

**Patenting Life Forms in Kenya
With Specific Reference to Stem Cell Research**

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Dedication

To Mummy and Daddy.

Table of contents

Chapter 1: Proposal

1.0	Introduction.....	1
1.1	Research Question.....	1
1.2	Research Objectives.....	4
1.3	Justification.....	4
1.4	Hypothesis.....	5
1.5	Literature Review.....	5
1.6	Research Methodology.....	7
1.7	Chapter Breakdown.....	8

Chapter 2: Patents, Patent Rights and the Bio-Patent (Patents of life forms) Debate

2.0	Introduction.....	9
2.1	Patents and Patent Rights.....	9
2.1.1	Definition of Patents.....	9
2.1.2	Justification for Grant of Patent Rights.....	9
2.1.3	Early history of Patents.....	11
2.1.4	Patentability.....	13
2.1.5	Term of Patent.....	20
2.1.6	Who may be granted a Patent.....	20
2.1.7	Rights of a Patentee.....	23
2.1.8	When to apply for a Patent.....	26
2.2	<i>Bio-patent Debate (Patenting of Life Forms)</i>	26
2.2.1	Introduction.....	26
2.2.2	Origins of Patents of Life Forms.....	27
2.2.3	Reasons Against Bio-patenting.....	30
2.2.4	Reasons for Patenting of Life Forms.....	42
2.2.5	Conclusion.....	46

Chapter 3: Stem Cell Research: Potential Sources of Stem Cells, and the Controversy in the use of Embryonic Stem Cells

3.1	Introduction.....	47
3.2	Definition of Stem Cells.....	47
3.3	Sources of Stem Cells.....	47
3.4	Debates on Stem Cell Research.....	53
3.4.1	Arguments against using Embryonic Tissue as a Source of Stem Cells.....	53
3.4.2	Reasons for use of Embryonic Stem Cells.....	57
3.5	Stem Cell Research in Kenya.....	59
3.6	Conclusion.....	63

Chapter 4: Patentability of the Results of Stem Cell Research

4.1	Introduction.....	63
4.2	Reasons why the Results of Stem Cell Research should not be Patented.....	63
4.3	Reasons for Patenting the results of Stem Cell Research.....	66
4.4	Summary and Recommendations.....	67
4.5	Last Word.....	73

Abbreviations and Acronyms

EPO	European Patent Office
FSR	Fleet Street Reports
GMO	Genetically Modified Organisms
KARI	Kenya Agricultural Research Institute
KEMRI	Kenya Medical Research Institute
KIPI	Kenya Industrial Property Institute
RPC	Reports of Patent, Design and Trade Mark Case
Tech Bd App.	Technical Board of Appeal

Table of Statutes

Human Tissues Act, Chapter 252, Laws of Kenya

Industrial Property Act, 2001

Penal Code, Chapter 63, Laws of Kenya

Science And Technology Act, Chapter 250, Laws of Kenya

Table of International Instruments

Agreement on Trade Related Aspects of Intellectual Property Law (TRIPs), 1994.

European Patent Convention.

Paris Convention for the Protection of Industrial Property (1883) as revised in 1967 (The Paris Convention Treaty).

Table of Cases

Catnic Components v. C Evans & Co. [1983] FSR 401

Davis v. Davis Tenn. 1992 842 S.W 2d 588

Diamond v. Chakrabarty United States Supreme Court (1980) 447 US 303, 100 S.Ct 2204

Dietrich v. Inhabitants of Northampton 138 Mass. 14 (1884)

Fomento v. Mentoire [1956] RPC 87, CA

Funk Seed Brothers v. Kalo Inoculation Company 333 US 127 (1948)

J. E. M Ag Supply Inc. v. Pioneer Hi-Breed International Inc. 534 US 124 (2001)

Moore v. Regents of University California 793 P. 2d 479 (Cal 1990) 111 S. Ct. 1388

Re Estate of the Late K; Ex Parte the Public Trustee (1996) 5 Tas R 365

Roe v. Wade 410 US 113 (1973)

The Harvard Mouse Case [1990] OJEPO 447, Tech Bd App [1991] EPOR 525

Van der Lely v. Bamford [1963] RPC 61, HL

Williams v. Nye (1890) 7 RPC 62, CA

Windsurfing International v. Tabur Marine [1985] RPC 59.

Yasmin v. Mohammed (1973) EA 370

PATENTING OF LIFE FORMS IN KENYA WITH SPECIFIC REFERENCE TO STEM CELL RESEARCH

CHAPTER ONE PROPOSAL

1.0 Introduction

Today in the medical field, there is a lot of research being conducted on stem cells. There is however a lot of controversy as to whether such research should be patentable. This dissertation aims to analyse the meaning of patentability of an invention, and thus whether stem cell research should indeed be patentable.

1.1 Research question

The focus or question that I will address in this dissertation is whether the results of stem cell research should be patented in Kenya. The TRIPs agreement, of which Kenya is a signatory, provides for patents in Section 5.

Article 27(2) thereof provides that

“Member states may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health...”

Article 27(3) provides:

“Members may also exclude from patentability:

- (a) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) Plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof...”

Thus, the agreement gives member countries discretion on whether or not to recognize inventions in the area of treatment of humans and animals, and also development of plant and animal varieties using human intervention. These animal and plant varieties that are developed through research are normally called life forms. As a consequence of this provision, there has been a lot of debate, from all sectors in

society, as to whether life forms should indeed be patentable. I will discuss these arguments later in this dissertation.

In Kenya, life forms have been patentable since 1989 when the Industrial Property Act¹ was passed. This Act was repealed by the 2001 Industrial Property Act, which also provided for the patenting of life forms. One of the reasons for the enactment of the Industrial Property Act in 1989 has been cogently summarised as follows:

“One of the rationales for the Industrial Property Act in 1989 was that Kenya had plant innovations and the country needed protection.”²

The government had recognised the need to protect inventions by its various agencies from exploitation by unauthorised third persons.

The current and very controversial debate as regards patenting of life forms is with regard to stem cell research. The debate is whether Governments should allow stem cell research, what sources should be used to obtain stem cells, and lastly whether the results of such research should be patented.

B.A Robinson has defined a stem cell as follows:

“A stem cell is a primitive type of cell that can be coaxed into developing into most of the 220 types of cells found in the human body, for example blood cells, heart cells, brain cells, among others.”³

These cells are regarded as primitive because they are undifferentiated, and thus can develop into any cell of the human body, once provided with the appropriate atmosphere. Some researchers regard these cells as offering the greatest potential for the alleviation of human suffering caused by diseases. Scientists are particularly excited about this area of research due to the perceived potential. It should be noted that in many countries, especially developing nations, the rates of HIV infection have

¹ Chapter 509, Laws of Kenya.

² Dr Ben Sihanya, in his LLB IV class notes on *Patents and Related Doctrines*, 2005.

³ B. A. Robinson, Human Stem Cell Research at <http://www.religioustolerance.org/res-stem.htm>. (Last accessed on 12th September 2005).

been particularly high. African examples being South Africa and Botswana. Thus, it has become more and more difficult to perform surgeries. This is because potential donors of organs for transplants or blood for transfusions have greatly reduced as their blood or organs have been tainted with the HIV virus and are thus not useable. Stem cells may be the solution for this problem, as the requisite blood or tissues (organs) required for transfusions and transplants may be sourced from stem cells⁴.

“Over 100 million Americans suffer from diseases that may eventually be treated more effectively with stem cells or even cured. These include heart disease, diabetes, and certain types of cancer.”⁵

Life forms are patentable in Kenya under the Industrial Property Act 2001. However, methods for the treatment of the human or animal body by surgery or therapy are excluded from patentability under Section 21 (3) (c) of the Act. This may be interpreted to mean that with regard to stem cell research, the methods of extraction of these cells may be patentable in Kenya, but the use of these cells once extracted in the treatment of diseases will not be patentable. I shall, in this dissertation, therefore explore whether this position in Kenya should stand, or whether the Act should be amended to provide for the patenting, in addition, the methods of treatment using the stem cells.

Potential sources of stem cells being discovered are:

1. The embryo.
2. The umbilical cord.
3. The spleen.
4. The nose
5. The human skin

However, there is a lot of controversy on the most appropriate source of these cells, as some people argue that using embryonic stem cells (stem cells from the embryo) is infact abortion. I shall discuss these issues thoroughly in Chapter 3.

⁴ As stated by Dr. Solomon SR Mpoke of Kenya Medical Research Institute (KEMRI) during an interview at his office in KEMRI on 7th October 2005.

⁵ B. A Robinson, “Human Stem Cell Research” at <http://www.religioustolerance.org/res-stem.htm>, (Last accessed on 12th September 2005).

1.2 Research Objectives

The specific objective of this research paper is to investigate and document reasons why stem cell research should be highly encouraged in Kenya through grant of patents.

1.3 Justification

Patenting life forms has been an ongoing debate for a long time, with arguments being presented on why life forms should and should not be patented.

Today, as a result of many factors, such as poor eating habits, excessive drinking and smoking, and so on, more and more people in the world today are in need of transplants of the various organs of the body: heart, marrow and kidneys being the most popular. However, there are very few donors of such organs particularly because it is difficult to obtain first, a willing donor, and secondly, one whose body tissue matches with the donees, and will thus not be rejected once the transplant has been performed. HIV/AIDS is also taking its toll on the world population. Thus, many organs cannot be used as a large number of potential donors have the virus or the disease, and this renders their organs unusable.

It is thus very important for the Government of Kenya to look into alternative measures to provide the requisite health care for their nationals. Stem cell research is a very viable area that has great potential. Organs and tissues may be developed using stem cells⁶. There should therefore be patents granted for such inventions, to promote further research that will help alleviate human suffering.

However, as stated earlier, there is controversy on the one of the best sources of stem cells, that is the embryonic stem cells. It is argued by many moralists that use of embryonic stem cells is infact abortion. The Government of Kenya, as it endeavours to provide better health services to its nationals should keep this in mind, as Kenya is a moral and religious nation.

⁶ KEMRI is beginning to look into stem cell research as a way of treatment of diseases, as stated by Dr. S. R. Mpoke, a researcher at KEMRI.

1.4 Hypothesis

The Government of Kenya should amend the Industrial Property Act 2001 by providing for the patentability of the results of stem cell research. Further, an Act of Parliament should be enacted to provide for research using human tissues or parts of living persons. This is because the Human Tissues Act⁷ makes provision with respect to the use of parts of bodies of deceased persons, for therapeutic, medical education and research purposes. There is therefore need for the enactment of a statute that provides for the use of tissues or parts of living persons for the purposes mentioned above.

1.5 Literature review

Several authors have provided arguments on stem cell research, both on why the results stem cell research should be patentable, and also why it should not. Jayashree Watal⁸ opines that biological material may be patentable in the European Union⁹.

He writes:

“Biological material has been defined ...as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. Even if such biological material has previously occurred in nature, it shall be patentable if it is isolated by means of a technical process, and is of course new and non-obvious.”

He continues:

“...An element isolated from the human body or otherwise produced by means of a technical process, including a sequence or partial sequence of a gene, may constitute a patentable invention...Patent exclusions include processes for human cloning, uses of the human embryo for industrial and commercial purposes and processes for modifying the germ line genetic identity of animals.”

⁷ Chapter 252, Laws of Kenya.

⁸ Jayashree Watal, (2001) *Intellectual Property Rights in the WTO and Developing Countries* Kluwer Academic Publishers (1st Edition) pp 164-169.

⁹ Under the European Patent Convention.

It is his view therefore that process patents should be granted for the extraction of stem cells, but for ethical reasons a patent should not be granted for the method of treatment.

Various articles have also been written on stem cell research, and particularly on the potential sources of stem cells. The most contentious of these sources is the human embryo, with the church arguing that using embryonic stem cells is abortion, and should thus patents should not be granted for such research. B.A Robinson¹⁰ and the Catholic Church¹¹ have written concise articles on their reasons against embryonic stem cell research.

Another position or point of view is held by some scientists,¹² who believe that embryonic stem cell research should be encouraged. It is their view that the human embryo is not a human being; it is just a mass of cells. In their view, it is wrong to classify such a mass as a human being. It is therefore not wrong to use these cells. Further, they argue that the embryonic stem cells have the greatest potential to develop fully into requisite organs. They therefore believe that embryonic stem cell research should be encouraged, as it will help in the treatment of many diseases that have defied conventional medicine.

In Kenya there is not much debate on patenting of the results of stem cell research. This may be because there is not much research (documented and available for public viewing) on stem cells. However, in many developed countries, particularly America and Canada, there is a lot of such research, both by private companies and also by the government.

¹⁰ B. A. Robinson, "Human Stem Cell Research" at <http://www.religioustolerance.org/res-stem.htm> (Last accessed on 12th September 2005).

¹¹ American Catholic Organization, "Embryonic Stem Cell Research" at <http://www.AmericanCatholic.org/>. (Last accessed on 12th September, 2005).

¹² For example the Stem Cell Research Foundation, at <http://www.stemcellresearchfoundation.org/resources/htm>. (Last accessed on 12th September 2005).

It is therefore important for Kenya's patent legislation to provide for stem cell research. This is because although we as a country may not have such research being conducted, there will be technology transfer from developed countries to developing ones of such research. In order to prevent infringement of such technology therefore, there ought to be in place sufficient legislation.

Also, in the not too distant future, Kenyan scientists and researchers will begin stem cell research¹³. There is therefore need to have a sufficient legislative framework in place.

1.6 Research Methodology

I will use both primary and secondary sources of material for my research. The primary source will include interviews with the relevant authorities at the Kenya Medical Research Institute (KEMRI), and the Kenya Industrial Property (KIPI), while the secondary sources will consist of various articles that have been posted on the internet on patenting of life forms and stem cell research as well as material in text books on the same.

1.7 Chapter Breakdown

Chapter 1: The Proposal

This shall be the introduction to the dissertation. It states the objective and scope of the dissertation.

Chapter 2: Patents, patent rights and the bio patent debate

This chapter gives an introduction into what patents are and the rights accruing to an inventor upon his being granted a patent. It will then delve into the bio patent debate, highlighting the arguments that have been put forward for and against the patenting of life forms.

¹³ As stated by Dr. SR Mpoke, a researcher at KEMRI during an interview in his office at KEMRI on 7th October, 2005.

Chapter 3: Stem Cell research

In this chapter, I shall discuss in detail the various sources of stem cells that have been discovered by researchers. I shall also discuss the various arguments that have been presented on which are the most appropriate sources of stem cells. This is because there is a lot of controversy and acrimony in the use of stem cells derived from an embryo. I will therefore state the advantages of using embryonic stem cells as well as the disadvantages.

Chapter 4: Summary and Conclusions

In this chapter, I shall discuss whether or not Kenya should allow stem cell research to be conducted, what would be the most appropriate sources of stem cells, and proposed reforms to the Industrial Property Act to enable and promote stem cell research in Kenya.

CHAPTER TWO

PATENTS, PATENT RIGHTS AND THE BIO-PATENT (PATENT OF LIFE FORMS) DEBATE

2.0 Introduction

In this chapter, I shall discuss what patents are, the rights that accrue to a patentee once a patent has been granted to him by the patent office, and lastly I shall delve into the Bio-patent debate. The purpose of this Chapter is to lay the foundation on which I shall then discuss stem cell research in its proper context.

2.1 Patents and Patent Rights

2.1.1 Definition of Patents

A patent can be defined as a set of exclusive rights granted by a government to an inventor or applicant for a limited amount of time (normally 20 years from the filing date). It can be said to be a contract entered into by an inventor and a government. The government promises to provide the exclusive rights to the enjoyment of his or her invention in return for disclosing the invention to the general public.

The Kenya Industrial Property Institute (KIPI) describes a patent thus:

“Patents offer inventors monopolies on their creation for specific periods, and thus providing incentives for research and development. Without the possibility of patent protection, many people might not take the risks or invest the time and money involved in devising and perfecting new products.”¹⁴

If the government did not encourage disclosure, a discovery could very well be kept a secret forever.

2.1.2 Justification for the grant of patent rights

The reason for patent legislation has always been to induce the inventor to disclose knowledge for the advancement of society in exchange for a limited period of exclusivity.

¹⁴ Kenya Industrial Property Institute (2005) *A Guide to Patenting in Kenya*, KIPI, Nairobi, pp 1-30.

It has long been recognized that these rights are nothing more than tools to achieve the public good.

The patent system encourages inventors to share their ideas with the general public through disclosure to the designated patent office (which in Kenya is the Kenya Industrial Property Institute (KIPI)), and thereby advancing the general status of technology. The advancement is accomplished by encouraging innovation through giving the inventor the right of exclusive commercial use, and by encouraging competitors to design around the invention. Thus, the knowledge of the inventor is preserved for the benefit of society and future generations.

P. Naranayan¹⁵ described the importance of the patent system. He opines that the exclusive rights granted to a patentee stimulate technical progress in four different ways. First, is that it encourages research and inventions. Secondly it induces an inventor to disclose his discoveries instead of keeping them as a trade secret. Thirdly, it offers a reward for the expenses of developing inventions to the stage at which they are commercially practicable; and lastly, it provides an inducement to invest capital in new lines of production that might not appear profitable if many competing producers embarked on them simultaneously.

However, patents do more than keep the creative wheel spinning. They are also a means of technological exchange. Each patent document describes a new aspect of technology in clear and specific terms and is available to anyone to read. As such, they are vital resources for entrepreneurs, researchers, academics, and others who need to keep up with developments in a particular field.

¹⁵ P. Naranayan (1990) *Intellectual Property Law* Eastern Law House, India, pp 44 (1st Edition).

2.1.3 Early history of patents¹⁶

The term "patent" originates from the term *patere* which means to lay open (to public inspection) and the term *letters patent*, which originally denoted royal decrees granting exclusive rights to certain individuals or businesses.

The first letter of patent was granted to John Kempe, a Flemish weaver in 1311. In 1474, the Republic of Venice issued a decree in which new and inventive devices, once they had been put into practice, had to be communicated to the Republic in order to obtain legal protection against potential infringers. England followed with the Statute of Monopolies in 1624 under King James I of England. Prior to this time, the Crown would issue letters patent providing any person with a "monopoly" to produce particular goods or provide particular services. This power, which was to raise money for the Crown, was widely abused, and the court began to limit the circumstances in which they could be granted. Parliament eventually restricted the crown's power explicitly through the Statute of Monopolies 1624 so that the King could only issue *letters patent* to the inventors or introducers of original inventions for a fixed number of years. The Statute of Monopolies was later developed by the courts to produce modern patent law; other countries soon adopted this innovation.

Patent application and registration in Kenya is traceable to the Patent Registration Act¹⁷ (Repealed), Chapter 508 of the Laws of Kenya. This statute was enacted in 1962 and provided for the grant of patents in the United Kingdom, which were subsequently registered in Kenya. The Registrar General, a department of the Attorney General's office, carried out registration of patents in Kenya.

¹⁶ Labour Law Institute, *Patents and patent rights* at <http://www.encyclopedia.laborlawtalk.com/> (Last accessed on 12th September 2005).

¹⁷ Chapter 508 Laws of Kenya (Repealed).

The Industrial Property Act.¹⁸ which was the law governing patents, was enacted in 1989. It was later revised in 2001. Prior to 1989, Kenya's patent law was essentially a neo-colonial issue and was based on the United Kingdom's patent system¹⁹. Under the Patent Registration Ordinance 1933, for one to obtain patent protection in Kenya, one had to obtain a certified copy of *letters patentes* from the United Kingdom's patent office. The Kenyan office only registered patents that had been granted in the United Kingdom.

The history of patent law in Kenya has been summarized thus:

"Kenya has a long history of intellectual property protection with the first patent registered in 1912. Like other laws in Kenya, Intellectual Property laws are a heritage of the colonial past. Indeed, until 1989, Kenya had a dependent patent system. In 1990 however, the Kenya Industrial Property Office was created with the enactment of the Industrial Property Act (Chapter 509 Laws of Kenya.) This signified a major shift from the prior system where Kenyan authorities merely re-registered Intellectual Property Rights granted in the United Kingdom.

With the creation of the World Trade Organization in 1995, and the coming into force of the TRIPs agreement, all members of the World Trade Organization were required to revise their national patent laws to conform to the requirements of TRIPs and World Trade Organization guidelines. Kenya as a member of the World Trade Organization and a signatory of TRIPs was obligated to amend the Industrial Property Act. This came into effect when the Industrial Property Bill was passed by Parliament on 13th June 2001."²⁰

The current law governing patents is the Industrial Property Act, 2001.

2.1.4 Patentability

The United States' Patent Act of 1790, stated patents could be obtained for "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof."

¹⁸ Chapter 509, Laws of Kenya (repealed).

¹⁹ Dr Ben Sihanya, in his LLB IV class notes on *Patents and Related Doctrines*, 2005.

²⁰ Hannington Odame, Patricia Kameri-Mbote and David Wafula (September 2003), *Governing Modern Agricultural Biotechnology In Kenya And Implications For Food Security*, Institute for Development Studies, Working Paper 199.

Patents are normally granted for inventions, whether objects such as machines, or processes. An invention has been defined under Section 21 of the Industrial Property Act, 2001 as a solution to a specific problem in the field of technology. An invention may relate to a product or a process.

Section 21 of the Act also enumerates inventions that shall be excluded from patent protection. They are:

- a. Discoveries, scientific theories and mathematical methods
- b. Schemes, rules or methods for doing business, performing purely mental acts or playing games.
- c. Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised in relation thereto, except products for use in any such methods.

This provision is to be distinguished from Article 27 of the TRIPS agreement that provides that diagnostic, therapeutic and surgical methods for the treatment of humans or animals *may* be excluded from patentability.

- d. Mere presentation of information.
- e. Public health related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease that the Minister responsible for matters relating to health may designate as a serious health hazard or as a life threatening disease.

Thus, any invention that does not fall within any of the above categories will be regarded as an invention under the Act and hence patentable.

Section 22 of the Industrial Property Act states that an invention is patentable if it is new, involves an inventive step, and is industrially applicable.

In order to be patentable, an invention must meet the following criteria:

1. It must be novel.

Section 23(1) of the Act states that an invention is new if it is not anticipated by prior art.

Novelty relates to whether the invention in question existed at some prior time in one form or another, or had been divulged to the public before the “inventor” filed his application for a patent.

An invention is not novel if there is a previously existing or divulged device or process that includes all of the elements of the claimed invention.

In *Van der Lely v. Bamford*²¹, the patentee claimed a hay-raking machine in which the rake-wheels were turned not by an engine but by contact with the ground. The patent was held to have been anticipated by a photograph in a journal, which showed a hay rake with this feature, and the invention was therefore held not patentable.

However, it must be noted that the disclosure of a prior invention will not amount to a publication of a later invention if the former merely points the way that might lead to the latter.

Cornish states:

“No system grants valid patents for inventions that are already known: that would be to encumber the industry with constraints upon the use of information without any sufficient return.”²²

Further, one cannot obtain a valid patent in Kenya if his invention was made public before he filed his patent application.

²¹ [1963] RPC 61, HL.

²² William Cornish (2003) *Cases and Materials on Intellectual Property* Sweet and Maxwell, London pg. 148 (4th Edition).

It has been reported²³ that foreigners account for most of the applications to the Kenya Industrial Property Institute. Many Kenyans are not aware of their rights as inventors and the procedure for getting their rights protected. Thus, the “money making machine”, a machine that is used for irrigation of plants cannot be patented in Kenya because it was released to the public for mass production before a patent application had been made by its inventors.²⁴

There is however a grace period of 12 months (which is sometimes called a priority date²⁵). If it is disclosed publicly, one can still file in Kenya within 12 months following that grace period.

This position must be distinguished with that of the Paris Convention Treaty. Under Article 4 of the Paris Convention Treaty, an inventor was given a priority date of up to 30 months.

Disclosure may be to a single individual or to the world at large. As long as the invention is already in the public domain, then it will not be granted patent protection.

In *Fomento v. Mentmore*,²⁶ the court held:

“On the contrary, if the information, whether in documentary form or in the form of the invention itself, has been communicated to a single member of the public without inhibiting fetter, that is enough to amount to a making available to the public...”

In *Catnic Components v. C Evans & Co*,²⁷ Falconer J held that there was no disclosure as all the persons to whom the inventor showed his drawings of an invention were bound by implied obligations of confidence.

²³ Hannington Odame, Patricia Kameri-Mbote and David Wafula, (September 2003), “Governing modern agricultural biotechnology in Kenya and implications for food security”, Institute for Development Studies, Working Paper 199.

²⁴ As stated by the Librarian of Kenya Industrial Property Institute (KIPI) during an interview in his office at KIPI on 12th September 2005.

²⁵ For example, Dr. Ben Sihanya in his teaching notes to LL. B IV on Patents and Related Doctrines, 2005.

²⁶ [1956] RPC 87, CA.

²⁷ [1983] FSR 401.

Identifying such "prior art" by the patent examiner is accomplished by a search of existing printed literature (technical journals, published and issued patents, among others) that predate the filing date of the particular patent application.

2. "Non-obviousness," "Inventive ingenuity", or "Inventive Step"

Section 24 of the Industrial Property Act states:

"An invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the application claiming the invention, it would not have been obvious to a person skilled in the art to which the invention pertains on the date of the filing of the application or, if priority is claimed, on the priority date validly claimed in respect thereof."

Even if an applicant's claim for an invention is technically novel, a patent can still be denied to the applicant if the applicant's subject matter is obvious. The purpose of forbidding patents on obvious technologies is to prevent a person from obtaining exclusive rights to what is effectively already in the possession of the public.

Patents will therefore be denied for 'inventions' that are a combination of two already known inventions. In *Williams v. Nye*,²⁸ the plaintiff patented a machine for making sausages that was in effect a combination of a mincing machine and a filling machine, both of which were in the public domain. He brought an action for infringement against the defendant. The defendant argued that the patent was invalid on the ground that the alleged invention consisted simply in joining two well-known machines, and therefore lacked an inventive step. The court held that the patent was indeed invalid because all the plaintiff had done was to substitute one part of a machine with another, and the overall function remained unchanged.

²⁸ (1890) 7 RPC 62, CA.

Accordingly, obviousness asks the question whether all previously known technology related to the invention would teach a "person having ordinary skill in the art" relating to the technical field of the invention, how to make the invention.

The standard of obviousness is a tricky question, and in deciding on whether or not to grant a patent, a delicate balance must be maintained. This is because if the requirements are set very high, virtually nothing shall be patentable. Similarly, if the requirements are very low, all kinds of trivial inventions can receive patents.

Oliver L.J. in *Windsurfing International v. Tabur Marine*²⁹ laid down general principles that should be considered by a court before granting a patent. Patent examiners generally use these principles before granting a patent. They are:

- a) The court must identify the inventive concept embodied in the patent.
- b) It must assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art in question;
- c) It must identify what, if any, differences exist between the matters cited as being 'known or used' and the alleged invention;
- d) It must ask itself whether, viewed without any knowledge of the alleged invention, those differences constituted steps which would have been obvious to the skilled man or whether they required any degree of invention.

In evaluating obviousness, it is necessary to evaluate the so-called subjective and objective indicators of obviousness. Subjective factors relating to obviousness are, for example, the scope and content of the prior invention as disclosed when applying for a patent by the prior inventor, and also the differences between the current invention and the prior invention.

²⁹ [1985] RPC 59, as quoted by William Cornish (2003) *Cases and Materials on Intellectual Property* Sweet & Maxwell, London, Pg. 163 (Fourth Edition).

The objective factors of obviousness are commercial success of the invention (inventions which will have a substantial demand in the market because of their technical superiority or tendency to cut costs), long-felt need (whether it fills in a niche or need in the society in which men's minds were likely to have been engaged upon a mode of remedying the pre-existing defect³⁰), failure of others, unexpected results (whether the invention was produced 'accidentally', that is, the invention was not the goal of the inventor when he embarked on his experiments), and scepticism by others (if while conducting his experiments, the inventor had, for example, been ridiculed by fellow scientists, who scoffed at his efforts saying he was wasting his time. If despite the criticism the inventor is able to invent something, then his work ought to be patented, provided it meets all the requirements for patentability).³¹

One may obtain a patent for an improvement to an existing patented invention although the original patent is still in force. In such circumstances, the original patentee has to license the patent applicant to use his invention. Only then will the patent office grant a patent for this invention.

3. Industrial applicability or utility

Section 25 of the Act states:

"An invention shall be considered industrially applicable if, according to its nature, it can be made or used in any kind of industry, including agriculture, medicine, fishery and other services."

The technology must be useful and have utility in commercial, industrial, trade, or agricultural sectors³². "Useful" means the invention must be of some, even if small, benefit.

³⁰ William Cornish (2003) *Cases and Materials on Intellectual Property* Sweet & Maxwell, London Pg. 174 (Fourth Edition).

³¹ John R. Wetherall "United States Biotechnology Concepts" at <http://www.cbdn.ca/english/discover/discover.html> (Last accessed on 12th September 2005).

³² Dr Ben Sihanya in his LLB IV class notes on *Patents and Related Doctrines*, 2005.

A valid patent cannot be obtained for something that does not work or that has no useful function. Thus, one cannot obtain a patent on an invention that is illegal or immoral. For example, a machine useful solely for producing counterfeit money is unpatentable.

4. Reproducibility

This relates to industrial applicability. A patent should be granted if the invention is reproducible³³. If, for example, a substance is produced in the laboratory while a researcher is experimenting with certain chemicals of unknown amounts, he cannot rush to the patent office applying for a patent. This is because although the invention may be industrially applicable, it must be capable of reproduction. The invention in this case is not reproducible because it was formed as a result of an "accident" in the laboratory.

A very practical example of the rules of patentability in Kenya is the Ozone Therapy treatment for HIV/AIDS. The Ozone Therapy method of "treating" HIV/AIDS was introduced in Kenya by Basil Wainwright in the late 1990's. This therapy could not be patented under the Kenyan Patent system because although it may have met the three requirements for patentability discussed above, it is a method of treatment of the human body, and such have been expressly excluded from patentability under the Industrial Property Act³⁴.

Professor Arthur Obel, who claimed to have discovered a cure for HIV/AIDS in form of a drug, known as "Pearl Omega"³⁵, should have applied for a patent from the then Kenya Industrial Property Organization (KIPO). If his "invention" met the four

³³ Dr Ben Sihanya in his LLB IV class notes on *Patents and Related Doctrine*, 2005.

³⁴ Judith Achieng', "Health-Kenya: New AIDS treatment runs into trouble", at <http://www.aegis.com/news/ips/1997/IP971104.html> (Last accessed on 28th October 2005).

³⁵ Judith Achieng, "New AIDS treatment runs into trouble", at <http://www.aegis.com/news/ips/1997/IP971104.html>. (Last accessed on 28th October 2005).

requirements for patentability discussed hereinabove, then he would have been granted a patent, and he need not have feared disclosing his invention and its contents to the Pharmacy and Poisons Board. Once patented (and on approval by the Pharmacy and Poisons Board), Obel would have been able to exploit his invention for the next 20 years without fear of infringement by other parties. As it stands, should the method of making Pearl Omega leak out, then Obel would have no protection under patent law.

2.1.5 Term of patent

Section 60 of the Act states that a patent shall expire at the end of twenty years from the filing date of the application.

Likewise, Article 33 of the TRIPs agreement states that the term of protection available for the protection of a patent shall not end before the expiration of a period of 20 years counted from the filing date.

Thus, if for example, a mousetrap patent is filed on January 1, 1996 and is issued or granted on January 1, 2000, it will lapse 20 years from filing: January 1, 2016. However, if the inventor comes up with a second improvement and claims priority to the first patent when filing the second patent on January 1, 1998, that second patent, *after grant*, would lapse 20 years from the earliest claimed priority: January 1, 2016.

2.1.6 Who may be granted a patent?³⁶

Patents are normally granted to four main groups of people:

1) Natural persons

A patent will be granted in respect of an invention, either to a single individual if he is the sole inventor or to two or more people if they are co-inventors, as a result of which they become joint owners of the invention.

³⁶ Dr Ben Sihanya in his LLB IV class notes on *Patents and Related Doctrine*, 2005.

Section 30 of the Industrial Property Act states that the right to a patent shall belong to the inventor. Further, if two or more persons have jointly made an invention the right to the patent shall belong to them jointly. The Act also states that the right to a patent may be assigned or may be transferred by succession.

2) Artificial or legal persons

These are mainly corporations or companies. An example would be where an individual invents a way of manufacturing a product, and instead of patenting it in his own name, he forms a company to be the owner of the patent, and responsible for its exploitation.

Further, a company may own a patent when one of its employees invents a product. For the employer (company) to own the patent, the invention must have occurred in the course of, and within the scope of employment. It is usually an express term in employment contracts that any invention occurring within the course of, and in the scope of employment, shall belong to the employer. This is normally the case where an employee has been employed for the purpose of research into an employer's product on how it can be improved.

An example would be the Omo detergent. If a person has been employed in the production unit of Unilever Kenya to research on how to improve it, then the patent of the improved 'Power Foam Omo Multi Active' detergent will belong to the company (Unilever) and not the researcher.

However, an invention can be owned jointly in equal shares between an employer and an employee where an invention results from the contribution of both the employer and employee.

An example of this would be where an employee is employed to assemble vacuum cleaners. In the course of his employment, he may invent a new way of manufacturing vacuum cleaners, which would be an improvement of the model he has been assembling. Because he has not been employed in the manufacturing

unit where one of his duties is to research into new ways of manufacturing more efficient vacuum cleaners, then the invention will not belong solely to the employer. It will belong to the employer and employee jointly because it was manufactured using the basic design of the manufacturer.

Section 32 (1) of the Act states thus:

“Notwithstanding section 30 and in the absence of contractual provisions to the contrary, the right to a patent for an invention made in execution of a commission or of an employment contract shall belong to the person having commissioned the work or to the employer.

Provided that where the invention is of exceptional importance the employee shall have a right to equitable remuneration taking into consideration his salary and the benefit derived by the employer from the said invention.”

However, an employee is entitled to equitable remuneration, taking into account the importance of the invention and the benefit derived by the employer from the invention.

Further, if the employee makes the invention in his own time, and without using the resources of the employer, then such invention shall belong solely to the employee.

3) Assignees of inventions

A patentee may assign the whole or any part of the patent rights. The assignee replaces the assignor and is entitled to his name being entered on the register of patents as the proprietor of the patent. The assignee can thereafter exercise all the rights of the proprietor of a patent.

4) The Government

Under section 17 of the Science and Technology Act³⁷, inventions made by scientists in research institutions established under the Act are patented in favour of the research institute and not the individual inventor. The government may

³⁷ Chapter 250, Laws of Kenya.

however be said to be the owners of such inventions because such institutions are government agencies. Thus, inventions by Kenya Medical Research Institute (KEMRI) belong to the government.

Further, governments may own patents when the rights of a patentee are assigned to them, or when the government acquires such rights by compulsory acquisition.

An example would be if malaria was to be declared a national disaster, and pharmaceutical companies that produce malaria medicines are not producing them in sufficient quantities. The Kenyan Government can begin manufacturing the malaria medicines using the formula (formulae) owned by various companies. It will however be required to pay sufficient royalties to those companies.

2.1.7 Rights of a patentee

Section 53 of the Industrial Property Act provides for the rights and obligations of a patentee. It provides that a patentee or owner of an invention has the following rights:

1. To be granted a patent upon the fulfilment of the requirements of the Industrial Property Act.
2. After the grant of the patent, to exclude other persons from exploiting the patented invention, as provided for in Section 54 of the Act.
3. To licence out the patented invention as provided for under the Act.
4. To receive royalties as in the case of compulsory licensing³⁸.

Section 54 provides for the rights of the owners of a patent. It states:

- “(1) The owner of the patent shall have the right to preclude any person from exploiting the protected invention by any of the following acts—
- (a) When the patent has been granted in respect of a product—
 - (i) Making, importing, offering for sale, selling and using the product; or
 - (ii) Stocking such product for the purposes of offering it for sale, selling or using the product;

³⁸ Dr Ben Sihanya in his LLB IV (2005) class notes on *Patents and Related Doctrines*.

(b) When the patent has been granted in respect of a process—

(i) Using the process; or

(ii) Doing any of the acts referred to in subsection (a), in respect of a product obtained directly by means of the process.

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

Hence, no person may produce, sell or offer for sale, or even import a patented invention without the patentee’s authority.

However, these rights are not unlimited:³⁹

- i. They only extend to conduct or acts done for industrial or commercial purposes. This does not include acts done for scientific research or experimentation. It will not be an infringement of a patentee’s rights if one pharmaceutical company uses the patented formula belonging to another company to see whether that product can be used for the treatment of a certain disease.
- ii. Compulsory licensing, or when the patents are mutually supporting that it would be impossible to work one patent without infringing another. This is the reason why in compulsory licensing, a government must pay sufficient royalties to the owner of a patented medicine because technically, the government is infringing the patentee’s rights by producing a similar and more affordable product for its citizens.
- iii. Under Section 56 of the Act, the rights of a prior user limit a patentee’s rights.
- iv. It must be noted that a patentee’s rights are limited to the claims that he made under the patent application. A patentee is therefore

³⁹ Dr Ben Sihanya *Op. Cit.*

only protected for what he claimed when he was granted the patent.

Thus, if in the patent application he claimed protection of a carpet Hoover, but a different company invents a device that operates on a similar principle to that Hoover, but is substantially different and is used to assist doctors in suctioning blood during surgery, then the first patentee cannot claim that the new invention infringes on his patent.

In addition, a patentee has the following obligations:

- a) To disclose the invention to the patent office, when applying for a patent. The disclosure must be in a clear and concise manner, and if possible, diagrams of the invention and how it works must be provided. In addition, the applicant must indicate at least one method of carrying out the invention.
- b) If the applicant has applied to any other foreign country or jurisdiction, and/or been granted such a patent, he must inform the patent office of this.
- c) The applicant must pay any requisite fees as he may be directed by the patent office, for example for conducting searches.
- d) To refrain from licensing or assigning his patent in a way that is prohibited by Section 69 of the Act, for example one that is harmful to the economic interests of Kenya.

The purpose of highlighting these rights and obligations is because they are the same rights that holders of bio patents have. It will therefore not be an infringement of a patent if the Kenya Medical Research Institute (KEMRI) uses a patented product such as a malaria drug, and conducts further research on it in order to try and get a medicine that will help combat the new strains of malaria. Similarly, if the Kenya Agricultural Research Institute takes one of

the varieties of soybeans, for which Monsanto⁴⁰ has been granted a patent, for research and development purposes, then this will not be an infringement of Monsanto's patent.

2.1.8 When to apply for a Patent

In Kenya, patents are given to the first inventor to file an application. It is therefore always wise for an inventor to file a patent application as soon as he finishes his invention. It is imperative never to advertise, display, or publish information concerning an invention (for example by a doctor telling his fellow doctors about his invention without informing them that such information is strictly confidential, and must not be divulged to anyone) until a patent application has been filed.

The inventors of the "money making machine" should first have applied for a patent over their invention before advertising it to the public, as discussed earlier. Public disclosure of an invention before filing makes it difficult, if not impossible, to obtain a patent. The only exception to this rule is when the inventor made the disclosure twelve months prior to his making a patent application (priority date).

An applicant should ensure that before he applies for a patent, it meets all the requirements outlined above as to novelty, inventive step, industrial application, and reproducibility. This is because if the invention does not meet all the above requirements, then he will have wasted his time and money, researching in that area, and also in the filing and search fees that he will have paid to the patent office.

2.2 The Bio-Patent Debate (Patenting Of Life Forms)

2.2.1 Introduction

A debate that has been raging for quite a while, especially in developed countries, and more recently in the developing countries, is whether life forms should be patented. The argument has been whether genetically modified organisms (whether of a plant

⁴⁰ A company in the United States that has been doing a lot of research and development on many plant varieties, and for which it has been granted patents.

or animal origin) should be patented since such organisms are products of nature. It is therefore argued that no one should be able to lay a claim on a specific plant or animal just because they have made an improvement on it.

In this chapter, I will discuss generally the main arguments advanced for and against bio patenting. However, as the main focus of the dissertation is stem cell research, I will delve into the arguments for and against stem cell research in Chapters 3 and 4.

2.2.2 Origins of Patents of Life Forms

The first landmark case on the patent of a life form was *Funk Brothers Seed Company v. Kalo Inoculant Company*.⁴¹ A patentee had claimed a patent for a mixture of bacterial strains which were used to infect plant roots, thereby aiding the plant in the fixture of nitrogen. The United States Supreme Court held that naturally existing products, even when combined in a new product, are not patentable. The court concluded that the product was a mere discovery of some handiwork of nature and hence not patentable. Writing for the majority, Justice Douglas said:

"Patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are the manifestations of laws of nature, free to all men and reserved to exclusively no one. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. A Biotechnology product will comprise patentable subject matter only if it amounts to a none naturally occurring manufacture or composition- a product of human ingenuity."

Patents of life forms began in earnest in 1980 after the famous *Diamond v Chakrabarty*⁴² case, the facts of which are outlined herein below.

⁴¹ 333 U.S. 127 (1948); Ulysess K. K. Justin, *Embryonic Stem Cell Patenting, the EU, Kenya and the USA* pp 49, 54.

⁴² United States Supreme Court (1980) 447 U.S. 303, 100 S.Ct. 2204. Adapted from http://www.mindfully.org/GE/Diamond_v_Chakrabarty-16june80.htm. (Last accessed on 12th September 2005).

In 1972, the respondent, Chakrabarty, a microbiologist, filed a patent application, assigned to the General Electric Co. The application related to Chakrabarty's invention of a human made, genetically engineered bacterium capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills. Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria, second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves.

The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: first, those microorganisms were "products of nature," and secondly, that as living things they were not patentable subject matter.

On appeal, the United States Supreme Court held that Chakrabarty's microorganism plainly qualified as patentable subject matter.

It stated:

"His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity "having a distinctive name, character and use."...The patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under 101."

The next landmark ruling on patenting of life forms of animal origin was the patent granted to Harvard Medical School for the "oncomouse", commonly known as "*The Harvard Mouse Case*."⁴³ A mouse was developed by the Harvard Law School that had been genetically engineered to carry a cancer-causing gene. The patent was granted in the United States, and eventually in other jurisdictions such as the European Union.

⁴³ [1990] O.J. E.P.O 476, Tech Bd App [1991] E.P.O.R. 525 as cited in Doris Estelle Long and Anthony D'Amato (2000) *A Coursebook in Intellectual Property Law* American Casebook Series, Minnesota, pp 192-194 (1st Edition).

Three ethical issues were raised when the patent application was made to the European Union Patent Office. First, was a basic interest of humanity to remedy widespread and dangerous diseases. Secondly, it was contended that if the patent was granted, there was a danger that the mice would escape and thus resulting in unwanted genes being released into the environment. Thirdly was the issue of cruelty to animals. It was contended that the last two aspects would justify regarding the invention as immoral, and would therefore be unacceptable unless the benefits gained outweighed the disadvantages. In the end, the courts decide that the benefits far outweighed the disadvantages pointed out.

The European Patent Office stated:

“The present invention’s usefulness to mankind cannot be denied. Cancer is one of the most frequent causes of death in many countries of the world and also causes severe suffering. Any contribution to the development of new and improved anti-cancer treatments is therefore a benefit to mankind and must be regarded as valuable and highly welcome to everybody. Legislation in contracting states allows animal testing under certain restrictions and subject to administrative approval.”

On patentability of the mouse, the court held that the invention was not contrary to public order and morality as provided under TRIPs. The court held thus:

“Exclusion from patentability cannot be justified merely because a technology is too dangerous. There are many examples of inventions the patentability of which has never been questioned which cannot be used without severe security measures. For example work with certain pathogens is allowed under very limited conditions only, and the release of material into the environment must be excluded by appropriate measures: Patentable inventions may nevertheless arise from such work.

In the overall balance the examining Division concludes that the present invention cannot be considered immoral or contrary to public order. The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals together with a low risk connected with the handling of animals by qualified staff can generally be regarded as beneficial to mankind. A patent should therefore not be denied.”⁴⁴

⁴⁴ [1990] O.J. E.P.O 476, Tech Bd App [1991] E.P.O.R. 525 as reported in Doris Estelle Long and Anthony D’Amato (2000) *A Course Book on Intellectual Property Law* American Casebook Series, Minnesota pp 192-194 (1st Edition).

I shall now delve into the heart of these arguments, looking at both sides of the coin-
pro bio patenting and anti-bio patenting.

2.2.3 Reasons against bio patenting

2.2.3.1 Moral/ethical considerations, which question the interference of humans with other life forms

The argument here is mostly by animal activists⁴⁵. They tend to question the human being's authority in using animals for testing. They argue that human beings are not superior to other animals. Further, they argue that in using animals for testing, they cause these animals undue suffering and pain. In their view therefore, human beings should stop research based on and using animals.

This was one of the main arguments raised in the *Harvard Mouse Case*.⁴⁶ It was argued by animal activists that to grant the patent would lead to cruelty of animals, which should be avoided.

2.2.3.2 Blurring of well known genetic distinctions

The argument here is that human beings, by patenting, will eventually blur the genetic distinction between various organisms. For example, there have been reports of cross breeding between mice and rats to produce rat producing mice, scientists are experimenting to see whether a cow can produce human milk proteins.⁴⁷

Rick Weiss⁴⁸ reports that scientists in Massachusetts are creating live embryos by combining cow and human cells.

⁴⁵ Dinyar Godrej, "8 Things you should know about Patents on life" at <http://www.newint.org/issue349/currents.htm>. (Last accessed on 12th September 2005).

⁴⁶ [1990] O.J. E.P.O 476, Tech Bd App [1991] E.P.O.R. 525 as reported in Doris Estelle Long and Anthony D'Amato (2000) *A Course Book on Intellectual Property Law* American Casebook Series, Minnesota pp 192-194 (1st Edition).

⁴⁷ Manfred Davidmann, "Creating, Patenting and Marketing of New Forms of Life" at <http://www.solbaram.org/>. (Article last accessed on 1st September 2005).

⁴⁸ Organic Consumers. "US Ruling aids Opponent of Patents for Life Forms", at <http://www.organicconsumers.org/toxiclink.html>. (Article last accessed on 12th September 2005).

It may also be used to genetically design families: "Let's have a blond-hair, blue-eyed boy. No girls please." This has been described as genetic discrimination, and which may eventually lead to selective abortion by Ted Peters⁴⁹. He argues that parents to be may decide that they do not want any girls, and so if a scan is performed on the pregnant mother and she is found carrying a girl, the pregnancy will be terminated.

Eventually, we shall have a new generation of animals that we don't even recognise, which clearly were not part of nature and creation of the world. It is my opinion that God never intended for a cow to produce human proteins. Cows and humans are separate and distinct creations. Further, it is my contention that if cow and human embryos were produced and cloned to a full creature, would such a creature be protected under the constitution of a country because it is partly human? I think not!

It is further argued that this is new technology, something that the human race has never seen before. It is argued therefore that by modifying genes, we might be creating new problems for society, as the long-term consequences of such genetic engineering are still unknown and these might be irreversible⁵⁰. Therefore, research into this area should be slow and very carefully monitored by government agencies.

2.2.3.3 Religious concerns that humans are playing God

Religious individuals and organisations argue that by genetic engineering, humans are playing God. They argue that God is the one true creator of life, and he should be respected as such.

Their position has been aptly summarised:

"As the ultimate creator, God's job is regulated by some of the highest and strictest standards in the universe. A few of the qualifications are listed in Job 38... The point of this passage is that it takes an all-wise, all-knowing, just and unbiased God to fill the shoes of creator, one will not be motivated by a million-dollar profit. I'd urge the

⁴⁹ First Things, "Patenting Life: Yes" at <http://www.firstthings.com/index.html>. (Article last accessed on 12th September 2005).

⁵⁰ For example Manfred Davidmann, "Creating, Patenting and Making of New Forms of Life" at <http://www.solbaram.org/articles>. (Last accessed on 12th September 2005).

government to seriously reconsider patenting life forms. Otherwise, like Mary Shelley's "Frankenstein," you might be creating a monster."⁵¹

In Kenya, when the Sunday Standard⁵² reported that scientists had succeeded for the first time in creating embryos by fertilizing a woman's ovule in the laboratory with a man's sperm, religious leaders warned that scientists were trying to play God.

For example, Anglican Bishop Alfred Chipman described the technique as an attempt by scientists to "play God."⁵³ Rev. Zablon Thamburi,⁵⁴ former presiding Bishop of the Methodist Church of Kenya, stressed that his church was not against science, but that church leaders wanted to be sure that the process would not be misused.

2.2.3.4 Bio Patents promote unsustainable and inequitable agricultural policies⁵⁵

On December 10, 2001, the United States Supreme Court issued its opinion in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,⁵⁶ a case that dealt with questions concerning the patenting of plants and seeds. The Supreme Court held for the general assertion that all life forms are patentable under current United States law, a position that has far-reaching implications for farmers and ranchers.

⁵¹Joy Adamson, "A Spiritual Case against Patenting Life Forms" at http://rbhatnager.csm.uc.edu:8080/soc_hindu_home.html. (Last accessed on 1st September 2005).

⁵² Sunday Standard, October 12 2003.

⁵³ Anglican Church, (2003) "In vitro fertilization" *Anglican Journal* at <http://www.anglicanjournal.com/129/10/world09.html>. (Last accessed on 11th October 2005).

⁵⁴ Anglican Church, (2003) "In vitro fertilization" *Anglican Journal* at <http://www.anglicanjournal.com/129/10/world09.html>. (Last accessed on 11th October 2005).

⁵⁵ Council for Responsible Genetics, "DNA Patents Create Monopolies on Living Organisms" at <http://www.actionbioscience.org>. (Last visited on 12th September 2005).

⁵⁶ 534 US 124 (2001), as cited by The Centre for Rural Affairs, "Life Form Patenting and Large Scale Agriculture: Implications and Recommendations." at <http://www.cfra.org/resources>. (Last accessed on 1st September 2005).

Bio-patents would result in farmers abandoning their traditional seeds which they used season after season, and instead buy genetically modified seeds because of their perceived advantages, such as being resistant to certain strains of diseases, or because they yield higher than the traditional varieties. However, these seeds are disadvantageous in the sense that they are terminator seeds; they can only produce the crop and not seeds for the next season.

Hope Shand and Pat Mooney state:⁵⁷

“The 12,000-year-old practice in which farm families save their best seed from one year's harvest for the next season's planting may be coming to an end by the year 2000. In March 1998, Delta ~ Pine Land Co. and the US Department of Agriculture (USDA) announced they had received a US patent on a new genetic technology designed to prevent unauthorized seed-saving by farmers. The patented technology enables a seed company to genetically alter seed so that the plants that grow from it are sterile; farmers cannot use their seeds.”

The result? Farmers are placed at the mercies of these multi-nationals, as they have to purchase new seed every year. For animals, if a company holds a patent for a specific breed, then every year that farmers' breed that animal and get new offspring, they will have to pay a certain percentage to the company holding the patent.⁵⁸

In Kenya, when the Industrial Property Bill was still being debated in Parliament, it was argued by some individuals that the Bill would result in serious implications on national food security. Gichinga Ndirangu said thus:⁵⁹

“...The Bill's implications call for more than a bare fleeting glance. In particular, small-scale farmers' ability to grow food through seed saving could be severely curtailed due to failure to protect indigenous and traditional knowledge systems....In most developing countries where small-scale farmers dominate food production, such strong patent legislation will constrain food. Kenya's Industrial Property Bill 1999 opens up this gruesome possibility. Parliament's singular duty must be to

⁵⁷Third World Traveller, “Terminator seeds threaten an end to farming”, at http://www.thirdworldtraveller.com/Transnational_corps/Terminatorseeds_Monsanto.html, (Last accessed on 11th October 2005).

⁵⁸ Centre for Rural Affairs, “Life Form Patenting and Large Scale Agriculture: Implications and recommendations”, at <http://www.cfra.org/resources>. (Last accessed on 12th September 2005).

⁵⁹ Gichinga Ndirangu, “Patents: New Bill a threat to Kenyan national Food Security” at <http://www.gene.ch/genet/1999/Jul/msg00017.html>. (Last accessed on 28th October 2005).

protect food production by small scale farmers by specifically excluding food and farming resources from patenting.”

He continues:

“Poor farmers, who produce 80% of Kenya’s food will be further marginalised given their inability to afford expensive seeds while they loose out their inability to save seed on account of patent rights secured by the transnationals.”

Action Aid country Director Thomas Joseph commenting on the Industrial Property Bill 1999 said thus on patenting and food security:

“We are not convinced that the Industrial Property Bill safeguards the interests of our small scale farmers. In opening up the scope for patenting products of biotechnological processes, the Bill opens the doors to biotech transnational corporations to exercise patent rights over seeds which will increase farmers’ dependence on the corporations and increase the cost of food production already under pressure from a lack of domestic subsidy support.”⁶⁰

2.2.3.5 Patenting of life forms will increase costs

Activists against bio patenting argue that by granting of patents of life forms, the costs will be raised. For farmers, as they purchase seeds, a certain percentage of the cost will be royalties payable to the patentee.⁶¹ Also, because of the added features of the seeds, such as resistance to drought and pests, the average cost of the seeds will increase. Further, majority of these seeds are hybrid seeds and therefore the farmer cannot save part of the harvest as seeds for the next planting season. He will therefore have to spend money each planting season to buy seeds.⁶²

Similarly, for the livestock, the farmers will have to pay royalties every year to the companies owning the patent for a particular breed of animals.⁶³

⁶⁰ Gichinga Ndirangu, “Patents: New Bill a threat to Kenyan national Food Security” at http://www.gene.ch/genet/1999_Jul/msg00017.html. (Last accessed on 28th October 2005).

⁶¹ Council for Responsible Genetics, “DNA Patents Create Monopolies on Living Organisms” at <http://www.actionbioscience.org>. (Last accessed on 12th September 2005).

⁶² Manfred Davidmann, “Creating, Patenting and Making of New Forms of Life.” at <http://www.solbaram.org/articles>. (Last accessed on 12th September 2005).

⁶³ Anon. “Court Rules that Mammals can be Patented” at <http://www.life.ca/nk/subrates.html>. (Last accessed on 1st September 2005).

It is estimated⁶⁴ for example that the cost of in vitro fertilization treatment in Kenya will be \$5,000 US. This is clearly way above what many childless couples in Kenya can pay. Such treatment will therefore only be for the rich. Dr. Joshua Noreh, who is the gynaecologist in charge of the first in vitro fertilization clinic, explained the reason thus:

“This is a costly affair since we import all the machinery and even sometimes we have to send the semen abroad for tests before insemination.”⁶⁵

According to Dr. Noreh, it costs approximately Kshs. 10,000.00 to test the sperm for genetic diseases and a similar amount to check for infections such as HIV not counting other peripheral expenses involved.

In Working Paper 199 by the Institute of Development Studies, the position has been illustrated thus:

“Before the introduction of Plant Breeders Rights, Kenya Agricultural Research Institute as a public research organization was involved in breeding crop varieties that were exclusively treated as public goods. This is likely to change with the liberalization of the seed industry, which requires farmers to pay royalties for the varieties they purchase...Farmers will start paying for varieties that they have been involved in nurturing instead of sharing benefits accruing from them.”⁶⁶

2.2.3.6 Enrichment of only a few individuals

Related to the above argument is that since the patents will be owned by only a few multi-national companies, mostly from developed nations, profits obtained will not be used for the benefit of the local country where the patented subject matter is being

⁶⁴ Anglican Church, (2003) “In vitro fertilization” *Anglican Journal* at <http://www.anglicanjournal.com/129/10/world09.html>. (Last accessed on 11th October 2005).

⁶⁵ Charles Njeru “Kenya’s test-tube baby still on course” at <http://www.allAfrica.com/stories/200509210729.html>. (Last accessed on 28th October 2005).

⁶⁶ Institute for Development Studies, Working Paper 199 September 2003: “Governing modern agricultural biotechnology in Kenya and implications for food security” by Hannington Odame, Patricia Kameri-Mbote and David Wafula.

used, but rather the money will be "shipped" back home. It has been estimated by Manfred Davidmann that the United States of America will gain \$61 billion a year from third world royalties.⁶⁷

As a result therefore, the rich become richer, while the poor become poorer because of all the money they spend in purchasing these products.

2.2.3.7 Patents in science promote secrecy and hinder the exchange of information⁶⁸

It has been stated that evidence suggests several areas in which patenting of genetic materials may actually be slowing innovation through delayed publications, increased secrecy, increased transaction costs due to royalty stacking, and excessively broad patents.⁶⁹

By patenting products of research, the free flow of ideas and information necessary for co-operative scientific efforts is reduced. Scientific materials required for research will become more expensive and difficult to purchase if one corporation owns the rights to the material. It is argued also that sometimes patents may be granted in a specific area of research too early, especially in the medical field, and as a result hinder any further research in that area.⁷⁰

Humanity may therefore lose out on a possible cure of a disease.

⁶⁷ Manfred Davidmann, "Creating, Patenting and Marketing of New Forms of Life." at <http://www.solbaram.org/>. (Last accessed on 1st September 2005).

⁶⁸ Council for Responsible Genetics. "DNA Patents Create Monopolies on Living Organisms". At <http://www.actionbioscience.org>. (Last accessed on 12th September 2005).

⁶⁹ Donald J. Williamson and Stuart M. Macleod, "Patenting of genetic material: Are the benefits to society being realized?" at <http://www.cmaj.ca/cgi/content/full/167/3/259>. (Last accessed on 22nd September 2005).

⁷⁰ Dinyar Godrej, "8 Things you should know about Patents on life." at <http://www.newint.org/issue349/currents.htm>. (Last accessed on 12th September 2005).

2.2.3.8 First World patenting of Third World genetic resources represents theft of community resources⁷¹

Many pharmaceutical companies send representatives (or bio-prospectors) to communities in the third world to gain knowledge on how they cure certain diseases, or deal with certain conditions. As most of these traditional healers are illiterate, and definitely not materialistic, they pass on this information for free. The pharmaceutical company then goes back home, makes a few modifications to the knowledge derived and then applies for a patent, which they usually get.

These companies will make millions of shillings on the sale of such medicines, while the source of this information gets nothing.

For example, the Neem tree, a native of the Indian subcontinent, has a myriad of applications in traditional Indian Ayurvedic and Tibetan medicine, agriculture, and household use, as well as being symbolic as "Gandhi's favorite tree." Its usefulness is known throughout India. The Latin name, *Azadirachta indica*, is derived from the Persian for "free tree," as even the poorest families have access to its beneficial properties. However, it is possible that Indian citizens will soon be required to pay royalties on the products produced from the Neem, since a patent has been granted to the U.S. Company W.R. Grace on a compound in the tree (*azadirachtin*) for the production of a bio-pesticide. In 1993, over five hundred thousand South Indian farmers rallied to protest foreign patents on plants such as the Neem, and launched a nation-wide resistance movement.⁷²

Patents held by the industrialised world on resources from the developing world will serve as a tool for the developed nations to accumulate more wealth from the already

⁷¹ Council for Responsible Genetics, "DNA Patents Create Monopolies on Living Organisms." at <http://www.actionbioscience.org>. (Last accessed on 12th September 2005).

⁷² Manfred Davidmann, "Creating, Patenting and Marketing of New Forms of Life" at <http://www.solbaram.org/>. (Last visited on 1st September 2005).

economically impoverished developing countries. Microorganisms, plants, animals and even the genes of indigenous people have been patented for the production of pharmaceuticals and other products. Multi-national corporations can make large profits on their "discoveries," while depriving the communities that have fostered this knowledge for centuries of the choice of how they would like to use their own knowledge and native species.⁷³

This argument has been summarized thus:

"For many years, these farmers have been custodians of traditional varieties adapted to various climatic conditions and suitable for meeting food security needs. Unfortunately, Plant Breeders Rights exclude the rights and traditional knowledge of farmers and do not recognise them as key players and part and parcel of the breeding process. Plant Breeders rights fail to appreciate the fact that the breeding process begins at the farmers' level before moving to the laboratories."⁷⁴

Other Examples.

In 1999 Larry Proctor, owner of a seed company POD-NERS LLC, obtained a US patent on Enola beans of a certain shade of yellow. POD-NERS then began suing Mexican bean exporters to the US for patent infringement on the yellow variety. However, Mexican farmers had been growing them for generations, and were therefore the losers. An international agricultural body is challenging the patent.⁷⁵

In Brazil, which has some of the richest biodiversity in the world, large multinational corporations have already patented more than half the known plant species. In Texas, a company called Rice Tec took out the patents on Basmati rice (which grows in the Indian and Pakistan regions) and has created a genetically modified Basmati rice, while selling it as normal Basmati and it was not against the law, either. In fact, four

⁷³ Manfred Davidmann *Op. Cit.*

⁷⁴ Hannington Odame, Patricia Kameri-Mbote and David Wafula (September 2003) "Governing modern agricultural biotechnology in Kenya and implications for food security", Institute for Development Studies, Working Paper 199.

⁷⁵ Dinyar Godrej, "8 Things you should know about Patents on life" at <http://www.newint.org/issue349/currents.htm>. (Last accessed on 12th September 2005).

of the patents were withdrawn in June 2000, when the Indian government formally challenged the patent.⁷⁶

A 1996 Christian Aid report claimed bio piracy cheated poorer countries out of \$4.5 billion a year. Today bio-prospectors working for biotech firms, pharmaceutical and agribusiness giants are off to the far corners of the earth hoping to come back with the (living) goods.⁷⁷

In 1995 the University of Wisconsin in the United States took out four patents on *brazzein*, an extremely sweet tasting protein that researchers had isolated from the berry of a plant growing in Gabon. The university has since granted licences to exploit the patents to several biotechnology companies that hope to introduce a *brazzein*-producing gene into fruit and vegetables to obtain products that taste sweet but are less rich in calories. There are big profits in this, though not for small farmers in Gabon. They know all about the plant, they have always used it and their way of life and farming practices have helped to ensure its survival. But they will get nothing at all out of the plans to exploit it.⁷⁸

J. O. Odek⁷⁹ (now a Professor of Law at the University of Nairobi) reported in 1994 that the University of California and Lucky Biotech Corporation of Japan have been granted patents for the sweetening proteins of two African plants, *katempfe* and the

⁷⁶ Anup Shah, "Food Patents-Stealing Indigenous Knowledge?" at <http://www.globalissues.org/EnvIssues/GEFood/FoodPatents.asp>. (Last accessed on 11th October 2005).

⁷⁷ Dinyar Godrej, "8 Things you should know about Patents on life" at <http://www.newint.org/issue349/currents.htm>. (Article last accessed on 12th September 2005).

⁷⁸ Frank Sueret and Robert Ali Brac de La Perriere, "No Patents on Biotechnology Products: Africa defies licences for life" at http://www.biotech-info.net/no_patents.html. (Last accessed on 11th October 2005).

⁷⁹ Odek, J.O. (1994) "Biopiracy: creating proprietary rights in plant genetic resources", *Journal of Intellectual Property Law*, 2 (141), pp 141-181, as reported by Robert Lostergard, Matthew Tubin and Jordan Altman "Stealing from the past: globalization, strategic formation and the use of intellectual property in the biotechnology industry", at <http://www.Robertostergard.us/linked%20files/stealingpast.pdf>. (Last accessed on 28th October 2005).

serendipity berry. The plants have been used for centuries by African peoples for their sweetening properties. The active ingredient in katempfe, a compound called thaumatin, is about 2000 times sweeter than sugar, making it the sweetest substance on the face of the earth, yet it is also calorie-free. The value of thaumatin and its further development in consumer products is expected to be worth at least \$900 million a year.

Requiring developing nations to pay royalties to the wealthy industrial nations for products derived from their own natural resources and innovation is robbery. Developing countries are arguing that since the genetic resources were obtained from them, then they should be the ones to be the greatest benefactors of any profits made.

2.2.3.9 Genetic resources are the common heritage of mankind

Activists against bio patenting also argue that genetic information is the common heritage of mankind, and as such should not be placed in the hands of one individual, but rather any benefits should be enjoyed by all humanity in equal proportion.

Reverend Eric Beresford has said:

“In England at the beginning of the industrial revolution, the Enclosure Act transferred common land into the hands of wealthy landowners and drove hundreds of thousands of people from that land into the cities and into abject poverty. What we are seeing today is the enclosure of the global commons. We are watching the biological and genetic heritage of the earth, a gift from God, which should be available to all of us, pass into the hands of a small number of multinational companies. This is not the purpose for which the Patent Act came into being. It is a development that threatens profound and destructive consequences for all of us.”⁸⁰

⁸⁰ Organic Consumers Organization, “Patenting Life a Dangerous Step” at <http://www.organicconsumers.org>. (Last accessed on 12th September 2005).

2.2.3.10 Patenting of life forms encourages greed, a vice that should be discouraged by society

Patents are granted for a minimum period of twenty years from the date of filing. During this time, the inventor is given exclusive rights to make and sell his invention at the price of his choice in order that he may financially benefit from it. It is argued that the power to create life could very well land into the hands of the rich and reckless, because realistically, money speaks louder than moral and ethical responsibility. And in the case of genetic engineering, the potential for abuses is ripe.

Williamson and Macleod argue thus:

"In general, genetic patenting issues mirror those associated with commercialization of research. Effort is placed disproportionately on discoveries that would maximize profits to the inventor, by targeting large, potentially lucrative markets, rather than on discoveries that would maximize benefit to society. This exacerbates existing disparities in the availability of treatments across socio-economic and ethnic groups within countries and between developed and developing countries. In addition, research into genetic "solutions" may overshadow research into the roles of less glamorous but important contributors to disease prevention."⁸¹

Rev. Zablon Thamburi, former presiding Bishop of the Methodist Church of Kenya, stressed that his church was not against science, but that church leaders wanted to be sure that the process would not be misused. He said:

"I am sure God supports scientific developments, but we oppose the commercialization of the process."⁸²

2.2.3.11 Introduction of a foreign culture to farming communities

Patents are derived from the concepts of individual innovation and ownership. This is a foreign concept to most farming communities which emphasise on the sharing of community resources and the free exchange of seeds and knowledge⁸³.

⁸¹ Donald J. Williamson and Stuart M. Macleod, "Patenting of genetic material: Are the benefits to society being realized?" at <http://www.cmaj.ca/cgi/content/full/167/3/259>. (Last accessed on 22nd September 2005).

⁸² Anglican Church, (2003) "In vitro fertilization" *Anglican Journal* at <http://www.anglicanjournal.com/129/10/world09.html>. (Last accessed on 11th October 2005).

Most farmers in Kenya currently utilize the traditional method of farming consisting of saving seeds and exchanging them with neighbouring farms. If neighbouring farms begin to buy the terminator seeds⁸⁴, poor farmers who exchange seeds with these farms will obtain sterile seeds from their crops. In effect, they will be forced to buy terminator seeds as well.⁸⁵

Gichinga Ndirangu puts it thus:

“There is also need to legislate against the introduction of terminator seeds whose genetic composition allows only a single reproductive cycle to increase farmers’ dependence on transnationals. The terminator seed poses a clear threat to natural crops through cross pollination which could severely undermine food production.”⁸⁶

I believe that by patenting life forms such as seeds, communities will be hindered from sharing left over seeds with their neighbours farmer whose cow is on heat cannot go to her neighbour and borrow a bull so that the cow may be served. This will be regarded as an infringement of the patentee’s rights, and thus a criminal offence. The result would be that the farmer has to pay a royalty to the patentee before they can use the bull. This is a way of life impossible to many African communities.

2.2.4 Reasons For Patenting Life Forms

Although there are many and very convincing arguments on why patents on life forms should not be granted, I believe that there are also very important benefits that will be gained by granting such patents. I shall discuss them herein below.

⁸³ Dinyar Godrej, “8 Things you should know about Patents on life” at <http://www.newint.org/issue349/currents.htm>. (Last accessed on 12th September 2005).

⁸⁴ Terminator seeds are those whose genetic composition allows only a single reproductive cycle.

⁸⁵ Adapted from Rural Advancement for Farmers International, “Advantages and disadvantages of terminator seeds”, at http://www.biotech-info.net/RAFI_abandon.html. (Last accessed on 28th October 2005).

⁸⁶ Gichinga Ndirangu, “Patents: New Bill a threat to Kenyan national Food Security” at <http://www.gene.ch/genet/1999/Jul/msg00017.html>. (Last accessed on 28th October 2005).

2.2.4.1 Reward for the scientist

It has been argued that patents are simply a reward for inventors for the work they have done. Just like any other employee or person is given a salary or other form of reward for work done, so too should scientists be rewarded by being granted a monopoly or exclusive rights for the exploitation of their "brain child." The lawyers for Harvard University, when arguing for the grant of patent for the oncomouse, in the *Harvard Mouse Case*⁸⁷ stated that researchers need to be assured of a financial reward for their work, thus promoting medically beneficial research.

2.2.4.2 The invention has met all the three requirements for patentability

Another technical argument that may be advanced is that patents are granted for inventions that are new, have an inventive step, have industrial utility and are reproducible. They argue that as long as an invention has met all these requirements, then issues of morality should not be considered. A patent should be granted.

It is further argued that majority of these inventions are really not for the detriment of human life but for the improvement, and therefore should be granted (that is, they are not against public order or morality.).

2.2.4.3 Financial gain for Governments

By allowing patents of life forms, scientists are able to exploit their patents and thus become more financially "endowed." This advantage of patents can be highly exploited by governments. Research Institutions can research and develop genetic strains, or even organisms such as the Harvard oncomouse. As the results of such research belong not to the scientists but to the research institutions, then the institutions, and thus the Government, will get a source of income through the exploitation of these patents. In addition, for patents that may be owned by individual

⁸⁷ [1990] O.J. E.P.O 476, Tech Bd App [1991] E.P.O.R. 525; as reported in Doris Estelle Long and Anthony D'Amato (2000) *A Coursebook in Intellectual Property Law* American Casebook Series, Minnesota pp 192-194 (1st Edition).

people, the Government will still be able to benefit highly through various taxes that may be imposed on patentees for any royalties that they may receive.

2.2.4.4 Food Security

As argued earlier in this Chapter, patenting of life forms promotes research. Research will thus continue to be done on so that drought and pest resistant seeds will be developed. This will greatly assist the third world countries that are constantly plagued with problems of food insecurity due to crop failure and also destruction of crops by pests. Food insecurity is a state in country when there is insufficient food to cater for all its nationals adequately, with a surplus remaining for the next year.

In 2000, a pro-biotechnology group in Kenya formed a new lobby group called the African Stakeholders Biotechnology Forum to popularize genetic engineering. They argue that Kenya, with its countless problems raging from drought to famine, stands to benefit if it adopts the technology.⁸⁸

Research has been conducted by the Jomo Kenyatta University of Agriculture and Technology and the Kenya Agricultural Research Institute (KARI) since 1995 on the use of tissue culture techniques (biotechnology) to produce banana suckers which will be used by Kenyan farmers. These suckers are to prevent the Kenyan farmers' practice of using disease-infected sucker material for propagation, which results in low yields of bananas and plantain. Laboratory-based micro propagation techniques provide disease-free planting material. This results in increased banana productivity, and hence helps achieve the goal of food security.

Dr. Florence Wambugu articulates this position:

"I am a passionate believer in the power of biotechnology to boost food production and fight hunger and poverty in the developing world. As one of nine children growing up on a small farm in Kenya, I know that African farmers need more tools for fighting plant diseases and overcoming other barriers to increased crop

⁸⁸ Adapted from an editorial report on the Nation, March 4th 2000 at <http://www.netlink.de/gen/zeitung/2000.html>. (Last accessed on 28th October 2005).

production. I do not believe that biotechnology is a silver bullet for African agriculture, but it is an indispensable tool that can have dramatic benefits. The African continent, more than any other, urgently needs agricultural biotechnology, including transgenic crops, to improve food production.”⁸⁹

Dr Kilemi Mwiria, the assistant minister in charge of higher and technical education, told scientists in a workshop said that Kenya’s marginal lands could yield more and boost the country’s food security if the technology was implemented well. He said biotechnology, if embraced, could revolutionize food productions in many countries.⁹⁰

2.2.4.5 Preservation of the environment.

It has been argued that patenting of life forms will promote research. This will be of particular importance in conservation of the environment. In Kenya, environmental degradation is on the increase because of felling of trees, especially the indigenous species. Biotechnology will help reverse these adverse consequences such as desertification through tissue culture and cloning techniques. Florence Wambugu explains it thus:

“Africa needs biotechnology to solve its environmental problems, and there is unlimited public demand for agricultural biotechnology products and services. In Kenya, the demand for tree seedlings reaches 14 million per year, whereas the country can only supply 3 million, a clear indication of the need for tissue-culture and cloning techniques to curb deforestation and boost reforestation using indigenous species threatened with extinction. These technologies are being successfully used in South Africa.”⁹¹

⁸⁹ Dr. Florence Wambugu “Statement on Biotechnology in Africa” at <http://www.bio.org/foodag/action/20030326.asp>. (Last accessed on 28th October 2005).

⁹⁰ Adapted from The East African Standard, February 4th 2005.

⁹¹ Florence Wambugu “Why Africa needs Biotechnology” at <http://www.agbioworld.org/biotech-info/topics/dev-world/africa.html>. (Last accessed on 28th October 2005).

2.2.5 Conclusion

Kenya's position on Genetic Engineering is hazy, and we are unsure whether biotechnology should be fully or partly embraced. In 2000, the Kenya Agricultural Research Institute, with the help of Monsanto, a multinational research organization, developed a modified potato, which the institution said was a major scientific breakthrough for the agricultural sector. However, the development did not go down well with conservationists, who criticized it saying the country was not ready for Genetically Modified Organisms (GMOs) as experts are still in the dark on their effects on human health and on the environment. Currently, scientists are split on whether Kenya should import or even grow GMOs, with some arguing that the use of technology is inevitable if Kenya is to industrialize by the year 2020.⁹²

The above is but a brief introduction of what a patent is, how it is granted and the various rights of a patentee. In the next chapter, I shall narrow down the debate to the area of stem cell research, an issue which is currently being debated on, especially in the medical field.

⁹² Adapted from an editorial report on the Nation, March 4th 2000 at <http://www.netlink.de/gen/zeitung/2000.html>. (Last accessed on 28th October 2005).

CHAPTER THREE

STEM CELL RESEARCH: POTENTIAL SOURCES OF STEM CELLS, AND THE CONTROVERSY IN THE USE OF EMBRYONIC STEM CELLS

3.1 Introduction

In this chapter, shall now narrow down the debate on stem cell research. I shall define what stem cells are, and the various sources of stem cells, and the arguments against the use of embryonic stem cells.

3.2 Definition of Stem Cells

B. A. Robinson⁹³ has defined stem cells as a type of primitive cell that can be coaxed into developing into most of the 220 types of cells found in the human body cell. Scientists have found ways of developing these stem cells into most types of human cells, such as blood, brain, heart tissue, nerve cells, bones, et cetera. They are confident that they will lead to treatments of many diseases such as severe burns, cancer, diabetes, heart disease, hepatitis, incomplete bladder control, leukaemia, lupus, spinal cord injuries, and stroke. Researchers believe that stem cell research shows promise to develop cures and/or new treatments for people world wide who currently suffer from a wide range of diseases.⁹⁴

3.3 Sources of Stem Cells

There are a number of sources of stem cells that are currently being investigated in the medical field. These sources are discussed herein below.

⁹³ B. A. Robinson, "Human Stem Cell Research: All view points" at www.religioustolerance.org/res-stem.htm (Last accessed on 12th September 2005).

⁹⁴ For example the "Coalition for the Advancement of Medical Research" in the United States, at <http://www.stemcellfunding.org/fastaction/>. (Last accessed on 12th September 2005).

3.3.1 Embryonic Stem Cells

Embryonic stem cells are the unspecialised cells that form the basic building blocks for all of the 220 specialized cell types in the human body. The primary sources for embryonic stem cells are aborted fetuses and donated and unused embryos that are created with sperm and egg and which are housed in vitro fertilization (IVF) facilities. These embryos are housed in these facilities to aid in research but more importantly are used to enable women who cannot, for one reason or another, conceive in the natural way. When a woman undergoes in-vitro fertilization, she is given medication that causes her to produce perhaps two dozen mature ova. These are then fertilized, usually by sperm provided by her husband. Two to five days after fertilization, two to four embryos are implanted in the woman's womb. Hopefully, this implanted embryo will then develop into a normal foetus and after nine months, a normal baby will be born!⁹⁵

The rest of the embryos are deep frozen in liquid nitrogen for potential future use. These are sometimes called "pre-embryos." They are smaller than a pinprick and consist of a number of identical, undifferentiated cells.

Researchers remove some of these embryos from liquid nitrogen storage, thaw them out, and allow them to mature to the blastocyst stage (the embryo when about three to four days old). This consists of a collection of 100 to 300 undifferentiated cells (that is they have not become specialized in any way, such as a mouth, arm or leg). The stem cells (which are the inner mass of the cells) are extracted and treated with chemicals to become specialized cell types, killing the embryo in the process. The stem cells are then used to treat the patient's disease or replace dying tissue.⁹⁶

⁹⁵ Kenya Medical Research Institute (KEMRI) is currently researching on this method of conception.

⁹⁶ Stem Cell Research Foundation, at <http://www.stemcellresearchfoundation.org/resources/resources.htm> (Last accessed on 12th September 2005).

It is argued by stem cell researchers that cells removed from embryos have two extremely valuable properties:

First is that they can divide for long periods of time in the laboratory to produce more stem cells.

Secondly, they can transform themselves into any of the cells present in the human body (for example skin cells, liver cells, heart cells, and so on).

3.3.2 The outer lining of the umbilical cord (Neo Natal Cord Blood Cells)

In July 2005⁹⁷, the Cell Research Corporation in Singapore and its team of scientists, headed by Chief Scientist, Dr Phan Toan Thang, discovered that the outer lining of the umbilical cord is a rich source of stem cells. Cell Research Corporation has successfully differentiated these stem cells that are found in the outer amniotic lining of the umbilical cord into specific cells such as skin, bone, and fat. The potential to form other cell types from these cord-lining stem cells is phenomenal and best of all, they are acquired from the afterbirth (placenta) that is plentiful and routinely discarded.

Another company in the United States-Thermo Genesis- has researched extensively on neonatal cord blood stem cells. This is because although they have similarities with embryonic and adult stem cells, they have some dramatic advantages. Like embryonic stem cells, they can become several-and perhaps all-the different tissue types; unlike both embryonic and adult stem cells, their harvest results in no donor risk; they have the capacity for many cell divisions; and they cause less “graft versus host disease”, a medical condition in which the donor cells attack the tissues of the patient’s body.

⁹⁷ Stem Cell Research Foundation at <http://www.stemcellresearchfoundation.org/resources/resources.htm> (Last accessed on 12th September 2005).

Philip H Coelho, one of the owners of Thermo Genesis,⁹⁸ stated:

“The first patient to be treated with cord blood stem cells in 1988 today shows no evidence of the Fanconi Anemia that he suffered from as a child. When he was diagnosed, there was no bone marrow match, which is not unusual. Luckily, in his case, there was a match using the cord blood stem cells from his mother’s later pregnancy. So far, more than 6,000 patients and 66 diseases have been successfully treated with neonatal cord blood stem cells. CBS recently reported on a case in South Korea in which a woman who had been paralysed for 20 years was able to take a few steps after being treated with stem cells from an umbilical cord injected directly into her spine.”

Dr. Brent Davidson⁹⁹ commented:

“Thousands of families have banked stem cells from umbilical cord blood in the United States. While considerably more work is required, I believe that the demonstration that these cells using the non-controversial umbilical cord blood stem cells are able to differentiate into a broad range of tissues could prove to be a significant scientific advance. I am particularly encouraged that these results provide proof of principle for use in many common illnesses possibly affecting a large portion of the population.”¹⁰⁰

3.3.3 Spleen¹⁰¹

In 2004, researchers at the Massachusetts General Hospital discovered that the spleen might be a source of adult stem cells that could regenerate the insulin-producing islets of the pancreas. Members of the same team also reported that these potential adult stem cells produce a protein previously believed to be present only during the embryonic development of mammals.

The finding both supports the existence of these splenic stem cells and also suggests they may be able to produce an even greater variety of tissues.

⁹⁸ In a lecture organized by the Heritage Foundation, “Federal Stem Cell Research: What the Tax Payers should know” held in June 2005. His presentation is available at <http://www.heritage.org/Research/Healthcare/wm749.cfm>. (Last accessed on 12th September 2005).

⁹⁹ Division head of Obstetrics and Gynaecology at the Henry Ford Health System.

¹⁰⁰ Ulysess K. K Justin, “Embryonic Stem Cell Patenting, the EU, Kenya and the USA” pp 205.

¹⁰¹ Stem Cell Research Foundation, at <http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th September 2005).

Denise Faustman, the director of the Massachusetts General Hospital Immunobiology Laboratory has said:

"There may be a previously undiscovered pocket of primitive stem cells in the spleen that are important for healing several types of damage or injury. If so, these cells could have much broader therapeutic applications than suggested by our earlier work. We know that if you have a major loss of blood, the spleen is turned on to supplement the bone marrow in replenishing your blood supply. We may find that the spleen kicks in to help with many more biological emergencies. What has been considered a practically unnecessary organ may actually provide critical healing cells"¹⁰²

4 The Nose

In March 2005, Griffith University¹⁰³ researchers¹⁰⁴ claimed to have successfully grown adult stem cells harvested from the olfactory mucosa, the organ of smell in the human nose. They demonstrated the cells could give rise not only to nerve cells but also to heart, liver, kidney, and muscle cells. The research team, led by Professor Alan Mackay-Sim, Deputy Director of the university's Institute for Cell and Molecular Therapies, has spent the past four years developing the research that will have potential clinical application in stem cell transplantation therapies and in understanding the biology of diseases.

Professor Mackay-Sim said the discoveries highlighted significant advantages of these adult stem cells over embryonic stem cells. Professor Mackay-Sim said:

"Our experiments have shown adult stem cells isolated from the olfactory mucosa have the ability to develop into many different cell types if they are given the right chemical or cellular environment. These adult olfactory stem cells appear to have the same ability as embryonic stem cells in giving rise to many different cell types but

¹⁰² Stem Cell Research Foundation, at
<http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th
September 2005).

¹⁰³ In the United States.

¹⁰⁴ Stem Cell Research Foundation, at
<http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th
September 2005).

have the advantage that they can be obtained from all individuals, even older people who might be most in need of stem cell therapies.

He continues:

Stem cells obtained from and transplanted into the same person would not be rejected by the immune system. Another advantage of adult olfactory stem cells is they are readily obtained from the nose and relatively easy to grow and multiply in the lab. In a few weeks we can make plenty of cells for transplantation or for studying their biology. We can get them from people with diseases and study the biology of those diseases as they affect the stem cells or the differentiated cells derived from them.”¹⁰⁵

3.3.5 Human Skin

Researchers at “The Hospital for Sick Children” in Toronto, Canada, in November 2004 showed that stem cells found in adult skin retain their embryonic capability of making many types of cells.¹⁰⁶

Dr. Freda Miller¹⁰⁷, the study’s principal investigator said:

“We think these stem cells are actually embryonic cells that go out into the skin during development and then stay in reservoirs in hair follicles. These stem cells are similar to a type of embryonic stem cell called a neural crest stem cell, and like neural crest stem cells, are endogenous and multipotent in nature. These neural crest stem cells generate the peripheral nervous system, and we are therefore now confident that we can make neural and other types of cells from the stem cells found in adult skin.”¹⁰⁸

¹⁰⁵ Stem Cell Research Foundation at
<http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th September 2005).

¹⁰⁶ Stem Cell Research Foundation, at
<http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th September 2005).

¹⁰⁷ A senior scientist in Developmental Biology in the Sick Kids Research Institute and a professor of Molecular and Medical Genetics and Physiology at the University of Toronto. She is also the Canada Research Chair in Developmental Neurobiology.

¹⁰⁸ Stem Cell Research Foundation, at
<http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th September 2005).

Thereafter, in June 2005, Researchers at Wake Forest University School of Medicine in the United States successfully isolated stem cells from human skin, expanded them in the laboratory and coaxed them into becoming fat, muscle and bone cells. Anthony Atala¹⁰⁹, who was the senior researcher on the project said:

"These cells should provide a valuable resource for tissue repair and for organs as well because these cells are taken from a patient's own skin; there would not be problems with organ or tissue rejection."¹¹⁰

3.4 Debates on Stem Cell Research

There is currently a lot of debate about stem cell research. The debate is two pronged: First is which cells should be used for stem cell research and treatment.

Secondly is whether the results of such research should be patented.

In this section, I shall deal with the first of these arguments, that is, what is the most appropriate source of stem cells, both for research and eventually treatment.

The next Chapter shall deal with the patentability of this research.

3.4.1 Arguments against using embryonic tissue as a source of stem cells

3.4.1.1 The embryo is a human being and should therefore not be used for research.

This argument has been propagated mostly by the church. The Catholic Church has been especially vocal on this issue stating their position that the embryo is a human being, although not fully developed. And as such, they state that the embryo should not be destroyed, whether for research purposes or treatment.

The late Pope John Paul II in his 1995 encyclical *The Gospel of Life* wrote:

"Human embryos obtained in vitro are human beings and are subjects with rights; their dignity and right to life must be respected from the first moment of their existence. It is immoral to produce human embryos destined to be exploited as disposable 'biological material'."¹¹¹

¹⁰⁹ The Director of the Wake Forest Institute for Regenerative Medicine.

¹¹⁰ Stem Cell Research Foundation, at <http://www.stemcellresearchfoundation.org/resources/resources.htm>. (Last accessed on 12th September 2005).

¹¹¹ Professor Thomas A. Shannon "Stem Cell Research-How Ethics Guide Us" at <http://www.amaricancatholic.org/Newsletters/cu/Archive.asp>, (Last accessed on 12th September 2005).

Their position has been that if stem cell research has to be done, then there are other sources of stem cells, from adults or from the umbilical cord of a child that has been born. The Catholic Church has no objection to research using these sources of stem cells. They state that since these other sources are extremely viable and produce good sources of stem cells then the human embryo *should not be used as a source of stem cells for research or even treatment.*¹¹²

Dr. Kelly Holloway¹¹³, who is a molecular and cellular pharmacologist and Patent Attorney, opined thus:

"Today's medical technology enables us to affirm what we have known for decades: that life does begin at conception. From conception, we are biologically alive. We are genetically human, we are genetically distinct, and we are sexually distinct ..."

A disabled woman at a Congressional hearing in the United States said thus:

"Do I want to see again? Dance again? Hear like I once did? I do not want those things at the cost of any living person and I consider live embryos to be people."¹¹⁴

It is thus argued that while a lot of good may come from such research, the end does not justify the means. Curing of thousands of people does not justify the destruction of others, even though they are just at the embryonic stage of development.

¹¹² Emphasis mine.

¹¹³ During a conference sponsored by the Heritage foundation-"Federal Stem Cell Research: What the Tax Payers should know" {held in June 2005. She is a molecular and cellular pharmacologist and Patent attorney in the United States, as well as the senior strategist at the Centre for Reclaiming America and a founder of Science Ministries, Inc. Her presentation is available} at <http://www.heritage.org/Research/Healthcare/wm749.cfm> (Last accessed on 12th September 2005).

¹¹⁴ B. A. Robinson, "Stem Cell Research" at <http://www.religioustolerance.org/emb-rese.htm>. (Last accessed on 12th September 2005).

3.4.1.2 Abortion and commercial exploitation of women

Closely related to the first argument is that stem cell research will encourage abortion. This is because embryos will stop being seen as human beings, but rather as objects of research, a mass of cells with no identity. In this context, Professor Thomas A. Shannon¹¹⁵ stated:

"A moral theologian whom I consulted said that opposition to federal funding on stem cells from embryos created expressly for this purpose also reflects fear that such approval may lead to direct federal funding for abortion... because this authorization could be used as an argument that embryos are not human persons."

Because there will be insufficient embryos obtained for the purpose of in vitro fertilization (IVF), women will be asked to volunteer their bodies to be used for mass production of embryos. This is possible by injecting a hormone into the body of a woman so that her body will release more ova that will then be extracted from her body.

Unfortunately, it is not the rich but the poor women in society who will volunteer themselves for such purposes. Dr Kelly Hollowell¹¹⁶ said:

"More important than the dollars and the difficulty associated with therapeutic cloning is that the process of harvesting a woman's eggs for stem cells places a woman at risk. Specifically, super ovulation regimens for fertility treatments would be used to obtain women's eggs. The risks associated with high-dose hormone therapy are debated, but there is a growing body of evidence that these practices, when used for standard IVF (in vitro fertilization), can cause various problems. These problems include memory loss, seizure, bone loss, lupus, joint pain, baldness, stroke, brain damage, infertility, cancer, and death. And this is under the conditions of IVF, not under the conditions for which we would need to produce eggs in large quantities for research purposes."

¹¹⁵ Professor Thomas A. Shannon, "Stem Cell Research-How Ethics Guide Us" at <http://www.americancatholic.org/Newsletters/cu/Archive.asp>. (Last accessed on 12th September 2005).

¹¹⁶ In a lecture organized by the Heritage foundation, "Federal Stem Cell Research: What the Tax Payers should know" held in June 2005. She is a molecular and cellular pharmacologist and Patent attorney in the United States, as well as the senior strategist at the Centre for Reclaiming America and a founder of Science Ministries, Inc. Her presentation is available at <http://www.heritage.org/Research/Healthcare/wm749.cfm>. (Last accessed on 12th September 2005).

3.4.1.3 Cost of extraction of embryonic Stem Cells, and the resultant high costs of treatment

It has been argued that while embryonic stem cells are extremely beneficial for treatment, it is very expensive to extract them.

Dr. Kelly Holloway¹¹⁷ states:

“...Specifically, the process requires women’s eggs. To treat, for example, only the 17 million diabetes patients in the United States would require a minimum of 850 million to 1.7 billion human eggs. You can literally envision women becoming egg factories. Collecting 10 eggs per donor will require a minimum of 85 million to 170 million women, and the total cost would be astronomical, at \$100,000– \$200,000 for 50 to 100 human eggs per each patient.”

In Kenya, there is little publicly available information on embryonic stem cell research, but for purposes of illustration of the costs that may be involved, we may use in vitro fertilization treatment. It was reported by KEMRI¹¹⁸ when it first began to offer the treatment that the whole process of in vitro fertilization, from initial screening, medical care, all the way to delivery of a baby or babies will cost approximately Kshs. 400,000.00. However, incase the first attempt is not successful, repeating the process will cost Kshs. 70,000.00. These high costs clearly marginalise the poor, and treatment using embryonic stem cells may have the same effect!

3.4.1.4 Safety of treatment using embryonic stem cells

It has been argued that it is wrong to use embryonic stem cells because they tend to produce tumours, they cause transplant rejection, and they sometimes form the wrong kind of cells.

¹¹⁷ In a lecture organized by the Heritage foundation, *Op. Cit.*

¹¹⁸ Kenya Medical Research Institute.

Dr Kelly Holloway¹¹⁹ states:

“After 20 years of research, embryonic stem cells haven’t been used to treat people because the cells are unproven and unsafe. It will be a minimum of 10 years before treatments *might* be available, and that is a very optimistic prediction.”

Philip H. Coelho¹²⁰ also opines thus:

“Embryonic stem cell lines are notoriously hard to obtain and maintain and it has been reported that they have triggered malignant carcinomas in animals. Knowledgeable researchers are cautious about expecting any clinical trials using embryonic stem cells in the near term.”

Others have argued that embryos are not human beings, and as such it is not wrong to use them for stem cell research and development. They argue that embryos are just undifferentiated cells. This line of argument goes to the heart of the debate on when life begins, and as a consequence whether abortion should be legalized, an area that is beyond the ambit of this paper.

3.4.2 Reasons for use of embryonic stem cells

The main reasons for the use of embryonic stem cells are that

1. They can divide for long periods of time in the laboratory to produce more stem cells.
2. Secondly, that they can transform themselves into any of the cells present in the human body (e.g. skin cells, liver cells, heart cells, and so on).
3. Thirdly, it is believed by some that life does not begin until the live birth of a child.

¹¹⁹ In a lecture organized by the Heritage foundation, “Federal Stem Cell Research: What the Tax Payers should know” held in June 2005. She is a molecular and cellular pharmacologist and Patent attorney in the United States, as well as the senior strategist at the Centre for Reclaiming America and a founder of Science Ministries, Inc. Her presentation is available at <http://www.heritage.org/Research/Healthcare/wm749.cfm> (Last accessed on 12th September 2005).

¹²⁰ In a lecture organized by the Heritage foundation, “Federal Stem Cell Research: What the Tax Payers should know” held in June 2005. His presentation is available at <http://www.heritage.org/Research/Healthcare/wm749.cfm>. (Last accessed on 12th September 2005).

In *Dietrich v. Inhabitants of Northampton*¹²¹, the Massachusetts Supreme Court reviewed a lower court decision regarding a fatal injury to a foetus: a woman who was four to five months pregnant fell on a defective road in the town of Northampton. The fall had precipitated the miscarriage. The Court noted that no court had ever permitted an action to be maintained by an infant who experienced injuries in his mother's womb and that the foetus, being an appendage of the mother, had no locus standi to sue. The Court argued that at the time of the injury, the foetus was part of the mother, and therefore the mother could recover injuries for the foetus.

In *Roe v. Wade*,¹²² Jane Roe, a single woman in the Texas County, instituted a federal action in March 1970 seeking a declaratory injunction that the Texan Criminal Abortion Statutes were unconstitutional. The Court held that those statutes were indeed unconstitutional, and abortion was hence legalized. The court noted that there has always been strong support for the view that life does not begin until live birth. The decision of the court in this case was based in part on the fact that the unborn have never been accorded recognition as a full legal person.

In *Re Estate of the late K: Ex parte the Public Trustee*,¹²³ the issue was whether two embryos were indeed human beings for the purposes of succession. The Court held that the common law has refused to confer legal rights upon a human embryo unless and until it is born having a separate

¹²¹ 138 Mass. 14 (1884); Ulysess K. K Justin, "Embryonic Stem Cell Patenting, the EU, Kenya and the USA" pp 171.

¹²² 410 US 113 (1973); Ulysess K. K Justin, "Embryonic Stem Cell Patenting, the EU, Kenya and the USA" pp 124.

¹²³ (1996) 5 Tas R 365 at 373; Ulysess K. K Justin, "Embryonic Stem Cell Patenting, the EU, Kenya and the USA" pp 176.

existence from its mother, and therefore has contingent or potential legal rights which vests and become enforceable upon its live birth.

It is therefore the belief of many that since a foetus is not a human being, then an embryo cannot be one either.

3.5 Stem Cell Research in Kenya

3.5.1 In Vitro Fertilization

There is a lot of research being conducted on in vitro fertilization (IVF). As discussed earlier, in vitro fertilization is a procedure whereby eggs are taken from a woman, fertilized in the laboratory using her partner's sperm, with the resulting embryos being transferred back to her uterus, two to five days later. This transfer is to help the embryo to develop normally. The technique is usually used to treat both women and men who are infertile. But it is normally the treatment of choice for a woman with blocked fallopian tubes, the avenue through which the egg travels from the ovary to the uterus. The first IVF baby, Louisa Brown, was born in July 1978 in England¹²⁴.

It was reported by Charles Njeru¹²⁵ that Kenya may soon celebrate her first test tube baby. He reported that according to information received from Dr. Joshua Noreh, who is the gynaecologist in charge of the first test tube baby clinic, of the women receiving the treatment, one of them has reached her seventh month in her pregnancy in October.

The remaining eggs that are not used for fertilization in the countries where stem cell research is being conducted are the ones that would be used to conduct embryonic stem cell research if it had began in Kenya.

¹²⁴ Gatonye Gathura and Obote Akoko, The Sunday Standard, October 12th 2003.

¹²⁵ Charles Njeru, "Kenya's first test-tube baby still on course", at <http://www.allAfrica.com/stories/200509210729.html>. (Last accessed on 28th October 2005).

3.5.2 KEMRI

There is currently no documented stem cell research being carried out in Kenya. According to Dr. Solomon S. R Mpoke,¹²⁶ KEMRI is still at the proposal stage. He however believes that it is an area of great potential. In his estimation, stem cell research in Kenya may begin in the next year, once KEMRI obtains approval and funding from the Government.

3.5.3 The Embryonic Stem Cell Bill for Kenya

Ulysess K. K Justin¹²⁷ has done a lot of research on stem cells, and especially embryonic stem cell research in various jurisdictions. He has published a draft Bill, the *Embryonic Stem Cell Bill for Kenya*, in which he proposes or suggests rules relating to the use of Gametes and embryos. He calls the Act *The Gametes and Embryos Act* whose purpose, if passed by Parliament, will be:

“ An Act of parliament to make provision for the promotion of medical advances in connection with human embryos and any subsequent development of such embryos; to increasing knowledge about the creation and development of embryos; or about disease, or enable such knowledge to be applied; to facilitating such knowledge through the grant and regulation of patents and for connected purposes.”

The main provisions of the Bill are:

- i. The object of the Bill is provided for in Section 8, which is to address concerns, including the increase of knowledge about the creation and development of embryos, or about serious disease, or enable such knowledge to be applied in the treatment of infertility, increasing knowledge of congenital diseases, miscarriage, more effective methods of contraception, knowledge about the development of the embryo; and enabling such knowledge to be applied in developing treatment for serious disease.
- ii. In Section 6, the Bill provides for the patentability of inventions containing biological material or a process by means of which

¹²⁶ A researcher at KEMRI, *Op. Cit.*

biological material is produced, processed or used, provided they meet the three basic requirements of novelty, involve an inventive step and are industrially applicable.

- iii. In Section 9, the Bill provides for the use of excess embryos removed from an adult's body to be used for someone else's pregnancy, for culturing of embryonic stem cells, and for the performance of scientific research.
- iv. Section 10 provides for the establishment of the Kenyan Medical Association Research Council Embryo Research Licensing Committee whose main functions are licensing as provided under the Act and to review information about embryos. The Section also enumerates the membership of the Committee.
- v. The Bill also provides for the licensing system, enumerates rules governing scientific research with embryos outside the human body, prohibited use of Embryos and gametes outside the human body, and also for various offences.

The Bill was published in 2005 and also has an explanatory memorandum where he explains what Stem Cell research is, as well as the various sources of stem cells (both adult sources and embryonic stem cells as discussed in this chapter), and their advantages and disadvantages.

He explains in great detail the value of the embryo in stem cell research, and the various moral, religious and ethical concerns raised by various people and organizations. Once presented to members of parliament (if at all), then this nation will be one step in the right direction-towards enacting an Act of Parliament that will provide for stem cell research.

¹²⁷ A lawyer in Kenya, and the drafter of the Embryonic Stem Cell Bill for Kenya.

3.5.4 Critique of the Embryonic Stem Cell Bill

In my opinion, members of Parliament should not pass this Bill in its current form. The regulatory structures (the Kenya Medical Association Research Council Licensing Committee) are acceptable, but embryonic stem cell research and hence its licensing under the Act, in my view, is not acceptable. I believe that life begins at conception, and embryos are therefore living beings that deserve protection, just like infants, from the legislature.

In *Davis v. Davis*¹²⁸, a divorce suit involved the battle for disposition of seven frozen embryos of a couple that had attempted to bear a child through in vitro fertilization. In answering the question when human life begins, the court concluded that it was at the point of conception.

The United Nations Resolution A-RES-37-7¹²⁹ states:

“Every form of life is unique, warranting respect regardless of its worth to man, and, to accord other organisms such recognition, man must be guided by a moral code of action.”

The Resolution is a plea that life forms, other than those falling within the traditional concept of human, are worthy of moral status.

The Bill should therefore be amended to provide for stem cell research using the various other sources described above.

3.6 Conclusion

As discussed above, there is a lot of excitement in the medical field because of the discovery of stem cells that can be used to treat a number of diseases. The next chapter shall discuss stem cells in relation to patentability, that is, whether the results of stem cells should be patented in Kenya.

¹²⁸ Tenn. 1992 842 S.W 2d 588,597; Ulysess K. K Justin, “Embryonic Stem Cell Patenting, the EU, Kenya and the USA,” pp 178.

¹²⁹ World Charter for Nature, adopted on the 28th of October 1982, as quoted by Ulysess K. K Justin, “Embryonic Stem Cell Patenting, the EU, Kenya and the USA” pp186.

CHAPTER FOUR

PATENTABILITY OF THE RESULTS OF STEM CELL RESEARCH

4.1 Introduction

This being the last Chapter, I shall delve into the debate on whether the results of stem cell research should be patentable. Various arguments have been raised, both for and against it, which I shall discuss. I am of the opinion that they should be patented, subject to some legislative regulation, and I shall therefore give recommendations on the regulatory mechanisms.

4.2 Reasons why the results of stem cell research should not be patented

In this segment, I will enumerate reasons against the patenting of the results of stem cell research. In the next one, I will present reasons why patents should be granted, despite the reasons enumerated below.

4.2.1 The patents will raise the costs of treatments, and therefore less accessible

The biotechnology industry claims that patents are necessary so that innovative, life-saving treatments will be developed. In reality however, patents will grant exclusive or monopolistic rights to the patentee. Thus, in order for the methods of treatment to be available to others, they will have to pay royalties. The costs of treatments will thus be even higher than they are already. I am of the opinion that the result of granting such patents will, in effect, be a way of shutting out millions of people, who, although in need of the treatment will not be able to afford it. Any treatment using stem cells will be for the rich. This is morally and ethically wrong.

In Kenya for example, cost of IVF treatment for people in Kenya has been estimated at \$5,000 US.¹³⁰ This can be used as an indicator of how expensive treatment using stem cell research would be.

In June 2001 Myriad Genetics Laboratories in Ontario, Canada, declared that hospitals in several provinces were violating its patent on a test of genetic susceptibility to breast cancer. Myriad demanded that all testing be conducted in its laboratory in the United States at a cost of about US\$2500, almost 5 times what is currently being charged. However, other provinces either stopped using the test or quietly went on as usual. In September 2001 the Ontario government announced that it would challenge private companies' rights to patent genes and to control, and profit from, diagnostic and medical treatments using the patent.¹³¹

4.2.2 Commoditification of the human body¹³²

There are fears that patenting of the results of stem cell research will eventually lead to the commoditification of the human being. Human beings may lose rights to parts of their bodies in favour of a research institution.

For example, in *Moore v. Regents of University of California*¹³³ 1976 a leukaemia patient named John Moore¹³⁴ had surgery at the University of California to remove his cancerous spleen. The University was later granted a patent for a cell line called "Mo," removed from the spleen, which could be used for producing valuable proteins.

¹³⁰ Anglican Church, (2003) "In vitro fertilization" at <http://www.anglicanjournal.com/129/10/world09.html>. (Last accessed on 11th October 2005).

¹³¹ Donald J. Williamson and Stuart M. Macleod, "Patenting of genetic material: Are the benefits to society being realized?" At <http://www.cmaj.ca/cgi/content/full/167/3/259>. (Last accessed on 22nd September 2005).

¹³² Eric Beresford, "Patenting Life a Dangerous Step" at <http://www.organicconsumers.org/> (Last accessed on 12th September 2005).

¹³³ 793 P. 2d 479 (Cal. 1990) cert. Denied 111 S. Ct. 1388.

¹³⁴ Council for Responsible Genetics, "DNA Patents Create Monopolies on Living Organisms" at <http://www.actionbioscience.org>. (Last accessed on 12th September 2005).

The long-term commercial value of the cell line was estimated at over one billion dollars. Mr. Moore demanded the return of the cells and control over his body parts, but the California Supreme Court decided that he was not entitled to any rights to his own cells after they had been removed from his body.

If ownership has been granted to strains of genes, then this trend will continue, even to the entire body of a human being.¹³⁵ Scientists may one day be able to "create" a human being, just like they were able to clone the famous sheep "dolly". The problem is that because that individual will be the result of the inventiveness of a scientist, the scientist will be vested with ownership. In my opinion, the individual will thus be a slave of its creator, having no constitutional protection, as they are not really a human being-a product of nature, but are the product of a laboratory.

4.2.3 The duration is too long

The Industrial Property Act 2001, as well as the TRIPs Agreement on Intellectual Property, provides that once a patentee has been granted a patent, then he will be protected for 20 years. I believe that patents should be granted for stem cell research. On the other hand, however, I am concerned that the period of protection of a patent is too long. If the goal and purpose of stem cell research is to get methods of treatment for diseases is the treatment of diseases that have defied other conventional treatments, then to provide protection for 20 years (minimum) is way too long. For this reason, I believe that patents should not be granted for the results of stem cell research.

4.2.4 Common good of humanity

If the purpose of stem cell research is to alleviate human suffering, then such research should not be patentable. Infact, it should be free for use by any hospital in the world

¹³⁵Ted Peters "Patenting Life: Yes" at <http://www.firstthings.com/index.html>. (Last visited on 12th September 2005).

for the treatment of their patients. A doctor is a professional, whose primary purpose and goal should always be trying to heal the human body and not make money.

4.3 Reasons for patenting the results of stem cell research

4.3.1 Medical purposes

The most compelling reason in my view why bio patenting should continue with regard to stem cell research is that it offers hope for the treatment of many diseases. Scientists are finding treatments for diseases in genetic structures of many organisms. Thus, it is to the advantage of humanity that bio patenting is continued. Many research companies (for example, the lawyers for Harvard University, when arguing for the grant of patent for the oncomouse, in the *Harvard Mouse Case*¹³⁶ stated that researchers need to be assured of a financial reward for their work, thus promoting medically beneficial research) undertake research projects because they believe that should they will produce a genetic strain that meets the requirements for patentability, that such results shall be patented and they will be able to exploit the patent for their financial benefit.

Thus, it would be to the benefit of mankind that bio patenting should continue. Scientists, with the motivation of the possibility of a grant of a patent, will continue research for the cure of many diseases. Thus patients with cancer, Alzheimer's, and other debilitating diseases may one day get a cure.

As earlier discussed in Chapter 3, stem cells can be used to develop any of the 220 cells in the human body. Today, the medical field, many potential organs that have been donated for transplants are being rejected because of the presence of the HIV/AIDS virus. Others are rejected due to incompatibility between the organ of the donor and the donee. Stem cell research is a possible way out. By using the stem cells

¹³⁶ [1990] O.J. E.P.O 476, Tech Bd App [1991] E.P.O.R. 525 as reported in Doris Estelle Long and Anthony D'Amato (2000) *A Course Book on Intellectual Property Law* American Casebook Series, Minnesota pp 192-194 (1st Edition).

of either the patient or a donor, it may be possible to develop or “grow” the requisite organs, and thus the standard of life of such patients will be greatly enhanced.¹³⁷

4.3.2 Financial gain

As discussed earlier in Chapter 2, there is great potential for financial gain, both for the individual inventor and the government. This is due to the exclusive rights of exploitation, manufacture and sale granted to a patentee for the period of 20 years. Although financial gain is not the primary consideration to promote research into stem cells, it is still a consideration non-the less, and should be taken into account.

4.4 Summary and Recommendations

In summary, the legislature should always take the following into consideration when dealing with stem cell research¹³⁸:

- a. Every human being, however conceived or created, is unique and deserving of protection.
- b. Every human being has the right to individual autonomy, that is, that his or her bodily integrity must not be invaded or compromised by others.
- c. No person or entity has the right to enslave, own, or control any human being, regardless of the stage of biological development.
- d. Any organism that is genetically human is a human being. Thus, an embryo is a human being, albeit not fully developed.

The following are my recommendations as regards stem cell research in Kenya.

1) Appropriate Source of the stem cells

As discussed earlier in Chapter 3, there has been a lot of acrimony and heated debate against the use of embryonic stem cells. Kenya is a moral and very spiritual country, and its people strongly believe in the sanctity of life. Sections 158- 160 of

¹³⁷ As discussed with Dr. Mpoke, a researcher at KEMRI, *Op. Cit.*

¹³⁸ Paige Cunningham. “The Right to Patent a Human Being: Fact, Fiction, or Future Possibility?” at <http://www.cbhd.org/resources>. (Last accessed on 12th September 2005).

the Penal Code¹³⁹ criminalize procuring abortions. Section 158 states that any person who assists a woman with child to procure an abortion is guilty of an offence. Section 159 of the Act provides that any woman who tries to procure an abortion is guilty of an offence, and Section 160 of the Act provides that any person who unlawfully supplies drugs or instruments to procure an abortion is guilty of an offence.

Section 71 of the current Constitution provides for the right to life. It provides:

“No person shall be deprived of his life intentionally...”

It does not however provide for where life begins. However, the Proposed New Constitution of Kenya¹⁴⁰, Article 35 provides thus:

“(1) Every person has the right to life except as may be provided for in an Act of Parliament.

(2) *The life of a person begins at conception.*

(3) Abortion is not permitted except as may be provided for in an Act of Parliament.”

The proposed new Constitution was drafted by the Constitution of Kenya Review Commissioners went round the country collecting the views of Kenyans on what they wanted the new Constitution to be like. The fact that Article 35 of the Proposed New Constitution is in the draft indicates that this position is what the majority of Kenyans wanted.

Many people will therefore be against embryonic stem cell research, because as discussed earlier, to extract the requisite cells the embryo will be destroyed, is destruction of life. The role of Government is the protection of human life and not its destruction. The right to life by each individual member of the society is clearly provided for under the Kenyan Constitution.

In *Yasmin v. Mohammed*¹⁴¹ the late Madan J discussed the function of the court to safeguard the interests of infants and the unborn.

¹³⁹ Chapter 63, Laws of Kenya.

¹⁴⁰ Kenya Gazette Supplement No. 63.

He said thus:

“This court is especially endowed with jurisdiction to safeguard the interests of the infants. The court is the parent of the infant...The welfare of the infant is paramount and is clear to the heart of the court....All infants fall within the ambit of the Guardianship of Infants Act and the court is charged with the sacred duty of ensuring that their interests remain paramount and are fully preserved.”

Stem Cell Research is a relatively new area in Kenya, as evidenced from the progress discussed in Chapter 3 on in vitro fertilization. As such, there has been no ruling from the courts on the legal status of the embryo. However, in my opinion, the court should accord the human embryo the same protection as an infant, and thus forbid the use of embryos in stem cell research.

Some scientists in developed countries, as discussed in Chapter 3, also argue that “the end justifies the means”, meaning that embryonic stem cell research should be continued and enhanced, as it is one of the areas with a lot of potential in finding treatment of human diseases. This however, as discussed in Chapter 3, is a very controversial debate.

In *The WARF Application*,¹⁴² WARF was responsible for developing the first technique to isolate human embryonic stem cells in 1984, and holds a Patent over the technology in a number of jurisdictions. The application concerned a claim disclosing the methods of preparing Embryonic Stem Cells from essential primate cells. It was accepted, but not demonstrated in the application that this method could enable the production of embryonic stem cells. Moreover, the sole method of production of the stem cell cultures that was described involved the use, and destruction of the embryos.

The Examining Division rejected all claims which could be extended to the human embryonic stem cells as invalid on the grounds of immorality. The main message of this ruling is that the moral concerns goes far beyond patenting itself. It implies that

¹⁴¹ (1973) EA 370, as quoted by Ulysess K.K Justin in his article on the Embryonic Stem Cell Bill for Kenya (Unpublished).

¹⁴² Ulysess K. K Justin, “Embryonic Stem Cell Patenting, the EU, Kenya and the USA” pp 37.

the mere use of embryos in the research and development of an invention is sufficient to bar the patentability of that invention. The Division pointed out in their ruling that embryonic stem cells derived from human embryos are not patentable.

This should be approach of the Kenyan courts and legislature.

Dr. Kelly Hollowell¹⁴³ said:

"Today's medical technology enables us to affirm what we have known for decades: that life does begin at conception. From conception, we are biologically alive. We are genetically human, we are genetically distinct, and we are sexually distinct."

Medicine has proved that an embryo is a human being. It may not be fully developed, but a living being non-the less. Therefore, use of embryonic stem cells should not only be highly discouraged, but infact criminalized with very heavy sanctions.

2) Compulsory Acquisition

Admittedly, costs of medical treatment may, and most probably will, rise. The costs that will result should not be a hindrance to medical care. The Government can compulsorily acquire such methods of treatment and provide the services at a cost that is affordable to her citizens. After all, one of the primary responsibilities of a government is to provide affordable health care for its citizens, and this is why Charity Ngilu, the minister for Health campaigned so hard for the passing of the National Social Health Insurance Fund Scheme Bill in 2003.

By using the taxes collected form the citizens, some of this money can be apportioned to the health sector so that this money offsets a certain amount of the medical fees. Individuals will thus be indirectly contributing to the provision of treatment of their sick neighbour.

¹⁴³ In a lecture organized by the Heritage foundation, "Federal Stem Cell Research: What the Tax Payers should know" held in June 2005. She is a molecular and cellular pharumatologist and Patent attorney in the United States, as well as the senior strategist at the Centre for Reclaiming America and a founder of Science Ministries, Inc. Her presentation is available at <http://www.heritage.org/Research/Healthcare/wm749.cfm>. (Last accessed on 12th September 2005).

3) Amendment of the Industrial Property Act, and enactment of a new Act

Section 21(3)(c) of the Industrial Property Act, 2001 provides that methods of treatment of the human body as well as diagnostic methods practised in relation with the same shall not be protected by the patent regime in Kenya.

This section can be interpreted in two ways in relation to the patentability of stem cell research. Firstly, it may be argued that both the method of extraction of the cells, as well as the final results of the cells are not patentable.

In the alternative, it may be argued that since the Act says “...methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised in relation thereto...” are not patentable under the Act, the Act may be said to disallow patentability of the stem cells once they have been extracted. The method of extraction may still be patentable.

Therefore, to avoid any doubts or confusion, the Industrial Property Act, 2001 should be amended to expressly allow for the patentability of the method of extraction of stem cells. Only the method of extracting the cells should be patented and not the final result (the stem cells).¹⁴⁴ Research aimed at obtaining and isolating elements valuable to medicinal production should be encouraged by the patent system.

To patent the final result (the extracted stem cells) would be disastrous to society, and especially the people of developing nations. This is because medical care would be unaffordable. Not only would they be forced to pay for the extraction of the cells, they would also have to pay for the final tissue that will have been developed for that particular disease. Not many hospitals would be able to afford to provide such medical services, and so treatment derived from the results of stem cell research would only be for the wealthy.

¹⁴⁴ A similar view is held by Henry Robertson, “Patenting Products of Nature” at <http://www.greens.org/s-r/index.html>. (Last accessed on 12th September 2005).

This position is supported in the case of *The New Zealand Leukaemia Patent Case*¹⁴⁵ where the question for determination was whether a patent may be granted for a method of treating of a disease or illness in human beings. The court held that it was unwilling to break new ground by granting such a patent. It was felt by the court that patenting of such methods was a matter that was best left in the hands of parliament.

In addition, as stem cell research is a complicated process requiring clear guidelines, it would be advisable to have a new Act of Parliament devoted entirely to stem cell research. Such an Act should set in place clear regulatory guidelines on which stem cells should be used. There is currently no act of Parliament dealing with the use of human tissues from living beings for research and therapeutic purposes. The Human Tissues Act¹⁴⁶ makes provision with respect to parts of bodies of deceased persons. There is therefore need for Parliament to enact another statute that will make provision for the use of tissues of living people.

4) Regulation of stem cell research

As stem cell research is a very specialized field even in the medical profession, a specific Board given the mandate to deal with stem cell research should regulate research into stem cells. Hence, before a patent is granted to an individual or organisation, the Board should approve it. Further, the investigative powers should be vested in the Board that is they should be charged with the responsibility of investigating cases of non-compliance with the regulations on stem cell research. KIPi,¹⁴⁷ should be vested with the powers of prosecution, that is, any cases of non-compliance should be reported to KIPi who will then begin prosecution proceedings against the infringer.

¹⁴⁵ In the Court of Appeal of New Zealand, 1982 (1983) FSR 593.

¹⁴⁶ Chapter 252, Laws of Kenya.

¹⁴⁷ Kenya Industrial Property Institute, established under section 3 of the Industrial Property Act.

5) Grant of funds

Research into other potential sources of stem cells should be encouraged. The Government should grant funds to institutions like the Kenya Medical Research Institute (KEMRI) to aid in research in the area of stem cells. Funds are necessary as extraction and experimentation of stem cells is an expensive venture.

6) Consultation with stake holders

Stem cell research is a new and undeveloped area in Kenya. Therefore, the Government should involve and consult all stake holders before embarking on the process. This will lead to its acceptability and reduce acrimony. This is very important, particularly if the Government decides to embark on embryonic stem cell research, where the Church is likely to be opposed.

While discussing Genetically Modified Organisms (GMOs)¹⁴⁸, Dr. Patricia Kamari-Mbote¹⁴⁹ said:

“Most governments are not consulting widely with stakeholders before accepting GMOs for agricultural purposes. Indeed in some countries the debate is still at the level of do we or do we not need biotechnology? This ignores the fact that there are already biotechnology activities ongoing in these countries”

4.5 Last Word

Although there is still a lot of research and experimenting that needs to be done before stem cells can be used in the treatment of human diseases, I believe that it is an area of great potential in curing many of the diseases that people are suffering from. The Government of Kenya should therefore fully support KEMRI once it begins research on stem cells. Many developed countries are benefiting a lot financially from

¹⁴⁸ Emmanuel Koro “Africa Lacks Adequate Expertise to tackle Bio Technology” at <http://www.Worldbank.org/devoutreach.winter01/document.asp>. (Last accessed on 28th October 2005).

¹⁴⁹ Then the deputy director for the African Centre for Technology Studies (ACTS) and lecturer at the University of Nairobi, faculty of Law in an interview in Kenya by Immanuel Koro, *Op. Cit.*

stem cell research. So should Kenya, and this can only happen if there is adequate and appropriate goodwill from the Government.

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