April 2014).

²⁰ Act 3 of 2001.

²¹ Act 3 of 2001 (n 20 above) part III & IV.

²² Act 3 of 2001 (n 20 above) sec 103.

²³ <http://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx> (accessed 2 April 2014).

2016 transition period available to the other EAC member states.²⁴ Like the Burundi law, the Act establishes non-working as a ground for withdrawing a patent. It also encompasses compulsory licensing on several grounds, including public health.²⁵

Rwanda

As a LDC, Rwanda is not under a TRIPS obligation to protect pharmaceutical patents until 2016.²⁶ Consequently, Rwanda's patent law, the Law no 31 of 2009 on the Protection of Intellectual Property,²⁷ excludes from patent protection, 'pharmaceutical products, for the purposes of international conventions to which Rwanda is party.'²⁸

The Rwandan legislation, like the foregoing laws in Burundi and Kenya, lays out the procedure and requirements for patentability.²⁹ It also provides for circumstances when a patent may be withdrawn, and this includes non-working and compulsory licensing on grounds of public health, among others.³⁰

The United Republic of Tanzania

The United Republic of Tanzania is made up of Tanzania-mainland and Tanzania-Zanzibar. Tanzania-mainland and Tanzania-Zanzibar maintain different sets of laws on patents.³¹ The relevant law for Tanzania-mainland is the Patents (Registration) Act of 1994.³² The accompanying subsidiary legislation is the Patent Regulations of 1994.³³ The relevant law in Tanzania-Zanzibar is the Zanzibar Industrial Property Act.³⁴

²⁴ TRIPS art 66.1; the Decision of the Council for TRIPS of 27 June 2002 on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for certain Obligations with Respect to Pharmaceutical Products (IP/C/25 1 July 2002).

²⁵ Act 3 of 2001 (n 20 above) sec 80.

²⁶ n 24 above.

²⁷ Law 31 of 2009.

²⁸ n 27 above, art 18.8.

²⁹ n 27 above, secs 1 & 3.

³⁰ n 27 above, art 7.

³¹ Adams & Adams (n 13 above) 575.

³² Cap 217 (incorporating Patents Act 1 of 1987 (as amended by Acts no 13 of 1991 and no 18 of 1991).

³³ Adams & Adams (n 13 above) 575.

³⁴ Act 4 of 2008 (Part II – cap I & II) & Part IV).

The United Republic of Tanzania is a party to TRIPS and the Paris Convention.³⁵ Both the mainland's and Zanzibar's patent laws provide for the requirements for patentability and the procedure of obtaining a patent.³⁶ They set out what constitutes patentable subject matter and both recognise that compulsory licenses could be issued on various grounds including public health.³⁷ A striking difference between the two laws, however, is on the duration of a patent: while Zanzibar's law grants patent protection for a period of 20 years, the mainland's law grants patent protection for a period of 10 years, extendible for further two terms of 5 years each.³⁸ Another striking difference is that the mainland's law does not incorporate the transition period allowed to LDCs. The Zanzibar legislation does incorporate this flexibility.³⁹

Uganda

The laws relevant to patents in Uganda are the Patents Act,⁴⁰ the Patents (Amendment) Act of 2002 and the Patent Regulations of 1993.⁴¹ Uganda does not utilise the flexibility that allows LDCs to exempt pharmaceutical products from patentability until 2016, even though the country qualifies as such. Uganda is also a member of the Paris Convention.⁴²

Uganda's Patent Act, like those of other EAC countries, stipulates the requirements for patentability, the procedure for applying for patents and what constitutes patentable subject matter.⁴³ Patent protection in Uganda, unlike in the other EAC states, is granted for an initial period of 15 years with an option of conditional renewal.⁴⁴ Like the other patent laws in the EAC states, Uganda's patent legislation provides for compulsory licensing on several stated grounds, including public health.⁴⁵

³⁵ http://www.wto.org/english/thewto_e/countries_e/tanzania_e.htm (accessed 2 April 2014); http://www.wipo.int/treaties/en/remarks.jsp?cnty_id=333C (accessed 2 April 2014); http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax_a.pdf (accessed 2 April 2014).

³⁶ Cap 217 (n 32 above) secs 7-13; secs 18-30; Act 4 of 2008 (n 34 above) secs 3-11.

³⁷ Cap 217 (n 32 above) sec 55; Act 4 of 2008 (n 34 above) sec 14.

³⁸ Act 4 of 2008 (n 34 above) sec 24; Cap 217 (n 33 above) sec 39.

³⁹ Act 4 of 2008 (n 35 above) sec 3.

⁴⁰ Cap 216 of 1993.

⁴¹ Adams & Adams (n 13 above) 628.

⁴² http://www.wipo.int/treaties/en/remarks.jsp?cnty_id=329C (accessed 2 April 2014); http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax_a.pdf (accessed 2 April 2014).

⁴³ Cap 216 of 1993 (n 40 above) secs 7-23.

⁴⁴ n 40 above, sec 31.

⁴⁵ n 40 above, sec 29.

4.2.2 The regional framework

It has been explained above that EAC member states envisage cooperation in several areas including in public health and IP.⁴⁶ It is on this basis that initiatives were launched that climaxed in the Policy and the Protocol. The Protocol reflects a commitment ‘...to the implementation of the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation...’⁴⁷

The purpose of the Policy, on the other hand, is to enable the EAC member states to ‘to utilize the Public Health-related flexibilities contained in the TRIPS Agreement and its related instruments in order to help address public health problems afflicting their populations.’⁴⁸ The Policy seeks to attain this by providing guidelines pursuant to which the EAC member states are to adjust their national legislation in order to fully utilise the Public Health-related WTO-TRIPS flexibilities.⁴⁹ The specific minimums that member states should incorporate in their national legislation are spelt out in the Policy. They are outlined below.

4.3 The regional framework’s policy statements

The Policy and the accompanying Protocol described above encompass a number of policy tools tailored to utilise the WTO-TRIPS flexibilities. The policy tools are styled as the recommended amendments to national patent legislation. This part elaborates on the provisions of the Policy regarding each of these policy statements.

4.3.1 Transition periods

The application of this flexibility is limited in the sense that it is only available to LDCs.⁵⁰ What this flexibility does is to exempt LDCs from the obligation to implement, apply or enforce patents on pharmaceutical products and processes as well as clinical test data protection until 1

⁴⁶ The Common Market Protocol (n 8 above) arts 5(3) k and 43.

⁴⁷ The Protocol, para 10 of the preamble.

⁴⁸ The Policy (n 11 above) para 2.2.

⁴⁹ n 11 above, para 2.3.

⁵⁰ See n 24 above.

January 2016.⁵¹ The LDCs were initially allowed a transition period until 1 January 2006 which was extended in 2002 to 1 January 2016.⁵²

What is the rationale behind transition periods for LDCs? The stated justification is that transition periods are useful ‘...in view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base.’⁵³

The ‘mailbox’ obligation comes hand in hand with the transition periods flexibility. The mailbox obligation requires countries that are not under obligation to grant pharmaceutical patents to nevertheless establish a mechanism for accepting patent applications upon which a decision to grant or reject a patent shall be made at the expiry of the transition period.⁵⁴ In explaining the significance of mailbox applications, Cynthia Ho notes that ‘the mailbox provision is important for ensuring that inventions created before patents are examined (and properly filed pursuant to the mailbox provision) are likely to become issued patents once patents on the products are permitted.’⁵⁵ The essence of the mailbox obligation is to ensure that patent applications are examined for patentability (in light of prior art), at the time of filing and not of examining the application – without the mailbox provision, inventors could easily be denied patents as a result of inventions that occurred subsequent to their inventions during the transition periods.⁵⁶

The Policy provides two ways to make use of the transition periods flexibility: first, that all EAC LDCs should take advantage of the 2016 transition period and provide in their national patent legislation for a possible extension of this period as may be agreed upon by the Council for TRIPS and second, that all EAC states abolish any mailbox provision in their patent laws.⁵⁷ Of note here is the reasoning behind the call for the abolition of the mailbox provision. According to the Policy, all LDCs that made available patent protection for pharmaceutical products on 1

⁵¹ The Policy (n 11 above) para 3.1.

⁵² http://www.wto.org/english/tratop_e/tripos_e/ldc_e.htm (accessed 2 April 2014)

⁵³ TRIPS (n 24 above) art 66(1).

⁵⁴ CM Ho *Access to medicine in the global economy: International agreements on patents and related rights* (2011) 85.

⁵⁵ Ho (n 54 above) 85.

⁵⁶ As above.

⁵⁷ The Policy (n 11 above) para 3.1.

January 1995 and only later chose to suspend it are not obliged to have a mailbox provision in their patent laws.⁵⁸

4.3.2 Patentability criteria

This flexibility seeks to take advantage of the perceived lack of precision in the definition of the criteria for patentability in TRIPS.⁵⁹ TRIPS lays out the conditions to be met before a patent can be granted: novelty, inventive step and industrial applicability.⁶⁰ The Policy notes that TRIPS ‘does not provide definitions for these three criteria...members have the flexibility to define these three criteria for patentability in their national patent legislation.’⁶¹ The Policy concludes that if the criteria are applied strictly, the EAC member states will have broad policy space to address the health needs of their populations. The Policy proceeds to stipulate the strict standards for the application of these criteria.

For novelty, the Policy directs that states can choose to assess novelty using wide prior art definitions consisting of:

...everything disclosed to the public whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be actually or theoretically accessed by the general public...⁶²

On the ‘inventive step’ requirement, the Policy postulates that that the invention has to be non-obvious to a person ‘highly’ skilled in the art. It is explained that if more expertise is used to adjudge the non-obviousness of an invention, it is more likely that the invention will be found obvious (and therefore not qualify for patent protection).⁶³ The Policy implores EAC states to strictly apply the ‘industrial applicability’ requirement by limiting the patentability of research tools to only those for which a specific use has been identified.⁶⁴ The explanation is that this will prevent the patentability of research tools that may have a variety of uses.

⁵⁸ As above.

⁵⁹ n 11 above, para 3.2.

⁶⁰ TRIPS (n 24 above) art 27.

⁶¹ The Policy (n 11 above) para 3.2.

⁶² As above.

⁶³ As above.

⁶⁴ As above.

4.3.3 Materials excluded from patentability

TRIPS explicitly outlines products and processes that states may exclude from patentability.⁶⁵ In addition to these express possible exclusions, the Policy proposes to exclude from patentability natural substances; new medical uses of known substances; and derivatives of medical products that do not show significantly enhanced therapeutic efficacy or significant properties.⁶⁶ In providing for these exclusions, the Policy proceeds from the premise that TRIPS does not define the term ‘invention.’ As such, the Policy opines, states have the flexibility to define the term in their national legislation and in so doing, exclude the aforementioned categories from the definition.⁶⁷

The Policy argues that in line with the aim of strengthening local generic manufacturers’ capabilities through reverse engineering of medicines based on naturally found micro-organisms, states should enact legislation excluding natural substances from patentability on the ground that they are not inventions due to their lack of technical contribution to the art.⁶⁸ The Policy further argues that national patent laws could still exclude natural substances from patentability even if they had been isolated or purified, although this would not prevent inventors from applying for patents on the processes of isolating a natural substance, the methods of using a natural product or where the substance itself was changed by means of genetic engineering.⁶⁹

The Policy explains that the exclusion from patentability of new medical uses of known substances is aimed at curbing the ‘ever-greening’ of patents – where new patents are granted for the discovery of a new use of a patented substance.⁷⁰ The reasoning behind the exclusion of derivatives of medical products from patentability is to prevent ‘slight and insignificant variations of originally patented pharmaceutical substances from restricting the public domain...’⁷¹ The Policy suggests two alternative approaches as to the requirements for the patentability of derivatives: the Indian approach which requires significantly enhanced

⁶⁵ TRIPS (n 24 above) arts 27 (2) & 3.

⁶⁶ The Policy (n 11 above) para 3.3.

⁶⁷ As above.

⁶⁸ As above.

⁶⁹ As above.

⁷⁰ K.M Gopakumar ‘Product patents and access to medicines in India: a critical review of the implementation of TRIPS patent regime (2010) 3:2 *The Law and Development Review* 326 365.

⁷¹ The Policy (n 11 above) para 3.3.

therapeutic efficacy and the US approach which requires an invention to have unexpected properties.⁷² The Policy proposes that EAC states can have in their legislation a provision to the effect that any structural similarities between a new invention and an originally patented substance create a presumption of lack of invention, novelty or inventive step and that the patent applicant will thus have the burden of proving the superior properties of the variation.

In addition to the foregoing, this policy statement also calls upon states to protect small scale inventions and traditional medicines in order to accommodate the interests of domestic inventors.⁷³ The Policy proposes alternative protection methods such as use-and-pay and compensatory liability in order to avert the effects that patents may have on blocking access, while ensuring access to the medicines.

4.3.4 Research exception

The Policy bases this flexibility on a provision in TRIPS which creates exceptions to the exclusive rights it grants with the proviso to the effect that ‘provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.’⁷⁴ The Policy argues that ‘since a strong research base is fundamental to the competitiveness of the EAC region vis-à-vis other markets and for the protection of social welfare in the region, it is important that a right balance is struck between the system of patent rights and the opportunity to conduct research.’⁷⁵

On this premise, the Policy implores the EAC states to enact legislation authorizing local scientists and researchers to use patented substances for both scientific and commercial research in order to gain new knowledge about the substance itself. The Policy states further that ‘the predominant purpose of the commercial research must be the improvement of the patented substances, as opposed to mere reverse engineering and copying of the patented invention.’⁷⁶ With regard to using patented research tools, the Policy recommends that states can enact

⁷² As above.

⁷³ As above.

⁷⁴ TRIPS (n 24 above) art 30.

⁷⁵ The Policy (n 11 above) para 3.4.

⁷⁶ As above.

legislation providing researchers with a right to claim a non-exclusive licence for the use of the patented research tools against payment of reasonable compensation.⁷⁷

4.3.5 Marketing approval – ‘Bolar’ exception

This Policy statement seeks to enable generic manufacturers to enter the market as soon as the term of a patent expires by having national legislation that, one, authorises the use of patented substances by interested parties seeking marketing approvals from regulatory authorities and two, clarifies the scope of the marketing approval(‘Bolar’) exception so that generic producers may use patented substances for acts reasonably related to the development and submission of information required for marketing approvals.⁷⁸ The Policy contends that this flexibility can be justified under Article 30 of TRIPS and that it would enable generic producers to file applications for market approvals of competing products even before a patent expires so that generic products can be introduced in the market as soon as the patent term ends.⁷⁹

4.3.6 Test data protection

Test data here refers to the information that pharmaceutical producers provide to Medical Regulatory Authorities (MRAs) regarding safety, effectiveness and quality that is generated in the preclinical and clinical testing of a medicine. TRIPS provides for the protection of this information against unfair commercial use.⁸⁰

The stated objective of this flexibility in the Policy is to avoid unnecessary costly and lengthy clinical trials of generic pharmaceutical products.⁸¹ This objective is to be attained by the enactment of legislation that permits MRAs to rely on the results of the original test data to assess the safety and efficacy of generic competing products, under what is called the misappropriation approach.⁸² The Policy also recommends that the EAC states should not enact legislation that establishes a linkage between patent protection and market authorisation.⁸³ In

⁷⁷ As above.

⁷⁸ n 11 above, para 3.5.

⁷⁹ As above.

⁸⁰ TRIPS (n 24 above) 39.3.

⁸¹ The Policy (n 11 above) para 3.6.

⁸² As above.

⁸³ As above.

other words, MRAs should not be prevented from granting marketing authorisation to generic producers on the ground that the patent is yet to expire.

4.3.7 Disclosure requirements

This Policy statement seeks to promote technological learning and follow-on innovations by local innovators.⁸⁴ This is to be achieved by enacting legislation that requires patent applicants to ‘disclose all modes and expressly indicate the best mode for carrying out an invention by experts skilled in the art, who reside in the respective EAC Partner states.’⁸⁵ The Policy also recommends that patent applicants could be required to provide information concerning their corresponding foreign applications and grants and further, that patent applicants can be obliged to disclose the International Non-proprietary Name (INN) of a pharmaceutical substance or active pharmaceutical ingredient as soon as possible.

This flexibility is grounded on the rationale behind disclosing inventions – that the disclosures need to be: sufficient, complete, thorough and precise in order to enable those skilled in the art to practise the invention based on the information disclosed; sufficiently definite to give the public notice of what constitutes an infringement; identify the best mode of practising the invention known to the inventor when they file a patent application.⁸⁶

4.3.8 Administrative opposition procedures

The Policy proposes that national legislation should be amended to widen the scope of pre- and post-grant administrative patent opposition procedures.⁸⁷ The argument is that with the advancements in technology, it is possible that patent examiners unfamiliar with prior art may lack expertise to assess the novelty or non-obviousness of an invention. Therefore, widening pre- and post-grant opposition procedures will expose patent applications to a stricter verification.

The Policy also suggests amendments to the Harare Protocol, which establishes African Regional Intellectual Property Office, to take into account third party oppositions and to permit EAC states

⁸⁴ n 11 above, para 3.7.

⁸⁵ As above.

⁸⁶ As above.

⁸⁷ n 11 above, para 3.8.

to subject patents granted by ARIPO in their territories, to a written approval of the respective national patent office.⁸⁸ The goal is to ‘ensure that patents are only granted to inventors that meet the three criteria for patentability and to avoid time- and cost-intensive post-grant litigation.’⁸⁹

4.3.9 Parallel importation

This Policy statement is designed upon TRIPS and the Doha Declaration on TRIPS and Public Health, whose joint effect is that states are free to choose their own regime of exhaustion of IP rights.⁹⁰ In this regard, the Policy recommends that EAC states should opt for a regime of international exhaustion. The Policy argues that this would enable third parties to import pharmaceutical products from markets in which the products are cheaper than the home market.⁹¹ The Policy, citing legal practice in a number of countries, contends that parallel importation also permits the importation of generic medicines which have been produced in third countries under compulsory licences.⁹² The Policy notes that this is yet to be tested before the WTO.

In the same vein, the Policy guides that EAC states can also provide for international exhaustion of copyright and trademarks to avert liability for infringement in case copyrighted or trademarked pharmaceuticals are imported.⁹³ The stated objective of this Policy statement is to enhance access to health products and medical devices.

4.3.10 Compulsory licensing

Flowing from the provisions of Article 31 of TRIPS, the Policy recommends an elaborate compulsory licensing regime for EAC states. This policy statement makes a number of stipulations whose intended effect is to widen the scope of utilising compulsory licences. It requires, for instance, that EAC states should: be free to determine and stipulate in their laws grounds upon which compulsory licences may be granted; exclude injunctive relief as a remedy available under independent review of government use of licences; authorise administrative entities (instead of courts) to grant compulsory licences; and, stipulate a maximum of 90 days as

⁸⁸ As above.

⁸⁹ As above.

⁹⁰ TRIPS (n 24 above) art 6.

⁹¹ The Policy (n 11 above) para 3.9.

⁹² As above.

⁹³ As above.

the period for prior negotiations before a compulsory licence can be issued.⁹⁴ The justification for the last two proposals is that this would make the process faster.⁹⁵

The Policy makes other recommendations. It suggests that EAC states should amend the compulsory licensing provisions in patent laws to include a provision authorising the export of up to 100% of pharmaceutical production to countries lacking sufficient pharmaceutical capacities and draft guidelines and regulations both as exporting and importing countries on the export/importation of pharmaceutical products into countries with insufficient pharmaceutical manufacturing capacities under the ‘Paragraph 6’ system.⁹⁶

The Policy further provides that EAC states: when importing pharmaceutical products under the Paragraph 6 system, can waive remuneration for import compulsory licences where its value has been taken into account when remunerating the patent right holder in the exporting country; can include in their patent laws a provision stating that the remuneration shall not exceed the UNDP recommended figure of 4%, and take into account anti-competitive behaviour when determining the amount of remuneration; spell out in their patent laws all four situations in which prior negotiations can be waived, namely in case of national emergency, other situations of extreme urgency, public non-commercial use – government use, and to remedy anti-competitive behaviour of the patent right holder; and, put in place institutional monitoring mechanisms for determining and actuating the four situations in which prior negotiations can be waived.⁹⁷

4.3.11 Anti-competitive behaviour and patent abuse

This policy statement urges EAC member states to design a policy preventing abuses of patent rights.⁹⁸ It is motivated by section 8 of TRIPS which provides that measures that are consistent therewith may be taken to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.⁹⁹ The objective of this policy statement is to create a ‘pro-competitive environment in order to

⁹⁴ n 11 above, para 3.10.

⁹⁵ As above.

⁹⁶ As above.

⁹⁷ As above.

⁹⁸ n 11 above, para 3.11.

⁹⁹ TRIPS (n 24 above) art 40.

promote transfer of technology for the development of local pharmaceutical production capacity.’¹⁰⁰ The Policy proposes that the EAC states can, in their legislation, first, identify licensing terms that may be considered unjustified restrictions of competition and authorise the patent registrar to refuse the registration of such licensing contracts and second, provide for remedies to patent rights abuse, such as compulsory licences.¹⁰¹

4.4 Conclusion

This chapter has discussed the EAC’s legal framework for patents and access to medicines. The chapter has highlighted the national patent laws in place in the EAC member states. It has elaborated the framework and spheres of EAC cooperation in order to explain the background against which the Policy and the accompanying Protocol were developed. Ultimately, the policy tools enshrined under the Policy and Protocol have been identified and described in terms of their definitive elements and how the Policy seeks to exploit them. This has laid the basis for critical assessment of these policy tools in the next chapter.

¹⁰⁰ The Policy (n 11 above) 3.11.

¹⁰¹ As above.

CHAPTER FIVE

A CRITICAL REVIEW OF THE EAC REGIONAL POLICY

5.1 Introduction

This chapter relies on the arguments and discussions in the previous chapters to critically assess the policy tools enshrined in the Policy. This is done through the prism of utilitarianism and the Game theory. The aim is to ascertain whether the specific policy tools strike the required balance between patent protection and access to medicines. By the conclusion of this chapter, it would have been demonstrated that the policy tools are strongly biased towards ensuring access to medicines through efforts at price reduction, at the expense of patent protection. Deriving from the premise that the EAC countries, like other African countries, are beset by peculiar so-called African diseases, which are largely neglected by foreign pharmaceuticals due to commercial considerations, an argument will be made that most of the recommended policy tools will only worsen the already bad situation. In other words, the policy tools are likely to prove counterproductive.

5.2 An Assessment of the policy tools

This part will show that while some of the policy tools are in consonance with the situation in the EAC states, majority of the tools are inappropriate and out of kilter with the situation.

5.2.1 Transition periods

This flexibility, in respect of pharmaceuticals, is available for LDCs – Burundi, Rwanda, Tanzania and Uganda in this case.¹ The transition period has been extended twice – it was initially set to end on 1 January 2006, but was extended to 1 January 2016.² As mentioned in chapter four, this flexibility recognises the economic, financial and administrative constraints faced by LDCs, and their need for policy space to develop a viable technological base.³

¹ TRIPS art 66.1.

² Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 WT/MIN (01)/DEC/220 November 2001 (01-5860) para 7; Decision of the Council for TRIPS of 27 June 2002 Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products IP/C/25 1 July 2002 (02-3664).

³ Chapter four part 4.3.1.

The transition period allowed for LDCs is distinguishable from that allowed for other developing countries – for other developing countries, the transition period was meant to permit them more time to implement TRIPS.⁴ For LDCs, as Hold and Mercurio note, ‘the provision recognizes that a rapid implementation of the Agreement could create a conflict with the economic interests and development priorities...’⁵

This distinction is buttressed by the fact that unlike developing countries, LDCs are not under the non-roll back obligation.⁶ The non-roll back obligation would be violated if a country ‘that already complies with intellectual property protection under the TRIPS Agreement in some form...reduces the level of compliance...’⁷ Utilisation of TRIPS flexibilities, however, is not rollback.⁸ The EAC policy tool on transition periods seeks to make use of the absence of the non-roll back obligation in respect of the mailbox provision.⁹ The Policy urges LDCs, (including those that had made patent protection available on 1 January 1995 and later suspended it), with a mailbox provision to abolish it.¹⁰

As explained in chapter three, the mailbox provision requires states that do not yet provide patents for pharmaceutical and agricultural chemical products to create a mechanism for receiving applications which will then be examined when the states begin providing such protection.¹¹ As Cynthia Ho explains, the goal of the mailbox provision is to ensure that patent applications are examined in light of the prior art that existed when the application was made and not when the application is examined.¹²

An argument is made here against both the abolition of the mailbox provision and (an extension) the use of transition periods in EAC states’ laws. Transition periods are no doubt an important

⁴ TRIPS (n 1 above) art 65.

⁵ A Hold & BC Mercurio ‘After the second extension of the transition period for LDCs: How can the WTO gradually integrate the poorest countries into TRIPS?’ (2013) *Swiss National Centre for Competence in Research Working Paper* no 2013/42/July 2013 7.

⁶ Hold & Mercurio (n 5 above).

⁷ http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm (accessed 9 April 2014)

⁸ As above.

⁹ The Policy para 3.1.

¹⁰ As above.

¹¹ TRIPS (n 1 above) art 70.8.

¹² CM Ho *Access to medicine in the global economy: International agreements on patents and related rights* (2011) 85.

flexibility for LDCs. They are a form of special and differential treatment.¹³ Importantly, they are a non-controversial flexibility grounded within the WTO legal framework since they are precisely agreed to by WTO members.¹⁴ LDCs can make use of this flexibility to address the dire medical needs of their populations while erecting the necessary institutional and technological frameworks for integration into the multilateral system.

However, it is here argued that EAC states should consider granting pharmaceutical patents despite the flexibility afforded by the transition periods. It is worth noting that in fact, Tanzania and Uganda, despite being LDCs, grant patents for pharmaceuticals.¹⁵ It is only Burundi and Rwanda that have provided for transition periods in their laws.¹⁶ The next part demonstrates the clear need for a paradigm shift by EAC states towards promoting local innovation and investment in the development of necessary medicines through patent protection.¹⁷ It is also in this regard that an argument is made in favour of retaining the mailbox provision, at least for Rwanda and Burundi that do not grant pharmaceutical patents yet. This is because the abolition of the mailbox provision will have the negative effect of not only stifling innovation but also discouraging disclosure of discoveries due to the absence of a guarantee of protection.

5.2.2 Patentability criteria and materials excluded from patentability

The Policy, as indicated in chapter four, seeks to utilize the patentability criteria flexibility in three ways. First, it recommends that states assess novelty using ‘wide prior art definitions.’¹⁸ This includes everything disclosed to the public whether by use (in written or oral form) including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be accessed by the general public.¹⁹ Second, with regard to the inventive step requirement, the Policy requires that the invention be non-obvious to a person highly skilled in the art.²⁰ Third, on

¹³ Hold & Mercurio (n 5 above).

¹⁴ n 2 above.

¹⁵ Chapter four part 4.2.1; Tanzania Patents (Registration) Act of 1994; Uganda Patents Act Cap 216 of 1993.

¹⁶ Law 1/13 of 2009 relating to Industrial Property in Burundi arts 17 & 381; Law 31 of 2009 on the Protection of Intellectual Property in Rwanda art18.8.

¹⁷ See part 5.2.2 below.

¹⁸ The Policy (n 9 above) para 3.2.

¹⁹ As above.

²⁰ As above.

industrial applicability, it is directed that applications for research tools' patents identify the specific use of the research tools.²¹ The Policy also excludes from patentability natural substances; new medical uses of known substances; and derivatives of medical products that do not show significantly enhanced therapeutic efficacy or significant properties.²²

The totality of these provisions is to make it difficult to obtain a patent. The threshold is set so high with the intended result that many applications for pharmaceutical patents will not be granted and as such, states will 'have enough policy space for public health purposes.'²³ There are arguments to support such a strict approach to patentability. For one, a strict criterion will prevent the patenting of known substances or small modifications on existing products and processes – a practice called the evergreening of patents.²⁴ It is argued that large established firms with experienced lawyers are more likely to take advantage of low patentability criteria to block generic competition through evergreening.²⁵ The ramification of this practice will be that consumers will have to pay for what would otherwise be in the public domain. Despite the persuasiveness of these arguments, this study contends that this approach is inappropriate in the context of the EAC states for the following reasons.

To begin with, the approach fails to recognise the need to foster innovation and develop domestic pharmaceutical capacity. In most developing countries, as Correa notes, 'the innovation systems are fragmented and weak, and they overwhelmingly depend on foreign innovations.'²⁶ Firms in such countries '...follow "imitative" or "dependent" technological strategies, usually relying on external sources of innovation, such as suppliers, customers and competitors.'²⁷ As such, 'a patent regime based on a low inventive threshold could be functional to the predominantly incremental innovation path prevailing in developing countries, as patents might encourage

²¹ As above.

²² n 9 above, para 3.3; chapter four part 4.3.3.

²³ As above.

²⁴ CM Correa 'Pharmaceutical innovation, incremental patenting and compulsory licensing' (2011) 41 *South Centre Research Paper* 5; K.M Gopakumar 'Product patents and access to medicines in India: A critical review of the implementation of TRIPS patent regime' (2010) 3:2 *The Law and Development Review* 326 332; W Kondro 'Supreme Court rules against drug patent "evergreening"' (2006) 175 *Canadian Medical Association Journal* 1508.

²⁵ A Kapczynskiti 'Harmonization and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector' (2009) 97 *California Law Review* 1571 1590.

²⁶ Correa (n 24 above) 2.

²⁷ As above.

minor innovations developed by domestic companies.’²⁸ A strict patentability criterion will thus undermine domestic firms. Further, a severe patentability test may result in non-disclosure of small innovations, and consequently, duplication of research and development costs by firms unaware of earlier innovations.²⁹

It is no longer contestable that developing countries now need to develop domestic pharmaceutical industries to address the medical needs of their populations. Of course the need to have a competitive technological capacity by 2016 when the transition period ends is one of the reasons.³⁰ The other reason, however, is that most of the diseases afflicting these countries (tropical/African diseases) – are peculiar to the region and are largely neglected by foreign pharmaceuticals.³¹ As Ferrara observes, these are diseases ‘for which the main problem is still lack of adequate incentive to produce effective drugs.’³² The reason why there is no research towards developing orphan drugs (medicines for neglected diseases) is that they are not profitable because they affect low income population groups.³³ Sell notes, correctly, that the ‘increasing commercialization of medicine means that the diseases of the poor will be ignored by firms for sound economic reasons.’³⁴

The available option is for the affected countries to develop domestic solutions. With stringent rules on patentability, it would become difficult to spur innovative activity from the small-scale, largely underfunded domestic firms whose innovation capacity is unlikely to meet a very high patentability threshold. The argument here is that the ‘formulation of a patent regime...should not be dissociated from the characteristics of the national innovation system of the country where such regime applies.’³⁵ This is the point that the Policy misses.

²⁸ n 24 above, 3.

²⁹ Y Mènière ‘Patent law and complementary innovations’ (2007) 18 <http://en.youscribe.com/catalogue/reports-and-theses/knowledge/humanities-and-social-sciences/non-obviousness-and-complementary-innovations-1599067> (accessed 9 April 2014).

³⁰ Under TRIPS (n 1 above) art 66.1, it could be extended further.

³¹ E Ferrara ‘Access to medicine: patent, price regulation and prizes’ (2009) *Washington College of Law International Legal Studies Programme* 16.

³² As above.

³³ SA Singham ‘Competition policy and the stimulation of innovation: TRIPS and the interface between competition and patent protection in the pharmaceutical industry’ (2000) 26 *Brooklyn Journal of International Law* 363 383; L Forman ‘Trade rules, intellectual property, and the right to health’ (2007) *Ethics and International Affairs* 337 350.

³⁴ SK Sell ‘TRIPS-Plus free trade agreements and access to medicines’ (2007) 28 *Liverpool Law Review* 41 50.

³⁵ Correa (n 24 above) 2.

5.2.3 Research exception, ‘Bolar’ provision and test data protection

These three flexibilities are related. As explained in chapter three, the research exception is aimed to ‘promote scientific and technological progress.’³⁶ The research exception flexibility allows researchers to use a patented substance for scientific research in order to fully understand the substance.³⁷ While the Policy allows this exception for both scientific and commercial research, it emphasises that ‘the predominant purpose of the commercial research must be the improvement of the patented substances, as opposed to mere reverse engineering and copying of the patented invention.’³⁸ The second aspect of the research exception flexibility in the Policy requires that legislation provides researchers with a right to claim a non-exclusive licence for the use of patented research tools against payment of reasonable compensation.³⁹

This flexibility is largely appropriate. One reason for this proposition is that the flexibility, if well utilised, has the potential to enhance scientific and technological advancement in the EAC member states. As explained in the foregoing part, the need for local focus on medicines for diseases peculiar to the region cannot be gainsaid.⁴⁰ Interestingly, this exception seems to acknowledge that local scientific and technological advancement may have to be premised on incremental innovations – it identifies the purposes of the research exception as being first, to fully understand the patented substance, and second, the improvement of the patented substance.⁴¹ In all preponderance, this appreciates the necessity of using existing inventions to enhance local innovation. This is one more reason why the strict patentability criteria described above is inappropriate. It is ‘dissociated from the characteristics of the national innovation system of the country...’⁴²

Additionally, the research exception does not seem to curtail the rights of the patent holder. There are strong limitations placed on the use of this flexibility. For one, it is only to enable a full understanding of the patented substance and two, even where it is for commercial research, the predominant goal is the improvement of the patented substance as opposed to mere copying

³⁶ The Policy (n 9 above) para 3.4.

³⁷ http://www.wto.org/english/tratop_e/tripos_e/tripos_e/factsheet_pharm02_e.htm (accessed 9 April 2014).

³⁸ The Policy (n 9 above) para 3.4.

³⁹ As above.

⁴⁰ See part 5.2.2 above.

⁴¹ The Policy (n 9 above) para 3.4.

⁴² Correa (n 24 above) 2.

and reverse engineering.⁴³ When a patented research tool is to be used, the Policy directs that reasonable compensation be paid to the patent-holder.⁴⁴

The ‘Bolar’ provision or the ‘regulatory’ exception enables generic manufacturers to use a patented invention before the end of the patent term and without the patent owner’s permission, to obtain marketing approval from regulatory authorities.⁴⁵ The purpose of this flexibility is to ‘ensure early entry of generic pharmaceuticals.’⁴⁶ The rationale for the Bolar provision is that often, regulatory approvals of medicines take a long time. If generic manufacturers have to wait until the expiry of the patent term before seeking regulatory approval, the entry of generic medicines into the market will be delayed and contemporaneously, the patent holder will *de facto* enjoy longer periods of protection beyond the patent term.⁴⁷ A WTO Panel has held that:

If there were no regulatory review exception allowing competitors to apply for regulatory approval during the term of the patent, therefore, the patent owner would be able to extend its period of market exclusivity, *de facto*, for some part...depending on how much, if any, of the development process could be performed during the term of the patent under other exceptions, such as the scientific or experimental use exception.⁴⁸

The Bolar provision strikes a proper balance between the private rights of the patent holder and the public interest of access to medicines. This is because the ‘exception is confined to conduct needed to comply with the requirements of the regulatory approval process,’⁴⁹ and ‘the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded.’⁵⁰ The generic manufacturers only enter the market at the expiry of the patent term. In this regard, the Panel noted as follows:

Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner’s rights themselves

⁴³ The Policy (n 9 above) para 3.4.

⁴⁴ As above.

⁴⁵ http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (accessed 9 April 2014).

⁴⁶ The Policy (n 9 above) para 3.5.

⁴⁷ *Canada – Patent Protection of Pharmaceutical Products* WT/DS114/R 17 March 2000 para 7.48.

⁴⁸ As above.

⁴⁹ n 47 above, para 7.45.

⁵⁰ As above.

are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products.⁵¹

As such, the use of this flexibility is unlikely to be a disincentive to research and innovation as it does not affect a patent holder's normal exploitation of the patent.⁵² Importantly, the WTO Panel jurisprudence is that 'the regulatory review exception...is a "limited exception" within the meaning of Article 30 of the TRIPS Agreement.'⁵³ The same is true for the research exception.⁵⁴ The flexibility on test data protection is however not as easy to endorse.

The test data protection flexibility is meant to avoid 'unnecessary costly and lengthy clinical trials of generic pharmaceutical products.'⁵⁵ This flexibility permits generic manufacturers to rely on test data submitted by the originator, for the approval of the generic medicines. This averts the duplication of costs and time in conducting fresh clinical trials.⁵⁶ Test data is a necessity for marketing approvals because '[a]s a practical matter, without this data, no pharmaceutical product with a new active ingredient would be marketed anywhere in the world.'⁵⁷ Yet, 'extensive testing directly translates into extensive costs for generating the data necessary to obtain approval of each new active ingredient.'⁵⁸ These also include the costs of generating the data associated with products that were abandoned in pre-clinical or clinical trials or were not approved by the health authorities.⁵⁹ In a nutshell, test data is an expensive necessity.

Test data protection is paradoxical. As indicated above, allowing generic companies to rely on original test data averts duplication of costs in fresh repetitive clinical trials and testing. This in turn translates into lower prices for consumers of the medicine.⁶⁰ This, however, 'would jeopardize the ability of the originator to recoup the costs of generating the test data, and would

⁵¹ As above.

⁵² TRIPS (n 1 above) art 30.

⁵³ The *Canada patent* case (n 47 above) para 7.50.

⁵⁴ http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (accessed 10 April 2014)

⁵⁵ The Policy (n 9 above) para 3.6.

⁵⁶ S Scafidi 'The "good old days" of TRIPS: The US trade agenda and the extension of pharmaceutical test data protection' (2013) 4:2 *Yale Journal of Health Policy, Law, and Ethics* 341 346.

⁵⁷ GL Skillington & EM Solovy 'The protection of test and other data required by article 39.3 of the TRIPS Agreement' (2003) 24:1 *Northwestern Journal of International Law & Business* 1 6.

⁵⁸ n 57 above, 8.

⁵⁹ As above, 8.

⁶⁰ Scafidi (n 56 above) 343.

reduce the incentives for the originator to generate the necessary test data to market the product...⁶¹ This is particularly pronounced in developing countries where, because of the low income levels, there is no market incentive to research and develop medicines for tropical diseases, as a result of which test data protection remains one of the few carrots to dangle.⁶²

The Policy recommends that EAC states' legislation should adopt a system to protect data against unfair commercial use and disclosure, while permitting the Medical Regulatory Authorities (MRAs) to rely on the original test data when assessing the safety and efficacy of generic medicines.⁶³ The Policy proposes the use of the misappropriation approach instead of the compensatory liability approach because under the latter, 'the generic competitor...would have to pay compensation to the data originator, and this might exceed the local generic producers' financial capabilities.'⁶⁴ This approach is unsuitable for the EAC states.

The Policy appears to pursue a narrow interpretation of 'unfair commercial use' by creating the appearance that reliance by MRAs on original test data to approve generic drugs is consistent with protecting the data from unfair commercial use.⁶⁵ This approach is in line with pundits who argue that MRAs' reliance on such data does not involve any disclosure to a third party and consequently, that the competitor does not benefit from the use of the original test data as the result of unfair commercial practices.⁶⁶ The other school of thought, however, considers unfair commercial use from the perspective of the effect of relying on the original test data. In this sense, it is argued that the MRAs' reliance on the test data accords a generic manufacturer an unfair commercial advantage because without the data, the generic medicines would not have been approved to enter the market.⁶⁷ The generic manufacturer gets a 'free ride.'⁶⁸

⁶¹ Skillington & Solovy (n 57 above) 10.

⁶² As above.

⁶³ The Policy (n 9 above) para 3.6.

⁶⁴ As above.

⁶⁵ As above.

⁶⁶ CM Correa 'Unfair competition under the TRIPS Agreement: Protection of data submitted for the registration of pharmaceuticals' (2002) 3 *Chicago Journal of International Law* 69 78.

⁶⁷ Scafidi (n 56 above) 346.

⁶⁸ Skillington & Solovy (n 57 above) 10.

In the broader context of the EAC states, using test data under the misappropriation approach without compensation is untenable. The main reason for this is that there is need to encourage research into cures for the peculiar regional diseases which continue to be neglected by foreign pharmaceuticals.⁶⁹ Consequently, as explained above, a conducive framework ought to exist to accommodate the local, small-scale, underfunded inventors.⁷⁰ Using test data developed at a great expense by a low-resourced enterprise to authorise its competitors without paying due compensation is certainly not one of the ways of incentivising local research.

Curiously, the framing of the Policy presupposes that originators of test data will always be foreign pharmaceuticals. For instance, it is explained that the payment of compensation under the compensatory liability approach ‘might exceed the *local* generic producers’ financial capabilities.’⁷¹ Further, the Policy also envisages government’s mitigating intervention to protect *local* generic producers ‘should the EAC Partner States become obliged, under constraint of a free trade agreement or in response to overwhelming bargaining power, to adopt a regime of data exclusivity prohibiting reliance.’⁷² This language illustrates that the underlying rationale of the Policy is that originators will be foreigners. It is out of kilter with the previous flexibilities, for instance, on research exception, which aim at domestic scientific and technological advancement. Even more tragic is that the language is out of kilter with the reality that these states need to develop local pharmaceutical bases to focus on their neglected diseases.⁷³ Moreover, in the absence of market incentives to attract foreign pharmaceuticals, it is incomprehensible why the remaining major incentive should be watered down.

5.2.4 Disclosure requirements, administrative opposition procedures and patent abuse

The disclosure requirements stipulated by the Policy are that the applicant must disclose ‘all modes and expressly indicate the best mode for carrying out an invention by experts skilled in the art, who reside in the respective EAC Partner State.’⁷⁴ The applicant would also be required to disclose the International Non-proprietary Name (INN) of a pharmaceutical substance or an

⁶⁹ Ferrara (n 31 above).

⁷⁰ Correa (n 24 above).

⁷¹ The Policy (n 9 above) para 3.6.

⁷² As above.

⁷³ Part 5.2.2 above.

⁷⁴ The Policy (n 9 above) para 3.7.

active pharmaceutical ingredient as soon as it is available.⁷⁵ The stated objective of this requirement is to promote technological learning and follow-on innovation by local innovators.⁷⁶

This requirement is in line with the fundamentals of patent law. Disclosure is ‘an essential feature of the arrangement between the patentee and the state...’⁷⁷ This is why ‘[a]dequate disclosure requires that the essential features of the invention are revealed in a way that would enable a person skilled in the particular field...to do so.’⁷⁸ In fact, in many jurisdictions, the disclosure requirement is so paramount that inadequate disclosure can invalidate a patent.⁷⁹ Some commentators hold that a stringent disclosure requirement may invalidate patents to significant inventions.⁸⁰ However, the predominant view is that disclosure should target to educate second-rank technicians rather than leading researchers in the field.⁸¹

The Policy has a variant – it requires disclosure to have specific focus on experts residing in the respective EAC states.⁸² This of course takes cognisance of the low technological and expert levels in these countries. The stated objective of disclosure: to promote technological learning and follow-on innovation by local innovators, fits in well with the research exception flexibility discussed above.⁸³ However, the high patentability criterion contradicts both.⁸⁴ These disclosure requirements are undoubtedly indispensable for technological growth in the EAC states.

Administrative opposition procedures, which provide for both pre- and post-grant opposition, are vital because it ‘...is necessary to check frivolous patents.’⁸⁵ These procedures ensure the integrity of patents since the public can provide evidence useful to evaluate patent applications against the patentability criteria.⁸⁶ For these procedures to be effective however, public access to

⁷⁵ As above.

⁷⁶ As above.

⁷⁷ H MacQueen *et al Contemporary intellectual property: law and issues* (2010) 378.

⁷⁸ As above.

⁷⁹ Eg the Industrial Property Act cap 509 Laws of Kenya sec 103; the Patents Act cap 216 Laws of Uganda sec 36; the Tanzania Patents (Registration) Act sec 64; UK Patents Act 1977 sec 14(3) & 72(1).

⁸⁰ WR Cornish *Intellectual property: patents, copyright, trademarks and allied rights* (1999) 135.

⁸¹ *Valensi v British Radio* [1973] RPC 337; n 80 above, 231.

⁸² The Policy (n 9 above) para 3.7.

⁸³ Part 4.2.3 above.

⁸⁴ Part 4.2.2 above.

⁸⁵ K.M Gopakumar (n 24 above) 345.

⁸⁶ C Correa & D Matthews ‘The Doha Declaration: Ten years on and its impact on access to medicines and the right to health’ (2011) *UNDP Discussion Paper* 29
http://www.undp.org/content/dam/undp/library/hiv/aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf
(accessed 11 April 2014).

information is crucial. In the EAC states, there is not strong awareness about patent applications as a result of which some may possibly escape the notice of credible challengers. More transparency is thus in required.⁸⁷ A possible argument against a strong opposition system is that it may be manipulated to delay the grant of patents.⁸⁸ This possibility can be remedied by an effective mechanism to sieve out *prima facie* frivolous opposition.

The other important stipulation in the Policy concerns anti-competitive behaviour and patent abuse.⁸⁹ This stipulation is founded on Article 8:2 of TRIPS, which allows member states to take appropriate measures consistent with TRIPS, to prevent rights-holders from abusing IPRs; unreasonably restricting trade or adversely affecting international transfer of technology.⁹⁰ It also relies on Article 40 of TRIPS which seeks to control anti-competitive behaviour in contractual licences.⁹¹ The stipulation recommends that EAC states should develop policies prohibiting the registration of licences with anti-competitive terms that restrict transfer of technology. It further recommends that compulsory licensing be used to remedy patent abuses arising from anti-competitive practices that unreasonably restrict trade and competition.⁹² The justification of this stipulation is undeniable. It recognises that some ‘patent strategies increasingly aim at blocking competition rather than seeking a reward for genuine innovations.’⁹³ Consequently, ‘[p]olicies aimed at enhancing access to medicines in developing countries should include an increased use of competition laws to remedy patent-based anti-competitive practices.’⁹⁴

5.2.5 Parallel importation

What is parallel importation? Simply put, it is the importation, without the permission of the patent holder, of a patented substance from another market where it has been legally introduced.⁹⁵ These imports compete directly with the still-patented products in the importing

⁸⁷ As above; K.M Gopakumar (n 24 above).

⁸⁸ K.M Gopakumar (n 24 above) 346.

⁸⁹ The Policy (n 9 above) para 3.11.

⁹⁰ TRIPS (n 1 above) art 8.2.

⁹¹ n 1 above) art 40.

⁹² The Policy (n 9 above) para 3.11.

⁹³ Correa & Matthews (n 86 above).

⁹⁴ As above.

⁹⁵ BC Mercurio ‘TRIPS, patents, and access to life-saving drugs in the developing world’ 8:2 *Marquette Intellectual Property Law Review* 211 242; Sell (n 34 above) 61.

market.⁹⁶ Parallel importation thrives on the concept of exhaustion of rights.⁹⁷ The argument is that once a product is introduced into the market, the patent holder has no rights over it and it can thus be sold anywhere.⁹⁸ Countries import medicines from other countries where the prices are lower than in the domestic market.⁹⁹ TRIPS is neutral towards compulsory licensing. It allows states to choose their own exhaustion of rights regime.¹⁰⁰ There are three possible exhaustion regimes – national, regional and international.¹⁰¹

National exhaustion excludes parallel importation; regional exhaustion allows parallel imports only from countries parties to a regional trade agreement while international exhaustion permits parallel importation from any country.¹⁰² The Policy recommends that EAC states adopt an international exhaustion regime.¹⁰³ The advantage of an international exhaustion regime is that it ‘favors consumer interests and access to medicine, because countries are free to import products from the country where they are legitimately sold for the lowest possible price.’¹⁰⁴ Another advantage is that parallel importation ‘obviates the need for a country to establish its own domestic manufacturing capabilities.’¹⁰⁵

A closer scrutiny of parallel importation, in light of the context of EAC countries, would however militate against the use of this flexibility. Pharmaceuticals use different prices in different regions depending on the income levels of the population and developing countries benefit under these differential pricing schemes.¹⁰⁶ However, parallel importation clearly

⁹⁶ C Barfield & M Groombridge ‘Parallel trade in the pharmaceutical industry: Implications for innovation consumer welfare, and health policy’ (1999) 10 *Fordham Intellectual Property, Media & Entertainment Law Journal* 185.

⁹⁷ K.M Gopakumar (n 24 above) 343.

⁹⁸ B Whobrey ‘International patent law and public health: Analyzing TRIPS’ effect on access to pharmaceuticals in developing countries’ (2007) 45 *Brandeis Law Journal* 623 632.

⁹⁹ ZA Zainol *et al* ‘Pharmaceutical patents and access to essential medicines in sub-Saharan Africa’ (2011) 10 *African Journal of Biotechnology* 12376 12385; K.M Gopakumar (n 24 above) 343.

¹⁰⁰ TRIPS (n 1 above) arts 6 & 28.

¹⁰¹ Correa & Matthews (n 86 above) 9.

¹⁰² As above; LR Helfer & GW Austin *Human rights and intellectual property mapping the global interface* (2014) 121.

¹⁰³ The Policy (n 9 above) para 3.9.

¹⁰⁴ CM Ho ‘A new world order for addressing patent rights and public health’ (2007) 82 *Chicago-Kent Law Review* 1469 1501.

¹⁰⁵ PB Sherman & EF Oakley III ‘Pandemics and panaceas: The World Trade Organization’s efforts to balance pharmaceutical patents and access to AIDS drugs’ (2004) 41 *American Business Law Journal* 353 375.

¹⁰⁶ Barfield & Groombridge (n 96 above) 224.

eliminates the incentive to use these schemes.¹⁰⁷ Parallel importation, it has also been argued, undermines a patent holder's monopoly rights which in turn disincentives investment in research and development of new medicines.¹⁰⁸ Yet, as the foregoing parts have demonstrated, the so-called African diseases have been neglected by western pharmaceuticals, exposing the need to promote local pharmaceutical activity.¹⁰⁹ In any event, given that market incentives to develop medicines for African diseases are already very low,¹¹⁰ adopting a flexibility that undermines patent holders' rights will only worsen the already bad situation.

Pundits have also cast aspersions on the utility of parallel importation in light of some external factors (relevant to EAC countries). First, given the low levels of per-capita income, even with parallel imports 'many countries, including those hardest hit by HIV/AIDS in Africa, might not be able to afford treatment for all those who need it.'¹¹¹ Second, parallel imports are often not useful due to structural problems such as government corruption.¹¹² In the same vein, it has been reported that some importers still proceed to resell the parallel imports at unreduced prices.¹¹³ Parallel importation also raises quality and safety issues. In fact, in 1999, Kenya banned the parallel importation of medicines over safety and quality concerns.¹¹⁴

5.2.6 Compulsory licencing

Compulsory licensing is where a government allows a third party to use a patent without the authorisation of the patent-holder, subject to monetary compensation.¹¹⁵ TRIPS and related instruments such as the Doha Declaration, discussed in chapter three, allow governments to issue

¹⁰⁷ AG Watson 'International intellectual property rights: Do TRIPS' flexibilities permit sufficient access to affordable HIV/AIDS medicines in developing countries?' (2009) 32:1 *Boston College International and Comparative Law Review* 143 154.

¹⁰⁸ JA Harrelson 'TRIPS, pharmaceutical patents, and the HIV/AIDS crisis: Finding the proper balance between intellectual property rights and compassion' (2001) 7 *Widener Law Symposium Journal* 154.

¹⁰⁹ See part 4.2.2 above.

¹¹⁰ Skillington & Solovy (n 57 above) 10.

¹¹¹ Z Lazzarini 'Making access to pharmaceuticals a reality: Legal options under TRIPS and the case of Brazil' (2003) *Yale Human Rights & Development Law Journal* 103 136.

¹¹² Whobrey (n 98 above) 633.

¹¹³ Sherman & Oakley III (n 105 above) 375.

¹¹⁴ DB Snyder 'South Africa's Medicines and Related Substances Control Amendment Act: A spoonful of sugar or a bitter pill to swallow?' (1999) 18 *Dickinson Journal of International Law* 175 191.

¹¹⁵ SM Ford 'Compulsory licensing provisions under the TRIPs agreement: Balancing pills and patents' (2000) 15:4 *American University International Law Review* 941 945; N Bass 'Implication of the TRIPS agreement for developing countries: Pharmaceutical patent law in Brazil and South Africa in the 21st century' (2002) 34 *George Washington International Law Review* 191 198.

compulsory licenses in certain circumstances.¹¹⁶ Compulsory licensing has been billed as an effective tool for enhancing access to medicines in developing countries.¹¹⁷ This is because the issuance of compulsory licenses facilitates the manufacture of generic medicines, thereby promoting competition and resulting in lower market prices.¹¹⁸ It has also been pointed out that the mere threat of issuing a compulsory license can have the effect of reducing prices of medicines.¹¹⁹

One issue with compulsory licensing is that it cannot be utilised by countries with no manufacturing capabilities.¹²⁰ As explained in chapter two, the 30 August 2003 Decision was developed to allow the export of medicines manufactured under compulsory licences to countries with no manufacturing capabilities.¹²¹ The Policy recommends that EAC countries amend their patent laws to include a provision authorising the export of up to 100% of pharmaceutical production to countries lacking sufficient pharmaceutical capacities.¹²² Such an amendment will facilitate exports/imports of medicines under the Paragraph 6 system amongst the EAC countries. This proposal seems to suppose that one or more of the EAC countries will have manufacturing capabilities.

As mentioned in chapter two, the Paragraph 6 system has been used only once.¹²³ This underpins the difficulties of using the system. Lisa Forman identifies these difficulties to include ‘persistent corporate and governmental threats of legal or economic sanctions and the complexity, cost, and limited duration and scope of the rules themselves.’¹²⁴ It is also unlikely that governments (often slow to meet their own health needs) will issue compulsory licenses just to help foreign

¹¹⁶ TRIPS (n 1 above) art 31; R Weissman ‘A long, strange TRIPS: The pharmaceutical industry drive to harmonize global intellectual property rules, and the remaining WTO legal alternatives available to Third World countries’ (1996) 17 *University of Pennsylvania Journal of International Economic Law* 1069 1099.

¹¹⁷ Mercurio (n 95 above) 222; L Ferreira ‘Access to affordable HIV/AIDS drugs: The human rights obligations of multinational pharmaceutical corporations’ (2002) 71:3 *Fordham Law Review* 1133 1135.

¹¹⁸ KM Bombach ‘Can South Africa fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement’ (2001) 19 *Boston University International Law Journal* 273 276.

¹¹⁹ KM Lybecker & E Fowler ‘Compulsory licensing in Canada and Thailand: Comparing regimes to ensure legitimate use of the WTO rules’ (2009) *Journal of Law, Medicine & Ethics* 222 235; Watson (n 107 above) 150.

¹²⁰ C Tuosto ‘The TRIPS Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences’ (2004) 26:12 *European Intellectual Property Review* 543.

¹²¹ D Matthews ‘Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health: A solution to the access to essential medicines problem?’ (2004) 7:1 *Journal of International Economic Law* 82.

¹²² The Policy (n 9 above) para 3.10.

¹²³ http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm accessed 15 March 2014.

¹²⁴ Forman (n 33 above) 341.

countries.¹²⁵ The possibility of offending domestic pharmaceuticals and other countries (developed), make the use of the system even harder.¹²⁶

These are not the only problems with compulsory licensing. The issuance of compulsory licences discourages investment in scientific research and development of medicines.¹²⁷ This is even more grim for EAC states because as Watson succinctly notes, common use of compulsory licenses ‘could be “the last blow” to the drug industry’s attempts to cure diseases of the developing world, which are overlooked even today.’¹²⁸ According to Mercurio, ‘...a developing country in a state of crisis could invoke compulsory license in such a situation, but it could be that no drug would be on the market to alleviate the problem due to lack of research and development in the area.’¹²⁹ In the same vein, Robert Bird says compulsory licenses may ‘cause patent-owning firms to avoid ventures in a certain nation and seek a more business friendly legal climate.’¹³⁰ This will have overall negative effects on the economy, including limiting technology transfer.¹³¹

A consideration of the Policy indicates deliberate measures aimed at making it easier, faster and cheaper to issue compulsory licenses by recommending shortened negotiation periods, broad compulsory licensing grounds and highly conditional compensation.¹³² This position is inappropriate in light of the foregoing discussion. Mercurio aptly remarks:

...a system of intellectual property that guarantees no return on investment and allows for the expropriation of intellectual property rights without proper compensation or enforceable limits will reduce the incentive to research and invest into the area and lead to a situation where the funding of cures for “third world diseases” ceases to exist.¹³³

Interestingly, while the relevant laws of all EAC states provide for compulsory licensing,¹³⁴ none of the countries, with the exception of Rwanda which has used the Paragraph 6 system only

¹²⁵ A Attaran ‘The Doha Declaration on the TRIPS Agreement and public health, access to pharmaceuticals, and options under WTO law’ (2002) 12 *Fordham Intellectual Property, Media & Entertainment Law Journal* 859 869.

¹²⁶ As above.

¹²⁷ Singham (n 33 above) 392.

¹²⁸ Watson (n 107 above) 153.

¹²⁹ Mercurio (n 95 above) 250.

¹³⁰ RC Bird ‘Developing nations and the compulsory license: Maximizing access to essential medicines while minimizing investment side effects’ (2009) *Journal of Law, Medicine & Ethics* 209 210.

¹³¹ Ferrara (n 31 above) 15.

¹³² Chapter four above.

¹³³ Mercurio (n 95 above) 250.

¹³⁴ Chapter four part 4.2.1.

once, has ever issued a compulsory license; and this is not because the countries have not been faced with epidemics. The only plausible explanation is the fear of economic repercussions, which include trade sanctions and capital flight.¹³⁵ Brazil, Thailand and South Africa have previously come under immense pressure, threats of sanctions and actual sanctions, for issuing compulsory licenses.¹³⁶

Again, just like with parallel importation, compulsory licensing does not necessarily result in affordable medicine because the people are just too poor.¹³⁷

The foregoing does not mean that compulsory licensing should not be available as a policy tool. Rather, the argument is that provisions on compulsory licensing must be tailored to balance public health needs and the rights of inventors.¹³⁸ The use of compulsory licenses, as the examples of Brazil and South Africa have shown, will earn international support on humanitarian grounds if it is limited to justifiable and genuine health emergencies.¹³⁹ On the contrary, if compulsory licenses are indiscriminately used to address non-emergency situations – like Egypt issuing a compulsory license for the sex-enhancing drug Viagra – the genuineness of such actions becomes questionable, leading to ramifications like the withdrawal of investors.¹⁴⁰

Other ways of minimising the negative side-effects of compulsory licensing include prior negotiations with patent-holders.¹⁴¹ As already indicated, the mere threat of issuing compulsory licensing has often resulted in pharmaceuticals lowering prices, although some commentators have been quick to point out that this strategy seems to work only for countries with strong market power like Brazil.¹⁴² The payment of adequate compensation is another way of reducing the negative effects of compulsory licensing.¹⁴³

¹³⁵ JL Greenbaum ‘TRIPS and public health: Solutions for ensuring global access to essential AIDS medication in the wake of the Paragraph 6 waiver’ (2008) 25 *Journal of Contemporary Health Law & Policy* 142 151.

¹³⁶ O Aginam ‘Global health governance, intellectual property and access to essential medicines: Opportunities and impediments for South-South cooperation’ (2010) 4:1 *Global Health Governance* 4; Watson (n 107 above) 151.

¹³⁷ Harrelson (n 108 above) 175; Sherman & Oakley III (n 105 above) 398.

¹³⁸ Mercurio (n 95 above) 250.

¹³⁹ Lybecker & Fowler (n 119 above) 225.

¹⁴⁰ Bird (n 130 above) 213.

¹⁴¹ Mercurio (n 95 above) 250.

¹⁴² Lybecker & Fowler (n 119 above) 235.

¹⁴³ Mercurio (n 95 above) 250; Bird (n 130 above) 214.

5.3 Conclusion

The flexibilities that the Policy recommends for member states have been critically considered. It has been demonstrated that the EAC countries do not have established domestic pharmaceutical industries. While this is so, foreign pharmaceuticals have neglected developing medicines for the so-called African diseases, which are peculiar to these countries. This neglect is due to the absence of market incentives, explained by the low per capita income levels in these countries. This situation, it has been argued, underscores the need to promote local pharmaceutical activity and create other incentives for investment in the development of orphan drugs – the medicines for African diseases. It is against this backdrop that arguments have been made against most of the recommended policy tools. These policy tools do not accord to the utilitarian theory which posits that patent protection will incentivise more research and invention. Similarly, the policy tools do not attain the Game theory Nash Equilibrium as they do not strike the pareto-optimal balance between the patent protection and access to medicines.

CHAPTER SIX

6. CONCLUSION AND RECOMMENDATIONS

The previous chapters have discussed a number of subjects and raised several issues pertinent to the subject of this research. Chapter one revisited, by way of introduction, the already too familiar tension between patent protection and access to medicines. The arguments that patent protection has the effect of raising the prices of medicines were captured.

The second chapter explained the theoretical approaches upon which this study is premised. This chapter also evaluated the justifications for patent protection. The main justifications – the natural rights theory and the utilitarian theory – were considered. In the final analysis, it was concluded that the utilitarian theory – which posits that patent protection is a necessary incentive for further research and invention, was more relevant to explain patents, especially for pharmaceuticals. This is because the development of medicines is expensive, involving extensive research and experimentation. Thus, there has to be a clear assurance that research and development costs would be recovered through patent monopoly rights, before pharmaceutical companies can undertake such costly investments. It was shown that the extant international framework for patent protection has heavy undertones of utilitarianism.

The third chapter, in addition to setting out the international framework for patent protection, also delved into the relationship between patent protection and access to medicines, highlighting how tensions between these two led to international intervention through the Doha Declaration of 2001. This Declaration affirmed that WTO member states have the right to use the flexibilities in TRIPS to address the health needs of their populations. As indicated in chapter four, the EAC states seek to use these flexibilities by approximating their national patent laws in line with the recommendations made in the Policy. The specific policy tools in the Policy were identified for critical analysis in chapter five.

What emerges from the analysis in chapter five is that the policy tools are aimed at enhancing access to medicines mainly through price reduction. This is done at the direct expense of promoting research and development of medicines which, according to utilitarianism, is

achievable through patent protection. This policy position which weakens the patent protection regime is not appropriate for the EAC states. This is because the EAC states are faced with peculiar, region-specific diseases – now christened the ‘African diseases.’ Currently, these diseases are largely neglected by the profit-driven pharmaceutical companies which do not have incentives to invest huge amounts in developing medicines for populations that cannot afford to pay for them. In other words, there is simply no market incentive for pharmaceuticals to invest resources in African diseases. Instead, focus is now on developed countries’ diseases. In these circumstances, the only standing incentive is patent protection. Consequently, any policy tools that eliminate this last straw will only worsen the already bad situation. In view of this, some recommendations can be made in addition to the suggestions that punctuated the discussions in previous chapters.

To begin with, the situation described above underscores the urgent need to develop local pharmaceutical activity and to create alternative incentives for investment into developing medicines for neglected diseases. Both of these can be attained through an appropriate patent protection regime. Such a regime must be one that is omniscient of domestic innovators’ limited capacity and consequently, avoid strict patentability criteria. This is because the limited capacity of domestic innovators has the effect that they focus on incremental innovations that improve on existing inventions since they cannot undertake new, major research. Strict patentability criteria will most likely drive them out of the field. It may also discourage disclosure of certain important discoveries for fear of not attaining the criteria and losing out by disclosure.

In developing local pharmaceutical activity, it is also necessary to find ways of affording patent protection to indigenous medicines and practices which for centuries, have been as useful to the people as western medicine is. It is the failure to protect these medicines and practices in the first place that has resulted in foreign pharmaceuticals appropriating the knowledge and patenting it, only to return with expensive medicines.¹ The proposal in the Policy to use pay-offs and use-and-compensate approaches, is not a suitable incentive. In the same vein, it is regrettable that not much attention has been paid to traditional medicine in promoting public health in these

¹ LA Whitt ‘Part one: interdisciplinary perspective: indigenous peoples, intellectual property & the new imperial science’ (1998) 23 *Oklahoma City University Law Review* 215.

countries. The suggestion here is that EAC states should consider accommodating traditional medical practitioners such as herbalists in the mainstream medical practice.

Increased collaboration with other governments, development partners and pharmaceutical companies could also be a useful way of promoting domestic pharmaceutical activity and finding lasting solutions to the access to medicines problem in these countries. The policy tools in the Policy largely aim to address short-term needs. Increased collaboration will help secure funding and extract concessions to develop not just the domestic pharmaceutical industry but also the entire health infrastructure. It has been pointed out that price is not the only impediment to access to medicines in developing countries; the absence of infrastructure, hospitals, doctors and nurses are in fact greater hurdles.² The need for collaborating with foreign governments is, for example, underscored when a country has to use the Paragraph 6 system: countries with manufacturing capacity have to issue compulsory licences to assist LDCs with no manufacturing capacity. In the case of pharmaceutical companies, collaboration can result in concessions like tiered pricing, where pharmaceuticals sell medicines in developing countries at lower prices because of the low per capita income levels.³ Concessions to reduce prices may also avert compulsory licences and its attendant side-effects.

The underlying problem, undeniably, is poverty. Chapter five has illustrated that even low-priced generic medicines are out of reach for a majority of the population in these countries. They simply cannot afford. Governments have to address these issues as a long term solution to the problem of access to medicines. One important fact that escapes debate is that most of the medicines for African diseases are in fact off patent!⁴ Hand in hand with poverty is the challenge posed by lack of awareness and certain traditional, religious and cultural practices. Even where medicines are available, some individuals still cite religious and cultural grounds as reasons for not using the medicines and certain medical practices. In some places, there is still denial and

² PB Sherman & EF Oakley III 'Pandemics and panaceas: The World Trade Organization's efforts to balance pharmaceutical patents and access to AIDS drugs' (2004) 41 *American Business Law Journal* 353 400.

³ AG Watson 'International intellectual property rights: do TRIPS' flexibilities permit sufficient access to affordable HIV/AIDS medicines in developing countries?' (2009) 32:1 *Boston College International and Comparative Law Review* 143 155.

⁴ A Attaran & L Gillespie-White 'Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?' (2001) 286 *Journal of the American Medical Association* 1886 (on anti-retroviral drugs) 1886.

ignorance about some diseases, especially HIV/AIDS.⁵ Governments have to focus expenditure towards these areas and foster prevention which is cheaper in the long run.

⁵ I Susser & Z Stein ‘Culture, sexuality, and women’s agency in the prevention of HIV/AIDS in Southern Africa’ (2000) 90 *American Journal of Public Health* 1042; RC Bird, ‘Developing nations and the compulsory license: Maximizing access to essential medicines while minimizing investment side effects’ (2009) *Journal of Law, Medicine & Ethics* 209 217 (on former South Africa’s President Mbeki’s controversial position on HIV/AIDS).

BIBLIOGRAPHY

Articles

Aginam, O 'Global health governance, intellectual property and access to essential medicines: Opportunities and impediments for South-South cooperation' (2010) 4:1 *Global Health Governance* 1

Attaran, A & Gillespie-White, L 'Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?' (2001) 286 *Journal of the American Medical Association* 1886

Attaran, A 'The Doha Declaration on the TRIPS Agreement and public health, access to pharmaceuticals, and options under WTO law' (2002) 12 *Fordham Intellectual Property, Media & Entertainment Law Journal* 859

Avafia, T & Narasimhan, SM 'The TRIPS Agreement and access to ARVs' (2006) *United Nations Development Programme* 3

Bale Jr, HE 'The conflicts between parallel trade and product access and innovation: The case of pharmaceuticals' (1998) 1 *Journal of International Economic Law* 637

Barfield, C & Groombridge, M 'Parallel trade in the pharmaceutical industry: Implications for innovation, consumer welfare, and health policy' (1999) 10 *Fordham Intellectual Property, Media & Entertainment Law Journal* 185

Bass, N 'Implications of the TRIPS Agreement for developing countries: Pharmaceutical patent law in Brazil and South Africa in the 21st Century' (2002) 34 *George Washington International Law Review* 191

Becker, LC 'Deserving to own intellectual property' (1992-1993) 68 *Chicago-Kent Law Review* 623

Bird, RC 'Developing nations and the compulsory license: Maximizing access to essential medicines while minimizing investment side effects' (2009) *Journal of Law, Medicine & Ethics* 209

Boldrin, M & Levine, DK 'Does intellectual monopoly help innovation?' (2009) 5:3 *Review of Law and Economics* 991

Bombach, KM 'Can South Africa fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement' (2001) 19 *Boston University International Law Journal* 273

Child, JW 'The moral foundations of intangible property' (1990) 73 *The Monist* 578

- Correa, C & Matthews, D 'The Doha Declaration: Ten years on and its impact on access to medicines and the right to health' (2011) *United Nations Development Paper Discussion Paper* 29
- Correa, CM 'Pharmaceutical innovation, incremental patenting and compulsory licensing' (2011) *South Centre Research Paper* 41
- Correa, CM 'Unfair competition under the TRIPS Agreement: Protection of data submitted for the registration of pharmaceuticals' (2002) 3 *Chicago Journal of International Law* 69
- Cullet, P 'Patents and medicines: The relationship between TRIPS and the human right to health' (2003) 1 *International Affairs* 79
- Davies, D 'The early history of the patent specification' (1935) 50 *Law Quarterly Review* 86
- Dinwoodie, GB 'The architecture of the international intellectual property system' (2002) 77 *Chicago-Kent Law Review* 993
- Drahos, P 'Developing countries and international intellectual property standard setting' (2002) 5:5 *Journal of World Intellectual Property* 781
- Ferrara, E 'Access to medicine: patent, price regulation and prizes' (2009) *Washington College of Law International Legal Studies Programme* 16
- Ferreira, F 'Access to affordable HIV/AIDS drugs: The human rights obligations of multinational pharmaceutical corporations' (2002) 71:3 *Fordham Law Review* 1133
- Ford, SM 'Compulsory licensing provisions under the TRIPS Agreement: Balancing pills and patents' (2000) 15:4 *American University International Law Review* 941
- Forman, L 'Trade rules, intellectual property, and the right to health' (2007) *Ethics and International Affairs* 337
- Foster, GK 'Opposing forces in a revolution in international patent protection: The US and India in the Uruguay Round and its aftermath' (1998) 3 *University of California Journal of International Law and Foreign Affairs* 283
- Gathii, JT 'The legal status of the Doha Declaration on TRIPS and public health under the Vienna Convention on the law of treaties' (2002) 15 *Harvard Journal of Law & Technology* 292
- George, E 'The human right to health and HIV/AIDS: South Africa and South-South cooperation to reframe global intellectual property principles and promote access to essential medicines' (2011) 18:1 *Indiana Journal of Global Legal Studies* 167
- Gopakumar, KM 'Product patents and access to medicines in India: A critical review of the implementation of TRIPS patent regime' (2010) 3:2 *The Law and Development Review* 326

- Greenbaum, JL ‘TRIPS and public health: Solutions for ensuring global access to essential AIDS medication in the wake of the Paragraph 6 waiver’ (2008) 25 *Journal of Contemporary Health Law & Policy* 142
- Grover, A; Citro, B; Mankad, M & Lander, F ‘Pharmaceutical companies and global lack of access to medicines: Strengthening accountability under the right to health’ (2012) *Journal of Law, Medicine & Ethics* 234
- Gutowksi, R ‘The marriage of intellectual property and international trade in the TRIPS agreement: Strange bedfellows or a match made in heaven?’ (1999) 47 *Buffalo Law Review* 754
- Harrelson, JA ‘TRIPS, pharmaceutical patents, and the HIV/AIDS crisis: Finding the proper balance between intellectual property rights and compassion’ (2001) 7 *Widener Law Symposium Journal* 154
- Hettinger, EC ‘Justifying intellectual property’ (1989) 18 *Philosophy and Public Affairs* 31
- Ho, CM ‘A new world order for addressing patent rights and public health’ (2007) 82 *Chicago-Kent Law Review* 1469
- Hold, A & Mercurio, BC ‘After the second extension of the transition period for LDCs: How can the WTO gradually integrate the poorest countries into TRIPS?’ (2013) *Swiss National Centre for Competence in Research Working Paper* No 2013/42
- Hughes, J ‘The philosophy of intellectual property’ (1988-89) 77 *Georgetown Law Journal* 287
- Kapczynskiti, A ‘Harmonization and its discontents: A case study of TRIPS implementation in India’s pharmaceutical sector’ (2009) 97 *California Law Review* 1571
- Kondro, W ‘Supreme Court rules against drug patent “evergreening”’ (2006) 175 *Canadian Medical Association Journal* 1508
- Kumar, SP ‘European border measures and trade in generic pharmaceuticals: Issues of TRIPS, Doha Declaration and public health’ (2009) 15:6 *International Trade Law & Regulation* 176
- Lalitha, L ‘Doha Declaration and public health issues’ (2008) 13 *Journal of Intellectual Property Rights* 401
- Lazzarini, Z ‘Making access to pharmaceuticals a reality: Legal options under TRIPS and the case of Brazil’ (2003) 6 *Yale Human Rights & Development Law Journal* 103
- Lucyk, S ‘Patents, politics and public health: Access to essential medicines under the TRIPS Agreement’ (2006) 38 *Ottawa Law Review* 193
- Lybecker, KM & Fowler, E ‘Compulsory licensing in Canada and Thailand: Comparing regimes to ensure legitimate use of the WTO rules’ (2009) *Journal of Law, Medicine & Ethics* 222

M'T Hoen, EF 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond' (2002) 3 *Chicago Journal for International Law* 42

Machlup, F & Penrose, E 'The patent controversy in the nineteenth century' (1950) 10 *Journal of Economic History* 1

Matthews, D 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: A solution to the access to essential medicines problem?' (2004) 7:1 *Journal of International Economic Law* 82

Mercurio, BC 'TRIPS, patents, and access to life-saving drugs in the developing world' 8:2 *Marquette Intellectual Property Law Review* 211

Rapp, RT & Rozek, RP 'Benefits and costs of intellectual property protection in developing countries' (1990) *Journal of World Trade* 86

Rott, P 'The Doha Declaration – good news for public health?' (2003) *Intellectual Property Quarterly* 2

Scafidi, S 'The "good old days" of TRIPS: The US trade agenda and the extension of pharmaceutical test data protection' (2013) 4:2 *Yale Journal of Health Policy, Law, and Ethics* 341

Schott, JJ 'Comment on the Doha Ministerial' (2002) 5 *Journal of International Economic Law* 195

Sell, SK 'TRIPS-plus free trade agreements and access to medicines' (2007) 28 *Liverpool Law Review* 41

Sherman, PB & Oakley III, EF 'Pandemics and panaceas: The World Trade Organization's efforts to balance pharmaceutical patents and access to AIDS drugs' (2004) 41 *American Business Law Journal* 353

Singham, SA 'Competition policy and the stimulation of innovation: TRIPS and the interface between competition and patent protection in the pharmaceutical industry' (2000) 26 *Brooklyn Journal of International Law* 363

Skillington, GL & Solovy, EM 'The protection of test and other data required by article 39.3 of the TRIPS Agreement' (2003) 24:1 *Northwestern Journal of International Law & Business* 1

Snyder, DB 'South Africa's Medicines and Related Substances Control Amendment Act: A spoonful of sugar or a bitter pill to swallow?' (1999) 18 *Dickinson Journal of International Law* 175

- Sterckx, S 'Patents and access to drugs in developing countries: An ethical analysis' (2004) 4 *Developing World Bioethics* 59
- Susser, I & Stein, Z 'Culture, sexuality, and women's agency in the prevention of HIV/AIDS in Southern Africa' (2000) 90 *American Journal of Public Health* 1042
- Tuosto, C 'The TRIPS Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences' (2004) 26:12 *European Intellectual Property Review* 542
- Velásquez, G 'The right to health and medicines: The case of recent negotiations on the global strategy on public health, innovation and intellectual property' (2011) 2 *South Centre Research Paper* 6
- Watal, J 'Access to essential medicines in developing countries: Does the WTO TRIPS Agreement hinder it?' (2000) *Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, MA, USA* 3
- Watson, AG 'International intellectual property rights: Do TRIPS' flexibilities permit sufficient access to affordable HIV/AIDS medicines in developing countries?' (2009) 32 *Boston College International & Comparative Law Review* 143
- Weissman, R 'A long, strange TRIPS: The pharmaceutical industry drive to harmonize global intellectual property rules, and the remaining WTO legal alternatives available to Third World countries' (1996) 17 *University of Pennsylvania Journal of International Economic Law* 1069
- Whitt, LA 'Part one, interdisciplinary perspective: indigenous peoples, intellectual property and the new imperial science' (1998) 23 *Oklahoma City University Law Review* 215
- Whobrey, B 'International patent law and public health: Analyzing TRIPS' effect on access to pharmaceuticals in developing countries' (2007) 45 *Brandeis Law Journal* 623
- Wu, CF 'Transnational pharmaceutical corporations' legal and moral human rights responsibilities in relation to access to medicines' (2012) 7 *Asian Journal of WTO & International Health Law & Policy* 77
- Zainol, ZA; Amin, L; Jusoff, K; Zahid, A & Akpoviri, F 'Pharmaceutical patents and access to essential medicines in sub-Saharan Africa' (2011) 10 *African Journal of Biotechnology* 12376

Books

Adams & Adams (2012) *Practical guide to intellectual property in Africa* Pretoria University Law Press

Aplin, T & Davies, J (2013) *Intellectual property law: text, cases, and materials* Oxford University Press

Bainbridge, DI (2012) *Intellectual property* Longman

Cornish, WR (1999) *Intellectual property: patents, copyright, trademarks and allied rights* Sweet and Maxwell

Hassim, A; Heywood, M & Berger, J (2007) *Health and democracy* Siber Ink

Baird, DG; Gertner, RH & Picker, RC (1998) *Game theory and the law* Harvard University Press

Dorothy, N (1984) *Science as intellectual property* Macmillan

Drahos, P & Braithwaite, J (2002) *Information feudalism: Who owns the knowledge economy?* New Press

Dugard, J (2012) *International law: A South African perspective* Juta & Co

Helfer, LR & Austin, GW (2014) *Human rights and intellectual property: Mapping the global interface* Cambridge University Press

Ho, CM (2011) *Access to medicine in the global economy: International agreements on patents and related rights* Oxford University Press

Locke, J (1690) *The second treatise on government* Indianapolis, IN: Hacket Publishing 1980

MacQueen, H; Waelde, C; Laurie, G & Brown A (2010) *Contemporary intellectual property: law and issues* Oxford University Press

Peters, H (2008) *The Game theory: A multi-leveled approach* Springer-Verlag Berlin Heidelberg

Rawls, J (1971) *A theory of justice* Harvard University Press

Chapters in books

Attas, D ‘Lockean justifications of intellectual property’ in Gosseries, A; Marciano, A & Strowel, A (eds) (2010) *Intellectual property and theories of justice* Palgrave Macmillan

Braga, CAP; Fink, C & Sepulveda, CP ‘Intellectual property rights and economic development’ in Maskus, KE (ed) (2000) *The WTO, intellectual property rights and the knowledge economy* Edward Elgar Publishing

Fisher, W ‘Theories of intellectual property’ in Munzer, SR (ed) (2001) *New essays in the legal and political theory of property* Cambridge University Press

Matthews, D ‘Intellectual property rights, human rights and the right to health’ in Grosheide, W (ed) (2009) *Intellectual property rights and human rights: A paradox* Edward Elgar Publishing

Rachels, J ‘What people deserve’ in Arthur, J & Shaw, W (eds) (1978) *Justice and economic distribution* Englewood Cliffs

Scherer, FM ‘The pharmaceutical industry’ in Culyer, AL & Newhouse, JP (eds) (2000) 1 *Handbook of health economics* New York: Elsevier Science BV

Shiffrin, SV ‘Lockean arguments for private intellectual property’ in Munzer, SR (ed) (2001) *New essays in the legal and political theory of property* Cambridge University Press

Spence, M ‘Justifying copyright’ in Mclean, D & Schubert, K (eds) (2002) *Dear images: art, copyright and culture* Ridinghouse

Statutes

Industrial Property Act Cap 509 Laws of Kenya

Law 1/13 of 2009 relating to Industrial Property in Burundi

Law 31 of 2009 on the Protection of Intellectual Property in Rwanda

Patents Act Cap 216 Laws of Uganda

The Tanzania Patents (Registration) Act

UK Patents Act 1977

Webpages

<http://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx> (accessed 2 April 2014)

<http://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf> accessed 10 October 2013

http://www.eac.int/index.php?option=com_content&id=44&Itemid=54&limitstart=1 (accessed 2 April 2014)

http://www.eac.int/index.php?option=com_content&view=article&id=1:welcome-to-eac&catid=34:body-text-area&Itemid=53 (accessed 2 April 2014)

http://www.undp.org/content/dam/undp/library/hiv aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf (accessed 11 April 2014)

http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax_a.pdf (accessed 2 April 2014)

http://www.wipo.int/treaties/en/remarks.jsp?cnty_id=329C (accessed 2 April 2014)

http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm accessed 15 March 2014

http://www.wto.org/english/thewto_e/countries_e/kenya_e.htm (accessed 2 April 2014)

http://www.wto.org/english/thewto_e/countries_e/tanzania_e.htm (accessed 2 April 2014)

http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (accessed 9 April 2014)

http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (accessed 10 April 2014)

Mènière, Y ‘Patent law and complementary innovations’ (2007)

<http://en.youscribe.com/catalogue/reports-and-theses/knowledge/humanities-and-social-sciences/non-obviousness-and-complementary-innovations-1599067> (accessed 9 April 2014)

Mwapachu, JV ‘EAC: past, present and future’ (2010)

www.firstmagazine.com/downloads/specialist/publication/detail.480.ashx (accessed 2 April 2014)