UNIVERSITY OF ZAMBIA
SCHOOL OF LAW

I recommend that the obligatory essay prepared under my supervision

By

Namangolwa Mateele

Entitled A CRITICAL ANALYSIS OF THE LEGAL IMPLICATIONS OF PATENTING BIOTECHNOLOGY

be accepted for examination. I have checked it carefully and I am satisfied that it fulfils the requirements relating to format as laid down in the regulations governing Obligatory essays.

.....
Mr.G.M.Kanja
(Supervisor)

24/11/03
.....
Date

Obligatory Essay

On

A Critical Analysis of the Legal Implications of Patenting Biotechnology

By

Namangolwa Mateele
(Computer No 97088064)

submitted to the university of Zambia in partial fulfilment of the requirements of the bachelor of laws (LLB) Degree programme

School of law
University of Zambia
Lusaka

November 2003

Dedication

In loving memory of my dearest mum.
You believed in me yet did not live long enough to see and cheer me through to the finish line.

ACKNOWLEDGMENTS

A work of this magnitude would not be complete without the support of friends and Family.

My list of thanks is in the following order.
First and foremost I would like to thank the almighty lord for seeing me through life this far.

My family for putting up with my academic life even at times when it was to their inconvenience. I thank you dad, Mum (late), Namonda, Tebuho, Mwangala for all your encouragement and support during my academic journey. I love you all.

Mr Kanja, my supervisor over this work. Sir with the help of your analytical mind, I have been able to put this paper in a professional standard. Thanks for your patience and tolerance.

Precious for that occasional noise during lectures, Harriet for those memorable times at the "neighbourhood", the "queens bench", Andrew, Iven, Eta for being such a darling by allowing me to use your PC and to all those whose names cannot be inscripted kindly feel free to fill up this space, its waiting for your pens.....

Table of Contents

Chapter four

Patent Scope Interpretation

Chapter five

Conclusion and Recommendations

That which has been is that which will be and that which has been done is that which will be done. So there is nothing new under the sun.

Ecclesiastes 1:11

CHAPTER ONE

1.0 GENERAL INTRODUCTION

In the world today, biotechnology stands out from any other field of technology. It is rapidly expanding, thus promising a great future for the well being of mankind. Hardly a day passes without reference to new developments in biotechnology[1] and most of these developments pose a great challenge to the patent process as they come with various legal implications.

The legality of changing the nature of plants, animals and human beings through biotechnology with respect to public order and morality has been emotionally disputed in many jurisdictions throughout the world. Generally there appears to be a contradiction between the industrial future significance of biotechnology and the public awareness accompanied with a strong debate against biotechnology.

Ever since the decision in **Diamond v Charkrabarty,** questions have been asked whether it is appropriate to extend the scope of patentability to 'everything under the sun made by man ', including human beings.[2]This decision led to the successful patenting of the cell line[3] of a Panama woman in 1995 by the U.S.patents office. Many questions have been asked whether or not it is

[1] Headline news such as 'Dolly the sheep', and also issue of GMO maize in Zambia in 2002.
[2] 206 U.S.P.Q.193 (U.S.1980.)
[3] A cell line is a group of cells taken from a human body that is capable of being sustained and grown in a laboratory culture media, and is therefore said to be 'immortal', a line of cells contains the complete genetic code, the genome of an individual.

be the subject of intellectual property. In particular biotechnological inventions demand intellectual property protection on the premise that they are 'novel' or even 'revolutionary'.

However it is the subject matter of biotechnology as complex as it is, that poses a great challenge to the patent system. it goes without saying that the patent system fuelled the growth of biotechnology industry but it has now come to be realised that this may not be the best means to sustain the growth. This is best demonstrated by the nature of biotechnology subject matter which sets it apart from other fields of technology.

The intellectual property regime is a means of acquiring ownership over a particular resource that is intangible in nature. It is a generic term that is used to designate the products or processes of human ingenuity or rather the subjective rights that the various legal orders grant to creators of intangible assets of intellectual origin. The system is more than ever important for the protection of intangible property especially in this day and age dubbed as the "age of intellect".

For purposes of this paper intellectual property rights will be described as the rights of exploitation in information. Information today has become a primary resource and it plays a vital role in the enhancement of economic and human life.[4] The control of non-information industries like agriculture and ownership of genetic information has become a major factor. Thus information can only be protected through the intellectual property regime

[4] Peter Drahos, "the Universality of Intellectual Property Rights: Origin and Development", in Intellectual Property and Human Rights.Geneva:WIPO & OHCHR,2000,p14

particularly under the patent system. The protection however does affect the interests that are subject of human rights claims.

Modern research and development involves a great deal of time and money. Parties investing in such research are looking to protect their investment. It takes 12 years to bring a new medicine on the market where average research costs over $300 million.[5] Such an effort can only be provided by industry once there is a certainty of a pay-off, where intellectual property protection through the patent system is the most obvious one. As a result of this the patent system has become important in the field of biotechnology.

A patent is a title conferred by the state that attests the grant of exclusive rights to the inventor for the exploitation of his invention. However in most jurisdictions contrary to the decision in **Diamond v Chakrabarty**, it is not "everything under the sun made by man" which is patentable. The patent system of Europe and America have shown inconsistencies when it comes to patentability of biotechnological inventions. The international patent convention, European patent convention (EPC) and national legislation are parallel. There is therefore a need to harmonise the patent systems and to come up with a general framework that shall address the legal problems of biotechnological inventions. This area shall be addressed in the recommendations in the final chapter.

It is therefore not surprising that the science that underpins the recent advances in biotechnology poses a series of problems for the existing system

[5] Nikolaus Thumm.Recent Developments with Intellectual Property Right Protection for Biotechnological Inventions-A Reflection on Spain, paper presented on 27th-29th may 2000.

of intellectual property protection. Concerns have been raised from all walks of life. In some cases these arguments are valid and are of real concern. According to Siddhartha biotechnology raises a series of questions and concerns relating to the consequences of releasing genetically modified organisms (GMOs) in the environment or to there potential effects on human health. Little is known about the behaviour of GMOs in the medium and long term. The risk posed by a particular biotechnological application is difficult to determine theoretically. It has to be determined empirically which takes time, and we are only at the beginning of these applications. [6]

However in most cases these concerns stem from a general misunderstanding of biotechnology and its potential applications, of the patent system and its limitations, and of other forms of legislation that control the use of this technology. There is increasing pressure to define the limits of available intellectual property rights concerning biotechnological inventions. What sort of protection should therefore be given to the fruits of extensive and often time consuming, costly research? Should ethical issues be dealt with by the patent system? How to encourage further research without at the same time discouraging further research.

Tensions contradictions and double standards between demand for the protection of intellectual property and that of regulation, as they are relevant to the nature of biotechnology and its impact on the environment and human society, obtain throughout the tortuous history of modern biotechnology.

---

[6] Siddhartha Prakash, "WTO Rules: Do they Conserve or Threaten Biodiversity?" The Journal of World Intellectual Property.Vol.3.No.1.Jan 2000

For the purposes of this paper, the legal issues raised will reviewed and analysed with a view to determining the scope of patentability. In chapter two, readers without any prior knowledge of biotechnology will find some useful background information on the meaning and applications of biotechnological inventions. This chapter will demonstrate that biotechnology is not a new technology as we have been made to believe but has existed with man in many different forms which are constantly being modified to meet the challenges of today. It shall also assert that caution must be duly exercised in allowing patents for biotechnology as there inherent impacts are not yet known.

The third chapter shall explore the legal avenue available for the protection of biotechnological inventions under the intellectual property regime notably, the patent system. It shall furthermore endeavour to assess arguments for and against the patenting of such products or processes of biotechnological inventions. The components that make up biotechnology subject matter shall be reviewed with the aim of assessing whether they fall under statutory subject matter and thereby patentable.

The fourth chapter will review the patent scope with respect to biotechnological inventions. Illustrations will be drawn from different jurisdictions to show how patent scope is interpreted and thereafter a conclusion shall be made pertaining to the extent of patent scope for biotechnological inventions. Whether it is the appropriate avenue for furthering growth of the industry with special attention to its subject matter.

Finally chapter five, which marks the peak of the paper, will make recommendations on how patent scope for biotechnological inventions must be interpreted. The paper generally takes a global comparative approach as the long term effects of products of biotechnological inventions transcend national boundaries. Every country must therefore become fully involved in this old but rapidly changing technology, which really represents the future.

CHAPTER TWO

2.0 NATURE AND MEANING OF BIOTECHNOLOGY

2.1 INTRODUCTION

The world of technology is no stranger to biotechnology. The production of beer and wine, which has existed side-by-side with man, involves a process using living organisms. However following its wider and revolutionary applications today, the term is viewed with ambivalent feelings of skepticism and curiosity. It has seized the imaginations of many and elicited concerns of virtually every fiber of society. Opinions about the nature, value, effects and utility have been put forth at various international fora and disagreements abound. Scientists and business executives view it as a significant leap into the future where diseases and hunger shall be a thing of the past. Political interest groups are questioning the longer-term effects of the application of biotechnology process and products to human and non-human, environment and communities. Non-specialists show a mixture of skepticism and curiosity about the motives of both research into biotechnology and its attendant industries.

2.2 WHAT IS BIOTECHNOLOGY

Biotechnology is a term that defies definition. Some of the various meanings attached to it by different scholars and scientists will be discussed hereunder. In general, this expansive field includes "many facets of medical research from drug discovery and design, to gene therapy and the diagnosis of genetic

diseases, to the use of **deoxyribonucleic acid (DNA)** evidence to identify individuals and genetic characteristics."

Technically, it has been defined as any technique that uses living cells, tissues, or genetic material to create, improve, or "develop micro-organisms for specific uses--including . . . techniques such as gene cloning and cell fusion."[7]

The **United Nations** defines biotechnology as, "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for living use." **University of Aukland professor Klaus Bosselmann** defines: Biotechnology can be defined as the creation of new varieties of plants, animals, and micro organism. In a sense, human kind has been modifying plants and animals for thousands of years, but the term 'biotechnology' has become popular with the rise of genetic engineering. Genetic engineering tends to be associated with that term, although there seems to be no reason why traditional selection methods used in plant and animal breeding should not also be regarded as biotechnology. According to **Lisa Conte, President and CEO of Shaman Pharmaceuticals, Biotechnology** "is fundamentally a technology that either improves on, or increases the quantity of natural products."

Biotechnology is the application of engineering and technological principles to living organisms or their components to produce new inventions or processes.

---

[7] Ivey, Laura, Development and commercialisation of Biotechnology," U. Pennsylvania Journal of International Business Law (1994): 299.

Reid Adler[8] defines biotechnology as "various genetic engineering techniques, developed during the past 20 years, which permit the controlled transfer of specific genes or groups of genes from one cell or genes or groups of genes from one cell of organism to another, thereby creating cells or organisms that would not likely occur in nature or through conventional breeding practices."

Biotechnology can be seen as encompassing all technology involving the processing of biological materials. Biotechnological inventions have already had a major impact on a number of industry including medical research, agriculture, animal production and health, dairy, beverages, food, and waste processing. The potential applications of biotechnology are very wide and new applications are constantly being developed. It is likely that in future, use of biotechnology innovations will be increasingly important to many sectors of industry in maintaining international competitiveness.[9]

2.3 BRIEF HISTORY

Karl Ereky, a Hungarian engineer, coined the term "biotechnology" in 1919.[10] At that time, the term meant all the lines of work by which products are produced from raw materials with the aid of living organisms. Ereky envisioned a biochemical age similar to the stone and iron ages.

---

[8] National Institute of Health U.S.A.www.nih.gov.org/ACCESSED TIME 9:45HRS 18TH September 2003

[9] Ann Murphy and Judy Perrella. Woodrow Wilson Foundation Biology Institute. "A Further Look at Biotechnology." Princeton, NJ: The Woodrow Wilson National Fellowship Foundation, 1993. p 2

[10] ibid p.3

Biotechnology is not new. Man has been manipulating living things to solve problems and improve his way of life for millennia. Early agriculture concentrated on producing food. Plants and animals were selectively bred, and micro organisms were used to make food items such as beverages, cheese, and bread.

The late eighteenth century and the beginning of the nineteenth century saw the advent of vaccinations, crop rotation involving leguminous crops, and animal drawn machinery. The end of the nineteenth century was a milestone of biology. Micro organisms were discovered, Mendel's work on genetics was accomplished, and institutes for investigating fermentation and other microbial processes were established by Koch, Pasteur, and Lister.[11]

Biotechnology at the beginning of the twentieth century began to bring industry and agriculture together. During World War I, fermentation processes were developed that produced acetone from starch and paint solvents for the rapidly growing automobile industry. Work in the 1930s was geared toward using surplus agricultural products to supply industry instead of imports or petrochemicals. The advent of World War II brought the manufacture of penicillin. The biotechnical focus moved to pharmaceuticals. The "cold war" years were dominated by work with micro organisms in preparation for biological warfare, as well as antibiotics and fermentation processes.[12]

---

[11] Michael Lane, Invention or Contrivance? Biotechnology, Intellectual property rights & Regulation. Paper prepared for the conference of the parties to the convention on Biological Diversity Jakarta,Indonesia,November 1995 UP-Dated EDITION(JANUARY 1996) p3 (www.charm.net/~gbarren/cv)

[12] Ibid p3

Biotechnology is currently being used in many areas including agriculture, remediation, food processing, and energy production. DNA fingerprinting is becoming a common practice in forensics. Similar techniques were used recently to identify the bones of the last Czar of Russia and several members of his family. Production of insulin and other medicines is accomplished through cloning of vectors that now carry the chosen gene. Immunoassays are used not only in medicine for drug level and pregnancy testing, but also by farmers to aid in detection of unsafe levels of pesticides, herbicides, and toxins on crops and in animal products. These assays also provide rapid field tests for industrial chemicals in ground water, sediment, and soil. In agriculture, genetic engineering is being used to produce plants that are resistant to insects, weeds, and plant diseases. [13]

New biotechnological techniques have permitted scientists to manipulate desired traits. Prior to the advancement of the methods of recombinant DNA, scientists were limited to the techniques of their time - cross-pollination, selective breeding, pesticides, and herbicides. Today's biotechnology has its "roots" in chemistry, physics, and biology. The explosion in techniques has resulted in three major branches of biotechnology: genetic engineering, diagnostic techniques, and cell/tissue techniques.[14]

2.4 APPLICATION OF BIOTECHNOLOGICAL INVENTIONS

Most third world countries are uniquely placed in a position to join the biotechnology world. Most of the resources used in biotechnology industry are

[13] ibid p3
[14] supra note 8,p6

found in third world countries and it is therefore imperative that they play a leading role in the regulation of this industry before they cry foul that is that the benefits are not accruing to them.[15] Third world countries are the hardest hit with disease, poverty, droughts and poor agricultural activities, which have contributed to the soaring poverty levels. This makes these countries to be in a state of crisis. High prevalence levels of diseases such as malaria and AIDS identify third world countries. All these do not have a cure. But there is a cure for starvation-food. Starvation is an unnecessary disgrace in our global society dubbed the 'age of technology'.

Biotechnology therefore offers an opportunity to enhance the food production of developing countries tropical countries in a safe clean and ecologically sound way. It will not solve the problems of world hunger but is a powerful tool in the struggle and thus a necessary tool. It offers advancements in the following areas.

In the field of biomedicine, biotechnology promises four major benefits: genetically engineered biochemical drugs, new vaccines, gene therapy, and quicker product development.[16]

There is an urgent need to keep horticultural production at par with a burgeoning world population. The requirement of fruits and vegetables is increasing and this has posed a great challenge for the conventional plant breeding technology. Hence an immediate need is felt to integrate biotechnology to speed up the crop improvement programmes.

---

[15] supra note 12, "Biotechnology Regulation in the third world" p 23

[16] Sukhada Mohandas, Applications of Biotechnology in Horticulture. Indian Institute of Horticultural Research article (www.fbae.org) ACCESSED TIME 15:00HRS 24TH August 2003

Biotechnology has revolutionised the entire plant-breeding programme by providing new strains of plants, planting material, more efficient and selective pesticides and improved fertilisers. Genetically modified fruits and vegetables have already found there way to markets in many countries which are still coming to grips with this new phenomenon of biotechnology which has been hailed as offering a great prospect for the future in terms of fighting hunger and disease.

The potential for economic growth and development in industries with applications in biotechnology such as the agriculture sector is considerable; with drought resistance high yielding maize varieties most families in third world countries will overcome their poverty. Most western countries, which had difficulties in growing winter crops, are now able to do so through the application of biotechnology products. [17]

In recent years biotechnology has created new vistas in the field of science and technology. The application of biotechnology in the field of environmental sciences has remained neglected till recently. First biotechnology is not a discipline but a field of activity in the environmental conservation, protection and above all application to ameliorate the dwindling scenario of natural resources. Secondly, genetic engineering per se is not a discipline but an exciting development, which will have an enormous impact on biotechnology. We have tried to draw attention to possible scientific

[17] John R.Rudolph, **A Study of the Issues Relating to the Patentability of Biotechnological Subject-matter.** A paper prepared for: Intellectual Property Policy Directorate Industry Canada January 31, 1996, p6 example he gave In Canada the anticipated winter wheat offers a number of advantages related to soil conservation, as well as drought and salination problems over spring wheat, which it would replace.

technological and also raise a number of environmental issues for further debate which are linked, directly or indirectly, with policies on environment.[18]

2.5 IMPACT OF BIOTECHNOLOGICAL INVENTIONS

As a powerful new technology, biotechnology carries with it a great substantial and unique threat to biological diversity, human health, communities and economies. Many researchers have detailed these threats and notably the European union is funding more research, and is quite sceptical about the use of biotechnology.

The new biotechnological processes, including genetic engineering, offer a vast spectrum of applications in agriculture and industrial production, but the social consequences of these technology-driven innovations will only be fully recognized over a period of years and decades. [19]

Genetically engineered crops are designed precisely for there ecological viability and therefore could invade various ecosystems; becoming destructive needs in various ecosystems.[20]These crops being created specifically to resist

---

[18]R.N.Trivedi. **Biotechnology and Environment** (Reprint). New Delhi, Anmol, 2002, viii, 204 p

[19] Achim Seiler (Germany) Biotechnology and Third World Countries: Economic, Interests, Technical Options and Socio-economic Impact.Profferred paper, ACCESSED 10:45 5th September 2003

[20] This was the fear in this country and hence a ground upon which turned donated as food aid by the US government. See also report of Zambian scientists who were sent to various countries to inquire into the implications of products of biotechnology.

certain pesticides and herbicides may in turn result in the pollutive use of these inputs as well as in excessive consumption of water.

Biotechnology raises a series of questions and concerns relating to the consequence of releasing GMOs into the environment or to there potential effects on human health. Little is known about the behaviour of GMOs in the medium or long term. The risk posed by a particular biotechnology application is difficult to determine theoretically. It has to be determined empirically which takes time and we are only at the beginning of these applications.

If not carefully used biotechnology applications will end up destroying our environment just as the 'Green revolution'. This time, though, the social impact will be even greater, notwithstanding the high potential for improving the situation of the poor which now is theoretically at hand in the form of the new techniques.

It is therefore against this background that strict regulatory measures are put in place and that a more cautious approach is adopted for patenting these inventions. The European standard in relation to patenting these inventions needs to be followed. The devastating effects of biotechnology will impact more on third world countries as they are said to be the world's centres of diversity.

As Achim puts it the main concern of the critics is therefore not initially the technology itself, notwithstanding the technical risks which do exist and are still not properly understood, but the inadequate transparency of the Research and development efforts of transactional companies and the strong trend towards the private appropriation of genetic starting materials and

shuttle techniques, under the control of those very enterprises on which the global markets for agricultural commodities will become dependent.

CONCLUSION

In view of what has been articulated in this chapter, it may be stressed that the field of biotechnology is a necessary evil. Its potential applications are very wide and it seems likely that in future use of biotechnology innovations will be increasingly important to many sectors of industry in maintaining industrial competitiveness. This therefore calls for a more stringent regulatory system that shall ensure that the processes and products do not fall into hands that might abuse them.

CHAPTER THREE

3.0 PROTECTION THROUGH THE PATENT SYSTEM

3.1 OVERVIEW OF THE PATENT SYSTEM

The law that governs innovations and which seeks to stimulate investments in the field of technology has in the recent past been extended to the field of biotechnology. Biotechnology innovations are subject to the same basic patent law and rules as other inventions.[21]The general policy behind most patent laws is to promote the progress of science by offering to investors limited monopolies over their inventions in exchange for public disclosure. According to Steve Price, "it is generally appreciated that some form of monopolistic control has been found necessary to propel western economic development for the last 200years.The development of an industrial society has coevolved with the development of the patent system". The first to invent is usually accorded this protection.

This however poses a great challenge to the patent system. According to a Franks and company report,[22] many of these laws were drafted before the foreseeable advent of biotechnology. As a result the system can be a little confusing in many jurisdictions such as Europe and African countries. However this problem will soon be a thing of the past with advances and improvements being made on a daily basis and this will accord an opportunity to extend the

[21] In the U.S.A, the protection arises from a constitutional guarantee, which states that congress shall have the power to promote the progress of science.

[22] Franks and Company, **Biotechnology-Extent of patent protection. Sheffield:** updated Monday, 17th February,2003.( )

available patent protection. The only exception would be the United States, which has opted for a wider construction of the patent laws.

A patent is a right granted to the inventor of a technological product or process that is new (or novel), useful (or is capable of industrial application) and involves an inventive step (non-obvious).[23]

Other authors such as Bainbridge describe a patent as a social contract between the state and an inventor whereby the later discloses his invention to the state and in return the state for its part assures him that no one shall use, manufacture, import or sell his invention without his permission. In other words he is granted an exclusionary right which if not properly used may result in a monopoly. Patents, which by definition reward inventors with monopoly rights in exchange for public disclosure of their inventions, harbour numerous tensions. For example, they encourage openness by granting exclusivity. They also create economic incentives for would-be innovators while generating new and often significant litigation and negotiating costs. Like all liberal economic policies, they strive, paradoxically, to attain a public benefit by encouraging private gain. [24]A patent is granted for a period of between 14 and twenty years depending on the jurisdiction under which it has been filed.

---

[23] Abbott et al. **The intellectual property: Commentary and Materials.**Hague:Kluwer law international,1999 P25

[24] Jonathan Kimmelman, Unlimited License: An Analysis of the Canadian Biotechnology Advisory Committee's Report on Patenting Higher Life Forms Canadian Centre for Policy Alternatives Accessed 12:02- 8/09/03

For an invention to be patentable, it must have;

(1) Patentable subject matter,

(2) Useful,

(3) Novel,

(4) Non-obvious, and

(5) Sufficiently enabled and described.[25]

These will now be looked at in detail as follows;

3.2 PATENTABLE SUBJECT MATTER

The first and foremost issue to be determined is whether a particular invention consists of patentable subject matter. Patentable subject matter in most jurisdictions and under international conventions is established by statute.[26] There is no accepted definition but it is usually defined by way of exceptions to patentability. This therefore means that anything not excepted shall qualify for patenting as patentable subject matter.

Most statutes exclude the following fields of technology from patentability;

- Discoveries of materials or substances already existing in nature
- Scientific theories or mathematical methods
- Methods of treatment for human or animals (but not products for use in such methods)

[25] D. Bainbridge, Intellectual property law, 1996, p 523

[26] See generally European Patent convention especially Article 52(4) of the EPC also provides that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application. Article 53(b) of the EPC provides that patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants and animals.

- Plants or animal varieties and the list goes on.

In order to ascertain whether biotechnology inventions are patentable its imperative to have a glimpse of what makes up biotechnology subject matter. As can be gleaned from the previous chapter it is very clear that biotechnology covers a wide field. But speaking from a patentability perspective, it can be asserted that in biotechnology there are three recognized types of subject matter and these are; bio-matter itself, methods and processes of making the bio-matter and/or the products and the uses of the bio-matter or the products of biotechnology.[27]

(a) BIO-MATTER ITSELF

This is a broad enough term that captures all products related to biotechnology and inclusive is the non-living and living matter. Living matter examples include, the cell which are the smallest wholly viable units of life. Or the smallest reproducible unit of life and it is this reproducible nature, which is unique to biotechnology invention. They come in different shapes and sizes. Human, animal or plant cell lines existing as individual cells isolated from the whole organisms or completely dependant on laboratory generated medium and culture conditions for survival. For instance microbes are unicellular organisms capable of living in the environment.[28]

---

[27] *Supra* note 24 p32

[28] M.D. Trevan et al., "Biotechnology: The Biological Principals", 1987,p.56

On the other hand we have non-living matter and this includes amino acids, pepetides, proteins, fatty acids, fats and nucleic acids. These are basically chemical compounds recognized by their common names as antibodies, hormones, enzymes, antibiotics, steroids, cholesterol and DNA molecules. Many biotechnology patents are directed to specific proteins.[29]

(b) Methods and processes of making products of biotechnology

This entails all those process for producing plants and animals, which require significant intervention by man or are "products of human ingenuity having a distinctive name, character and used".[30] Methods for the creation of products of cells such as hormones or enzymes and the like. The most common processes included under biotechnology are fermentation, chemical and diagnostic processes as well as treating human or animal bodies and methods of controlling pests.

(c) Methods of use or uses

Some inventions deal with the end product of biotechnology, which of course includes all bio-matter. The only kinds of limitations on this subject matter pertains to whether a process or method involving the of biotechnology (or any other technology for that matter) involves treating a human being or animal by

---

[29] ibid, p.57
[30] ibid,

surgery or therapy. In such cases, method "claims" may not be allowed in many jurisdictions.

A number of developing countries have also sought to limit further, what constitutes a patentable invention. For example, the Common Industrial Property Regime of the Andean Pact countries provides that the following shall not be considered as inventions:

> "Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing."[31]

3.2.3 USEFUL

This requirement does not require an invention to be commercially useful but must as Adams puts it, "of some measurable benefit, more than a mere curiosity".[32] Thus, it must be capable of industrial application as this is what usefulness entails. Often, the written description and enablement requirements will sufficiently disclose an invention's usefulness. It has proved a daunting task to assert practical usefulness in biotechnology. For instance the creation of a micro organism or new cell line may not show its utility there and then. This was the line of reasoning followed by the courts in *Brenner v. Manson*,[33] where the

---

[31] Article 15(b) of Decision 486 of the Common Intellectual Property Regime of Andean Community. Source:

[32] Adam, I, Hasson, Patenting Biotechnology: Inherent Limits, April 19, 2002.www.bc.edu/bc-org/avp/law/st-org/iptf/commentary/content/2002041901.html. ACCESSED TIME-10: 22 FRIDAY 19/09/O3

[33] 383 U.S. 519 (1966).

court held that merely producing something that is the object of scientific research is insufficient to justify the grant of a patent. Thus biotechnology invention has to be refined and developed to the point where a specific and conspicuous benefit exists. This explains why the courts apply stringent tests demanding a biotechnology patent to have a practical utility.

3.2.4 Novelty

Perhaps the most fundamental requirement in any examination as to substance is that of novelty and it is the undisputed condition of patentability.[34] This is more so because this requirement ensures that grant of a patent will not provide a monopoly to the right holder for something that was already in existence or known. According to the WIPO handbook[35] novelty is not something that can be proved or established; only its absence can be proved.

An invention is said to be new if it ahs not been anticipated by the prior art. What constitutes prior art differs in many countries depending on the convention one uses. Throughout the world one of the following three main systems are adopted by different countries for assessing novelty:

- Local novelty-an invention must neither be publicly used nor published in the particular country in which the applicant seeks patent grant.

[34] E. Turrini, "The Concept of Novelty - Our View of the Case law of the Boards of Appeal of the European Patent Office" (1991) 22 IIC 932.
[35] Wipo Reading Material, p.445

- Relative novelty-an invention must neither be published in any country in the world nor used publicly in the particular country in which the applicant seeks a patent.
- Absolute novelty-prior to the filling of the application, the invention must not have been published or publicly used in any country.

3.2.5 Inventive step (non-obviousness)

Patents are said to be granted to something that provide some advancement or step forward in technology. Prima facie biotechnology innovations qualify because they unquestionably offer a great deal of advancement in the field of medicine, agriculture and other fields.[36] Thus as alleged invention is said to lack an inventive step if it would be obvious to a person of general skill in the art. The degree of thought and imagination will differ and only a small degree of imagination or a small step above what was previously known, that shall constitute an inventive step. For instance the bacteria invented by Chakrabarty was something not anticipated by prior art and not obvious to a person skilled in the field of technology. The same can be said of the Harvard 'oncomouse' and many other such biotechnological inventions developed over the years.

[36] S.Gupta, p.5

3.2.6 Sufficiently Enabled and Described

The contract with society for the granting of a patent is that a limited monopoly period will be awarded in return for which the applicant will fully disclose his invention.[37] The extent of the disclosure considered necessary to satisfy the applicant's part of the contract varies amongst countries. In some countries including the US, the applicant is required not only to fully disclose his invention in a manner that would enable another party to put it into practice, but must also disclose the best mode for doing so. U.S. case law has shown that there is a distinction between the requirements of a written description and the enabling disclosure. The sanction for non-compliance is usually the loss of the patent. [38]

The specification filed with the application for a patent must sufficiently describe the invention along with the best method by which it may be performed in enough detail to allow a person of average skill in the relative field to rework the invention with no further experimentation or invention. To some extent it has to include a clear description of how to use an invention.[39] Thus in the case of biotechnological invention, this calls for deposit for instance of micro organisms as this shall as nearly as possible accurately describe the invention unlike when it is just written down on paper.

---

[37] Drahos, p10
[38] Adam, note 32
[39] Cornish.

3.4 CONCEPT OF INVENTION

Many of the products and processes of biotechnology occur in nature, and so with such origins, many of those products and processes are somewhat familiar to most people notwithstanding there complexity. It's from this fact that one wonder whether there can ever be an invention in biotechnology. For instance people can identify with genetically altered tomatoes, furry creatures like the Harvard 'oncomouse', or mushrooms. Such familiar subject matter compels an observer in the street to query whether one can 'invent' something like the Harvard mouse let alone whether such things can be patented.[40]

From a scientific perspective an invention means something which is new and is both the process of, and the result of, the bi-, tri-, multisociation of previous discovery (which forms the relevant background) which has a purpose, or some level of value or does something. Put simply, it is new and has utility. Utility is thought of as providing a solution to some existing problem.[41] This definition puts invention more in line with statutory invention, which shall be discussed, in the next chapter.

These themes or elements of invention are applicable to all fields of human endeavour therefore looking at the knowledge, discovery, integration and solutions in biotechnology, it is clear that there are inventions in biotechnology.

---

[40] D.M. Stotland, "Is Biotechnology Patentable in Canada?" (1991) 9 Can. Intell. Prop. Rev. 1.

[41] M.Lane,supra note 11

Further the ability to create Recombinant DNA is one of the greatest inventions of biotechnology in this century.

According to the **WIPO** handbook there is a difference between an invention and a discovery and these two terms should not be unjustly used to prevent the reward of innovation.[42] If a sophisticated process isolates an unknown micro organism, such a micro organism is not a process but a scientific discovery because it is already available in nature. The other view is that the isolation itself requires an important intervention by man using a highly sophisticated process and that the result is a solution of a technical problem. Further that isolated micro organisms is not different from chemical substances extracted nature, which is patentable subject matter.

The following briefly illustrates what types of biotechnology inventions can qualify for patenting.[43] This is as is the position in most jurisdictions.

(a) **Micro organisms** are commonly patented and this includes new strains which have been specifically genetically engineered to include a specific gene or gene required for a particular metabolic pathway. Also obtained for DNA sequencing. Plasmids[44] and other transposable elements have been subjects of granted patents.

---

[42] WIPO handbook Policy and Law: Intellectual Property. Geneva: WIPO 2001p444

[43] For more see Franks and company report note 22

[44] Plasmids are hereditary units physically separate from the chromosomes of the cell. see for further details Franks and Co report, ibid

(b) **Pharmaceuticals** are patentable due to the fact that they require large investments and the time taken for a drug compound to satisfy the regulatory requirements often means that the lifetime of a patent for a drug compound, and hence financial reward, may be eroded.

(c) **DNA** sequences are also patentable and this has resulted in the sudden rise of the human genome project. This and other genome sequencing projects have provided an explosion in the number of novel sequences.

3.8 JUSTIFICATIONS FOR PATENTING BIOTECHNOLOGICAL INVENTIONS

As with other forms of inventions capable of being patented, biotechnology too has not been spared from the controversy that has marred this type of intellectual property regime. Some of the concerns raised are genuine and are real whereas the bulk of these stem from a general misunderstanding of biotechnology, and its potential applications, the patent system and its limitations, and of other forms of legislation that could be used to control the use of this technology. Some of the concerns raised against patenting of biotechnology are,

- **morality** -gene patenting is a very emotional subject and currently the European directive on biotechnology does not allow the patenting of

human beings unlike in the US where human beings have been patented. The TRIPs agreement also prohibits the patenting of inventions that are against public order or morality (article 27.1).

- **Human rights** -they assert that the inherent dignity of an individual must for all intents and purposes be respected and that at no time should body parts be subjected to patenting. A question forming part of this argument is whether such individuals whose parts are patented can benefit from the rewards derived from the use of the patent.
- **Ownership and commercialisation of life**-this reduces life forms to 'products of manufacture'. This is indeed true to a certain extent. During the days of slavery, human beings were traded as commodities. Nature too has for centuries been exploited for commercial ends. The only differences between the past practices and the current technology are that biotechnology makes it easier and potentially more economical, for us to select desirable genetic traits. Moreover an individual with unique genetic characteristics may refuse to consent to patenting of genes in which case a patent would not be granted.[45]
- **Exploitation of resources**-it is feared that multinationals that are the major sponsors of this technology will engage in gene prospecting and thereby exploit nations' resources to the latters detriment. They will exploit without authority and acknowledgment of or reward to the

[45] see generally the California decision in Moore v Regents of the University of California which decided that Moore had no property rights to his bodily tissues and that they were freely donated, as they would any other organ donor. For citation see Michael Lane supra note,11

country. However, the provisions of the convention on Biological diversity (the Rio Convention) of 1992[46] gives signatory states the right to exploit resources by establishing laws which prevent MNCs from doing so.

- **Indigenous people**-Perhaps the most genuine and real concern is that of indigenous peoples. Allowing patents for certain life forms and genetic material may be an insensitive to the beliefs of the indigenous people and may exploit their knowledge.

In addition to promoting technological innovation and to the transfer and dissemination of technology, biotechnology patenting is justified under the following grounds,[47]

- **Biotechnology contributes to life saving medical treatments.** Advances in biotechnology have enabled the development and increasing availability of life saving medication and contributed towards the eradication of disease. It has also helped with the completion of the human genome project. With this project scientists will be able to cure birth defects in the womb.

- **Biotechnology may increase human welfare**-Biotechnological inventions have the potential to provide increased and more reliable

[46] Which as of 1st January 1999,175 countries have ratified.
[47] Michael Blakeney, Director, Queen Mary Intellectual Property Research Institute Queen Mary, University of London, *Legal Aspects of Biotechnology.*

food harvests for the world's population, and to provide alternative means of producing goods that will use fewer resources.

- **Biotechnology may have positive environmental effects-** Biotechnological advances may result in production processes and products that are less polluting and use less resources. There is also the potential to clean up existing pollution and to improve waste management through biotechnological processes. E.g. US $ 100 billion worth of crops are destroyed annually by soil-dwelling nematodes damaging crop plants. Chemical nematicides are the only option for crop protection, but these are among the most toxic and environmentally damaging pesticides that are in widespread use. Biotechnological inventions serve as an alternative to this.[48]
- **Dissemination of information-**patents are more advantageous to both the patent holder and society. Patent protection is regarded as society's payment for full disclosure of information about the patented product. It therefore means providing enough detail for a person skilled in the same or most clearly related area of technology to construct and operate the object. If properly negotiated they are beneficial to all parties than trade secrets.

[48] S.Gupta,note,5

CONCLUSION

This chapter has highlighted the fact that the patent system is the only available means of protecting biotechnology. Since biotechnology inventions are creations of the mind there is an inherent need for legal protection. The most common and effective means of protecting biotechnology inventions is through the patent system. Biotechnological inventions from what has been discussed so far do qualify for patent protection and should not therefore be treated differently. The next chapter therefore gives an insight on the two approaches adopted by most countries in patenting biotechnology that is, a broad and narrow approach. There is an inherent need to balance between the award of a broad patent and the need to stimulate innovation.

CHAPTER IV

4.0 PATENT SCOPE INTERPRETATION

4.1 INTRODUCTION

The statutory definition of invention as found in the Zambian *Patent Act* creates a subset of invention within the set established under the discussion of the concept of invention as developed in chapter three above. The statutory definition of invention, in comparison with the concept of invention, is a narrower view of what is invention. The question addressed below is whether, and if so to what extent, this narrowing impact on the ability to find whether biotechnological subject matter fits the definition of statutory invention. As part of the analysis we will examine whether biotechnology can be accommodated within judicial interpretation of the elements of statutory invention or if modification is necessary to accommodate biotechnology. As part of the discussion, a number of critical issues, which are peculiar to biotechnology in respect of patentability, will be canvassed.

4.2 STATUTORY INVENTION

The Zambian Patent Act at section 2[49] defines the word "invention" as follows:

> *"invention" means any new and useful art (whether producing a physical effect or not), process, machine, manufacture or +composition of matter, which is not obvious, or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention.*

[49] cap 400 of the Laws of Zambia

Thus, the "elements" of patentable "invention" under Zambian law are as follows:

- the subject matter must be one of:
  an art,
  process,
  machine,
  manufacture or
  composition of matter;
- newness or novelty; and
- it must be useful.
- not obvious

From the above it is clear that the meaning of invention under Zambian law is broad and it embodies all the pertinent requirements for patentability. On the other hand we have the Canadian patent Act[50] which defines an invention as meaning;

> *"invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter.*

Thus the fourth element, which is not yet explicit from the statute (Canadian), is the requirement of non-obviousness, or inventive step. Non-obviousness has been judicially imported into this "statutory" definition of invention and is assessed by an examination of the subject-matter on the basis

[50] John Rudolph, note 17

of an objective standard which involves a determination by a worker skilled in the relevant art. Thus in terms of convenience, the Zambian Act provides a good definition of invention.

4.3 BIOTECHNOLOGY AND PATENT SCOPE

Before something can be considered as patentable a preliminary determination must be made with respect to the propriety of the subject matter, that is, is it an "art", "process", "machine", "manufacture", or "composition of matter"? This first step in the analysis of patentable invention clearly distinguishes statutory invention from the conceptual approach to invention, the latter being entirely uninfluenced by the nature of the subject matter.

Two aspects of biotechnology which are currently not proper subject matter in Zambia, since the statute is silent on there status and as discussed below a number of other jurisdictions, are methods of medical treatment and human beings and body parts.

4.3.1 Methods of Medical Treatment

In Canada, where a biotechnological process or method, or a process or method involving a product of biotechnology (or any other technology for that matter) involves treating a living human being or animal by surgery or therapy, claims to such "methods" may be construed as methods of medical treatment

and may not be allowed. This is the case notwithstanding the fact that there is nothing, which explicitly relates to this point in the statute.[51]

This is to be contrasted with the United States. Although the U.S. statute is also silent on the issue of methods of medical treatment and at one time, like in Canada, patents were not available for medical therapeutic and diagnostic methods, however, according to current case law no such bar exists. In Japan, legislation specifically indicates that methods of medical treatments for human beings are excluded from patentable subject matter.[52] The basis for this legislation is a policy to allow doctors to practice without concern about infringing patents.[53] As is the case in Canada, only treatment methods are excluded, products including medical devices and pharmaceutical compounds are patentable subject matter.

4.3.2 Human Beings

Directly tied to this area of non-patentable subject matter is the question of the patentability of any subject matter relating to humans. Indeed, the question of the patentability of humans or human body part is an excellent example of how limiting the scope of subject matter which can or cannot be patented, can help define social policy in a country.[54] The European Union Biotechnology Directive No **98/44/EC** explicitly provides under article 5(1) that;

---

[51] ibid,
[52] Dean Nakamura, *Biotechnology Bits and Pieces, at*
[53] Adam, note,p.
[54] Claire Baldock and Oliver Kingsbury, The biotechnology Directive and its relationship to the EPC

> The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene cannot constitute patentable inventions.

The TRIPs agreement also restricts the patenting of products or processes, which are contrary to morality per article 27.

4.4 Categories of Statutory Invention

As outlined in the foregone, there is no argument that biotechnological methods, processes and uses can easily be included under the headings of art, or process, as appropriate, subject to the "method of medical treatment" caveat. Indeed, even in respect of the most controversial subject matter, namely plants and animals, or any other higher life forms, the U.S Patent Office has indicated that processes for producing plants and animals, which "require significant technical intervention by man", are proper subject matter and may be patentable if the other criteria of patentability are fulfilled.[55]

It is equally clear that none of the different subject matters of biotechnology can, in any aspect, be included in the "machine" category. Consequently, in respect of the products *per se*, a key issue has been, and still is in respect of higher life forms, whether such products of biotechnology fit within the terms "manufacture and/or composition of matter" in the light of how these words have been construed by the Courts.

[55] Ronald A.Rader,Trends in Biotechnology Patenting,1990,p13

the terms "manufacture and/or composition of matter" in the light of how these words have been construed by the Courts.

4.4.1 Manufacture and Composition of Matter

The term "manufacture" has not been well defined in the legislation of most countries and is often used in conjunction with "composition of matter". Manufacture has been used in a manner by which it is possible to infer the meaning to be attributed to it, for example, as per MacLean, J. in ***Hosiers Ltd. v. Penmans Ltd.*** [56]stated:

> "If a product is known to the trade, its production by a new process or new instruments cannot make it new. A manufacture is not new and patentable until the creative act in which it originated, is distinct from that required to invent the process or apparatus by which it is made."

From this "manufacture" is meant to be an end product, i.e., a manufacture - a result from a process of creation, which presumably involves input from a human. The ***Concise Oxford dictionary*** provides support for this conclusion based on its definition of manufacture: "making of articles by physical labour or machinery...". The word "manufacture," like discovery and invention, can mean the process or it can mean the result and this duality complicates the understanding.

---

[56] [1967] RPC 479

In Canada, reliance on British case law for interpretation has introduced some complications in understanding definitions, for example, some British decisions go so far as to suggest that the word "manufacture" is synonymous with invention and often the analysis is tied up with the notion of "manner of manufacture" Unfortunately this blurring of concepts takes the inquiry a step further from ultimately answering the question of "invention."[57]

However, in the British case of ***Re Application of Compagnies Reunies des Glaces & Verres***[58], "manufacture" was succinctly defined as "a manner of adapting natural materials by the hands of man or by man-made devices or machinery." This definition, particularly with respect to human involvement, is in accord with the definition used in the Canadian decision in ***Application of Abitibi Co***[59] where the Commissioner of Patents stated through the Patent Appeal Board:

> *"...Chakrabarty's invention is patentable because it is a non-naturally occurring manufacture or composition of matter - "a product of human's ingenuity having a distinctive name, character and use"."*

The ***Abitibi*** decision was concerned with the patentability of a microbial culture system and represented the first decision in Canada allowing claims in a patent

[57] Kenneth D. Sibley, The Law and Strategy of Biotechnology Patents, 1994,p131
[58] (1931), 48 R.P.C. 185 at 188
[59] (1982), 62 C.P.R. (2d) 81

extent on the *Chakrabarty* decision, which was a decision of the United States Supreme Court.

Prior to 1980 there had been no court decisions on the patentability of life forms, *per se*. In the United States, patents for such subject matter were simply not allowed. However, in 1980 Chakrabarty's claims for life forms *per se* were allowed by the Unites States Supreme Court. As a consequence, the name Chakrabarty became a commonplace name in the biotechnology patent field. The facts of the case were straightforward: Chakrabarty had developed genetically engineered bacterium capable of breaking down multiple components of crude oil. In the patent application he had made 3 types of claims including process claims for the method producing the bacterium, claims for an inoculum (the mixture which would be applied to an oil site) including the bacterium and claims to the bacterium. The examiner had allowed the claims to the process and methods. The critical issue in the case was whether a claim to bacteria was permissible under U.S. patent law.

The case ended up in the United States Supreme Court, which looked to the definition of what a patentable invention is under U.S. patent law. The Court found that a bacterium, which had been genetically engineered, could be considered a "manufacture" as well as a "composition of matter" as those terms appeared in the U.S. statute. The critical message delivered by the Court was

that so long as sufficient input by man was involved in the "invention", the subject matter could satisfy these elements of the definition of invention.[60]

Returning to the Canadian ***Abitibi*** decision, the only reservation expressed by the Patent Appeal Board with respect to the patentability of living matter was in respect of higher life forms where the concern expressed was the *ability of those reading a disclosure to such an invention to be able to replicate the invention.* They did not express any concern that the words "manufacture" or "composition of matter" was not broad enough to capture this subject matter. However, when the issue of higher life forms as proper subject matter came before the Federal Court of Appeal in the Canadian decision of Pioneer Hi-bred:"Marceau J., in a separate judgment rejected the appellant's argument that the words "manufacture" and "composition of matter" found in s. 2 applied to the new soy bean strain. He stated:

> *I have not been convinced. Even if those definitions were held to be applicable to a micro-organism obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. Such a plant cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means."*

[60] 206 U.S.P.Q.193 (U.S.1980.)

This use of terminology relating to "...a combination of two or more substances united by chemical or mechanical means" reflects Mr. Justice Marceau's understanding of the expression "composition of matter" which appears to flow from early Canadian decisions such as that of Idington, J. who stated:

> "Our Statute provides for a patent issuing to 'any person who has invented any new and useful...manufacture or composition of matter...' It is admitted the composition need not be a chemical, but may be a mechanical one."

and the notion of a combination of chemicals, as in composition of chemicals as was used in ***Chipman Chemicals Ltd. v. Fairview Chemical Co.*** however, Marceau, J. states[61]

> "I am prepared to accept that the Canadian patent legislation does not support the assumption that life forms are definitely not patentable."

This double negative is in contrast with His Lordship's earlier remarks and consequently it is not clear that the words "manufacture" and "composition of matter" encompasses living matter. Undoubtedly they do, but unfortunately:

> "The Supreme Court of Canada declined to address the question as to whether this soybean variety could be regarded as an "invention" within the meaning of s.2 of the Patent Act."

---

[61] at page 495, [Pioneer Hi-bred Federal Court of Appeal] judgment.

There is no higher authority on the point of whether higher life forms are unpatentable. The policy of the Canadian Patent Office, as reflected in the Canadian Manual of Patent Office Procedure (MOPOP) is that plants and animals i.e., higher life forms are **not** patentable subject matter. However, this apparent bar to living matter as proper subject matter does not extend to **all** living subject matter. Indeed, as provided by *The **Abitibi*** decision, the Patent Office has stated that inventions for new microbes such as bacteria, yeast, molds, fungi, actinomycetes, algae, cell lines, viruses and protozoa may be patentable. Note that the distinction between this patentable subject matter and that of plants and animals is that the former are unicellular while the latter are multi-cellular complex integrated organisms, or "higher life forms". Note however, as indicated above, the Patent Office does indicate that processes for producing **plants and animals** which "require significant technical intervention by man" may be patentable. This, of course, invokes the *Chakrabarty* element of human intervention, which is the *sine qua non* of "manufacture" and "composition of matter".

Finally, as outlined above, where a process or method involving a product of biotechnology, (or any other technology for that matter) involves treating a living human being or animal by surgery or therapy, claims to such "methods" may not be allowed. Although not explicit, it is reasonably apparent that the words "manufacture" and "composition of matter" of the Canadian *Patent Act*

can include all life forms of biotechnology, as has been found in the United States.

The position of the Patent Office in respect of higher life forms is divergent from the impressions of Patent examiners and Patent Agents practising in the field of biotechnology: namely that the words "manufacture" and composition of matter" in the *Patent Act* are broad enough to include all living subject matter. The Patent Agents, as did the Commissioner in ***Abitibi,*** could see no reason for drawing a line on the applicability of the definition to "higher" life forms. Indeed, it is a conclusion of this paper that all subject matter of biotechnology, including higher life forms, "fit" into the enumerated categories of the definition of invention and consequently, from the perspective of proper subject matter, are patentable.

CONCLUSION

This chapter has strived to show that biotechnology subject matter is patentable provided it falls under statutory meaning of invention. The decision of the U.S.Supreme court firmly holds that biotechnology inventions fall under the category of "manufacture" or "composition of matter". Thus if biotechnological invention meet the requirements of new, useful and involve an inventive state, then patents for such an invention shall be granted. Thus it would be safe to state that "everything under the sun made by man is patentable provided it meets the legal requirements of patentability.

CHAPTER FIVE

5.0 CONCLUSON AND RECOMMENDATIONS

5.1 INTRODUCTION

This chapter which marks the end of this paper aims at making an overall conclusion and thereafter some recommendations on the existing system of patenting biotechnology, bringing out some aspects in legislation that need to be amended.

CONCLUSION

Having highlighted some of the most contentious issues that have become synonymous with the patenting of biotechnology, this research paper has noted the following as a way of concluding the study.

The patenting of biotechnology has evolved in such a way that it affects both developed and developing countries. Developing countries must take an active role in the development, promotion and regulation of the industry as there is a high possibility that more than ever their interests and those of multinationals will clash due to a number of misconceptions they harbour about biotechnology.

These relate in particular to the application of the patent system to the new generation of technologies, particularly in the life sciences and information technology. The development of biotechnology has been accompanied by the

more widespread patenting of living things, whose patentability was confirmed in the US by the Supreme Court case of Diamond versus Chakrabarty in 1980.

The paper concludes by stating that there can be invention pertaining to the subject matter of biotechnology and that this subject matter falls within the scope of patentable invention provided that it meets the requisite requirements for grant of patent.

Further that the patent system is the only appropriate avenue for patenting biotechnology and that there is no urgent need for the moment to redefine the bundle of rights enjoyed by the patentee. If at all, there are any modifications to be made to the patent system they must be with respect to the concept of novelty, non-obviousness and complete description. Since most biotechnology matter is self-replicating, it is imperative that legislation provides that a sample is presented before the patents office.

The scope of patenting biotechnology although broad in leading biotechnology countries like the U.S can still be narrowed under the current legislation as demonstrated by the European Union. The paper therefore has noted that there are two approaches to patent scope interpretation namely narrow and broad approach. It is still not too late to adopt the narrow approach considering the fact that there are still many contentious issues that are yet to be addressed such as the safety of biotechnology inventions or rather products or processes.

If properly regulated the industry shall assist in resolving the hunger problem that affects billions of people worldwide. Although there are some setbacks these shall with time be resolved and a time shall come when biotechnology industry will be a leading technological industry providing employment to the many still unemployed. The growing number of patent applications attests this. For instance in the U.S, and to a lesser extent worldwide, the number of patents granted has been rapidly rising. Between 1981 and 2001, the number of patents granted in the U.S has increased from 71000 to over 184000, an increase of 159%. In the last five years the rise has accelerated, the number of patents granted has increased by over 50%, compared to an increase of under 14% in the previous five years. This increase appears to reflect growth in the intensity of patenting (for example, per dollar spent on research), rather than a 50% increase in the number of inventions. In the 1990s, US R&D expenditures increased in real terms by nearly 41%, while patents granted rose by over 72% in the decade to 2001.[62]

The paper further concludes that contrary to many sentiments biological material can be invented and as such are not scientific discoveries. Both the statutory concept of invention and the scientific concept as highlighted in the foregone have clearly manifested to the fact the biotechnological subject matter can be invented.

---

[62] Ibid.

5.2 RECOMMENDATIONS

5.2.1 RE-DESIGN PATENT'S ACTS

It is recommended that in order to deal with issues of patentability, amendments to the various patent's Act especially for developing countries are made. Developing countries are yet to bring there legislation in sync with the current developments in the field of biotechnology and technology as a whole. The current legislation and administrative procedures are not well equipped to move at par with the developments in the field of technology. Thus there is an urgent need to enact legislation that shall meticulously address the problems raised by patenting biotechnology innovations. It is hereby proposed that a Biotechnology Patent Act be enacted that will specifically deal with issues of biotechnology and further that World IntellectualProperty Organisation (WIPO),must spearhead the implementation of such an Act. Thus such an Act will become an international convention so that the laws relating to biotechnology innovations are fully harmonised and all the doubts, scepticism and fears that people have shall be duly addressed and made clear.

It is proposed that such an Act should provide limited rights to those who develop new, non-obvious and useful methods and processes of manufacturing known as products of nature.This shall enable individuals in developing countries access such products and use them beneficially. This can be a solution to the current controversy about patenting and pharmaceutical products. The term of protection should equally be reduced to say maybe not more than ten years and

the date of application, with priority on the basis of first to file. The rights conferred would be with respect to process (es) claimed.

This Act should operate as a supplement to the patents Acts and the TRIPs agreement. It is not intended to replace the existing legislation but to bring it in tune with modern realities that call for the recognition and acceptance of biotechnology products and processes.

5.2.2 PATENTABLE INVENTION

Although the word invention has been clearly defined and interpreted by the courts it is felt that more still needs to be done with respect to biotechnological inventions.

TRIPS requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step (non obvious) and are capable of industrial application (useful)." It does not however define the term "invention", nor does it prescribe how the three criteria for patentability are to be defined. This explains why there are disparities in interpreting this article and it is against this background that the following recommendation is proposed.

The word 'invention' must be redefined to read,

" in this Act, except as otherwise provided, invention... and for clarification does not include the following;

1. the human body parts in their natural state, except subject matter isolated from the human body or otherwise produced by means of a technical process;
2. processes for modifying the genetic identity of the human body contrary to the dignity of humans.
3. processes for the modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without substantial benefits to man or animals.

The European directive on biotechnology draft is an appropriate vehicle for implementing the above. The draft directive has been worded in very clear and concise language as it endeavours to put to rest the voices of discontent.

The other areas that need reform are the words, "composition of matter" and "manufacture". These two terms must be detached from the word invention and defined in line with there subject matter, thus it should read,

In this Act, except as otherwise provided... manufacture or composition of matter includes biological material, including plants and animals. The wording must be clear enough to clarify what may and may not be patentable.

In this way, no harm shall be done to the already developed jurisprudence concerning the legal interpretation of the terms. This modification also keeps this

clearly identified aspect of meaning within the required framework of the "new and useful" elements of the definition of 'invention'.

The final recommendation is that the ethical issues must be adequately dealt with.The current European Directive makes some provisions regarding the moral and ethical issues of patent law in the area of biotechnology. However, although it includes an indication of inventions considered to be contrary to *ordre public* or morality, it also sets out to distance itself from these issues by re-affirming the fact that substantive patent law cannot replace national, European or international laws which may impose restrictions or prohibitions on the use or commercialisation of biotechnological research.

REFERENCES

BOOKS

Abbott et al. The intellectual property: Commentary and Materials. Hague: Kluwer law International, 1999

Bainbridge, D. Intellectual property law. London: Pitman publishing,1996

Drahos, P. Intellectual Property and Human Rights. Geneva: WIPO & OHCHR, 2000

Rader, R.A.Trends in Biotechnology Patenting. New York: Boston Publishing Co, 1990

Sibley, K.D. The Law and Strategy of Biotechnology Patents.London: Stevens and Sons, 1994

Trevan, M.D. et al. Biotechnology: The Biological Principals. New Delhi: Universal Law Publishing, 1987

Trivedi.R.N. Biotechnology and Environment(Reprint). New Delhi: Anmol, 2002

WIPO, Handbook Policy and Law: Intellectual Property. Geneva: WIPO 2001

STATUTES

Patents Act-cap 400 of the Laws of Zambia

TRIPs Agreement
European Directive on Biotechnological Inventions

ARTICLES

Baldock, C and Oliver Kingsbury. The biotechnology Directive and its relationship to the EPC

Blakeney, M. Legal Aspects of Biotechnology. University of London,

Franks and Company, Biotechnology-Extent of patent protection. Sheffield: updated Monday, 17th February 2003. (www.franksco.com)

Hasson, A.I. Patenting Biotechnology: Inherent Limits April 19, 2002.www.bc.edu/bc-org/avp/law/st-org/iptf/commentary/content/2002041901.html. ACCESSED TIME-10: 22 FRIDAY 19/09/03

Kimmelman, J. Unlimited License: An Analysis of the Canadian Biotechnology Advisory Committee's Report on Patenting Higher Life Forms Canadian Centre for Policy Alternatives http://www.policyalternatives.ca Accessed 12:02- 8/09/03

Lane, M. Invention or Contrivance? Biotechnology, Intellectual property rights & Regulation.November1995 UP-Dated EDITION (JANUARY 1996). (www.charm.net/~gbarren/cv

Nakamura, D. Biotechnology Bits and Pieces, http://www.sughrue.com/articles/genetic/deanbits.htm

Prakash, S. "WTO Rules: Do they Conserve or Threaten Biodiversity?"The Journal of World Intellectual Property.Vol.3.No.1.Jan 2000

Rudolph, J.R. A Study of the Issues Relating to the Patentability of Biotechnological Subject matter. A paper prepared for: Intellectual Property Policy Directorate Industry Canada January 31, 1996

Seiler, A.Biotechnology and Third World Countries: Economic, Interests, Technical Options and Socio-economic Impact.Profferred paper, ACCESSED 10:45 5th September 2003

Stotland, D.M. "Is Biotechnology Patentable in Canada?" (1991) 9 Can. Intell. Prop. Rev.

Thumm, N. Recent Developments with Intellectual Property Right Protection for Biotechnological Inventions-A Reflection on Spain, paper presented on 27th-29th may 2000.

Turrini, E. "The Concept of Novelty - Our View of the Case law of the Boards of Appeal of the European Patent Office" (1991) 22 IIC 932.