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NOVELTY IN PATENTS: A Case for the Review of the Patenting Regime in Kenya.

By:

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A paper submitted in partial fulfillment of the requirements for the award of a Master's Degree in Law.

DECLARATION

I, **CLAUDE BENARD MUTHEE KAMAU**, do hereby declare that this is my original work and no portion of this work has either been submitted or is being submitted for a similar or for any other degree in this or any other University.

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DEDICATION

Dedicated to the memory of my father, may he live on forever!

ACKNOWLEDGMENTS

There are many who deserve more than just a "thank you" for their assistance and support in my arduous journey towards the preparation and conclusion of this paper. To you all I give my thanks and more specifically…

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To my **family** my love, for your prayers and love, for your unwavering emotional and financial support and for persevering and not complaining even when I littered the house with pages of this thesis, holding one draft after another.

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Finally, I attribute all my achievements to God, *"…Lord, though you have given me so much, I ask now for one thing more; A grateful heart!"*

"…In the name of the father, of the son and of the holy ghost, Amen."

ABBREVIATIONS AND ACRONYMS

ARIPO	African Regional Industrial Property Organization
EAC	East African Community
EPA	Economic Partnership Agreement
EPC	European Patent Court
EPO	European Patent Office
FDI	Foreign Direct Investment
GATT	General Agreement of Tariffs and Trade
IP	Intellectual Property
IPR	Intellectual Property Rights
ITO	International Trade Organization
KIPI	Kenya Industrial Property Institute
NTB	Non-Tariff Barrier
OECD	Organization of Economic Cooperation and Development
PCT	Patent Cooperation Treaty
RTA	Regional Trading Arrangement
R&D	Research and Development
ToT	Transfer of Technology
TRIPS	Trade Related Aspects of Intellectual Property
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNDP	United Nations Development Programme
UNCTAD	United Nations Convention on Trade and Development
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

STATUTES

1) The Kenyan Industrial Property Act, (Act No. 3 of 2001);
2) The U.K. Patent Acts of 1949 and of 1977;
3) The European Patent Conventions of 1973 and of 1995.

INTERNATIONAL CONVENTIONS AND AGREEMENTS

1) The Agreement Establishing the World Trade Organization, (WTO);
2) The Trade Related Aspects of Intellectual Property Agreement, (TRIPS) of 1994;
3) The General Agreement on Tariffs and Trade, (GATT);
4) The World Intellectual Property Organization (WIPO) Convention;
5) The Paris Convention for the Protection of Industrial Property (Paris Convention);
6) The Berne Convention for the Protection of Literary and Artistic Works (Berne Convention);
7) The African Regional Intellectual Property Organization, (ARIPO) Harare Protocol of 1982;
8) The Patent Cooperation Treaty, (PCT);
9) The Agreement between the World Intellectual Property Organization and the World Trade Organization of 1995;[1]
10) The African Regional Industrial Property Organization, (ARIPO) Treaty.

[1] [WIPO note] This Agreement was concluded in Geneva on December 22, 1995 and entered into force on January 1, 1996.

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CHAPTER ONE
INTRODUCTION

1.1 Background to the Study

Where would the world be without inventions and innovations; at a backward stage of industrial development without a doubt? Technological progress and economic vitality in any modern nation, Kenya being no exception, depends largely on the ability of its nationals to be creative and innovative and to endeavour aggressively in the promotion of trade both within and without its borders.[1]

Intellectual Property (IP) is property in creations or inventions of the human mind, such that only the inventor can appropriate the benefits of having made such creation(s). IP is sometimes regarded as protecting the physical embodiment of an otherwise intangible asset. It is a recent categorization of property, in the sense that previously, only physical or tangible matter or objects were considered capable of constituting property.[2] IP rights are like any other property rights; they allow the creator or owner, of a patent, trademark, or copyright to benefit exclusively from his or her own work or investment. These rights are outlined in Article 27 of the Universal Declaration of Human Rights (UDHR), which sets forth the right to benefit from the protection of moral and material interests resulting from authorship of any scientific, literary, or artistic production. Further IP shares many of the characteristics associated with real and personal property. e.g., it is an asset, and thus like any other form of property it can be bought, sold, licensed, exchanged, or gratuitously given away. Further, the IP owner has the right to prevent the unauthorized use or sale of this property. There are several other compelling reasons for the protection and promotion of IP. First, the progress and well-being of humanity rests on its capacity for new creations in the areas of technology and culture. Secondly, the legal protection of these new creations encourages the expenditure of additional resources, which leads to further innovation. Thirdly, the promotion and protection of IP rights spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life.

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[1] "A Guide to Patenting in Kenya", Kenya Industrial Property Institute (KIPI) Booklet; Ministry of Trade and Industry (2006) Edition.

[2] This is the most noticeable difference between IP and other forms of property, the fact that it cannot be defined or identified merely by physical parameters. It must be expressed in some discernible way to be protectable. http://www.pvr.govt.nz/download/document/pvrguide.rtf. Visited on 8th June 2006.

As the concept of IP evolved and developed over the years, more and more people in all walks of life benefited from the exclusive rights that are accorded by IP regimes. It was therefore only a matter of time before IP became the subject of international trade. IP has been in the international arena for a long time. The World Intellectual Property Organization (WIPO)[3] existed and administered a number of IP treaties.[4] To introduce IP into international trade arena, arguments were cited that it was a non-tariff barrier (NTB) to international trade. The trend in international trade in the post World War II era had been marked by movement towards liberalisation. The attempts at the Havana Charter negotiations to establish the International Trade Organization (ITO)[5] signified the beginning of efforts to remove restrictions to global trade. However, Part IV of the Charter, headed the "General Agreement of Tariffs and Trade," or GATT, was adopted by 23 countries in 1947. It was retained with the main objective of liberalizing trade among them through reduction of tariffs on the basis of reciprocity.[6] Over the years, GATT extended both its membership and scope through the mechanism of rounds of multilateral trade negotiations.

The most significant trade round was perhaps the Uruguay Round that was held between 1986 and 1994, at the end of which the World Trade Organization (WTO) was born.[7] The WTO is a multilateral or international trade arrangement.[8] It incorporates protection of IP in the provisions of the Agreement on the Trade Related Aspects of Intellectual Property (TRIPS),[9] which is binding upon members as part of a single undertaking. The strengthening of the intellectual property rights regime, in particular through the adoption of TRIPS, is the subject of intense scrutiny and debates in most countries of the world. By providing for minimum levels of protection of intellectual property rights

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[3] It later became the subject of a specialized UN Agency - TRIPS.

[4] Treaties that WIPO administered included the WIPO Copyright Treaty, WIPO Performance and Phonograms Treaty among others.

[5] The Charter however never took off. It was not ratified because the general feeling was that it adopted a very ambitious approach to global trade, thus "[it] died aborning."

[6] To achieve this, contracting parties negotiated a series of tariff concessions, which were bound such that they could not raise them with respect to products from other contracting party territories.

[7] Members signed the Marrakesh Agreement as well as annexes as a single undertaking, on 15th April 1994.

[8] The WTO is different from GATT because, first, it is an institution with members while GATT was a mere agreement with contracting parties. Second, it has a dispute settlement mechanism to enforce its various agreements while under GATT the mechanisms of retaliation or imposition of trade sanctions such as trade embargoes were relied upon. Dr. Andronico Adede, "*Origins and History of the TRIPS Negotiations*," in ICTSD (Christophe Bellmann, Graham Dutchfield and Ricardo Melendez-Ortiz, editors) (2001). Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability Earthscan Publications Ltd, London, Sterling, VA.

[9] TRIPS is Annex 1C of the Final Act Embodying the Uruguay Round of Multilateral Trade Negotiations negotiated during the Uruguay Round which had been launched at Punta Del Este in 1986. It came into force on January 1st 1995 with respect to developed countries.

generally based on the average Organisation of Economic Cooperation and Development (OECD) levels of protection, TRIPS constitutes a significant challenge to a number of developing countries, which have to make significant changes to their legislations to be in compliance.

The subject matter of Intellectual Property law is very wide and includes literary and artistic works, films, computer programs, inventions, designs and marks used by traders for their goods or services. The law therefore, is an instrument that deters others from copying or taking unfair advantage of the work or reputation of another and it provides remedies should this happen. There are several different forms rights or areas of law giving rise to rights that together make up intellectual property; such as copyrights, rights in performances, the law of confidence, registered designs, design rights, trade marks, passing off. This list is not exhaustive and there are other rights, for example, geographical indicators and the rights associated with plant and seed varieties protection. However the focus of this thesis shall be on patents and more-so, on the requirement of "novelty" as a pre-condition for the grant of a patent.

A "patent" is a limited monopoly that is granted in return for the disclosure of technical information.[10] A patent right, because it gives its owner a monopoly, is the form of intellectual property *par excellence*. Under this Faustian pact, the applicant is required to disclose their invention so that it can be used (or worked) by a "person skilled in the art".[11] In return the state (in the guise of the Patent Office) issues the applicant with a patent that gives them the exclusive right to control the way their patented invention is exploited for a twenty (20) year period.[12] The patent system promotes technological and business competition because patent holders must disclose the details of their inventions in exchange for the protection they receive during the specified period which they have exclusive rights over their exploitation. As a result, both they and their competitors race to improve those inventions and to use the technology to create new ones.[13] Patent protection is given, not to all inventions, but only to patentable inventions. In Kenya

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[10] L. Bently and B. Sherman '*Intellectual Property Law*' 2nd Ed. Oxford University Press (2004) at pg. 323.
[11] This is a notional person who has the requisite skill and knowledge appropriate to the type of invention in question.
[12] This period can be considered to be the international standard, as it is the period outlined in Article 33 of the TRIPS Agreement.
[13] Kamil Idris, Director General of WIPO, '*INTELLECTUAL PROPERTY: A Power Tool for Economic Growth*'; An Overview of the World Intellectual Property Organisation [WIPO].

while the protection provided by a patent, which is limited to twenty (20) years,[14] is not as long as the protection provided by copyright law or (possibly) trademark registration, the rights granted are more extensive. The rights granted to the patent owner cover most commercial uses of the patent invention. In addition, the rights will be infringed irrespective of whether or not the defendant copied from the patented invention. In part, the breadth of the patent monopoly is offset by the by the fact that patents are only granted if an applicant complies with the registration process. Unlike copyright, which rises automatically upon creation of the work, patents are only granted upon the applicant's satisfaction of the requirements of registration. Although the granting process may not be as onerous as some would like, it does impose some limits and safeguards on the types of inventions that are patented, the scope of the monopoly granted, and the nature of the information that is disclosed in the patent. By their nature, patents usually protect ideas, as expressed in their description and claims, but there are several controls on the monopoly status they confer upon proprietors. For example, compulsory licences may be available after the first three years from the grant of patent, or it may be indicated on the register of patents that a licence is available as a matter of right. A compulsory licence would be appropriate if the patent was not being worked or if the proprietor was limiting supply of a patented product in order to maintain unjustifiably high prices. As such, rather than merely being seen as a prerequisite to grant, patent registration should be seen as a process in which policy goals are implemented and enforced by the state.

Since patents offer inventors monopolies on their creations for specific periods,[15] and thus provide incentives for research and development. Without the possibility of patent protection, many people might not take the risk or invest the time involved in designing and perfecting new products. However patents do much more than just keep the creative wheel spinning, they are also a means of technological exchange.[16] It is said that each patent document describes a new aspect of a technology in clear and specific terms and is available for anyone to read, as patents are made public specifically to promote the sharing of knowledge.[17] Hence patents are vital resources for entrepreneurs, researchers, inventors, academicians and any others who may need to keep up with new developments in their respective fields. In Kenya persons who wish to patent their

[14] Section 60 of the Industrial Property Act, Act No. 3 of 2001.
[15] In Kenya patents rights are protected for a period of 20 years. See Section 60 of the Industrial Property Act (Act No. 3 of 2001).
[16] Ibid note 1.
[17] Ibid note 1.

creations do so under the auspices of the Kenya Industrial Property Institute (KIPI).[18] F. D. Laet[19] posits that patents and patent documents influence the technological and economic development of a region by:-

- Protecting the right of the commercialization of inventions and as such encouraging scientists and technicians to express their knowledge and experience in practical use;
- Informing the public of this new knowledge, so that they can learn from it and endeavour to improve and expand on this new knowledge;
- Notifying manufacturers and industrialists about new invented products, uses and or processes, so that with the consent of the inventor, they can be implemented and marketed and consequently put to general use;
- Warning industrialists on the research activities of their competitors which are shown by increased patent filings in a particular field of technology;
- They are the main utility for the transfer of technology and foreign direct investment to the non-industrialized countries;
- Patents also encourage Research and Development (R&D) at universities and other research centres.

In line with the TRIPS Agreement, the Kenyan Industrial Property Act (Act No. 3 of 2001) outlines in detail the requirements for the patentability of an invention in Kenya.[20] It provides that to qualify for patenting, an invention must satisfy the following criteria: -

(i) It must be new (novelty);
(ii) It must involve an inventive step; and
(iii) It must be industrially applicable.

The Industrial Property Act (Act No. 3 of 2001) establishes the Kenya Industrial Property Institute (KIPI)[21] to administer the Act under the supervision of the Ministry of

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[18] Kenya Industrial Property Institute (KIPI) housed at Weights & Measures premises on Kapiti road, off Mombasa road, South "C", Nairobi. P.O. BOX 51649 Nairobi – Kenya.
[19] F. D. Laet, *'PATENTS: From Protection through Information to Development'*; EPO and ARIPO booklet (March 2005).
[20] Section 22 provides briefly thus, 'An invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use'.
[21] Section 3 of the Industrial Property Act, (Act No. 3 of 2001).

Trade and Industry and a Managing Director who was a specialist in the field of IP was appointed to head the Institute.[22] In Kenya a patent application is made by filing a patent specification together with the necessary forms and the application fees at the Kenya Industrial Property Institute in Nairobi. The patent specification includes the request, a description of the invention, one or more claims, drawings or a formula where necessary for a clear understanding of the description and an abstract. A patent application consists of specification and often drawings or formulate and an abstract. The abstract is a brief summary of about a hundred and fifty (150) words of the content of specification. The specification comprises:-

(a) A clear and complete description of the invention and its usefulness;
(b) Claims that define the boundaries of the patent protection.

In Kenya, patents are given to the first inventor to file an application. Thus even if one can prove that they were the first to conceive an invention, they lose the race if a competitor inventor makes an application for patenting the same invention before they do.

1.2 Statement of the Problem

This research project explores the extent to which the issue of "novelty" as a pre-condition to patenting has been dealt with by the Kenyan legal framework. Section 22 of the Industrial Property Act of 2001[23] as drafted is vague, ambiguous and unclear. It provides for three basic preconditions for the grant of a patent. It posits that an invention must be novel, it must involve an inventive step and it must be capable of industrial application. However, this research shall pay particular attention to the issue of "novelty" as a pre-condition to the granting of a patent. Thus it shall attempt to answer *inter-alia* the question of whether the discovery of a new advantage of an old thing used in an old way is "novel". It shall concentrate on three specific types of inventions and the problems that have arisen when assessing their novelty; to wit inventions that relate to medical uses, non-medical uses and the so-called selection inventions.

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[22] The Managing Director of KIPI as at August 2006 was Professor Otieno Odek, a former lecturer at the faculty of law, University of Nairobi.
[23] Section 22 provides briefly thus, 'An invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use'.

As such, this thesis does not intend to be so bold as to dictate to the draftsman how the various sections of the Act ought to be drafted, rather it shall merely endeavour to expose the problem of the term "new" as a pre-condition for patenting and present possible solutions thereof. Hence, this paper should be construed to be more of a guideline when reviewing the conditions for the grant of a patent, and more specifically as regards the condition of "novelty" in the granting of a patent.

1.3 Objectives of the Study

It is my submission that section 22 of the Industrial Property Act of 2001[24] as drafted is vague, ambiguous and unclear. Specifically, it the term "new" as a pre-condition for the grant of a patent that makes this section vague, ambiguous and unclear. It does not take into account the various dynamics of the term "new". Thus, it is the intention of this study to:-

1. To expose the ambiguities and irregularities inherent in section 22 of the Industrial Property Act that provides for the requirement of "novelty" of an invention as a pre-condition to the granting of a patent.

2. To make an in-depth analysis of several pertinent issues relating to patents and more specifically on the issue of "novelty" as a pre-requisite to the granting of a patent. This shall be ideally to expose whether a discovery of a new advantage of an old thing used in a new way is "novel".

3. To expose what the requirements for patentability in Kenya are and to test whether they in conformance with the TRIPS Agreement. Thereby, I intend to settle the question whether these conditions both under the Kenyan Industrial Property Act and under the TRIPS Agreement are realistic for developing economies, at the very best.

4. Finally, to settle the issue that indeed patents are related to trade and therefore explain why it is that Kenya needs to "overhaul" her provisions on novelty as a

[24] Section 22 provides briefly thus, 'An invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use'.

pre-condition for the grant of a patent and resultantly her institutional and policy mechanisms and whether a review of her IP legislation is requisite.

1.4 Research Questions

This study shall examine in-depth, the broad issue of the pre-conditions of granting of a patent in the context Kenya's legal and institutional framework. Further I shall undertake to examine the pre-conditions of granting of a patent in Kenya in relation with the various multilateral and interlocking regional trade arrangements relating to IP. In relation thereto I shall investigate the following issues:-

1. Firstly, what exactly is "novelty" and how is it determined? To what extent does the requirement of novelty apply to the granting of a patent? Does the traditional approach to addressing the issue of novelty that treats a claim to a "product for a particular use" as a claim to the product *per se* so that the product would lack novelty even if the product had previously been employed in a different use, still apply in Kenya to-date?[25]

2. Secondly, how does the Industrial Property Act deal with the issue of the novelty of inventions? Further, does it recognize the discovery of a new advantage of an old thing used in a new way as "novel"?

3. Third, to what extent does TRIPS provide for the issue of novelty in the granting of patents? Further, to what extent does Kenya integrate the provisions for the granting of patents in light of those laid out in the multilateral trade arrangements, specifically the TRIPS Agreement?[26]

4. Does Kenya need different IP provisions than are provided in the TRIPS Agreement? If so, should these provisions be incorporated in the Constitution or in subsidiary legislation? Finally, are there any lessons to be learnt from the IP regimes of other countries?

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[25] Such as was in the case of Adhesive Dry Mounting v Trapp (1910) 27 RPC 341; Jacob, "Novelty Use of Claims" (1996) 27 IIC 170'173.

[26] Other multilateral trade arrangements include Economic Partnership Agreements (EPAs) between an RTA and another, or with a country. They are so called because they imply commitments by a comparatively large number of countries.

1.5 Justifications for the Study

This is a value laden issue, in terms of research. There is a notable lack of literature on the issue of novelty as a pre-requisite condition to the granting of a patent in Kenya. As such this study may be used as an exploratory or guideline paper to lead more research into this area. This issue has been selected because it is directly related to and connected to; *inter alia*, trade, public health, protection of innovation, transfer of technology (ToT), food security and the flow of foreign direct investment (FDI) into the economy.

For many years, the primary goal of the research carried out in many areas of science and technology was the creation of either new products or new uses of old things. On the whole, the fruits of this research have been well served by patent law. This can be seen in the fact that patent law has long recognized the discovery of new things[27] (such as the discovery of aspirin) and the discovery of new ways of using old things[28] (such as the discovery that aspirin rubbed on the skin acts as an effective insect repellent) as being novel. In the last forty years or so, a number of changes have taken place in the type of research undertaken in various industries. These changes were motivated by a realization that in certain fields (notably in relation to pharmaceutical and biological inventions) the possibility of discovering new things or the finding of new uses for old things was decreasing. As a result, the focus of research shifted to concentrate on the discovery of new uses (or purposes) of old substances used in old ways. The problem that confronted researchers working in this way was that traditional (British) patent law refused to recognize the discovery of a new advantage of an old thing used in an old way, as being novel. This would mean, for example, that if someone discovered that as well as being useful in the curing of headaches, that the consumption of aspirin also thinned the blood (and was thus useful in preventing blood clots), they would be unable to patent the invention. The reason for this is that the traditional British (and resultantly, Kenyan) approach treated a claim to a product to a "product for a particular use" as a claim to the product *per se*, so that the product would lack novelty even if the product had previously been employed in a different use.[29] The problem that confronted this "new" style of

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[27] Claims to a substance provide protection not only over the thing itself, but also over all subsequent uses.
[28] Typically, new uses are claimed as a "new method of using the old article".
[29] See *Adhesive Dry Mounting vs. Trapp* (1910) 27 RPC 341; Jacob, "Novelty of Use Claims" (1996) 27 IIC 170, 173.

research was, in short, that patent law was not willing to recognize "novelty of purpose" as a basis on which an invention could be patented.[30]

1.6 Hypothesis

Trade and IP are inseparably intertwined, thus the protection and promotion of IP is not only beneficial but it is incumbent on any developing economy. There is need to address the issue of novelty in the context of patents as many innovations and creations are rejected by KIPI on the grounds that they are not a new idea, yet it is my submission that they are. Thus the hypothesis of this study is essentially that the Kenyan IP regime is in dire need of an overhaul, as much time and energy is spent on innovations and discoveries especially as relates to medical uses, non-medical uses and the so-called selection inventions, yet these are not patentable in Kenya due to a myriad of constraints and shortcomings in our IP legal regime and primarily due to the pre-condition of "novelty" in the granting of a patent.

1.7 Scope of the Study

The study will look at IP generally and examine its treatment in the country. It shall focus mainly on the issue of novelty as a requirement of patentability. However, it shall not examine, in-depth, the various trade arrangements to which Kenya is a member save if they directly affect her IP regime. I shall not delve into the IP commitments in any of the economic partnership agreements (EPAs) that COMESA and the EAC, for example, may negotiate with Kenya. In such cases it shall only be stated if there is a possibility of conflict with Kenya's IP regime. This is in order to try and give a bigger picture of the extent of the problem of novelty as requirement for the granting of a patent in Kenya and to identify whether there is a potential way forward or a solution to a legal provision that in my opinion leaves a lot to desired.

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[30] Lionel Bentley and Brad Sherman, "*Intellectual Property Law*", 2nd Edition, Oxford University Press (2004); Novelty in Patents.

1.8 Theoretical Framework

Legal positivism is the thesis that the existence and content of law depends on social facts and not on its merits. English jurist John Austin[31] formulated it thus: "The existence of law is one thing; its merit and demerit another. Whether it be or be not is one enquiry; whether it be or be not conformable to an assumed standard, is a different enquiry."[32] The positivist thesis does not say that law's merits are unintelligible, unimportant, or peripheral to the philosophy of law. It says that they do not determine whether laws or legal systems *exist*. According to positivism, law is a matter of what has been posited (ordered, decided, practiced, tolerated, etc.); as we might say in a more modern idiom, positivism is the view that law is a social construction. Good laws arise from good policies and good policies emanate from philosophy: an understanding of fundamentals.[33] Austin thought the thesis "simple and glaring." While it is probably the dominant view among analytically inclined philosophers of law, it is also the subject of competing interpretations together with persistent criticisms and misunderstandings. Legal positivism's importance, however, is not confined to the philosophy of law. It can be seen throughout social theory, particularly in the works of Marx, Weber, and Durkheim, and also (though here unwittingly) among many lawyers, including the American "legal realists" and most contemporary feminist scholars.[34] Although they disagree on many other points, these writers all acknowledge that law is essentially a matter of social fact. Whether a society has a legal system depends on the presence of certain structures of governance, not on the extent to which it satisfies ideals of justice, democracy, or the rule of law. What laws are in force in that system depends on what social standards its officials recognize as authoritative; for example, legislative enactments, judicial decisions, or social customs, hence the significance of the sanctity of the right to quiet possession of private property (as is the focus of this thesis).

Intellectual property, in the form of patents has a role to play as a protector of inventions and innovations that human beings create. For one to develop an invention with economic ramifications he or she needs an assurance that the same will be protected and

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[31] Austin, John (1832). "*The Province of Jurisprudence Determined.*" Ed. W.E. Rumble, 1995. Cambridge: Cambridge University Press, (1790-1859).

[32] Ibid at page157.

[33] Dr. Imre Loefler, Nurturing Nature. The (Kenya) Standard Newspaper, Wednesday, December 15, 2004

[34] See Dworkin, Ronald (1986), "*Law's Empire.*", Cambridge MA: Harvard University Press.

so will have exclusive rights over the invention. Once people have secured such incentives, innovation comes along. Technological progress and economic vitality follows and thus the realization of development. In Intellectual Property law (patent law to be more specific), the relationship is one that rests on contract, that is, a social contract between the state (in the guise of the Patent Office) and the inventor, whereby the inventor enjoys protection from infringement in return for the disclosure of the invention to enable it to be worked by a person "skilled in the art".

As Kenya strives to climb up the ladder of development, the protection of inventor's rights to reap the economic benefits of their creations ought to be part of this process. Therefore with the constant pressure to maintain international competitiveness, and with every country striving to assert its position in the global market, Kenya should take pre-emptive steps in ensuring that its economic growth remains in tandem with global standards. This starts with the tiny step of promoting and protecting innovation and creativity within Kenya first. Patents therefore have to be protected due to the centrality of the role that they play in the enhancement of global trade.[35] This study shall, as such, be premised upon a positivist foundation; upon a basis of the inalienable right of the individual to the quiet enjoyment of property and thus the need for the protection of such right (and consequently the need for this thesis).

1.9 Methodology

Not much has been done on this area, therefore this study, more than anything else, will be largely exploratory. This study is meant to be descriptive, comparative and analytical. It shall explore the various problems that may arise by virtue of the requirement of novelty as a pre-requisite to the granting of patent as stated before. This study shall focus on the realm of the real (which is essentially a description of what is) and on the ideological (logical, if you like).

Primary data shall be drawn mainly from interviews with experts in the fields of and IP to guide both the analysis of potential problems as well as in making recommendations. As such, interviews with individuals from the relevant fields or institutions such as KIPI shall be essential.

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[35] http://www.answers.com/main/ntquery?method=4&dsid=2222&dekey=(Good+(accounting)&gwp=8&curtab=2222_1 (accessed on December 12th 2005).

Secondary data shall mainly be on a literature-based approach shall be used. The study shall mainly rely on primary sources of information including, *inter alia*, libraries, international trade and IP textbooks, case law as well as any other instruments relating to the relevant trade and IP regimes. From this information, the study shall analyse the issue of the novelty of a creation or invention. It is also on this basis that an analysis of any litigation that may currently be ongoing shall be imperative to this paper.

Other sources shall be the Internet, newspaper articles and journals. These will be helpful especially in highlighting issues not yet captured in textbooks, as well as highlighting current affairs and emerging issues. Particularly, the Internet is expected to ease access to data that would only be available with a lot of effort and expense.

1.10 Literature Review

This study shall draw plenty from the various diverse approaches to the patents of. However, so as to appreciate the issue of patents in its entirety, I engaged author's that discussed diverse aspects of "Patents" which, though may not deal specifically with the issue of "novelty" as a requirement for the granting of a patent, proved very useful to this study. W.R Cornish, in his book "*Intellectual Property: Patents, Copyright, Trade marks and Allied Rights,*" Sweet and Maxwell, London 5th edition, page 3, says that the subject of intellectual property is mainly concerned with marking out by means of legal definition types of conduct which may not be pursued without the consent of the right owner. A position reiterated by Jennifer Davis, "*Intellectual Property Law*", (2003), Lexis Nexis, 2nd Edition and Simon Thorley, M.A., Richard miller B.Sc., Guy Burkill, M.A., Colin Birss, M.A. and Douglas Campbell, M.A., "*Terrell On The Law Of Patents*" (2006), London Sweet & Maxwell, 16th Edition. Thus the innovator of a patent or a licensee of such innovator has the exclusive rights to it and no one else should use it in any manner without express authorization from its owner. David Bainbridge's, "*Intellectual Property*", (2002), Pitman Publishing, London, 5th Edition and Lionel Bentley and Brad Sherman, "*Intellectual Property Law*", (2001), Oxford, 2nd Edition proved integral to the preparation of this paper.

Other authors like Dr. Bernard Sihanya's, "*Intellectual Property Confronts Counterfeiting in Africa: Protecting Innovators and Consumers in Cybersociety*" and Joseph Gopo's and Patricia Kameri Mbote's "*Biotechnology- A Turning Point in Development or an Opportunity That Will Be Missed?*" also proved to be invaluable to this study. Other secondary materials that proved essential in writing this thesis are the World Intellectual Property Organisation (WIPO) "*Intellectual Property and Traditional Cultural Expressions/Folklore*" Booklet, the (WIPO)[36] *Intellectual Property*, "*A Power Tool for Economic Growth*", by Kamil Idris, Overview and the (WIPO) *General Information Booklets*. Other literary works of great significance hereto include Jayashree Watal's, "*Intellectual Property Rights in the WTO and Developing Countries, the ICTSD text 'Resource Book on TRIPS and Sustainable Development*", the "*Development, Trade and the WTO*", a Handbook published by the World Bank and also the ICTSD text "*Trading in Knowledge Development Perspectives on TRIPS, Trade and Sustainability*". These shall be relied upon largely, to guide us in identifying and defining the issues that TRIPS neglected, but which are of great importance to Kenya.

1.11 CHAPTER BREAKDOWN

CHAPTER ONE

This Chapter is the dissertation proposal, which is discussed hereinabove. The essence of this Chapter is to introduce and define to the reader what intellectual property (IP) is and in particular patents. The point of this Chapter is to give the reader a general understanding of the research paper and the intellectual property issues that shall be canvassed herein.

CHAPTER TWO

This Chapter will concern itself with patents, more specifically with the requirement of "novelty" in the granting of a patent. The point of this Chapter is to give the reader a general understanding of patents as well as the treatment of the same both under the

[36] As at July 1998, Dr. Kamil Idris was the Director General of the World Intellectual Property Organisation (WIPO). http://www.wipo.int

TRIPS Agreement and under the Kenyan IP regime[37]. In particular the study will comment on the requirements for the patentability of a creation or of an invention. It shall seek to give the reader a vivid understanding of the various dynamics of the requirement of "novelty" of an invention as a pre-condition for the granting of a patent.

CHAPTER THREE

In this Chapter I shall move away from the general principles of "novelty" that have concerned the thesis thus far to concentrate on three specific types of inventions and the problems when assessing their novelty. In particular I shall look at the novelty of inventions, which relate to medical uses, non-medical uses, and the so-called selection inventions. The research shall canvass the various arguments that revolve around the novelty of these selected items and expose the ambiguities inherent in the blanket requirement of "novelty" in the granting of a patent in Kenya as espoused by the Industrial Property Act[38].

CHAPTER FOUR

This Chapter will seek to draw conclusions from the fore-going, as well as suggest some recommendations if any, from which both Kenya and other countries in Developing Africa may draw lessons.

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[37] As espoused by the Industrial Property Act (Act No. 3 of 2001).
[38] Act No. 3 of 2001.

CHAPTER TWO

NOVELTY IN PATENTS: A Kenyan and a Comparative Perspective

2.1 INTERNATIONAL PATENT TREATIES AND THEIR INFLUENCE ON KENYAN PATENT LAW

As we noted earlier, international treaties have long played an important role in shaping the various aspects of Kenyan Patent law. The need for international protection of intellectual property first became evident when foreign exhibitors refused to attend the "International Exhibition of Inventions" that was held in Vienna in 1873 because they were afraid that their ideas would be "stolen" and exploited commercially in other countries.[39] The roots of the protection and promotion of intellectual property go back to 1883, when *Johannes Brahms* was composing his third symphony, *Robert Louis Stevenson* was writing "Treasure Island" and *John* and *Emily Roebling* were completing construction of the New York's Brooklyn Bridge. That year marked the birth of the **Paris Convention for the Protection of Industrial Property (Paris Convention)**, the first major international treaty designed to help the people of one country obtain protection in other countries for their intellectual creations in the form of industrial property rights. The Paris Convention entered into force in 1884 with 14 member states, which set up an International Bureau to carry out certain administrative tasks. In 1886 copyrights entered the international arena with the **Berne Convention for the Protection of Literary and Artistic Works (Berne Convention)**. Like the Paris Convention the Berne convention set up an international bureau to carry out administrative tasks. In 1893, these two small bureaux united to form an international organization called **United International Bureaux for the Protection of International Property** (best known by its French acronym **BIRPI)**. Based in Berne, Switzerland, with a small staff of seven, this small organisation was the predecessor of the World Intellectual Property Organisation (WIPO). In 1960, BIRPI moved from Berne to Geneva to be closer to the United Nations and other international organisations in that city. A decade later, in 1970 following the passing of the **WIPO Convention** in 1967, BIRPI became WIPO, undergoing structural and administrative reforms and acquiring a Secretariat answerable to the member states. In 1974, WIPO became a specialized agency of the United Nations

[39] Background on the World Intellectual Property Organisation (WIPO); General Information Handbook. (July 1998 Edition).

with the mandate to administer intellectual property matters at an international scale. Further, on 15th April 1994 members to the WTO established the **Agreement on the Trade Related Aspects of Intellectual Property (TRIPS)** to further combat the abuse of IP rights within the member states.[40]The most important treaties that have influenced Kenyan Patent law are the **Trade Related Aspects of Intellectual Property (TRIPS) Agreement**, the **Patent Cooperation Treaty (PCT)** and the **African Regional Industrial Property Organization (ARIPO)** which I highlight in greater detail hereunder.

(i) The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Indeed TRIPS had a dramatic effect on many developing countries, Kenya being one of them. There has been a lot of debate in recent years about the reform of TRIPS.[41] The member states are currently in the process of reviewing and updating the 1994 Agreement. Two areas of reform that concern the gist of this thesis are, namely patents and public health and the patentability of plant and animal inventions. One issue that attracted a lot of attention in recent years is the extent to which patents restrict access of life saving drugs. This issue came to light when patentees attempted to challenge legislation in South Africa that would have their patented medicines (for the treatment of HIV/AIDS) to be sold at a much cheaper price. Triggered by the dispute in South Africa, the 4th WTO Ministerial Conference, held at Doha in November 2001, focussed on access to patented medicines in both developed and developing nations. Delegates noted that Article 31(f) of TRIPS, which provides that medicines produced under compulsory licences, must predominantly be for the domestic market, creates problems for countries that are unable to manufacture the patented medicines themselves. This debate caused a ripple effect across the developing nations and eventually the WTO member governments agreed that the obligations under Article 31(f) were to be waived, at least until the Article is amended.

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[40] Members signed the Marrakesh Agreement as well as annexes as a single undertaking, on 15th April 1994.
[41] See L. Bently and B. Sherman *'Intellectual Property Law'* 2nd Ed. Oxford University Press (2004) at pg. 345.

(ii) The Patent Cooperation Treaty (PCT)

The Patent Cooperation Treaty was signed in 1970 and came into operation from 1978. An application for a foreign patent within Kenya is made possible through the PCT, which is administered by WIPO. The key feature of the Treaty is that it provides for a system of international application and a preliminary examination procedure. This Treaty provides a simpler procedure for filing applications for patents. It enables an inventor to file a single patent application rather than several applications in several languages, one in each country that is a member of the Treaty. Therefore the PCT simplifies, and reduces the cost of, obtaining international patent protection and thus facilitates public access to a wealth of technical information relating to the inventions. This Treaty however does not necessarily affect the substance of the Kenyan Patent regime, as it is a treaty that merely facilitates the filing of international patents between the various member countries. As at 15th October 2003, the PCT had 123 contracting states. It is important to note that the PCT only provides for an international application and a search: the authority to grant the patent remains with the national patent office.[42] Furthermore only Kenyan nationals and residents can file an application for a patent under the PCT in Kenya.

(iii) The African Regional Industrial Property Organization (ARIPO) Treaty

This is another Treaty that allows a Kenyan investor, either a national or resident in Kenya, to apply for a patent protection in all or any of the selected ARIPO member states. The African Regional Industrial Property Organization (ARIPO) in Harare, Zimbabwe also provides for a single patent application procedure for all its more than 12 African member states. Much like the PCT, this Treaty also does not necessarily affect the Kenyan patent regime, as it is a treaty that simply facilitates the filing of international patents between the various member countries.

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[42] The Pct was signed in Washington 1970; amended in 1979; modified in 1984. See K. Pfanner, *'The Patent Cooperation Treaty: An Introduction'* (1979) *EIPR* 98; D. Perrot. *'The PCT in Use'* [1982] *EPIR* 67; C. Everett, *'Patent Cooperation Treaty (PCT)'* (1984) 13 *CIPAJ* 383; Anon. *'Patent Cooperation Treaty (PCT)* in 1992' (1993) 75 *JPTOS* 354; *J.* Cartiglia, *'The Patent Cooperation Treaty: A Rational Approach to International Patent Filing'* (1994) 76 *JPTOS* 261; J. Anglehart, *'Extending the International Phase of PCT Applications'* (1995) 77*jptos* 101.

2.2 PATENT PROTECTION UNDER THE TRIPS AGREEMENT

A noted earlier, a patent is an "intellectual property right" granted for the exclusive commercial use of an invention. Patent protection receives rather extensive treatment under the TRIPS Agreement. For a minimum of 20 years from the filing date,[43] member states must confer upon patent owners exclusive rights to prevent third parties who without consent, purport to make use, offer for sale, or import the patented product or process, or in the latter case, a product obtained directly by that process. Further, patent owners shall have the right to assign, or transfer by succession the patent and to conclude licensing contracts.[44] Courts in most systems can stop patent infringement at the owner's instance. Conversely, a court can also declare a patent invalid upon a successful challenge by a third party. Patents provide incentives to individuals, which encourages innovation through two ways. First, it gives them recognition for their creativity and second, there is a material reward for those inventions that are marketable.[45]

Patentable inventions under Article 27 paragraph 1 include "any invention whether products or processes, in all fields of technology, provided that they are *new*, involve an *inventive step* and are *capable of industrial application*". The terms "inventive step" and "capable of industrial application" may be deemed by a member state to be synonymous with the terms "non-obvious" and "useful" respectively.[46] The requirement of "novelty"

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[43] See Article 33 of the TRIPS Agreement.

[44] See Article 28 of the TRIPS Agreement.

[45] Apart from providing protection for the owner, patents ensure dissemination of valuable information. All patent owners are obliged, in exchange for patent protection, to publicly disclose information on their invention at the patent office. This increases the total amount of technical knowledge in the public domain and promotes further creativity and innovation in other researchers and inventors. Disclosure is in the patent application. The date from which patent right is deemed to start is usually the date of filing of complete specification. This right is known as the right of priority. Under the Paris Convention, to obtain rights in other member countries, the application must be filed on the same day in other member countries if it is desired to have the rights started from the same day. However, there are practical difficulties in synchronizing the activities. For facilitating simultaneous protection in member countries, the Convention provides that within 12 months of national filing, if patent applications are filed in those member countries, the patents, if granted in member countries, will be effective from the date of national filing. In other words you maintain the priority or the same date of filing in all the member countries and no one else in those countries can obtain the patent rights on a similar/identical invention from the same or a later date. In case the applicant after a second look at the patent application finds that the patent contains more than one invention or on his own accord wishes to divide the application, he can claim the initial date of priority for subsequent patent applications. The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. See 'Frequently Asked Questions – Patents'; http://www.indiainbusiness.nic.in/faq/patents, visited on 20th June 2006.

[46] Article 27 Par 1. To be protectable, the invention must therefore be of practical use. Second, it must show an element of novelty, that is, some new characteristic that is not known in the body of existing

imports that the invention has never been disclosed to the public, or been published, or been anticipated by prior art before the date of filing of the application for the patent. As such, in *Windsurfing International Inc v Tarbur Marines, (Great Britain) Ltd*[47] a patent sought to protect a sailboard was refused on the grounds that the same had been anticipated by a boy's toy sailboard prior to the application. The child had been playing with it in the public. It was therefore considered by the court not to be new. However in *Pall Corporation v Commercial Hydraulics (Bedford) Ltd*[48] it was held that delivering samples in confidence to persons who know that they are experimental and secret did not make the invention available for the public and was thus still novel. Fourthly, its subject matter must be "patentable" under law. In Kenya, scientific theories, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, or methods for medical treatment (as opposed to medical products) are generally not patentable.[49]

Members of the TRIPS Agreement must not discriminate in availing patent rights to inventions on grounds of place of invention, field of technology or whether products are imported or locally produced. They however retain discretion to exclude from patentability those inventions in situations where the prevention of their commercial exploitation is necessary to protect public order or morality, human animal or plant life or health or to avoid serious prejudice to the environment. They can also exclude inventions that are diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Plants and animals and essentially biological processes for their production are also not patentable; however micro-organisms, non-biological and microbiological processes are excluded form this latter category, and therefore can be protected by patents.[50] Under Article 29 of TRIPS, members must impose on patent applicants the condition of sufficiently clear and complete disclosure of the patent such that a person skilled in the art can carry out the invention. It is in this sense that patents foster innovation. Protection ends upon expiry of the patent, the owner loses exclusive

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knowledge (or "prior art") in its technical field. Third, it must show an inventive step, which could not be deduced by PHOSITA, i.e. person having ordinary kill in that area. Lord Molton in *Gillette Razor v Anglo-American Trading Co. (1913) 30 RPC 465* said that, in determining whether PHOSITA should be a mechanical genius or mechanical idiot 'the court will consider....what is displayed to the public....'. See also Ben Sihanya, (2005) *'IP Law Talking Points, Patents and Related Doctrines, Teaching Notes and Materials,'* LL.B. IV, University of Nairobi at pg 6.

[47] 782 F.2d 995 (Fed.Cir 1986).

[48] [1990] FSR 329.

[49] See section 21 of the Industrial Property Act, 2001.

[50] See Article 27 of TRIPS.

rights to the invention. It is then considered to have entered the public domain and is now, available for commercial exploitation by others.

2.3 THE REQUIREMENT OF "NOVELTY" IN PATENTS

2.3.1 What Is An Invention?

Before I even canvass the question of what amounts to a "new" invention, it is first necessary to identify what amounts to an "invention". While the characteristics of an invention play a key role in shaping many aspects of the novelty examination and consequently the fate of many inventions,[51] it has received very little attention.[52] The Oxford Learners Dictionary 6th Edition defines the term "invent" as "to produce or design something that has not existed before". F. D. Laet[53] also says that an invention is an innovation in a field of technology. As such, an invention is a technical solution to a problem in industry or agriculture, or a new technical means to alleviate living conditions. An invention can be relative to all fields of technology. An invention can deal with either a simple tool or method, such as a spade or the electrolysis of water, or it can deal with complex machinery, systems or processes such as computers, complex chemical processes or gearing systems.

However, although the question of what amounts to an invention has been settled rather universally it is important to note that different approaches have been taken by different states towards the determination of what amounts to "novelty". For example, the U.K. and the European Patent Office (EPO) have taken different approaches towards this determination, as we shall see later on in this thesis.

2.3.2 WHAT IS THE STATE OF THE ART?

The "state of the art" can broadly be defined to include all matter (whether a product, process, information about either or anything else) which, at the priority date of the application had been made to the public by written or oral description, or by use in any

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[51] *Glaverbel v British Coal* [1994] RPC 443; [1995] RPC 76, 82 (HL); Evans Medical Patent [1998] RPC 517.
[52] Lionel Bentley and Brad Sherman, *'Intellectual Property Law'*, 2nd Edition, Oxford University Press (2004); Novelty in Patents.
[53] Ibid F. D. Laet, *'PATENTS: From Protection through Information to Development'*.

other way.[54] Hereunder I shall canvass the various features for the determination of the state of the art.

2.3.2.1 No Geographical Limits

There are no geographical limits on where the state of the art should be disclosed as such it includes information that is available anywhere in the world.

2.3.2.2 No Restriction on the Mode of Disclosure

Information will become part of the state of the art irrespective of the way in which it was made available to the public. Consequently information shall become part of the state of the art as a result of written descriptions (such as prior published patents[55] or journal articles[56]); through prior uses,[57] exhibition sales,[58] or by oral communications (although in the latter case difficult evidentiary questions may arise).[59] If the information is accessible, then its age, obscurity, duration, language, or location is irrelevant.[60]

2.3.2.3 Potential Rather than Actual Disclosure

Information is part of the state of the art if it is open to or capable of being accessed by the public. As such, there is no need to demonstrate that anyone actually had access to the information in question (all that matters is that had they wanted to they could have accessed the information).[61]

2.3.2.4 Priority Date

Once accepted for filing, a patent application is assigned a number and a filing date, which is also known as the "priority date". However, this is not a grant of patent. It

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[54] Ibid Bentley and Brad Sherman, *'Intellectual Property Law'*.

[55] T877/98 [2001] *OJEPO* Special Edition No. 3, 20 (a patent becomes part of the public domain upon publication in the relevant Official Journal and not upon notification of the decision to patent.).

[56] This includes a magazine available to the public one day before the priority date, but not a doctoral thesis which has been placed in a library archive and is yet to be indexed: *Research Corporation/Publication*, T381/87 [1990] *OJEPO* 213; [1989] *EPOR* 138. See also *Exxon Mobil*, T314/99 (2) June 2001.

[57] *Enchteriberg/Rear –view mirror*, T84/83 [1979-85] *EPOR* 793, 796. On prior use as prior art under the EPC see Castro (1996) 27 IIC 190; and under French law see Mandelo (1996) 27*IIC* 203.

[58] *Telemechanique/Power Supply Unit*, T482/89 [1993] *EPOR* 259; [1992] *OJEPO* 646.

[59] *Hopper Trading/T-Cell Growth Factor*, T877/90 [1993] *EPOR* 6. CIPA, Para. 2.23. See also *University of Pennsylvania*, T1212/97 (22 Aug 2001) (Discussing the problems in interpreting the information provided by a lecture given to an audience of over 100 people). Ibid Bentley and Brad Sherman, *"Intellectual Property Law"*.

[60] *Windsurfing International v Tabor Marine* [1985] *RPC 59*.

[61] *Inpan Styrene Paper/Foam Particles*, T444/88 [1993] *EPOR 241*. There is no requirement that a person be likely to examine the document: *Hoechst/Polyvinyl ester Dispersion*, T93/89 [1992] *OJEPO* 718; [1992] *EPOR* 155; *Woven Plastics v British Ropes* [1970] *FSR* 47; *Harris v Rothwell* (1887) 4 *RPC* 225.

simply means that the application will be published 18 months after the filing date. Kenya follows a "first-to-file-rule". Where two or more applications claiming the same invention are filed, only the earliest application shall be patented and the latter applications cannot claim to be part of the state of the art, regardless of whether the inventors or the applicants are identical or not.[62]

2.3.2.5 Material Specifically Excluded from the State of the Art

There are two general situations where information in the public domain will specifically be excluded from the state of the art. First is whether the information was obtained unlawfully or was disclosed as a result of a breach of confidence.[63] This re-asserts the old adage that information is only available to the public if the recipient is free in law and in equity to divulge its contents.[64] Secondly is where the disclosure was due to or made in consequence of the inventor displaying the invention at an "international exhibition".[65]

It is however important to note that the exclusions only apply to disclosures that are made in the 12 month period immediately preceding the date of filing the patent application.[66] Any disclosures made outside this period will thus form part of the state of the art.

2.3.3 WHAT IS PRIOR ART?

In Kenya, patent applications are made public eighteen (18) months after their filing date, or an earlier foreign filing date where applicable. Anyone else may raise questions about the patentability of an invention or one of its claims by filing what is known as "prior

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62 'A Guide to Patenting in Kenya', Kenya Industrial Property Institute (KIPI) Ministry of Trade and Industry (2006).

63 A relevant example includes disclosure by employees (*Robert Bosch/Electrical machine*) T1085/92 [1996] *EPOR* 381); submission of an article to a refereed journal (*Research Corporation/Publication*, T381/87 [1989] 3 *EPOR* 138); and disclosures at a meeting with a manufacture (*Macor Marine Systems/Confidentiality Agreement*, T830/90 [1994] *OJEPO* 713; *Telecomunications/Antitoxidant*, T173/83 [1987] *OJEPO* 465; [1988] *EPOR* 133). Cf. *Deodorant Detergent/Unilever*, T585/92 [1996] *OJEPO* 129 (early publication by Brazilian Patent Office as a result of a lamentable error was unfortunate and detrimental but not an evident abuse since evident abuse required the state of mind of the abuser to be influenced by its relationship with the applicant as with breach of confidentiality). On the timing of the disclosure see *University Patents*, G3/98 [2001] *OJEPO* 62.

64 *Humpherson v Syer* (1887) 4 RPC 407; *Bristol Myer Application* [1969] RPC 146; *James Industries Application* [1987] RPC 235; T818/93 and T480/95 [1997] *OJEPO 20-21;* Robert Bosch/Electrical Machine T1085/92 [1996] *EPOR* 381; *Research Foundation/Translation Inhibitor*, T838/97 (14 November 2001) (oral presentation of an invention to a conference of 100 experts, who were told that the information could not be used without specific authorization, was a private communication that did not form part of the public domain).

65 Lionel Bentley and Brad Sherman, *'Intellectual Property Law'*, 2nd Edition, Oxford University Press (2004); Novelty in Patents at page 448.

66 Ibid 'A Guide to Patenting in Kenya', at page 5, see also *KIPI Introduction to inventions and Patents.html*, visited on 20th June 2006.

art". This is information that discloses that the patent information was already in the public domain by the date of filing the patent application. The prior art can be patents, any published material or material made public in any other another way.

Once the technical features of an invention have been identified, it becomes necessary to ascertain the nature of the information that has been disclosed by the prior art. In order to do this, it is first necessary to ask: what material forms part of the state of the art? Once this is determined (and the prior art relevant to the invention in question has been determined), it is then possible to determine the nature of the information disclosed by the prior art.

2.3.3.1 What Information is Disclosed by Prior Art?

The information disclosed by the prior art is restricted to the information that the person skilled in the art is able to derive from the prior art in question. In considering the way prior art is interpreted by a person skilled in the art, it is important to distinguish between situations where the prior art consists of a document and where it is a product.

2.3.3.1.1 Interpreting Documents

Documents are interpreted as if they were being read at the date of their application, and not the priority date of the invention. Given that the act of interpretation usually takes place after the date on which the document was published, it is important that the documents are neither read retrospectively[67] nor are construed in light of the events, which have taken place since their publication. The information available is that which a person skilled in the art would derive from reading the document in light of the common general knowledge. Another important rule of interpretation is that the information must be drawn from a single document. This means that it is not possible to combine together separate items in prior art. In a similar vein, it is normally not possible to combine elements from within a single document.[68] The only occasion where it is permissible to combine documents together is where a primary document inevitably leads to a second document; that is where the person skilled in the art would read different documents as if they were one.[69]

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[67] *Rhone-Poulenc/Taxoids*, T77/97 [1998] *EPOR 256*.

[68] *Draco/Xanthines*, T7/86 [1985] *EPOR* 65; [1988] *OJEPO* 381; *Scanditronix/Radiation beam collimation*, T56/87 [1990] *OJEPO* 188; [1990] *EPOR* 352.

[69] If the disclosure reveals one part of the product, and another disclosure another element, there is no anticipation: *Bayer/Diastereomers*, T12/81 [1979] B *EPOR* 308; [1982] *OJEPO* 296. *Texaco/Reaction injection*

2.3.3.1.2 Interpreting Products

There are a number of special rules to deal with situations where the prior art consists of a product, such as a drug or a machine that has been released to the market. In circumstances where the product is the same as the invention some problems in interpretation arise especially where the technical information necessary to anticipate an invention is not immediately apparent from looking at the product, but can only be obtained if the product is analysed.[70] The information available to the public also includes the information that a skilled person would be able to derive from the product if they analysed or examined it.[71] Any information that is obtained as a result of an analysis undertaken by a person skilled in the art must be obtained without undue burden or without the need to exercise any additional inventive effort.[72] The amount of information that is revealed by an examination depends on the type of analysis that is undertaken.[73] Given the various fields of research there are and the amount of time and energy spent on inventions, the question has arisen as to whether limits should be placed as to the type of analysis that should be undertaken in interpretation.[74]

2.4 PATENTABLE INVENTIONS

For an invention to be considered as being "new" it must not already have been available to the public. An invention is novel if it does not form part of the "state of the art". The "state of the art" is described as comprising all matter[75] made available to the public before the priority date of the invention whether by written or oral description, use,

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moulded elatomer, T279/89 [1992] *EPOR* 294, 298; *Amoco Corporation/Alternative claims*, T153/85 [1988] *OJEPO* 116, 123; *ICI/Latex Composition*, T77/87 [1990] *OJEPO* 280; [1989] *EPOR* 246, 251.

[70] See L. Tournroth, 'Prior Use' (1997) 28 *IIC* 800, 800-1; Paterson, para. 10-07 in Lux Traffic, Aldous J distinguished between cases of prior use where the public had access to the invention and were able to handle it, and prior uses which allowed the public only to observe the object. The circumstances in which each would anticipate would differ, disclosure being much more likely in cases of handling. This, however, was not conclusive. In *Luchtenberg/Car Mirro*, T84/83 [1979-85] *EPOR* 793, 796, the TBA accepted that the use of a mirror attached to a car in public for six months might be revealed if all aspects were disclosed. Cf. *Pfenningabsatz* [1966] *GRUR* 484, 486.

[71] *Thomson/Electron tube*, T953/90 [1998] *EPOR* 415.

[72] *Availability to the Public Decision*, G1/92 [1993] *EPOR* 241; [1993] *OJ EPO* 277, Undue Burden, however, seems to carry with it a subjective element.

[73] It also depends on the general nature of the invention. In *Wesley Jessen Corp. v Coopervision* [2003] RPC 355, 384 (the skilled addressee would have all the information he would require to form a contact lens in the public domain, which was not a product of high technical sophistication).

[74] Ibid Lionel Bentley and Brad Sherman, '*Intellectual Property Law*'.

[75] Whether a product, a process, information about either, or anything else (in other words, anything)

exhibition or in any other way.[76] An invention that already forms part of the state of the art is said to have been "anticipated". If an invention has been anticipated, it is not a patentable invention.[77]

As we have already observed, the "state of the art" comprises all matter (whether a product, process or any information relating to either) which has been made available to the public, whether in Kenya or elsewhere, before the priority date of the invention.[78] Information is made available not just by written or oral description, but "by use in any other way". The state of the art includes matter contained in applications, which although published after the invention in question, nonetheless have an earlier priority date. It is therefore necessary to consider first how novelty, or its absence, is assessed, before going on to look at the circumstances in which a prior invention is considered to have been "made available to the public"

2.4.1.1 Anticipation

For the subject matter of a patent to have been "anticipated", the earlier invention must coincide with it exactly. According to Sachs J. in *General Tire and Rubber Co. v Firestone Tyre and Rubber Co.* (1972), a signpost however clear, upon the road to the [latter] patentee's invention would not suffice. The prior invention must be clearly shown to have planted his flag at the precise destination before the patentee. Anticipation may be based on the prior publication of an invention for its prior use. It was held in *General Tire*[79] that to determine whether an invention has been anticipated, the prior publication and the latter claim are to be construed as at their "respective relevant dates" (i.e. their dates of publication) by a reader skilled in the art. This means that, when construing the earlier document, the reader skilled in the art will be assumed to be skilled in the art as it was at the time of its publication, and any later technical advances are irrelevant.[80] Similarly, the later claim will be claim will be construed in light of the state of the art at its own publication date.

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[76] The phrase 'made available to the public' was used in the definition of 'published' in the UK Patents Act 1949 section 101 and should be given the same meaning: *PLG Research Ltd v Ardon International Ltd.* [1993] FSR 197. At least one member of the public should be free in law and in equity to use it.

[77] Jennifer Davis, "*Intellectual Property Law*", 2nd Ed., Lexis Nexis UK, Butterworth's Core Text Series at pp. 32.

[78] See 'WHAT IS THE STATE OF THE ART' 2.4 above.

[79] This case concerned anticipation by earlier publication of the invention. See chapter 2.9 of this thesis.

[80] This point was decided in *Kirin-Amgen Inc v Transkaryotic Therapies Inc* (2002).

2.4.1.2 Clear and Unmistakable Directions

In order to anticipate a later invention, the earlier publication must contain clear and unmistakable directions to do what the patentee claims to have invented (*General Tire v Firestone* [1972]). Further in order to invalidate a subsequent patent, the earlier publication must be such that a person of ordinary knowledge of the subject would at once perceive and understand and be able practically to apply the discovery without the necessity of making further experiments, because something essential was not disclosed.[81] To put more succinctly, the earlier publication must provide an enabling disclosure. It must, as a matter of necessity, enable a person skilled in the art to perform the invention.

2.4.1.3 Ordinary Knowledge

A patent is considered to be anticipated if someone with ordinary knowledge of the subject can look at the earlier publication, and can understand and replicate the steps that led to the invention. Such a person would have the common general knowledge attributable to a notional skilled person with the relevant background technical knowledge.

2.4.1.4 Disclosure

A claim may have been anticipated by prior art, but in order for it to be invalidated for anticipation the prior art must have been made available to the public. Further, oral disclosures will not anticipate a patent if they are in confidence, whether express or implied. In *Visx Inc. v Nidek Co Ltd*,[82] the patents in suit related to laser apparatus used to alter the shape of the cornea to correct myopia, hyperopia and astigmatism. The defendant counterclaimed for revocation of the patents on the basis, *inter alia*, of a number of oral disclosures, including one claimed to have been made on a train journey. Neuberger J said that the burden of proof lies with the person alleging prior disclosure[83] but in this case the numerous alleged oral disclosures were either insufficient to anticipate the patents or the defendant had failed to show that they were made in confidence.

[81] Ibid Jennifer Davis, '*Intellectual Property Law*'.
[82] [1999] FSR.
[83] However, as opposed to the legal burden, the evidential burden may shift according to the state of the evidence from time to time: *Dunlop Holding Ltd's Application* [1979] RPC 523 at 542 per Buckley J.

2.4.1.5 Availability to the Public

"Made available to the public" was interpreted to mean the same thing as "published" in the UK Patents Act of 1949.[84] To constitute prior art, the information given must have been communicated to any member of the public "who was free in law and equity to use it as he pleased". According to Purchas LJ, *Genetech's Patent* (1989) the public is the "community of research workers skilled in the art in general". The act or series of acts that make the invention available to the public do not have to be on a particularly wide scale.[85] Using an invention in public in one locality will only suffice to anticipate a patent. In *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd*,[86] the Court of Appeal held that a 12-year old boy, who built a sailboard and used it for a few weekends at a caravan site at Hayling Island in Hampshire, had effectively anticipated a later patent for a sailboard which was declared invalid for want of novelty (and also because it lacked an inventive step). However, an invention is not made available to the public if the disclosure is by someone under a duty of confidentiality, for instance, by a researcher to a fellow employee while both are under a duty of confidentiality to their employer.[87] Thus, in *Pall Corporation v Commercial Hydraulics* (1990), sending out examples of filter cartridges under confidence to recipients who knew that they were experimental and secret did not amount to making the invention "available to the public".

2.4.1.6 No Additional Inventive Activity

Further, while the person skilled in the art may be allowed to draw upon the general knowledge common to the field, for a claim to have been anticipated by prior art a the prior art must place the skilled person in a position whereby they are able to work the invention without the need for further information, nor the need to engage in any new experiments, or in some other additional inventive activity.[88]

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[84] This was the *dicta* in *PLG Research Ltd v Ardon International Ltd* [1993] FSR 197. It was held that at least one member of the public should be free in law and in equity to use it.

[85] In *Uni-Continental Holdings Ltd v Eurobond Adhesives Ltd* [1999] FSR 263, the sale of two cartridges with nozzles for dispensing acrylic adhesives before the priority date was sufficient to invalidate the patents for the nozzles.

[86] [1985] RPC 59.

[87] Ibid, Jennifer Davis in her *'Intellectual Property Law'*.

[88] This was decided in *Hills v Evans* (1862) 31 LJ Ch 457; 45 ER 1195 (HL).

2.4.2 OBJECTIVE NOVELTY

The question of whether a disclosure enables the public to work an invention is decided objectively.[89] This means that there is no need to show that a member of the public actually worked the invention, nor that they were aware of its existence. Importantly, this has been held to mean if it is an inevitable consequence of following the information disclosed in the prior art that the invention is made, and then the invention will have been anticipated.[90] If the instructions probably, normally or only sometimes produce the product, however, there will be no anticipation.[91] In these circumstances, there is no need for the person skilled in the art to know that they are producing the product in question: all that matters is that the prior art discloses information, which if followed, inevitably leads to the invention. To use the analogy often used in this context, "if the recipe which inevitably produces the substance is part of the state of the art, so is the substance made by that recipe".[92] It does therefore not matter that the cook was ignorant of the fact that they were in fact producing the product.

2.5 NON-PATENTABLE INVENTIONS

Certainly, not every invention that satisfies the "novelty", "inventive step" and the "industrial applicability" requirements is patentable. Certain inventions may have all the attributes of a patentable invention, but will be excluded from patenting on other grounds.[93] An invention will not necessarily come within this ambit only because it is illegal. In Kenya, the non-patentable inventions include:-

- Plant varieties as provided for in the seeds and varieties Act;
- Inventions contrary to public order, morality, public health and safety and principles of humanity and environmental conservation;

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[89] *Merrell Dow Pharmaceuticals v Norton* [1996] RPC 76, 88, 89, 90. 'This does not affect the principle that the prior art directions or information that will inevitably result in the use of a patented process or creation of the patented product invalidates by anticipation' see also *Kaye v Chubb* (1887) 4 RPC 289, 298.

[90] See *Inhale Therapeutic Systems v Quadrant Healthcare* [2002] RPC 21 where Laddie J. reviewed his earlier judgment in *Evans Medical Ltd's Patent* [1998] RPC 517; *Smithkline Beecham PLC'S Patent No 2* [2003] RPC 607, 631.

[91] See ibid *General Tire v Firestone* [1972], inevitability has been held to mean 99 cases out of 100 (*Femento v Mentmore* [1956] EPOR 104); 'tantamount to 100 percent probability' (*Allied Signal/Polyoefn Fiber*, T793/93 [1996] EPOR 104). It seems that at the EPO the inevitability of the disclosure needs to be satisfied 'beyond all reasonable doubt': *Allied Signal/Polyoefn Fiber*, T793/93 [1996] EPOR 104.

[92] See ibid *Merrell Dow Pharmaceuticals v Norton*. See also *CPC/Flavour Concentrates Decision*, T303/86 [1989] EPOR95; *Bayer/Diastereometers*, T12/81 [1979-83] B EPOR 308, 312. See also 'Availability to the public'.

[93] See section 26 and 27 of the Industrial Property Act.

- Any invention, which in the opinion of the Managing Director of KIPI, appears to be prejudicial to Kenya or to the safety of the public.

2.6 SECRET OR INHERENT USE

One of the most important changes that have taken place with the shift to enabling disclosure is in relation to the issue of whether a prior secret or inherent use is able to anticipate a subsequent patent. Basically, a secret or inherent use occurs where something is created, usually either accidentally or as an unknown by-product of some process, without the public knowing of its existence. While it was possible for a secret or inherent use to anticipate an invention under the 1949 U.K. Patents Act, this is no longer the case under the 1977 U.K. Patents Act.[94] The position in the 1949 Act was elaborated in *Bristol Myers' Application*,[95] where the question arose as to whether Bristol Myers' patent for an ampicillin compound (an artificial antibiotic derived from penicillin) had been anticipated by the fact that before the priority date of the invention, Beecham had made small quantities of the ampicillin. At the time the ampicillin was made, Beecham did not know about the invention nor were they aware of its particular advantages. While the prior art conveyed no relevant information about the product to the general public, nonetheless the House of Lords held that the patent had been anticipated by secret or uninformative use. The explanation for this was two-fold: First, had the patent had been granted, the patentees would have been able to stop another trader from what they had been doing before (the right to work doctrine); Secondly, the test for anticipation was co-extensive with the test for infringement. Given that for a defendant to infringe it was not necessary for them for them to realize that what they were doing was actually an infringement. Such knowledge was therefore equally unnecessary when determining whether the invention was novel.

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[94] The 1977 Patents Act introduced a substantial qualification into the old principle that a patent cannot be used to stop someone from doing what he has done before. If the previous use was uninformative, then subject to section 64 [which provides a defence for secret use before the priority date] it cannot. See also *Merrell Dow Pharmaceuticals v Norton* [1996] RPC 76, 86 (HL).

[95] [1975] RPC 127. Such an approach would mean that a prior secret would anticipate a patent even if it were not clear how the invention worked. This is because such a use would give the public the benefit of the old invention even without their knowledge. Under the 1977 U.K. Patents Act, it seems that there is nothing to prevent a person concealing the use of their old invention in this manner, though it has been suggested that in a clear case of fraud, the Patent Office can decline to grant the patent. See also H. Frost, '*Why Europe Needs a Sales Bar*' [1996] EIPR 18; R. Jacob, '*Novelty of Use Claims*' (1996) 27 IIC 170.

The question of the status of secret or inherent use under the 1977 U.K. Patents Act was considered by the House of Lords in *Merrell Dow v Norton*.[96] This decision arose from the fact that in 1972, the claimant was granted a patent for the antihistamine terfenadine: a drug used in treating hay fever and other allergies. When patients took terfenadine, it was transformed (or metabolized) in the body to produce a number of different products (or metabolites). While terfenadine proved to very efficient in the treatment of hay fever, it had several unwanted side effects notably that it led to heart-related problems in some patients. As the initial patent was nearing the end of its duration, the claimant identified and isolated the particular metabolite that acted like an antihistamine. It was accepted that prior to this the specific metabolite that acted as an antihistamine had not been identified. In 1983, the claimant obtained a patent for the making of the newly identified metabolite with the antihistamine effects within the human body by the ingestion of the terfenadine. This of course carried with it the obvious advantage that while it was useful in the treatment of hay fever, it did not have with it any of the side effects associated with terfenadine. After the grant of a patent for the metabolic acid, *Merrell Dow* brought an action against *Norton* claiming that by supplying terfenadine, the defendant was facilitating the making of the patented metabolite, thereby infringing on the second patent.[97] The defendants counter-claimed arguing that the second patent had in-fact been anticipated by prior use. The argument for anticipation by prior use relied on the fact that terfenadine had been made available to and used by volunteers in clinical trials before the priority date of the patent. As the patented metabolite was produced in the livers of the volunteers when they took terfenadine, the second patent had been anticipated and was thus invalid.

Lord Hoffman in his judgment said that albeit under the 1949 Act such mere uninformative use of this kind was sufficient to invalidate a patent, this was not the case under the 1977 Act.[98] Lord Hoffman said that when determining novelty the starting point was whether there had been an enabling disclosure of the claimed invention.[99] More importantly, Lord Hoffman pointed out that while an invention may have been in

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[96] *Merrell Dow Pharmaceuticals v Norton* [1996] RPC 76 (HL): I. Karet, '*A Question of Epistemology*' [1996] EIPR 97; See also V. Vossius and T. Vossius, '*Prior Written Disclosure and Prior Public Use under German Law and the EPC*' [1994] EIPR 130.

[97] This was on the basis that it amounted to a contributory infringement under Section 60 (2) of the U.K. Patent Act.

[98] As such *Bristol Myer's Application* [1957] RPC 127 was no longer good law.

[99] 'The question is not what may have been "inherent" in what was made available (e.g. by a prior written description or in what has previously been used [prior use]. Rather it was what has been made available to the public.) *Merrell Dow Pharmaceuticals v Norton* [1996] RPC 76 (HL).

existence before the priority date through secret or prior use, this was not in itself sufficient to invalidate a patent or a patent application. The reason for this is that "the use of a product makes the invention part of the 'state of the art'[100] only in so far as that use makes available the necessary information".[101] While the patented metabolite was inevitably produced in the body of the volunteers when they took the terfenadine, this working of the invention was not as a result of information that had been made available to the public. The uninformative consumption of the terfenadine, which secretly or inherently produced the metabolite, did not in any way disclose any information that would have allowed a person skilled in the art to use that information to produce the metabolites. As such the House of Lords held that the prior use was not anticipatory.[102]

It should be pointed out that the invention was anticipated by the earlier patent. In the case of anticipation by use, the acts relied upon conveyed no information which would have enabled anyone to work the invention: that is, to make the acid metabolite in the body. In contrast, the earlier patent made information available to the public that enabled it to do an act that resulted in the production of the patented metabolite. The terfenadine specification taught that the ingestion of terfenadine produced a chemical reaction in the body. For the purposes of working the invention in this form, this was a sufficient description of the making of the patented metabolite.[103]

2.7 PRODUCT-BY-PROCESS CLAIMS

Albeit product-by-process claims are permissible in the U.K., they are only allowed at the EPO where it is impossible or at least very difficult, to define the product in any other way. In part, this is due to the differences in the way the product-by-process claims are interpreted. This difference also manifests itself in the way the novelty of such claims is assessed in the U.K. and at the EPO.

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[100] See part 2.4 of this thesis 'WHAT IS THE STATE OF THE ART'.

[101] L. Bently and B. Sherman '*Intellectual Property Law*' 2nd Ed. Oxford University Press (2004). Lord Hoffman emphasized that the invention, which was a piece of information, must have been made available to the public, [*Merrell Dow Pharmaceuticals v Norton* [1996] RPC 76 (HL)].

[102] This rule applies in the U.K. whether the prior art is a prior application, a prior use, description, or set of instructions. The 'information deriving from a use is governed in principle by the same conditions as is information disclosed by oral or written description'.

[103] See ibid L. Bently and B. Sherman '*Intellectual Property Law*' 2nd Ed. Oxford University Press (2004).

At the EPO, a product-by-process claim will only be novel if the product itself is novel. Novelty therefore, cannot be conferred by the process alone. That is the EPO "does not recognize that novelty can be conferred on a known substance by a novel process for producing that substance".[104] This means that even if the process claimed is novel, a product-by-process claim will be anticipated (and thus held to be invalid) unless the product itself is also novel. In contrast, the U.K. Court of Appeal explicitly rejected such an approach saying that there was no reason why the limitation of claims to products produced by a process could not impact novelty.[105] If a person invents a new method of extracting gold from a rock, that person can obtain a claim to the process at the EPO as an Art.[106] The European Patent Court (EPC) implies that by granting such a patent, the person would also monopolize the gold when produced directly by the process.[107] As such product-by-process claims are *prima facie* valid in the U.K. provided the process is itself patentable, however this is not the case in the EPC. Therefore, while this may seem to suggest that old products (such as gold) are able to be re-monopolized every time a new process is invented, it is important to note that protection only applies to products made by that process.

2.8 BIOTECHNOLOGICAL INVENTIONS

While a number of changes have taken place in patent law to accommodate biotechnological inventions, for the most part they are treated in a similar manner to other types of inventions. The test for novelty is no exception to this general rule: a biotechnological invention will only be anticipated and thus be deemed to be invalid where there has been an enabling disclosure.[108] Despite this, questions sometimes arise where biotechnological inventions are based on natural materials. In this context it is important to note that a natural substance (such as a polynucleotide sequence) that has been isolated for the first time, will not lack novelty because it was already present in nature (e.g. in the human genome). Here, patent law draws a distinction between the

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[104] U.K. Patent Office, Examination Guidelines foe Patent Applications Relating to Biotechnological Inventions, para 13 (as at September 2002); See also *Kirin-Amgin v Transkaryotic Therapies* [2003] RPC 31, para 296 (CA).

[105] *Kirin-Amgin v Transkaryotic Therapies* [2003] RPC 31.

[106] See Article 64 (2) of the European Patent Convention.

[107] *Kirin-Amgin v Transkaryotic Therapies* [2003] RPC 31, para. 33 (CA). 'I can discern no reason in principle or in practice why a claim to a product made by a certain process could be invalid simply because the product is not novel, if the process is novel, so that a claim to a process would be valid.' Ibid L. Bently and B. Sherman *'Intellectual Property Law'*.

[108] See e.g. *Asahi's Application* [1991] RPC 485 (HL); *Genetech's (Human Growth Hormone) Patent* [1989] RPC 613; U.K. Patent Office, Biotechnology Guidelines as at Sept. 2002, para. 8-11.

invention (the isolated "artificial" polynucleotide) and the natural substance (the polynucleotide that exists in nature).[109] The artificial nature of the isolated substance provides the requisite difference between the prior art and the invention, necessary to ensure novelty.[110]

[109] *Howard Florey Institute's Application* T74/91 [1995] *OJEPO* 388. See also D. Schertenteib, '*The Patentability and Protection of DNA-Based Inventions in the EPO and in the European Union*' [2003] *EIPR* 125; EPO, USPTO, JPO Trilateral Project 24.1, '*Biotechnology Comparative Study on Biotechnology Patent Practices*'.

[110] See ibid L. Bently and B. Sherman '*Intellectual Property Law*' 2nd Ed. Oxford University Press (2004).

CHAPTER THREE

CRITICAL GAPS IN THE KENYAN "NOVELTY" REGIME

The most critical issue in today's IP regime relates to "the new use of an old thing". This is a rather new area to the Kenyan patent regime. Furthermore, this is also a fairly grey area in international intellectual property law and different states have adopted different approaches to the question of the patentability of "the new use of old things". Similar to the preceding chapter, herein we shall expose the gaps in the Kenyan novelty regime by adopting a comparative approach using, the EPO and the UK positions on the same.

A case example is where English case law appears to diverge from the view taken by the European Patent Office (EPO). English authorities hold that the new use of a known thing, where there is no additional ingenuity, is not a patentable invention. Conversely, an invention involving the new use of a known thing is patentable, if the new use overcomes the practical difficulties that the patentee was the first to identify.[111] Thus, if the invention is sufficiently different, the new use will not be considered to be part of the "state of the art". By contrast, in the EPO case concerning a new use of an old thing,[112] the claim was for compounds for controlling fungi and the patent application contained teaching as to how to carry this out properly so as to achieve the desired effect. It was held by the Enlarged Board of Appeal of the EPO:-

> *'With respect to a claim to a new use of a known compound, such new use may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim (for example, the achievement in a particular context of that technical effect). If that technical feature has previously not been made available to the public by any of the means as set out in the EPC Act 54(2), then the claimed invention is novel, even though such technical effect*

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[111] Parks-Cramer Co. v Thornton & Sons Ltd. [1966] RPC 407. Prior to the 1977 UK Patents Act, there had to be novelty in the mode of using the old product as distinguished from 'novelty of purpose'. See also Gadd & Mason v Manchester Corporation. (1892) and the case of Lane-Fox v Kensington and Knightsbridge Electric Lighting Co. Ltd. (1982) 9 RPC 413.

[112] *BASF/Triaazole Derivatives* (1989).

may have inherently taken in the course of carrying out what has previously been made to the public."[113]

The later EPO case, *MOBIL/Friction-reducing additive*[114] confirmed that it was possible to patent an invention which involved the new use of a known thing. The claim was for the use of a friction-reducing additive in a lubricating oil. This same additive was already known to be rust reducing. No new means were employed to produce the lubricating effect. The issue was whether this claim lacked novelty. The Enlarged Board of Appeal suggested that a new use of a known compound may reflect a newly discovered technical effect which could be considered as a functional technical feature of the relevant claim. If that technical feature had previously not been made available to the public, the claim would be deemed to be "novel" even though it had inherently taken place in the course of what had previously been made available to the public.[115]

However, the UK in the subsequent case of *Merrell Dow*[116] contradicted the view taken by *Mobil Oil.* In the appeal to the House of Lords in *Merrell Dow,* although their lordships approved *Mobil Oil,* Lord Hoffmann cast some doubt on that decision. Considering the UK's provisions on infringement, he said it would be difficult to tell, for a second invention such as that in *Mobil Oil,* whether the alleged infringer was using it for the forbidden purpose. That is, how can one tell whether a person is using the oil additive as a lubricant (lawful after the expiry of the first patent) or to reduce friction (which would infringe the second patent)? However, whichever purpose the person alleged to have infringed had in mind is irrelevant to the existence of the infringement. It may at best, reduce the exposure to damages. If a person used the additive for the purpose of lubrication, it would also reduce friction, whether or not he knew this. The danger, similar to that perceived by the Court of Appeal in *Merrell Dow,* is that the patent monopoly can be extended beyond its normal life if the patentee can discover a hitherto unknown effect. This might be acceptable if it involves a "new use not previously carried

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[113] See the case of *BASF/Triaazole Derivatives* ibid.
[114] [1990] *EPOR* 73.
[115] The Enlarged Board of Appeal said that 'making available to the public' means that the invention must have been communicated to the public or laid open to inspection. It further posited that inherency does not arise under Article 54(2) of the European Patent Convention.
[116] *Merrell Dow Pharmaceuticals Inc v H. N. Norton & Co. Ltd.* [1995] *RPC* 233.

out" (not being a previous unknown and inherent use), but not if it involves a "known use" but for a "new purpose".[117]

3.0.1 Collocations

If the invention simply combines into one apparatus, two machines that had formerly been used separately, each of which performs its normal function, it is not patentable. This is true even if the resultant combination is novel. In the famous sausage machine case,[118] a filling machine was combined with a mincing machine to produce a machine for mincing meat and putting into skins to produce sausages. Since both the original machines were already known and were combined in the "simplest possible manner" it was held not to be a patentable invention. Similarly in *Merrell Dow v Norton* [1996], the combination of ibrufen with a decongestant was not an inventive step even though the product was a more effective drug, because each ingredient was performing its usual and known function. If there had been a synergy between them that had produced a whole new effect, it may very well have been a patentable invention.[119]

However, an opposite decision was reached in the *Sabaf Case*[120]. The claimant's patent related to burners for gas hobs. In particular, the patent addressed the fact that current burners were too tall to be used for hobs, resulting in complications in the mixing of oxygen and gas. The defendant argued that at the heart of the claimants patent was a mere *collocation* of two known concepts[121] that the claimant had simply combined to produce the desired effect. It was therefore held to be invalid for non-obviousness. The Court of Appeal however found for the claimant. According to Gibson LJ, the question in a case involving a collocation was whether it would be obvious to a "person skilled in the art", using his common general knowledge to combine these concepts. If there is some interaction between the features of the invention combining these two or more concepts and it would not have occurred to the unimaginative "person skilled in the art" to put them together to produce that interaction, there may be an inventive step.

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[117] David I. Bainbridge in his "*Intellectual Property*"; 5th Ed.; (2002). Pearson Education Limited, *www.pearsoned.co.uk* at part IV.

[118] *Williams v Nye* [1890].

[119] Jennifer Davis, "*Intellectual Property Law*", 2nd Ed., Lexis Nexis UK, Butterworth's Core Text Series at 2.54.

[120] *Sabaf SpA v Menenghetti SpA* [2003].

[121] It was argued that the patent was a *collocation* of firstly a radial mixing passage and secondly the drawing in of air from above the hob unit.

In finding that the claimants patent was "not obvious" the U.K. Court of Appeal pointed out that its interpretation coincided with the EPO's view on collocations as set out in its "Guidelines for Substantive Examinations".[122] These Guidelines which cite the example of *Williams v Nye* as a collocation that is not patentable, also endorse the view that a mere combination of two or more features, even if they are wholly or partly known, which interact with each other such that they produce a wholly new technical result is patentable.

3.0.2 Analogy

The general position of the UK Courts is that inventions that are simply analogous to another patented invention or information that forms part of the state of the art was outlined in the case of *Morgan v Windover.*[123] Lord Herschell in this case opined quite categorically that:-

> *"...the mere adaptation to a new purpose of a known material or appliance, if that purpose is analogous to a purpose to which it has already been applied, and if the method of application is also analogous so that no inventive faculty is required and no invention is displayed in the manner in which it is applied, is not the subject matter of a patent."*

3.1 THE DISCOVERY OF A NEW ADVANTAGE OF AN OLD THING USED IN AN OLD WAY

In this section we move away from the general principles of novelty that have concerned us thus far to concentrate on three specific types of inventions and the problems that have arisen when assessing their novelty. In particular, we look at the novelty of inventions that relate to medical uses, non-medical uses and selection inventions.

For many years the primary goal of the research carried out in many areas of science and technology was the creation of either new products or the new uses of old things. On the whole, the fruits of this research have generally been served well by patent law. This can

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[122] These are guidelines set down by the EU. to guide the EU. Courts and the European Patent Office in settling the issue of the patentability of inventions.

[123] [1890]. In this case, the invention was the use of springs normally used in the rear part of a carriage in the front of a carriage.

be seen by the fact that patent law has long recognized the discovery of new things[124] (such as the discovery of aspirin) and the discovery of new uses of using old things[125] (such as the discovery that aspirin rubbed on the skin acts as an effective insect repellent) as being novel.

In the last forty years or so, a number of changes have taken place in the type of research undertaken in various industries. These changes were motivated by a realization that in certain fields (notably in relation to pharmaceutical and biological inventions) the possibility of discovering new things or the finding of new uses for old things was decreasing. As a result, the focus of the research shifted to the discovery of new uses (or purposes) of old substances used in old ways. The problem that confronted researchers working in this way was that British patent law in traditionally refused to recognize the discovery of a new advantage of an old thing used in an old way, as being novel. This would mean, for example, that if someone discovered that as well as being useful in the curing of headaches, that the consumption of aspirin also thinned the blood (and was thus useful in preventing blood clots), they would be unable to patent the invention. The reason for this is that the traditional British approach treated a claim to a product to a "product for a particular use" as a claim to the product *per se*, so that the product would lack novelty even if the product had previously been employed in a different use.[126] The problem that confronted this "new" style of research was, in short, that patent law was not willing to recognize "novelty of purpose" as a basis on which an invention could be patented.[127]

The EPO was the first to lead the way in the undermining of this principle followed by the UK Courts. One of the first areas where the general rule was relaxed was in relation to medical uses[128] (*thus the bias of this research*). With the EPO leading the way and the UK Courts following, this was interpreted to include second and subsequent medical uses. Albeit initially seen as an exception that left the general rule intact, the EPO and arguably

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[124] Claims to a substance provide protection not only over the thing itself, but over all subsequent uses.
[125] Typically, new uses are claimed as a 'new method of using the old article'.
[126] See *Adhesive Dry Mounting vs. Trapp* (1910) 27 RPC 341; Jacob, "Novelty of Use Claims" (1996) at chapter 1.2. ibid, IIC 170, 173.
[127] Lionel Bentley and Brad Sherman, "*Intellectual Property Law*", 2nd Edition, Oxford University Press (2004); Novelty in Patents and ibid chapter 1.2. of this thesis.
[128] It is arguable that selection patents, discussed below, were also an early exception to the general rule about the non-patenting of novelty of purpose.

now the UK Courts, have recognized novelty of purpose irrespective of the field of technology albeit to different extents.

3.2 MEDICAL USES OF KNOWN PRODUCTS

When the EPC was being drafted it was decided that methods of the treatment of the human or animal body should not be patentable.[129] Likewise, the Kenyan position is that methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced in relation thereto, except products for use in any such methods shall be excluded from patent protection.[130] While the pharmaceutical industry was able to patent new substances,[131] the proposed blanked exclusion of methods of medical treatment in the EPC[132] presented them with a problem. The reason for this was that most of the research then being carried out was not into the creation of new substances and drugs. Rather, most of the research focussed on the discovery of new uses of old substances or the discovery of new benefits from old substances. As such the exclusion of methods of medical treatment from the scope of patent protection would have had a dramatic impact upon medical research. As such to appease the interests of the pharmaceutical industry, section 2 (6)/Article 54 (5) of the EPC was introduced. Section 2 (6) provides that:-

> "*...the fact that an invention consisting of a substance or composition for use in a method of medical treatment forms part of the state of the art, shall not prevent the invention from being taken to be new, if the use of that substance or composition in any such method does not form part of the state of the art*"[133]

Essentially, section 2 (6)/Article 54 (5), which permit the patenting of new uses of old substances used in old ways (in a medical context), create a statutory exception to the traditional British view that the mere discovery of purpose could confer novelty of an

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[129] PA sec. 4 (2); EPC Art. 52 (4). Further, Art. 27 (2) of the TRIPS Agreement also provided that diagnostic, therapeutic and surgical methods for the treatment of humans or animals were exempted from patentability.

[130] Section 21 (3) (c) of the Industrial Property Act, 2001.

[131] P.A. sec 4 (3) and EPC Art. 52 (4) leave open the possibility of claims to new substances or compositions. Consequently, while it is not possible to obtain a patent for a method of preventing headaches involving the taking of aspirin, aspirin is patentable *per se*.

[132] Now to be found in section 4 (2) and Article 52 (4) of the EPC.

[133] This was apparently based on French law. Patterson, para. 9. 61. R. Singer, '*The European Patent Convention*' (1995), 167; *Hoffman-La Roche/Pyrrolidine Derivatives*, T128/82 [1984] *OJEPO* 164; [1979-1985] B EPOR 591.

invention.[134] In essence the provisions confer novelty via the new *purpose* (the new pharmaceutical use of a known substance), even though "the substance itself is known and comprises part of the state of the art".[135]

3.2.1 Second and Subsequent Medical Uses of a Known Product

When enacted, it was widely believed that section 2 (6) Article 54 (3) only applied to the discovery of the first medical use of known products a position supported by a normal reading of the provisions. Given this interpretation, it would have meant that claims for second or further medical uses of products would have lacked novelty.

The question of the scope of Article 54 (5) was considered by the Enlarged Board of Appeal of the EPO in *Eisai/Second Medical Indication.*[136] Basing its argument on the legislative history of the EPC and the principle that an exception to patentability should be construed narrowly, the Board suggested that as well as protecting first uses, Article 54 (5) also applied to second and subsequent medical uses. The Enlarged Board of Appeal went on to say, however, that this was conditional on the fact that claims were drafted in a style known as the "Swiss form of Claims". Basically this meant that the patent had to claim the "*use of a substance for the manufacture of a medicine for a specified new therapeutic use*".[137] This would mean that for the discovery that the consumption of aspirin was useful in the thinning of blood to be valid, the applicant would have to claim the "use of aspirin in the making of a medicament for use in the prevention of blood clots".[138]

One of the most notable features of a Swiss Claim is that it is directed at the manufacture of the known substance. This ensures that the invention is not excluded on the basis that it is a method of medical treatment under section 4 (2)/Article 52 (4).[139] At

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[134] See A Benjamini, '*Patent Infringement in the European Community*' (1993), 80 ff.; G Patterson, '*The Patentability of Further Uses of a Known Product Under the EPO*' (1991) EIPR 16; G Patterson, '*Product Protection in Chemistry: How Important for the Protection of an Apparatus, Device or Substance Are Statements Made in a Patent as to their Purpose*' (1991) 22 IIC 852; G Patterson, '*Novelty of Use Claims*' (1996) 27 IIC 170.

[135] See A. Horton, '*Methods of Treatment and Second Medical Use*' (Aug 2000), Patent World 9 as quoted by Lionel Bentley and Brad Sherman, "*Intellectual Property Law*".

[136] *Eisai* G5/83 [1985] *OJEPO* 64. See also the EPO Patent Guidelines.

[137] Second Medical Indication: Switzerland [1984] *OJEPO* 581. See also Germany [1984] *OJEPO* 26; Netherlands [1988] *OJEPO* 405.

[138] Patents have been allowed where the novelty of the invention lay in the frequency of drug administration.

[139] As the Enlarged Board of Appeal said in *Eisai*, the Swiss-type use of claim use of claim is not prohibited by Art. 52 (4) and is capable of industrial application: G 5/ 83 [1985] *OJEPO* 64.

the same time, the novelty of a Swiss Claim arises from the new therapeutic application (the drug and first medical use already being known).[140] As a result, the focus of the patent shifts so that the novelty of the invention is not in the way the substance is used, nor in relation to the substance itself. Rather, the novelty of the invention is in the new therapeutic use (or purpose) that has been discovered. This is even the case "where the process of manufacture does not differ from known processes, using the same active ingredients".[141]

In the United Kingdom the status of second medical use in patents was considered by the Patents Court sitting in Banc in *Wyeth's Application*.[142] Following this decision, it is clear that section 2 (6) of the 1977 U.K. Patents Act includes second and subsequent medical uses that are drafted in the Swiss form. The patent in *Wyeth's Application* arose out of research carried out by Wyeth in relation to pharmaceuticals known as guanidines. While prior to this it was known that guanidines lowered blood pressure, Wyeth discovered that guanidines were also useful in treating and preventing diarrhoea.[143] Wyeth subsequently lodged a patent application to protect their discoveries. Wyeth's Application included three claims. First the application claimed "a guianidine for use as an anti-diarrhoeal agent". This was rejected on the ground that since a medical use of guianidine was already known, section 2 (6) could not confer novelty on the application. Second, Wyeth claimed "the use of guianidine in the treatment of diarrhoea". This was also rejected on the basis that this was essentially a claim to a method of medical treatment and, as such, was directly in conflict with section 4 (2). Third, Wyeth claimed "the use of a guianidine in the preparation of an anti-diarrhoeal agent for the treatment or prevention of diarrhoea". While this claim, which was drafted in the Swiss form, was refused by the examiner on the basis that it was inconsistent with existing UK case law, the Patent Court sitting in Blanc allowed it on appeal. Although the Patents Court said that the better interpretation of section 2 (6) was that it only applied to first medical uses,[144] the Court took judicial notice of the fact that the Board of Appeal in *Esai* had construed Article 54 (5) to cover second and subsequent medical uses. In recognition of the need for the harmonization of patent law, the Patents Court followed the lead of the EPO and permitted the claims in the Swiss form. In so doing the Patents Court

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[140] A. Horton, *'Methods of Treatment and Second Medical Use'* (August 2000). Patent World 9.
[141] Ibid Lionel Bentley and Brad Sherman, *"Intellectual Property Law"* at pg 459.
[142] [1985] RPC 545.
[143] *Schering's Application* [1971] RPC 337.
[144] Since the 1977 UK Patents Act could clearly have specified otherwise if it had so intended.

confirmed that section 2 (6) includes second and subsequent medical uses of a known substance.

3.2.2 REQUIREMENTS OF A SWISS CLAIM

The finding in *Wyeth's Application* has been confirmed, albeit somewhat reluctantly, by the Court of Appeal in *Bristol-Myers v Squibb*.[145] In light of the general acceptance of second medical use in the UK and the EPO, attention has subsequently shifted to the details of the Swiss claim. As a result it is clear that for a Swiss claim to be valid it is necessary to show that the patent claims the *manufacture* of a medicament.[146] It is also necessary to show that the novelty of the invention arises from the discovery of a *new therapeutic purpose* and not in some other aspect of the invention. In turn, it must also be shown that a second medical use claim *actually* works.

(i) Manufacture of a Medicament

As we observed earlier, one of the key features of a Swiss claim is that by focusing on the *manufacture* of something that can be used in a medical treatment rather than a method of medical treatment *per se*, the patent does not fall foul of the method of medical treatment exclusion in section 4 (2)/Article 52 (4) and consequently it may also be construed not to violate section 21 (c) of the Kenyan Industrial Property Act of 2001. In recognition of the fact that an unpatentable invention may be drafted in such a way so that it appears to comply with the Swiss format, the courts in the UK have been careful to look at what is actually patented. Indeed as Aldous LJ said in *Bristol-Myers*, the form of the claim is not always determinative of the fate of the patent. Instead it is necessary to look at the *effect* of the invention.[147] Thus for a Swiss claim to be valid, the invention must be for the *manufacture* of a medicament and not a surreptitious attempt to monopolise a new method of medical or veterinary treatment. That is, it is necessary to show that what the patent teaches is how to manufacture a drug for use in the treatment of a patient, rather than how to treat the patient (which is the teaching that the Swiss-type claim is

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[145] *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, 18, 24-6, Aldous LJ, para. 48; Buxton LJ, para. 76-81. See also D. Stenfeld, 'A Second Medical Use Case' [2001] EIPR 107; *Monsanto v Merreck* [2000] RPC 77, 92 (CA); *Pharmaceutical Management Agency v Commissioner of Patents* [1999] RPC 752 (High Court of New Zealand).

[146] Which is suggestive of the 'manner of manufacture' as used in British Patent law, from 1624 to 1977?

[147] In *Pfizer/Sertraline*, T158/96 [1999] *EPOR* 285, 288: claim 1 was directed to the 'second or subsequent therapeutic application of sertraline... the said therapeutic application being the treatment or prevention of obsessive-compulsive disorders'. The TBA said that claim 1 was construed as 'implicitly including the functional technical features that sertraline, when formulated into a medicament and administered to patients, achieves a therapeutic effect or any pharmacological effect which directly and unambiguously underlies the claimed therapeutic application.'

designed to avoid).[148] The patent in dispute in *Bristol-Myers* was for a particular regime covering the dosage and infusion duration of the anti-cancer drug taxol. One of the inevitable side effects of the use of taxol is that it leads to a fall in the patient's white blood cells (a condition known as known as "neutropenia"). *Bristol-Myers* claimed that the novelty of their invention lay in the discovery of a regime of dosage/infusion of taxol that reduced the side effects of neutropenia, without losing any benefits of the taxol. It was previously thought that it was necessary to infuse patients over a 24-hour period with high doses of taxol (greater than 170mg). *Bristol-Myers* discovered that short infusion of about three hours at a dosage level between 135mg had the same benefits, but with fewer side effects.

The Court of Appeal rejected the patent saying that it was merely an attempt to monopolise the new method of treatment by drafting it along the lines of the Swiss-type claim. The Court herein held that each step of the patent application was directed to a method of treatment. In particular, the Court noted that the predicament given to the patient prior to the taxol is chosen and administered by the doctor at the time of administration. More importantly, the medicament that treats the disease is produced in the patient under the supervision of the medical team. As a result, it could not be viewed in common parlance as an industrial application or manufacture. Thus, the application was for an invention of a method of medical treatment and hence was not patentable.[149]

A similar approach was also adopted by the EPO in *Proctor & Gamble* (which concerned a regime for the administration of drugs in the treatment of gastro-intestinal disorders). The Technical Board of Appeal said that when considering the possible limits of what could be recognized as a further medical indication (or a new therapeutic application), it is appropriate to consider whether "the sole distinguishing feature relates to non-commercial and non-industrial medical activities". The Board recognized that the pharmaceutical industry was attempting to optimize the maximum therapeutic effects of drugs and medicaments by investigating the optimum regimen for their administration. Nonetheless the Board said:-

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[148] *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, 28, para. 93 (Buxton LJ).

[149] The CA was reinforced by the fact that the foundations for infringement were based on the defendant's clinical trials at hospitals: which were treatments of humans, *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, and para. 55 (Aldous LJ) (CA).

> *"...determination of the best individual treatment schedule, in particular the prescribing and modification of drug regimes used for the administration of a particular medicament, so as to comply with the specific needs of a patient, appear to be in the first place part of the typical activities and duties of the doctor in accordance with their traditional skills of curing, typical non-commercial and non-industrial medical activities which Article 52(4) EPC intends to free from restraint."*[150]

One of the consequences of the decisions concerned with the meaning of the manufacture of a medicine is that they have limited the possibility of Swiss claims from being used to protect treatment regimes. Indeed it has been suggested that it is now questionable whether a prescribing regime could ever amount to a further medical indication, and thus not fall foul of the method of treatment exclusion.[151]

(ii) New Therapeutic Application

The second feature of a Swiss claim is that it must disclose a new therapeutic application. That is, it is of paramount importance to show that the novelty does not "lie in the method of use", but in the new therapeutic purpose for which the substance is used.[152] In order to achieve this, it is necessary to show that the new use is unconnected with previous known uses.[153] In turn,[154] it is therefore necessary to show that the application "necessarily entails the use of a substance for a new and entirely different use from what is already known".[155]

The new therapeutic purpose may take a number of different forms. Perhaps the most well known example is where someone discovers that a pre-existing use of an existing compound can be used to solve a different disease. An invention may also qualify as a new therapeutic purpose where the discovery relates to the application of a known substance used in a known way to a new target group of patients. In particular it has been held that the application of a vaccine to a new class of animals can be regarded as a

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[150] *Proctor & Gamble/Gastrointestinal Compositions,* T317/95 [1999] EPOR 528, 538. See also *Nycomed/Contrast Agent for NMR Imaging,* T655/92 [1998] EPOR 206.
[151] *Proctor & Gamble/Gastrointestinal Compositions,* T317/95 [1999] EPOR 528, 538. See also A. Horton, 'Methods of Treatment and Second Medical Use' (Aug. 2000) *Patent World 11.*
[152] *Bristol-Myers Squibb v. Baker Norton Pharmaceuticals* [2001] RPC 1, 26, para. 83 (Buxton LJ) (CA).
[153] *Wyeth's Application* [1985] RPC 545, 566.
[154] This is because if the novelty can lie in the nature of the use, rather than in the end result at which the use aims, then the invention would effectively for the method of treatment.
[155] *Bristol-Myers Squibb v. Baker Norton Pharmaceuticals* [2001] RPC 1, 26, para. 83 (Buxton LJ) (CA).

new therapeutic application for which novelty can be derived.[156] It has also been recognized that a "second medical use could arise from a different mode of administration of the same pharmaceutical product".[157]

These decisions can be contrasted with the *Bristol-Myers* decision where the Court of Appeal held that the patent for the regime covering the dosage and infusion of the anti-cancer drug taxol could not be described as a second medical use. Rather it was merely an unpatentable discovery of new information of an old use. The reason for this was that the drug (taxol) was exactly the same; and the therapeutic application or purpose (namely the attempt to treat cancer) was exactly the same. The only difference was that if the drug is infused over a shorter period of time, the undesirable side effects of neutropenia are minimized without affecting the therapeutic benefits of taxol.[158] In short, the Court of Appeal held that as the patent was for an improvement of improving the administration of an existing treatment, it was not a new therapeutic purpose. In a similar fashion, it has also been held that "a known effect cannot become novel for the sole reason that it presents a hitherto unknown increase in a known activity".[159] Nor could a further reduction in the formation of known impurities in an old product constitute a second medical use.[160]

(iii) An Effective Therapeutic Application

To be valid, it is imperative to show that the second medical use claim actually works (at least on some individuals). As such, it is not enough to show merely that a compound is being used to try and treat an illness. As Laddie J said, a "second medical claim only survives because the compound is effective to achieve a new treatment". This would not be the case if the same result could be achieved from a placebo. In this situation, the

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[156] *Duphar/Pigs 11*, T 19/86 [1988] EPOR 10 (immunization of infected pigs in contrast to the immunization of healthy pigs). See also T233/96 (4th May 2000) (treatment or diagnosis of the same disease with the same compound could be a novel therapeutic or diagnostic application provided it was carried out on a new group of subjects which was distinguished from the former group by its psychological or pathological status.).

[157] *HGC/Serono,* T51/93 (subcutaneous administration versus intramuscular administration) (cited in A. Horton, 'Methods of Treatment and Second Medical Use' [Aug. 2000] *Patents World 9,* 10). Cf. *ICI/Cleaning Plaque*, T290/86 [1991] EPOR 157: (both medical uses were for the prevention of tooth decay).

[158] *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, 28, para. 111 (Hollmann J) (CA). The inevitable consequence of using the art that the person skilled in the art could have done what was claimed without the need for any more information.

[159] *Dow/Sequestering Agent,* T958/90 [1994] EPOR 1.

[160] *American Cynamid/Melamine Derivatives,* T279/93 [1999] EPOR 88, 92. The Board was unable to find any new physical activity not already required by the old use.

benefit is said to flow from the fact that the patient believes that they are being treated, and "not because of any peculiar feature or efficacy of the patented compound".

3.3 NON-MEDICAL USES OF KNOWN PRODUCTS: (Novelty of Purpose Patents)

Shortly after the scope of the medical use exception was clarified, the question arose as to whether patent law should also recognize novelty in non-medical fields.[161] The question arose as to whether patent law should recognize the discovery of new uses for old substances used in old ways, irrespective of the field in which the invention was made. This question was particularly important given that a great deal of non-medical research is devoted to the discovery of new applications of known compounds.

The status of novelty of purpose patents under the EPC was first considered by the Enlarged Board of Appeal in *Mobil/Friction reducing additive.*[162] This decision arose from Mobil's attempt to patent a substance for use as a friction-reducing additive in lubricating oils. The application was opposed by Chevron on the basis that the substance was already known and on the basis that it was already being used to inhibit rust-formation in ferrous metals. In response Mobil applied to amend their application to limit it to the use of the substance for reducing friction, saying that its usefulness for this purpose had not previously been known. The question that thus to be considered by the Enlarged Board was whether the discovery of a new use of a known substance used in an old way could be patented. The Enlarged Board of Appeal held that while using an old substance in a new way to achieve a new purpose might be novel, the use of an old sustenance in an old way to achieve a new purpose would not. In the latter case, the only difference between the discovery and the old use was that it was carried out with a different purpose in mind the applicant would be doing the same thing with the same substance. Given that on the fact of the case the same substance (the additive) was used in the same way (for example by pouring it into the engine). It may have been reasonable to presume that the attempt to patent its use as a friction reducer when was previously thought only to inhibit rust

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[161] G. Patterson, 'The Patentability of Further Uses of a Known Product under the EPC' [1991] *EIPR* 16; G Patterson, 'Product Protection in Chemistry: How Important for the Protection of an Apparatus, Device or Substance are Statements Made in a Patent as to their Purpose?' (1991) 22 IIC 852; G. Patterson, 'Novelty of Use Claims' (1996) 27 IIC 170; C. Floyd, 'Novelty under the Patents Act 1977: The State of the Art after *Merrell Dow*' [1996] 9 EIPR 480.

[162] G2/88 [1990] EPOR 73. See also *Bayer's Application* G6/88 [1990] *OJEPO* 114.

would have failed. This was not the case. The reason for this was as the Board of Appeal went on to say, that a claim for the use of an old compound in an old way for a new purpose could be interpreted to include "the function of achieving the new purpose (because this is the technical result)".[163] In such a case, the fact that the substance achieved the new purpose would be an objective "functional-technical feature" of the invention, rather than something which only resided in the mind of the user. In relation to the case in hand, the Enlarged Board of Appeal said that the invention exhibited a functional technical feature in that the substance operated to reduce friction. As such the Board held that claims for the use of a specified lubricant for the reduction of friction in engines were patentable: even though the lubricant had previously been used as a rust inhibitor. As a result of this decision, it is now clear that in the EPO, the discovery of a new purpose of an old thing used in an old way is patentable, irrespective of the field in which the invention takes place.[164] However this is not the position in the U.K.

A number of criticisms have however been made of the *Mobil* decision.[165] Nonetheless, it is clear that in the UK, it is now possible to patent the discovery of a new purpose for an old thing used in an old way.[166] Unlike the British pre-1977 law, the mere fact that the sole point of novelty of an invention lies in the discovery of a new purpose no longer means that the application would be disallowed automatically. The key feature of a novelty of purpose claim is the discovery that a known use of a known substance achieves a new purpose. The only aspect of the invention that is novel is the third element (*the discovery of the new purpose*). The step that facilitated the acceptance of novelty of purpose patents was the decision that prior secret use does not destroy the novelty of a patent. As we observed earlier, under pre-1977 British law it was possible for a prior secret use to anticipate a later patent. Under the old law, the discovery that a known substance used in a known way could be put to hitherto an unknown purpose would not have patentable. This is because the new purpose would have been inherent in the pre-

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163 *Mobil/Friction reducing additive*, G2/88 [1990] EPOR 73.

164 The Court of Appeal in *Bristol-Myers* said that the Swiss claim was based on a different logic to *Mobil Ortho/Pharmaceutical prevention of skin atrophy*, T254/93 [1999] EPOR 1.

165 C. Floyd, 'Novelty under the Patents Act 1977: The State of the Art after Merrell Dow' [1996] 9 EIPR 480; CIPA, para. 2.21; A. White, 'The Novelty Destroying Disclosure' [1990] EIPR 315; J. Lane, 'What Level of Protection is Required to Anticipate a Patented Invention by Prior Publication or Use' [EIPR] 462. These problems are particularly acute in the UK (and not at the EPO) because the EPO is only concerned with issues of validity, whereas British Courts have to deal with both validity and infringement.

166 *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, 18, Aldous LJ, para. 49 noting that *Mobil* had been considered in some detail and applied by the House of Lords in *Merrell Dow* (admittedly on a different point). Aldous LJ. Said, 'it is unlikely that [the Court of Appeal] would conclude that *Mobil* was wrongly decided when the House of Lords did not so conclude.' See also Buxton LJ. Para. 81.

existing use of the known substance. The fact that the use was secret would not have affected the fate of the invention.

As we have observed, under the existing law a prior secret use will no longer destroy the novelty of a later patent. As the Enlarged Board said in *Mobil*, the "question to be decided is what has been 'made available to the public': the question is not what may have been 'inherent' in what was made available". 'Under the EPC, a hidden or secret use, because it has not been made available the public, is not a ground for the rejection of the validity of a patent. As such, "the question of 'inherency' does not arise" under the EPC (nor under the 1977 Patents Act).[167] In so doing this opened up the possibility for patent protection to be given to the discovery that a known substance used in a known way could be put to a new purpose. Once this step was taken, deciding the status of a discovery that a known substance used in a known way could be put to a new purpose is relatively straightforward. As the Enlarged Board of Appeal said in *Bayer*, the question to be decided in these circumstances is, as with all inventions, whether the invention has already been made available to the public.[168] This has been reflected in subsequent case law, which has focused on whether the purpose that has been discovered is actually new.[169]

In those cases where novelty of purpose patents have been accepted, the applicant has been able to show that they have "two distinctly different effects, two distinctly different applications or uses of the same substances, which can clearly be distinguished from each other".[170] For example, in *Mobil* the patent was for the use of an additive as a lubricant, whereas the state of the art revealed use of the same additive as a rust inhibitor. Similarly in *Bayer* the patent application was directed to the use of a compound as a fungicide, whereas the state of the art described use of the same compound as an agent for influencing plant growth.[171] In both cases, the patent revealed that the known substance used in a known way could be put to a new purpose.

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[167] *Mobil/Friction Reducing Additive*, G2/88 [1990] EPOR 73, 88 (EBA).
[168] *Bayer/Plant Growth Regulating Agent*, G6/88 [1990] EPOR 257, 265 (EBA).
[169] In many ways the reasoning used in relation to new purpose is similar to that used in relation to second and subsequent medical uses. The main difference is that in this context there is no need to show manufacture.
[170] *Robertet/Deodorant Compositions*, T892/94 [1999] EPOR 516, 526.
[171] *Bayer/Plant Growth Regulating Agent*, G6/88 [1990] EPOR 257.

However in contrast, in *Robert/Deodorant compositions*, the patent was rejected on the basis that it lacked novelty. The applicants discovered that 'aromatic esters' when used as an active ingredient in a deodorant composition have the capability of inhibiting esterase-producing micro-organisms on the human skin. The prior art disclosed the use of aromatic esters as an active ingredient in deodorizing products. The Technical Board of Appeal rejected the application saying that all the patent did was to disclose information about a pre-existing purpose. That is, it was merely an *ex post facto* explanation of what had already taken place. While in *Mobil* and *Bayer* a new purpose had been discovered, all that had been disclosed in this case was more information about a known purpose. The application was merely an explanation of a prior event, rather than the discovery of a new purpose *per se*. As such, it could not be held to be novel. A similar conclusion was reached in *Ortho Pharmaceuticals* where the Technical Board of Appeal said that "the mere explanation of an effect obtained when using a compound in a known composition, even if the effect was not known to be due to this compound in the known composition, cannot confer novelty on a known process if the person 'skilled in the art' was aware of the occurrence of the desired effect".[172]

The principles used to determine novelty purpose patents are similar to those used for other types on inventions. In other respects, however, notably in terms of the problems that arise when deciding whether a novelty of purpose patent has been infringed, they mark a more radical change of direction.

3.4 SELECTION PATENTS: (Generic Disclosure)

The third area that I wish to focus on is on the novelty of so-called selections patents. As with methods of medical treatment and novelty of purpose patents, selection patents developed in response to a particular problem. This rose from the fact that in some fields, such as organic chemistry, a researcher may discover that a particular combination of molecules produced certain results. In some instances, the researcher then extrapolates from this initial discovery to assert that the same qualities will be produced by a range of variants or homologues. This is referred to as a generic or general disclosure. In so doing, the researcher (potentially) discloses an extremely broad range of compounds. Problems arise when it is subsequently discovered that some of the compounds which were

[172] *Ortho Pharmaceuticals/Prevention of skin atrophy*, T254/93 [1999] EPOR 1, 8. This was reinforced by the fact that the specific purpose in question was also known.

outlined in the generic disclosure are particularly advantageous or have uses other than were initially envisaged. As the compounds have already been made available to the public, by the prior generic disclosure appears to prevent subsequent claims being made for individual members of the group.[173] This led to the potential problem that if the generic disclosure was able to anticipate, it would act as a disincentive for further research to be carried out in relation to the materials already disclosed. The question that underpins the doctrine of selection patents is whether or not and if so, the extent to which, a prior generis disclosure anticipates subsequent inventions in the same field.

In the UK the classic answer to this problem is provided by the 1930 decision of *IG Farbenindustrie*.[174] This decision concerned an application to resolve IG Farbenindustrie's patent for a process of manufacturing certain azo and aromatic amine dyestuffs. This was on the ground that in light of a prior disclosure in an expired patent the invention lacked novelty. In response, IG Farbenindustrie claimed that there were potentially millions of combinations of azo and aromatic amine dyestuffs outlined in the expired patent. They also argued that the particular group of dyes that they had selected had peculiar and beneficial properties in that they withstood certain processing techniques required of cotton.[175] Maugham J said if the compounds in question had previously been made they would have lacked novelty. If the compounds had not been previously made, however, the patent might be valid if it could be shown that:

(i) the selection was based on substantial advantage resulting from the use of selected members;

(ii) all members of selected class possessed the advantage in question, and

(iii) if the selection was in respect of a special character, that it could fairly be said to be peculiar to the selected group.

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[173] This is exacerbated by the fact that (at least until recently) British patent law did not normally allow patents for discoveries of new advantages.

[174] (1930) 47 RPC 289, 322-3. See also *Shell Refining and Marketing Patent* (Revocation) [1960] RPC 35, 52; P. Grubb, Patents in Chemistry and Biotechnology (1986), 132. While mechanical subject matter does not readily lend itself to the idea of selection, there have been a number of selection patents for mechanical inventions. See also *Clyde Nail Russell* (1916) 33 RPC 291, 306 (Lord Parker); *Shell Refining and Marketing Patent* (Revocation) [1960] RPC 356, 54; *El Du Pont de Nemours (Witsiepe's) Application* [1982] FSR 303, 314; *Hallen v Brabantia* [1991] RPC 195.

[175] More specifically, the advantage claimed was 'fastness to kier boiling under pressure in caustic liquor'.

While of the facts, *IG Farbenindustrie's* patent was held to be invalid,[176] the decision helped to establish the principle that selection inventions are potentially patentable where it can be shown that the "inventiveness" of the application lies in a particular selection from a known field. Selection patents:

> *'...enable a valid patent to be obtained for the selection of a product or process from a range of known or obvious products or processes because of surprising and non-obvious advantages over the others... The selection must be based on a substantial advantage of special character. The selected member or class must have the advantage, and the specification must direct the mind of the skilled reader to the advantage of the selection from the class.*'[177]

Although, Maugham J's judgment was approved in subsequent decisions,[178] a number of issues remain unclear.[179] Many of the uncertainties result from a failure to differentiate clearly between novelty and inventive step. Another reason for the confusion can be traced to the fact that while Maugham J expressly said that the three propositions outlined the judgment were not meant to be exhaustive, nonetheless they have often been treated as if they were definitive guidelines as to when a selection invention will have been anticipated. Another problem is that it is often forgotten that selection patents are not limited to new uses; they apply, at least potentially, to the discovery of new substances, new uses for old substances, and new purposes for old substances used in old ways.[180] Perhaps the great uncertainty that exists in relation to selection patents is whether the doctrine has any continued relevance under the 1977 UK Patents Act. In light of recent changes, notably, the shift to enabling disclosure, the consequential move away from secret or inherent use, and the apparent acceptance of the discovery of new purposes as conferring novelty, and there are good reasons for suggesting that it does not.

To argue that under British law the doctrine of selection patents should be jettisoned in favour of the more general rules about novelty is not as radical as it may first seem. This

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[176] This was because the dyestuffs claimed did not have the property which the applicant alleged.
[177] *Boehringer Manheim v. Genzyme* [1993] FSR 716.
[178] *El Du Pont de Nemours (Witsiepe's) Application* [1982] FSR 303, 309.
[179] It should be noted that there is some inconsistency in the EPO decisions in this area, e.g. *Pfizer/Penem,* T 104/92 [1995] EPOR 207 is inconsistent with *Sanofi/Enantiomer*, T658/91 [1996] EPOR 24.
[180] It is only if this is correct that selection patents provide obvious tactical advantages over patents for 'uses' that the EPO has recently recognized. Moreover, if this were not the case the requirement demanded particularly by the EPO of novelty *per se* rather than mere novelty of use, would be unnecessarily stringent.

is because the issues which arise with selection patents are really no different from the question which Lord Hoffmann said underpinned the novelty examination more generally: *viz.* how specific must a disclosure be for an invention to be "known" or "made available" to the public? (*The key difference is that with selection patents the question is rephrased to be: how specific must a generic or general disclosure be for it to destroy the novelty of a subsequent invention which incorporates the prior knowledge?*) While Lord Hoffmann wisely answered that it always depends on the invention in question, the doctrine of selection patents has attempted the impossible and tried to stipulate in advance the type of disclosure that is needed to anticipate. Given the futility of this, it may be better if the novelty of selection patents was determined through the general rules of novelty.[181] If this approach was adopted, it would mean that a prior generic disclosure would only anticipate a selection invention if it was enabling: that is, if the disclosure placed a skilled person in a position whereby they could "work" the invention in question.

It appears that this is in fact the approach that has been adopted at the EPO where the rules on selection patents have been treated as being consistent with, rather than an exception to, the general rules of novelty. In these circumstances a prior generic disclosure will anticipate a substance if it can be characterized as an enabling disclosure.[182] This can be seen, for example, in *Bayer/Diastereomers*:[183] a decision that concerned an application for the diastereomeric form of a compound, which was useful in treating mycoses (fungal diseases such as ringworm). The problem that confronted the applicants was that a prior patent had disclosed a group of compounds including the compound in question, as well as the method by which the compound could be produced. The Technical Board of Appeal rejected the application on the basis that it was lacking in novelty. In so doing the Board held that the teaching of a prior document was not confined to the detailed information given in the examples of how the invention is carried out. Rather, it embraces any information in the claims and description enabling a person skilled in the art to carry out the invention. The Technical Board of Appeal stressed that the essential point is what a person skilled in the art carrying out the invention could be expected deduce from the earlier closure.

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[181] In *IG Farbenindustrie*, Maugham J argued that the rules applicable to 'selection patents' did not differ from the general rules of patent law: a view, which was reaffirmed in *Shell Refining and Marketing Patent (Revocation)* [1960] RPC 35.

[182] *Sanofi/Enantiomer*, T658/91 [1996] EPOR 24.

[183] T12/81 [1982] *OJEPO* 296; [1979-85] *EPOR* B-308.

CHAPTER FOUR
CONCLUSION & RECOMMENDATIONS

From the previous chapters, it is rather evident that this is an area new to the Kenyan Patent regime. Though the issue of "novelty in patents" has not come before the courts for determination, is not to say that this research is premature, rather its aim is to provide a backdrop to the problem of "novelty in patents". Accordingly, the study has established that there lies an inadequacy in the Kenyan law to regulate the Patent regime, and more specifically the status of novelty in patents. The study demonstrates the need for a regulatory framework in Kenya that protects the interests of the inventor and those of the public at large.

4.1 Reform

While the status of the second and subsequent medical uses in Kenya is an issue that has not come up for clarification in the courts, it poses a real threat to our patent regime. However, given the backdrop of both the UK and the EPO, it is clear that there remains a degree of suspicion about second (and subsequent) medical use patents. Buxton LJ captured the tone of these concerns when he said in Bristol-Myers that the acceptance of Swiss claims may seem "to be doubtfully gives proper weight to the first sentence of Article 52(4)/section 2(6)". These concerns have not been adopted in the EPC 2000, which is more concerned to ensure that the law is transparent and that it reflects current practice. As a result, the jurisprudence that is developing in this area will become even more important in the determination of a more comprehensive analysis of the status of Kenyan patenting requirements.

There are the two changes in the EPC 2000 that relevant here. The first is that it takes medical uses out of Article 52 EPC and places them with the other exceptions to patentability in Article 53 EPC 2000. This is to be replicated in the proposed amendments to the 1977 Patents Act. The second change is in relation to second and further medical uses. Article 54 (5) of the EPC 2000 specifically allows applicants to a claim second and further medical uses of known substances or compositions, without having to use a Swiss-type claim. While this is intended to simplify and clarify the manner

in which patent protection can be obtained for second and further medical uses, it provides second and further medical use claims with an official stamp of approval. Under the UK Patent Bill 2004, it was proposed that the 1977 Act be amended to implement the new position under EPC 2000.

In order for reforms to achieve their desired objectives, that is to develop a more comprehensive patenting procedure, that can be used as a vehicle to foster sustainable economic growth, there is need for the relevant government officers and other interested parties to be appraised on the nature, importance and objects of patents (generally) and the consequently the need for more comprehensive patenting procedures. Thus there is indeed a need for civic education.

Finally, in a bid to ensure that the application of patent laws stays in touch with the reality of prevailing circumstances, both nationally and internationally, Kenya needs to develop a set of guidelines that can be used to guide the Courts and the Kenya Industrial Property Institute (KIPI) in addressing patent issues.

Therefore, as we opined earlier, as Kenya strives to climb up the ladder of development, the protection of inventor's rights to reap the economic benefits of their creations ought to be part of this process. Therefore with the constant pressure to maintain international competitiveness, and with every country striving to assert its position in the global market, Kenya should take pre-emptive steps in ensuring that its economic growth remains in tandem with global standards. This starts with the tiny step of promoting and protecting innovation and creativity within Kenya first. Patents therefore have to be protected due to the centrality of the role that they play in the enhancement of global trade. Hence only by so doing can we guarantee Kenya's technological progress and economic vitality.

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