KEMRI Bioethics Review

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Intellectual Property Rights Ethics

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The **KEMRI Bioethics Newsletter** is published every 3 months and hosted on the KEMRI website. We publish articles by KEMRI affiliated authors and from other contributors from all over Kenya. The scope of articles ranges from ethical issues in **biomedical science, healthcare, technology, law , religion and policy.**

The chief editor encourages submisssion of articles as a way of creating awareness and discussions on bioethics

please write to ddrt@kemri.org

Letter from the Ag DDRD

Dr Evans Amukoye.

Welcome to this issue on Intellectual Property Rights (IPR) and Bioethics. In this issue we feature articles on IPR and traditional medicine, IPR and Bioethics and IPR issues in scientific publishing. We also feature Frequently Asked Questions on IPR and what is expected of Scientists who use the KEMRI Scientific and Ethics Review Unit (SERU) on the filling for annual renewal of research.

Research is the heart of innovation and generation of new knowledge for utilization in various sectors. IPR protects and rewards innovation and new knowledge, Without IPR, there would be lack of competition and exclusiveness in knowledge generation and limited profits/rewards for innovativeness. This ultimately this would discourage research and development. Inventors need to benefit from their innovations in order to spur further research and innovation.The most developed nations of the world rely on research and innovation and this has contributed to economic growth, development and better living standards in these nations. Developing nations like Kenya need to harness the available human resource capacity and the power of Innovation to eradicate prevailing tropical and neglected diseases that still affect the populations.

Local scientists must thus recognize the importance of innovative research and the potential of new knowledge on economic development. New frontiers in innovation in the medical research sector in patenting and licensing include in biotechnology, drugs and medical science. Some recent success stories of revenues from patented novel innovations have attracted a lot of attention, e.g. the patent covering Emtrivia – an anti-retroviral drug that generated revenues of 525 million US dollars for Emory University and 25 per cent of that amount for some of the Emory inventors. http://www.emory.edu/news/Releases/emtri/

It is this regard that the institutes had to develop an IPR policy cognizant of the need of making knowledge generatedat the institute available to the society and most importantly to encourage innovation and original research at the institute. The dedicated Marketing and IP department was set upto inform and advice scientists in KEMRI on IPR issues pertaining medical research.All these efforts are geared towards empowering our researchers to harness IP in commercialization of the discoveries produced by scientific research.

I challenge and encourage scientist to use research to generate new knowledge and innovative interventions to eradicate diseases like malaria, jiggers and other many neglected, tropical and new and emerging and lifestyle diseases that continue to plague populations in Kenya and beyond. In this we shall be working towards achieving our mission of improving human health with a potential of a reward from the benefits of the invention.

Dr Evans Amukoye

Ag DDRD,KEMRI

A Word from the Director KEMRI

Dr Gerald Mkoji
Ag Director, KEMRI

Welcome to this issue on Intellectual Property Rights (IPR) and Ethics. IPR allows an individual or entity exclusive rights to use a discovery, invention, ideas or other intangible assets, without having to worry about competition atleast for a specific period of time. Such rights are protected by law through say patents, trademarks, copy rights, trade secrets etc, to encourage innovation, and often, commercialization. IPR protection is important in that it can potentially spur industrial development and economic growth.For an academic or research institution, IPR protection could help build a financial base to support investment or Research and Development. IPR protection is one way to reward inventors for their discoveries and inventions, and to gain recognition.

KEMRI's main mandate is to conduct research for health, and the institution plays a crucial role in generation of knowledge and product development. Therefore, it is important that IPR protection is entrenched in KEMRI and other public academic and research institutions to ensure beneficial use of knowledge. As Kenya aspires to become a knowledge–based economy come 2030, IPR protection is likely to become a critical area of focus. While Kenya seems to be in the forefront in Information & Communication Technology (ICT) inventions, it still lags behind in the areas of health inventions, judging by the number of IPR applications registered at the Kenya Intellectual Property Institute (KIPI).Consequently, it is crucial that Kenyan researchers appreciatethe potential impact of their novel ideas and discoveries not only, on human health but also, on the national economy.

KEMRI's IPR Policy,approved in 2015, explicitly prescribes the procedures, terms and applicable conditions for IPR, and captures guidelines on handling and protection of IPR that arise from collaborative projects.

The KEMRI Intellectual Property (IP) Office should therefore, be in the forefront in helping KEMRI scientists and technologists understand the Policy through awareness campaigns, and advise them appropriately on matters related to IPR.

The KEMRI Scientific and Ethics Review Unit (SERU) is now keen in ensuring that KEMRI researchers articulate and adequately address IPR implications in their research proposals to safeguard their discoveries and innovations, and to avoid disputes. The KEMRI Intellectual Property (IP) Office should therefore, be in the forefront in helping KEMRI scientists and technologists understand the Policy through awareness campaigns, and advise them appropriately on matters related to IPR. Given that most of KEMRI's research is funded through external collaborative partnerships, it is critical that IPR matters are managed in a way that is fair and beneficial to all parties involved.

The KEMRI IPR Policy is key in exploiting the potential of innovations that come out of KEMRI for the benefit of the Kenyan population. In fact, Kenya's Vision 2030 emphasizes the impact of Science, Technology and Innovation on the macroeconomic stability of our nation.

Young scientists in KEMRI have an opportunity to make discoveries and inventions through the support of KEMRI internal grants funding mechanism, which was established to encourage them grow in their careers, and contribute to science. Likewise, the senior scientists are encouraged to, not only mentor the young scientists, but also, to actively engage in cutting edge research that will yield new innovations and technologies for application in healthcare, and address the health challenges facing our nation.

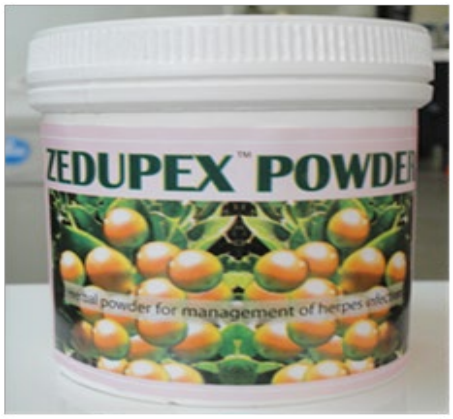
Article by:
Festus M. Tolo, Ph.D.,
Principal Research Officer, CTMDR,
Head, Natural Products Research and Drug Development Programme (NAPREDA),
KEMRI

In the ever increasing demand for natural products for maintenance of good health and the rise of modern information technologies that facilitates rapid communication and data transfer, awareness of the value of protection of traditional knowledge, and in particular "traditional medicine" has become a reality. This is more so at a time when the wealth of nations lies increasingly in the knowledge their people hold. Intellectual Property Rights (IPR) in relation to traditional knowledge has become a vital issue in a number of non-industrialized countries where such knowledge has assumed critical dimensions as efforts are put in place to conserve and protect it.

Intellectual Property Rights in the context of traditional medicine

Intellectual Property Rights conveys legal ownership over certain intangible assets, such as artistic works, commercial designs, and pharmaceutical technologies.Some of the common types of IPR include: patents, trademarks, copyrights, geographical indications, protection for plant varieties and trade secrets. IPR generally provides creators of original works, economic incentives to develop and share ideas through a form of temporary monopoly. One of the most important types of IPR for traditional medicines is patent protection. A patent grants a set of exclusive rights to an inventor for a limited time that prevents others from commercially using the patented invention without permission. Once a patent is expired, third parties may use the claimed invention without the consent of the patent owner. A trademark is another important form of IPR and protects words, phrases, symbols and designs that identify a source of goods. This helps consumers identify products with preferred characteristics, such as a specific brand of herbal medicine. Trademarks have been used to market products that are based on Traditional Medical Knowledge (TMK), such as Truong Son Balsam, a traditional balm of medicinal plants from Vietnam [1,7] or Zedupex, a herbal remedy for management of herpes developed by a team of scientists in KEMRI based at the Centre for Traditional Medi-

cine and Drug Research (CTMDR) [2].



Zedupex powder developed at the KEMRI-CTMDR is an antiviral agent for management of herpes due to Herpes simplex virus types 1 and 2 (HSV-1& HSV-2) infection. A trade mark is in registry at KIPI, Kenya.

However, while trademarks can help distinguish authentic goods, they do not prohibit third parties from using traditional knowledge. IPR holders may also elect not to disclose information about an invention, and to protect their invention through secrecy. A trade secret is information not generally known or reasonably discoverable, through which an IPR holder can obtain some economic advantage. Trade secrets must be the subject of efforts that are reasonable under the circumstances to maintain secrecy; once trade secrets become known they generally cease to enjoy protection. Plants are generally not protectable as an IPR, however, new plant varieties may be protected under a "sui generis"registration system. Protection applies to new varieties of plants that have been invented with human involvement. A "sui generis" system simply means "one that is of its own kind" and refers to a unique set of protections for a particular subject matter, for example, the African Union, a regional organization, has developed a model law that protects both plant varieties and traditional knowledge (TK) [3]. The objectives of this legislation include ensuring the sustainable use of biological resources, benefit-sharing and the protection of TK. Indigenous peoples and local communities have the right to refuse third parties access to TK when they determine that sharing access may threaten the integrity of their cultural heritage.Providers of IPR include the World Intellectual Property Organization (WIPO) and the Kenya Industrial Property Institute (KIPI), a government parastatal under the Ministry of Industrialization and Enterprise Development in Kenya.

What is Traditional Knowledge?

Traditional knowledge (TK) is considered as the collective heritage of a particular indigenous group of people or local community."Traditional" means that the knowledge is created in a manner that reflects the community's traditions; it is often intergenerational and created and held collectively. "Traditional", therefore, does not necessarily mean "old" but is related to the way in which the knowledge is created, preserved and transmitted from generation to generation within a system, held by local individuals, families, lineages or indigenous communities. From time immemorial, these local individuals or communities have a store-house of knowledge about their geographical flora and fauna. However, the local individuals and communities do not have the means to safeguard their traditional knowledge in the increasing global process of extraction, exploitation and commercialization. This view is shared by many scholars and researchers; "It is a stark reality that globalization is threatening the biodiversity, bio-information and creativity of indigenous approaches into proprietary knowledge for the commercial profit of a few…"states Dr.Sonia Jain of Deemed University, Rajasthan, India, in her article "Traditional Medicine and Intellectual Property Rights-An Indian perspective" [4]. The contribution of the traditional and indigenous peoples to the conservation of the world's biodiversity and related traditional medicinal information is immense. Everyday ethnobotanical and related surveys and researches provide new information about the cure of various diseases, body improvement and skin care remedies, natural oils and other health care objects. Sharing and access to world's biodiversity resources are seen as a basic human right but this conflicts with the property rights of the "inventor" traditional or indigenous groups. Trade is using all available material for commodification including materials, traditional methods and

ideas for medicine and in most of the times without any benefit to the country and community of origin. One notorious example often referenced is the derivation of plants extracts vinblastine and vincristine from the Madagascar rosy periwinkle; the drugs have earned the manufactures millions of dollars over the years but it is claimed that neither the shamans who gave the knowledge to the researchers nor the government of Madagascar have received any compensation for their contribution [5]. Commodification of what are collective resources –often a secret or sacred nature- is not only disrespectful to local culture or the individual contributor of the knowledge but a violation of human rights.

Catharanthusroseus (L.)G.Don(Madagascar rosy periwinkle) native to Madagascar.Source of vinblastine and vincristine used in cancer management

What is Traditional Medicine?

Traditional Medicine (TM) plays a crucial role in health-care and serves the health needs of a vast majority of people in developing countries. Access to "modem" health care services and medicine may be limited in developing countries. TM therefore becomes the only affordable treatment available in remote communities. The World Health Organization (WHO) defines traditional medicine as the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observations handed down from generation to generation, whether verbally or in writing. Health care providers worldwide including major pharmaceutical giants are turning to incorporate many of the TM into their mainstream activities. As traditional medicines are largely based on medicinal plants indigenous to various communities where the system has been in usefor several centuries, the effort is on accessing them either directly or through the use of modern tools of breeding and cultivation, including tissue culture, cell culture and transgenic technology need IPR protection.

The role of WIPO and KIPI as custodians of traditional medical knowledge

The World Intellectual Property Organization(WIPO)is primarily concerned with "protection" of traditional medical knowledge in the Intellectual Property (IP) sense i.e. protection against unauthorized use by third parties. WIPO continuously seeks to develop an international legal instrument that would provide effective protection of traditional cultural expressions/folklore and traditional knowledge (including traditional medical knowledge), and address the IP aspects of access to and benefit-sharing of genetic resources.Calls for the protection of traditional medical knowledge are often based on a number of cases involving misappropriation by unauthorized third parties, who have patented compounds derived from traditional medicines without the prior consent of traditional medical knowledge holders and without fair compensation.Kenya Industrial Property Institute (KIPI) is an equivalent of WIPO in Kenya formed by the Industrial Property Act, 2001. The KIPI Traditional Knowledge Unit factions include:-

i. Developing a traditional knowledge database for Kenya,

ii. Developing a simplified classification system of Kenya's traditional knowledge products and processes based on the hierarchical structure of the International Patent Classification,

iii. Developing office guidelines on avoiding inappropriate intellectual property claims by placing the information in the Public domain,

iv. Ascertaining the potential TK holders, as individuals or communities,

v. Creating awareness in local communities on the importance of traditional knowledge and genetic resources.

Why there is need for IPR on traditional knowledge

The issue of 'protection' of traditional knowledge needs to be looked at from two perspectives, the 'protection' may be granted to exclude the unauthorized use by third parties of the protected information. On the other hand, the 'protection' also means to preserve traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it. Further, the protection also promotes self-respect and self-determination. While recognizing the market-based nature of IPRs, other non-market-based rights could be useful in developing models for a right to protect traditional knowledge, innovations and practices. To date, debate on IPRs and biodiversity has focused on patents and plant breeders' rights. Provisions under undisclosed information or trade secrets could be invoked to protect traditional knowledge that is not available in the public domain. Geographical indications and trademarks, or "sui generis" analogies, could also be the alternative tools for indigenous and local communities seeking to gain economic benefits from their traditional knowledge. According to WIPO, the following challenges are still standing on the way for a realistic IPR on traditional medicine knowledge:-

i. Current IP regimes were not designed to accommodate traditional knowledge, and many experts have claimed that conventional patent laws are inadequate to protect TK and biodiversity.

ii. Patent protection is limited in duration, and that may be problematic for TMK that TMK holders believe should be protected retroactively and/or indefinitely.

iii. TMK holders are also presented with significant obstacles in attempting to obtain patents for TMK. The most significant challenge may be the requirement for novelty in any new invention. In the European Union, if an invention becomes publicly available in any way before a patent application is filed, the application will be rejected. The United States of America has a similar requirement with a one-year grace period.Making the invention publicly available may include selling the invention, disseminating information about the invention, or documenting the invention in a way that documentation can be accessed by a third party. Because many traditional medicines have been used for generations, disseminated in local communities, and documented in publicly available sources, these medicines may fail to qualify for patent protection.

An example of a successful case story of an IPR application

In 2002, an important precedent was set when the San nation, one of the South Africa's oldest tribes, reached an agreement with the Council for Scientific and Industrial Research (CSIR) of South Africa, a government body, and signed a pact that acknowledged the San were holders of traditional knowledge. For centuries the Khoi-San have chewed Hoodia (Hoodia pilifera), a cactus plant, to stave off hunger and thirst during hunting trips in the desert.

Scientific name: *Hoodia pilifera*(L.f.) Plowes;
Subsp. *pilifera* (L.f.) Plowes
Family: Asclepiadaceae (Apocynaceae) (Milkweeds family)
In: Asklepios No. 56:10,1992

The theft of intellectual property rights of the San be-

gan in 1996 when researchers at CSIR were able to isolate the hunger suppressing component of the Hoodia plant. The newly identified component was named P57 and patented. The next year CSIR, which retained ownership of the patent, brought in company to further develop P57, in turn, licensed one of the giant pharmaceutical companies to develop and market the compound. The San had shared their knowledge of Hoodia with CSIR, but they were not party to share of a product that could be worth billions of dollars as a natural appetite suppressant. After three years of negotiations, the San and the CSIR have agreed to share the profits from developing an anti-obesity drug [6].

Further Reading

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3. African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000, (OAU), available at http://www.grain.org/brl_files/oau-model-law-en.pdf.
4. Dr. Sonia Jain.Traditional Medicine and Intellectual Property Rights-An Indian Perspective.Mody Institute of Technology & Science(Deemed University)Lakshmangarh-332311(Rajasthan)
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6. Finger, J.M. Poor People's Knowledge: Promoting Intellectual Property in Developing Countries. Herndon, VA, USA: World Bank, 2003.
7. Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade (WIPO Publication No. 628), www.wipo.int/export/sites/www/freepublications/en/global_challenges/628/wipo_pub_628.pdf

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PRIM&R is currently accepting session proposals and poster abstracts for our 2017 Institutional Animal Care and Use Committee Conference (IACUC17) taking place March 18–21, in New Orleans, LA.

If you have an idea for a session that you would like to see at the conference, You invited to contribute to the Call for Session Proposals by August 26, 2016. Your submissions will help ensure that conference sessions cover a broad spectrum of topics If you conduct empirical research in the field of animal care and use or have implemented a program to improve the functioning of your institution's IACUC, showcase your work for an audience of your peers by sharing a poster at IACUC17. Submissions for the-Call for Poster Abstracts are due by October 7, 2016.

For Full details visit http://www.primr.org/iacuc17/

COPYRIGHT IN SCIENTIFIC LITERATURE

By Cynthia Kimani
Librarian, KEMRI Digital Library.

Copyright and Rights Related to Copyright.

Copyright is the rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films).Also the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations.

According to the KEMRI intellectual property rights policy;

"*Intellectual Property* shall mean any new or useful process, machine, composition of matter, life form, article of manufacture, software and copyrighted work and know-how and information associated with the above. It includes but is not restricted to such things as new or improved devices, circuit layouts, chemical compounds, drugs, genetically engineered biological organisms, data sets, databases, software or unique and innovative uses of existing inventions."

INTELLECTUAL PROPERTY RIGHTS AND MEDICAL RESEARCH.

The legal framework regulating Intellectual Property Rights on medical research in Kenya include:

1. Constitution of Kenya 2010
2. Industrial Property Act, 2001; (patenting medical research)
3. Copyright Act, 2001; (protection of research findings and publications)
4. Science, Technology and Innovation Act 2012; (the Act creating KEMRI)
5. Science, Technology and Innovation Policy (guide on protection of IPR's on KEMRI research)
6. Strategy and the national development blueprint,
7. Kenya Vision 2030.

Copyright and Scientific papers

The term copyright is a legal aspect that protects the works of the original creator to avoidduplicationby another. Copyright endows a lot of rights to the writers of a paper, or the producers of any creative work these rights more often get signed away by the publisher or distributors of these works. In the scientific peers, the agreement and rights given by copy rights can be very challenging considering that science is a progressive field. More of scientific research findings are based on another source. Unfortunately most sci-

entist sign contracts with corporate entities who may have their own rights hence may hinder the progress of science because of their unique rights. Hence the overall argument here is that scientific works should not be duplicated but should be cited and allowed to be viewed as they were from the original authors.

Another important aspect is that authors submitting their works should acknowledge that they are aware of all the terms and conditions of the journals they plan to publish with. Policies on plagiarism and copyrights vary and researchers need to be keen especially when signing copy right transfer agreement for their papers

Legal frameworks should be well understood by authors, for example they should be aware that the holder of the copyright has a right to reproduce published work. A copyright appears with "© year <name of individual or publisher>. The date range indicates when the material was created or modified. Copyright work is either in print or internet. When an author is using material from any source should always make sure all proper permissions are obtained.

Once a copyright transfer agreement has been signed by the author to the publisher the ownership automatically shifts to the publisher. More often than not one may request the author of the original work to use published material but the holder of the copyright is the owner of the works hence should be consulted for use. The terms of the copyright may depend and this is the only time the original author may re use his own work.

The Kenya copyright act is enacted in **The Copyright Act, 1966 (Chapter 130) (consolidated version of 1995)**

Further reading and references

https://www.informs.org/Find-Research-Publications/INFORMS-Journals/Author-Portal/Publications-Policies/Guidelines-for-Copyright-Plagiarismhttps://www.informs.org/Find-Research
http://www.wipo.int/wipolex/en/text.jsp?file_id=128405
http://www.copyright.go.ke/

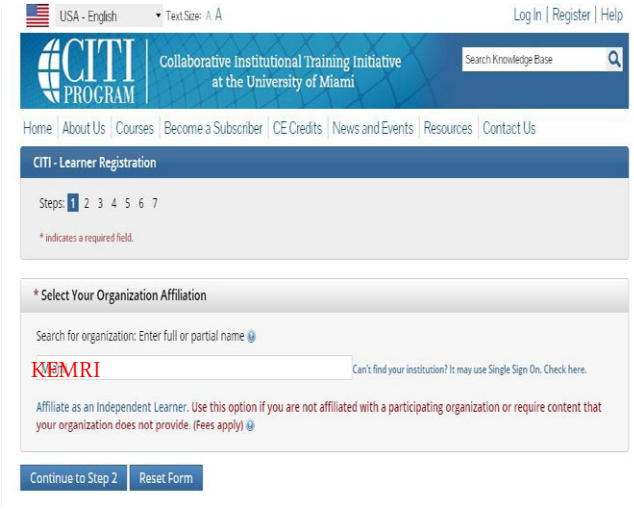
CITI ONLINE REGISTRATION AND TRAINING

KEMRI registered with Collaborative Institutional Training Initiative (CITI) in 2011. The main aim of CITI training is to provide access to upto date ethics training for researchers and other staff directly involved in research as a way of building capacity in research ethics. The training also encourages responsible conduct of research with human subjects. SERU currently requires all Principal investigators(PIs) and CO PIs involved in a study to show evidence of up to date basic ethics training before their proposal is reviewed. KEMRI encourages everyone involved in research with human subjects to take part this training.The training can be accessed online at *https://www.citiprogram.org/*

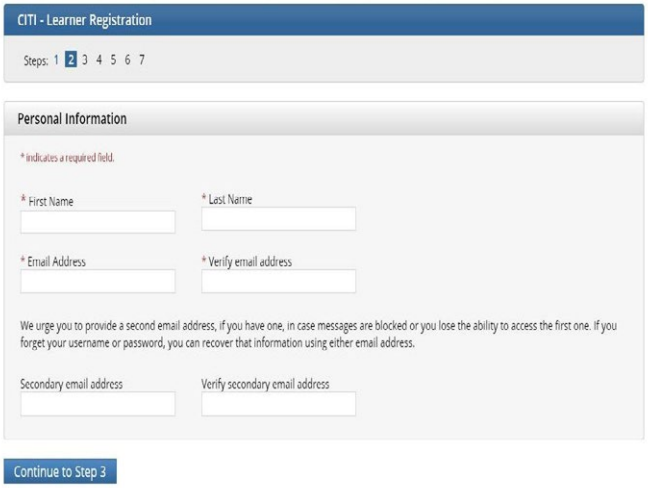
Step by Step Registration Guide

Adapted from CITI helpdesk. *https://support.citiprogram.org/customer/en/portal/articles/163300-how-do-i-enroll-in-a-citi-course-for-the-first-time-*

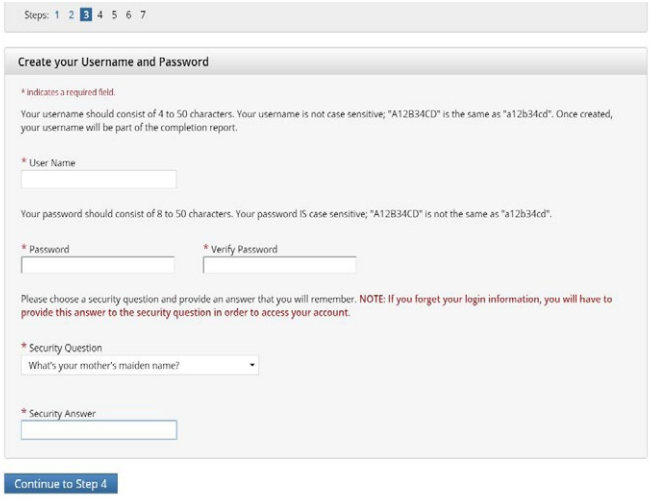
To register first time Go to www.citiprogram.org and click on the "Register" button located in the blue log in box to the right of the homepage



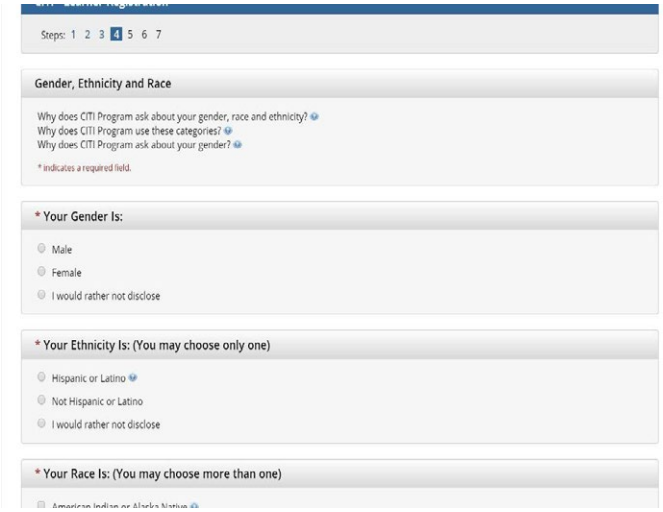
Step 1 Choose Kenya Medical Research Institute from search box.



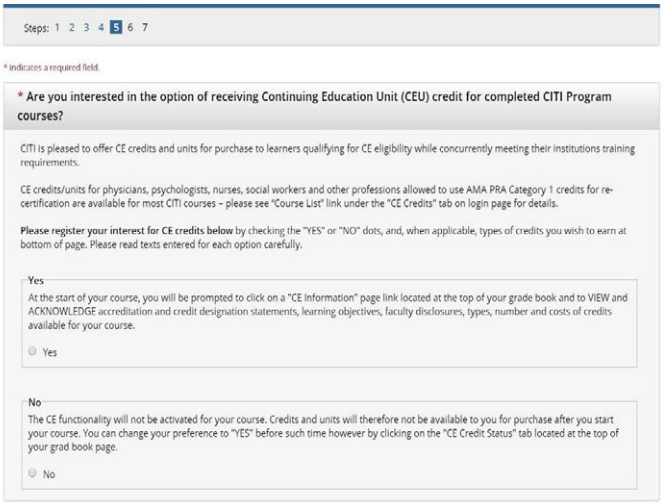
Step 2 enter your first and last name along with your email address.
Please enter your name here as you would like it to appear on your completion report received at the end of the course.



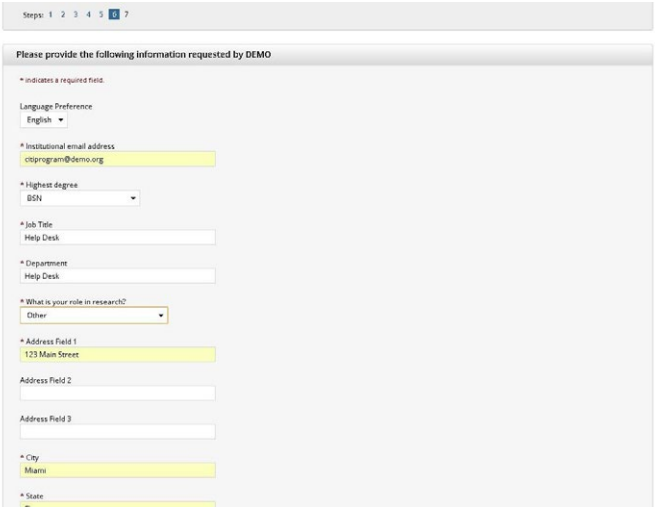
At Step 3 you will choose a username and password for your account. Please follow the on screen instructions for the expected parameters of each field. Passwords are case sensitive.



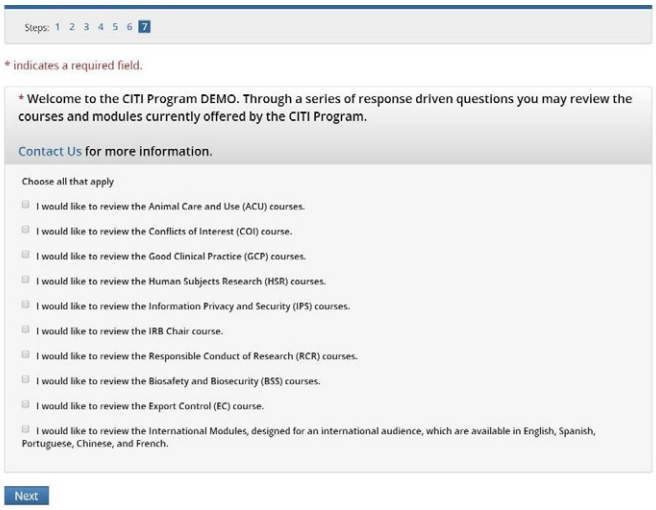
Step 4 collects demographic information. All information provided is voluntary. Use the blue information question marks for more information on specific categories.



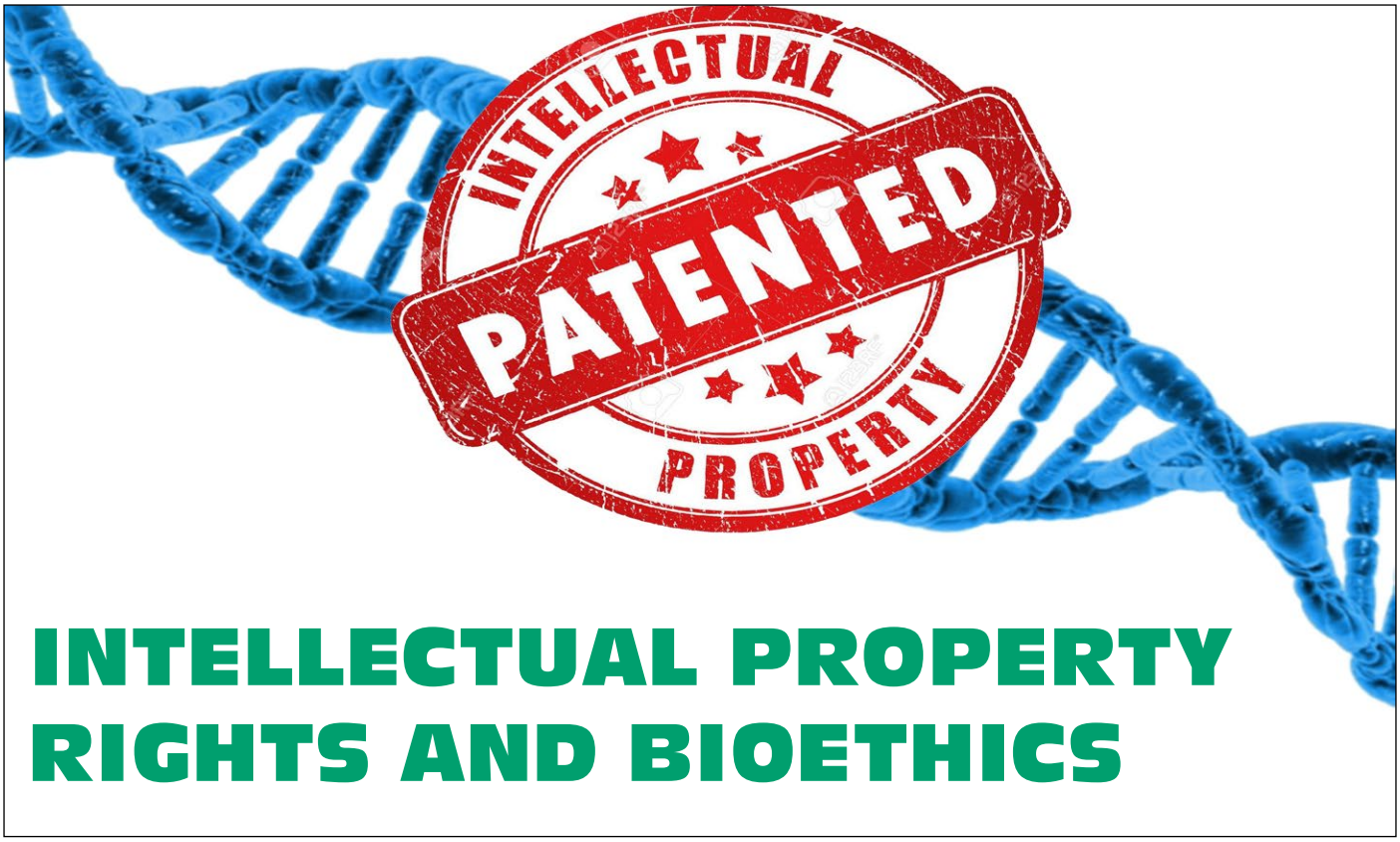
Professionals seeking credit for CITI Program courses can make their selection for Continuing Education credits during Step 5.



Step 6 is institutional specific. Each institution determines the fields listed on this page and what information is required or optional. Some institutions request very specific information such as a employee ID number or campus name.



The questions in Step 7 enroll you in CITI Program courses. . Please read each question carefully to ensure you are enrolled in the correct course.



INTELLECTUAL PROPERTY RIGHTS AND BIOETHICS

By David Nguru
Head Marketing And IP Department, KEMRI

Introduction

In 1953 James Watson and Francis Crick announced the discovery of the structure of DNA signifying the beginning of the modern age of biology and biomedicine. In June 2000 the then US President Bill Clinton announced the news that the first map of the human genome was complete and predicted that genome science would revolutionize the diagnosis, prevention and treatment of most if not all human diseases. Technological advances, including unlimited data storage in clouds and enormous supercomputing power, have created a burst of disruptive genomic sequencing applications. This has allowed scientists to predict and understand the genetic basis for diseases which in turn has paved wayfor new treatments to be devised with therapies tailored to patients by genotype. It is expected that the technological progress in the genomics market will not stop any time soon with the market estimated to be worth US $20 billion by the year 2020.

Like in any other advancing field, advancing knowledge about DNA and the human genome has presented legal and ethical puzzles. . One of the major puzzles has arisen in the field of intellectual property, and principally the issue of protection of discoveries and inventions that arise out of the unfolding knowledge about the genetic makeup of human and other living species under patents. With the advances in knowledge in the field of biotechnology the law of patents was invoked and adapted to provide protection in the field. The controversies arise from the fact that many people wonder whether patent law, devised in earlier times for mechanical and similar inventions, is suitable to be applied in the life sciences. The controversies could also be attributed to some extent to the need to spur creativity and innovation while at the same time maintaining human dignity and access to the greatly needed fruits of research and resultant improved healthcare.

This article borrows extensively from existing literature to highlight the various controversies and suggested solutions in this ongoing debate.

Interaction / intersection between Intellectual Property and ethics in life sciences research and commercialization

Intellectual property refers to the legal rights

which result from intellectual activity in the industrial, scientific, literary and artistic fields. It is divided into three branches; industrial property, copyright and plant breeder's rights. Countries have laws to protect intellectual property for two main reasons. One is to give statutory expression to the moral and economic rights of creators in their creations and the rights of the public in access to those creations. The second is to promote, as a deliberate act of Government policy, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social development. Intellectual property law aims at safeguarding creators and other producers of intellectual goods and services by granting them certain time-limited rights to control the use made of those productions. Those rights do not apply to the physical object in which the creation may be embodied but instead to the intellectual creation as such.

Inventors are rewarded for their creativity and are motivated to continue to produce goods and services that the entire society benefits from. These rights protect the innovator's investments and create a market for them. Recognition of property rights creates a less vulnerable market for innovators by guaranteeing that there is a fixed reward to be earned on their investment in innovation. This is done by giving them the right to impose a charge on the use of their knowledge, thus providing the reward for their investment. Without clearly defined rights, these intellectual outputs are subject to copying, which can prevent a return on investment sufficient to cover fixed costs and compensation for the high degree of market uncertainty.

Ethics is the discipline concerned with what is right or wrong and has theoretical and practical aspects. It seeks to establish norms or standards of conduct (normative ethics) and to analyze the basis of judgment about what is right or wrong (descriptive ethics). Applied or practical ethics refers to the application of theoretical ethical tools and norms to address actual moral choices. Bioethics deals with ethical implications of research and medical applications. Itis thus concerned with the ethics and philosophical implications of certain procedures, technologies and treatments such as organ transplants, genetic engineering and care of the terminally ill.

Intellectual property protection aims to promote policy objectives that are consistent with widely accepted ethical principles, however there are different ways of analyzing the ethical basis of Intellectual Property Rights. Some of these laws and principles have 'natural rights' basis, which reflects an inherent entitlement to the reward and recognition of one's knowledgeable and creative contributions whereas there is still a strong utilitarian flavor to intellectual property law and policy as a conscious tool for the promotion of social welfare.

A utilitarian approach to ethics assesses the moral value of an action according to its contribution to social utility and welfare.This approachhas increasingly been emphasized in the current debate on intellectual property as a tool of public policy. This is echoed in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement which statesthat "the protection and enforcement of Intellectual Property Rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge in a manner that is conducive to social, economic welfare and balance of rights and obligations."

Controversies in the relationship between IPRs and bioethics

As the field of biotechnology continues to evolve, various controversies have been outlined in what some view as a complex relationship between IPR and bioethics. These include:

1. Should biotechnological discoveries or inventions be protected under IPRs and specifically patents?
2. How should sample donors be treated where IPRs may be sought?
3. Does patenting or obtaining of other IPRs impede further research or restrict access to healthcare in the life sciences?

Patentability of genes and other living materials -

Should biotechnological discoveries or inventions be protected under IPRs and specifically patents

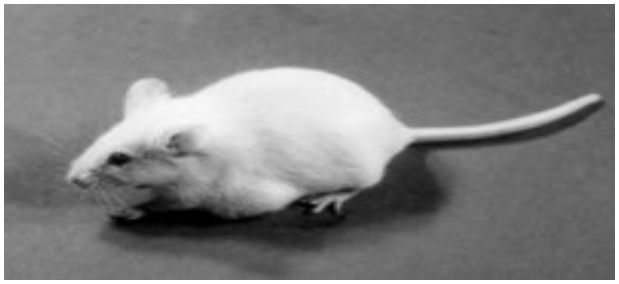
Some individuals, groups, cultures and nations adhere to the position that any patenting of human, animal or plant genes, tissues and related biomedical innovations is unethical. This position is based on the argument that patenting 'commodifies' lifeforms and that living materials are naturally occurring and thus isolation and description of "nature's handiwork" should not qualify as patentable subject matter.

Other concerns of those who oppose the patenting of living materials are that:

1. Patenting will facilitate and accelerate applications and commercialization of biotechnology
2. Patenting will lead to greater animal suffering;
3. Patenting undermines the dignity of humans and other species by making their genes and cells subject to ownership by others.

(Box 1 below provides an example of arguments in regard to the oncomouse that developed at Harvard University.)

There has been much ethical debate about the patenting of mammals – such as mice bred to be highly susceptible to cancer, for use in medical research. Some argue that patenting genetically modified mammals – however inventive they may be – is inherently immoral. Others take the view that a utilitarian balancing of welfare effects is required. Still others view the question as ethically neutral.



Box 1: the Oncomouse bred at Harvard University

In support of these arguments, the Council for Responsible Genetics issued the Genetic Bill of Rights in 2000 which contends that "all people have a right to a world in which living organisms cannot be patented, including human beings, animals, plants, and all of their parts." Similar statements have also been echoed by religious leaders in 1995 and the French Justice Minister, Elisabeth Guigou, in 2000.

Among those who defend gene patents are those who wish to offer a reward to the researcher, who, like other workers, should be able to reap the benefits of their work. Thus, in return for the time, energy, and resources spent on their work, a patent should be given in compensation. These proponents believe that there exists the natural right for man to be compensated for the fruits of his labor, an argument used in favor of property rights in general, and derived from the theory of John Locke, which originally stated: "I made it, I created it, it is mine; it would not exist without me." One of the most common arguments in favor of bio-patents is their great social utility, which surpasses any other consideration. Bio-patents serve as a necessary incentive to encourage and support innovations. Without them, competitors would prefer to let others innovate, so they can copy the final product and sell it for a lower price than the innovator can, since they would not have to pay the cost of research and development.

The language of different patent laws originated from inventions in physics and chemistry.It thereforewould be preferable to create a system of protection that is more compatible with biological inventions. On verifying bio-patents, it seems that intellectual property rights are implicated; however, there is still a great deal of confusion as to whether or not genes are property and to whom they belong. These questions can no longer be ignored. A patent by definition implies what could be thought of as a "negative" right, meaning the exclusion of others from using the patent.

Among those who have voiced their support for the patentability of genes and other living materials on ethical grounds is the United Nations Educational, Scientific and Cultural Organization (UNESCO) International Bioethics Committee that concluded in 2002 that, "law on intellectual property serves useful purposes, has a foundation in ethical principles and

universal human rights, and often contributes to the benefit of humanity." UNESCO, in accordance with its calling to promote the sharing of knowledge, feels that the fact of knowing of a human gene or its partial sequences in its natural state cannot be the object of intellectual property rights, and that this knowledge must be freely accessible to all those involved in research world-wide. This does not rule out the fact that the results of research may be covered by intellectual property rights. Other proponents of patentability in the life-sciences argue that eliminating patent protection from biotechnology inventions would make those innovations less rather than more ethical in part by making new technologies less transparent as companies would rely more on trade secrets in place of patents which place a requirement for public disclosure.

In regard to international agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires countries to provide IP protection for most biotechnology products.However the agreement allows World Trade Organization (WTO) countries to exclude bioengineered animals from patentability and specifically provides that countries may elect to include a provision in their patent laws that denies patents for specific inventions and innovations that are unethical. In Kenya, the Industrial Property Act, 2001, that governs patents and other industrial property in the country has a public morality clause [Article 26(b)] that denies patent protection to inventions that are contrary to public morality. The European Union also has the ordre public clause but a number of other nations including the United States have declined to include such a morality clause. In countries where such a clause exists in law controversial patents could be challenged both during the application and post issuance. Most countries also prohibit patents related to the cloning of human beings, modification of human germ lines, use of human embryos for commercial purposes and genetically engineering animals in ways that cause suffering without a substantial medical benefit to human beings.

Bio-prospecting - How should sample donors be treated where IPRs may be sought based on the results of the research they are participating in

Another issue that has generated debate in regard to the interaction between bioethics and intellectual property rights has to do with bio-prospecting and related bio-piracy. Bio-prospecting can be defined as the systematic search for and development of new sources of chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature. So, in brief, bio-prospecting means looking for ways to commercialize biodiversity. Lately, exploration and research on indigenous knowledge related to the utilization and management of biological resources has also been included into the concept of bio-prospecting. Thus, bio-prospecting touches upon the conservation and sustainable use of biological resources and the rights of local and indigenous communities.

Where bio-prospecting is not effectively handled it may lead to bio-piracy. Bio-piracy is,"the illegal appropriation of living materials - micro-organisms, plants, and animals (including humans) - and the traditional cultural knowledge that accompanies it." The corporations and individuals extract, "improve", and patent genes from living materials and thus claim the materials for themselves and also take the cultural knowledge that accompanies the material. The appropriation is illegal because it is done without the necessary consent from the originating communities and is thus in violation of international conventions and, where they exist, domestic laws.

Another point of note concerns biological colonialism. By assuming that the human tissue is a natural resource, like iron and oil, researchers could look for "exotic" genes from remote civilizations, genes that could serve as raw material for a new and lucrative type of medical practice. This practice could result in exploitation of indigenous races, which are considered primitive by the western world, without giving them any part of the profits. This practice would amount to exploitation of developing countries (sources of abundant genetic resources) by de-

veloped countries.

Two issues that have been at the forefront of ethical debate and related to bio-prospecting and bio-piracy are prior informed consent and benefit sharing. Prior consent refers to the procurement of advance approval from relevant entities before obtaining biological samples with the issue here being from whom the consent should be sought. Controversies tend to arise when only some of the entities but not all – individual, local community, tribe, local government – have provided the required consent (**See box 2 below in regard to the Hagahai peoples case).**

Box 2. The Hagahai People's Case

The Hagahai are an indigenous community in Papua New Guinea. Many members of the tribe carried a retrovirus that normally causes T-cell leukemia (a disease caused when human immunecells themselves are infected with the virus), but they appeared immune to the disease.Researchers established a cell line of T-cells infected with the HTLV-1 virus which had potential usein screening for this form of leukemia and in developing a vaccine. A patent on the cell line was issued in 1995, in the name of the US Department of Health. But patenting a cell line developed from a blood sample from an indigenous donor raised bioethics issues that led to the patent being disclaimed and dedicated to the public domain in 1996. The patents sparked controversy on several issues: consent, including cross-cultural communication and recognition of diverse value systems, the ethics of patenting of inventions derived from human tissue, and equitable sharing of benefits

Another issue in regard to consent is whether the consent process must include disclosure that the collected material may be used to secure a patent. A complication that usually arises is that, except for rare cases, most patentable inventions arising from human tissue are based on findings using large numbers of samples, complicating and accentuating the requirement for prior consent on future patents from each individual tissue donor.

In regard to these controversies the European Union's Group of Advisers on the Ethical Implications of Biotechnology, in 1996, endorsed the need for prior consent before using a donor's tissue to develop a patentable invention by stating: "The ethical principle of informed and free consent of the person from whom retrievals are performed must be respected. This principle includes that the information of this person is complete and specific, in particular on the potential patent application on the invention which could be made from the use of this element. An invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent, will not fulfill the ethical requirements." In the context of plant and animal samples the Convention on Biological Diversity requires informed consent from the appropriate national authorities as a condition of access to plant or animal genetic resources. Several nations have also adopted their own laws requiring prior informed consent for the collection of plant and animal resources.

Box 3 – Kenya's Management of its biological resources

Management, utilization and conservation of the Kenya's biological resources is governed by various laws. The country has ratified the Convention on biological diversity (CBD), Nagoya Protocol 2010, ITPGRFA, CITES, Cartegena Protocols, among others which govern access and use of genetic resources. In addition the country has put in place domestic mechanisms that include the Constitution, legislations such as EMCA 1999, subsidiary legislation legal Notice 160, Wildlife Conservation and management Act 2013, Forest Act 2005, NACOSTI Act 2012 among others to regulate access and use of biological resources.Key elements for accessing Kenya's genetic resources include: (1) Prior Informed consent – PIC - from competent resources providers as defined by the law (both genetic resources and associated knowledge) and the communities - for example those seeking to undertake research on wildlife biological resources will seek PIC from the Wildlife Management Authority; (2) Research permits to conduct research on the country's biological resources are issued by National Commission for Science, Technology and Innovation (NACOSTI); (3) Work permits from Immigration Service Department (4) Access permit - All accessing Kenya's biological resources for research and development are required to obtain an access permit from NEMA. This is governed by EMCA 1999, the "Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006; and (5) Export permits from competent institutions

http://meas.nema.go.ke/abs/download/Biological%20Authorization%20Procedures.pdf

In regard to benefit sharing there is the ethical objection that paying significant financial benefits to individual tissue donors may unduly induce some individuals to participate in research. Another challenge in benefit sharing is that there is usually uncertainty in identifying who should decide how the benefits will be shared within the populations especially in populations that are dispersed and difficult to define in terms of a recognized governance structure. Despite these concerns the emerging international consensus seems to be that groups participating in research should receive some benefit. The International Declaration on Human Genetic Data provides that: "Benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with society as a whole and the international community." When the research results in commercial products the Human Genome Diversity Project suggested two mechanisms for returning benefits to the sample donors: (i) paying a set percentage royalty to the benefit of the sampled populations; or (ii) negotiating a reasonable financial payment with a trustee for the sampled populations, with the proceeds for the population's benefit. For non-profit Institutions it has been suggested that they should ensure that immediate health benefits as determined by community needs could be provided.

A first step in order to avoid bio-piracy and address benefit sharing would be to develop an integrated and comprehensive national policy on access and benefit sharing (figure 1 provides a proposal on a possible access and benefit sharing concept). Benefits can be tangible as well as intangible, and should be fairly shared among the parties involved. Tangible benefits may include fees, royalties, profit sharing arrangements, etc. Intangible benefits could for instance be the strengthening of institutional capacity, provision of subsidized healthcare and other services, etc.

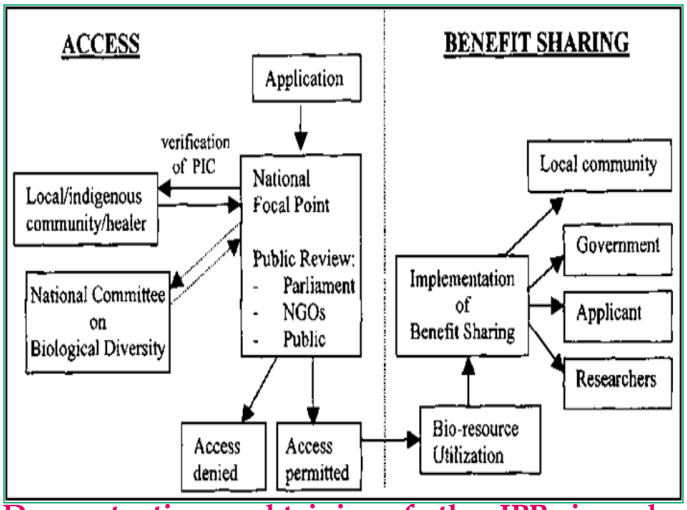


Figure 1: Possible access and benefit sharing concept - Adapted from World Health Organization

Does patenting or obtaining of other IPRs impede further research or restrict access to healthcare solutions in the life sciences?

A possible argument against patents is that the process of transforming biological knowledge into private knowledge threatens the continuance of scientific cooperation, and slows down the rate of innovations. Moreover, businesses uniting universities and industries result in secrecy in research laboratories and a growing amount of skepticism in relation to the value of exchanging information among colleagues. There is concern that patented inventions are unduly restricted or costly due to high licensing fees, exclusive licensing or similar access-limiting strategies by the patent owner and this could adversely affect medical research and health care. An example is cited of Myriad Genetic's patents on breast cancer genes (BRCA 1 & BRCA 2) which due to their high licensing fee and monopoly limited access for health care providers and researchers and thus adversely

Box 4: Genes for screening for cancer in women

BRCA-1 and BRCA-2 are two genes linked to susceptibility for breast and ovarian cancer. The risk of falling ill increases if these genes show certain mutations. Identifying the mutations is therefore important for diagnosis and for monitoring higher-risk women. Myriad Genetics Inc., in collaboration with the University of Utah, sequenced the BRCA-1 gene, and applied for patent protection in 1994. The ensuing multifaceted debate over this patent partly concerned the ethical dimension of how a patent on a valuable diagnostic test should be licensed.

affected research and healthcare. (See box 4 below)

Exclusive licensing may also limit access to important scientific tools, materials and procedures with some commentators believing that "upstream" patenting of research tools and genes will result in excessive and overlapping proprietary hurdles that will impede scientific research. The commentators therefore feel that privatization of biomedical research should be more carefully deployed to sustain both upstream research and downstream product development or otherwise more intellectual property rights will lead to fewer useful products for improving human health. An earlier survey of university geneticists in the United States indicated that majority of the geneticists felt that patenting and commercialization of research could be impeding the scientific ideals of openness and sharing with the withholding of data by colleagues slowing progress in the field.

The counter argument is that patents do not hinder pure scientific research, since any scientific use of the patented invention does not constitute a violation of the patent. Apart from this experience has proven that an effective transfer of technology from research laboratories to industries can only be done by way of an active and effective policy of patenting and licensing. Another argument in favor of patents is that if they were abolished, people would seek other ways to protect their innovations, resulting in the keeping of commercial secrets, which, in relation to accessing information, is much worse than patenting. Applications for patents demand the revelation of the technology involved, while the protection of industrial or trade secrets does not require this disclosure. Contrary to the argument for confidentiality of research, it can be pointed out that upon submitting applications for patenting (at least in Europe), secrecy is not guaranteed. On the contrary, by submitting these applications, an immediate publication of the invention is permitted. In addition, it should not be forgotten that a common practice among scientists in this area is of not sharing the results of their research until their papers have been published (this is not so very different from the practice of patenting).

In the early 1990's debate arose in regard to access to essential medicines especially anti-retroviral drugs used in the treatment of HIV / AIDS. The contention was whether to allow the use of generics as opposed to patented drugs. In the present day one would notice that the use of generics especially in Africa and other developing countries may have surpassed the use of the patented drugs due to their cheaper price.

Resolving the controversies in the relationship between IPRs and bioethics

Apart from the proposals and guidance presented by the international agreements and other solutions mentioned in this article various other measures have been cited as possible solutions to the outlined controversies. These include: compulsory licensing, prohibition of exclusive licensing, liability exemptions for clinical uses of patented materials and tests, expanded experimental-use exemptions, patent pools and open-source approaches to life sciences research.

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Courtesy of KEMRI IP and Marketing Department

This series of commonly posed questions from the KEMRI IP department is meant to raise awareness among researchers at the Institute of the potential value of intellectual property arising from their work and issues involved in its exploitation.

What is Intellectual Property?

Intellectual Property is literary, artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks; service-marks, and commercial names and designations; protection against unfair competition; and all other rights resulting from intellectual activity in industrial, scientific, literary and artistic fields.

What are the various types of Intellectual Property?

i) Patents

A patent is a certificate or document granted by a state that gives exclusive rights to the owner of an invention within a given country for a certain period usually 20 years. The patent document describes an invention and creates a legal situation in which the invention can normally only be exploited with the authorization of the owner of the patent. Patent rights can be sold, leased, licensed or acquired.

ii) Utility Model

Any form, configuration or disposition of element of some appliance, utensil, tool, electrical and electronic circuitry, instrument, handicraft mechanism or other object or any part of the same allowing a better or different functioning, use, or manufacture of the subject matter or that gives some utility, advantage, environmental benefit, saving or technical effect not available in Kenya before and includes micro-organisms or other self-replicable material, products of genetic resources, herbal as well as nutritional formulations which give new effects. It must be new and industrially applicable

iii) Trademark

A trademark is a basically a sign that is used to distinguish the goods or services offered by one enterprise from those offered by another. It must be distinctive and not deceptive. The sign may consist of one or more distinctive works, letters, numbers, drawings or pictures, monograms, signatures, colours or combination of colours etc. It may consist also of combinations of any of the said elements. The trademark can also be a word, a symbol, a design, or a combination of these, used to distinguish the goods or services of one person or organization from those of others in the market place.

iv) Industrial design

Any composition of lines or colours or any three dimensional form, whether or not associated with lines or colours: Provided that such composition or form gives a special appearance to a product of industry or handicraft and can serve as a pattern for a product of industry or handicraft.

v) Copyright

The domain of copyright is the protection of literary and artistic works and includes writings, music and works of the fine arts such as paintings and sculptures and technology based works such as computer programs and electronic databases. Copyright protects works that is the expression of thoughts, and not ideas.

How can protection be achieved for the various Intellectual Property Regimes?

External registration is essential in the case of patents. All patents are published and give full details of the invention. In Kenya Kenya Industrial Property Institute (KIPI) is the national body charged with receiving, processing and granting patent applications. Copyright including that on computer software requires no external registration and comes automatically. It is however fit to establish ownership of each item by attaching a statement such as;

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Who decides whether to seek protection or allow for immediate publication?

The decision is normally taken jointly by the inventor and the IP Manager.

What aspects are relevant in deciding between protection and publication?

The assessment of the commercial worth of the inventor is indirect relevance in deciding whether or not to apply for a patent. The IP Manager and you jointly should try to reach a clear view about what commercial end-product might result. Will it be a pharmaceutical preparation, or a new medical instrument? Such assessments are far from easy, but nevertheless ought to be attempted. It should be borne in mind that it can often take from 5 to 10 years to develop a new product or process, and longer if clinical trials are involved. Specialist market research might be necessary.

If the invention is indeed patentable, but for whatever justifiable reason the decision is taken not to proceed, the wise thing to do is to publish forthwith. This will ensure that no one else can patent it.

When and how should a patent application be made?

Prior publication means that an invention cannot be patented in most countries. Describing an invention in the scientific literature, or in a conference paper, or in a poster session, or at an exhibition, or on the Internet, or indeed in any formal or informal public meeting (even over coffee), constitutes public disclosure. It is prudent to check with the IP office before publicizing your invention in any way whatsoever.

Researchers, understandably, wish to publish the results of their work without delay particularly if they are leaders in their field. If absolutely necessary the IP office can prepare and file a patent application within a week. Thus in general there should be little need to delay publication significantly.

If the IP office agrees that you have made an invention with commercial promise, the next step will be to conduct search on of existing databases to see whether your invention has already been patented, or whether there is any damaging 'prior art' contained in claims of other patents which include your idea and which could negate your invention.

The date on which the application is filed with KIPI will become the patent's 'priority date'. The same date will be carried over into all subsequent foreign filling even though they are filed later.

What happens next in the patenting process?

If a patent is not to be abandoned, then on or before the first anniversary of the priority date, full patent claims must be filed and decisions taken on foreign filings. This is normally done via a Patent Co-operation Treaty (PCT) application which designates the countries to be covered. During the year following the priority date, two objectives should be actively pursued. The first is concerned with the invention itself. The patent application will have described the novel idea constituting the invention, but it will probably not have been demonstrated at that stage to be feasible in practice i.e. that it can be made. The year gives the opportunity to make progress towards reducing the invention to practice, so that the strongest possible claims can be made in the patent specification. Submission of final claims would normally take place just before the first anniversary of the priority date.

The second objective is to assess industrial interest

in the invention, and here the IP office will be closely involved. Unless the patent is abandoned, the patent specification will be published 18 months after the priority date. Its contents will thus enter the public domain. Many major companies examine all patents relevant to their industrial sector immediately after they are published. This in itself may result in an approach from one or more firms with expressions of interest in acquiring access to the technology covered by a patent.

What is the position of inventors?

The inventor or inventors must be named on the patent. It is important that only the Researcher(s) actually responsible for creating the new invention should be so named. If a genuine inventor is left out, or someone who did not contribute to the actual inventive step included, the patent could be open to challenge.

Can inventors be rewarded?

There is a revenue sharing arrangement in place as detailed in the KEMRI IPR Policy.

How can income be obtained from Intellectual Property rights

Income can be obtained through licensing, through assignment or by straight forward sale. A license allows a licensee exclusive use of the intellectual property rights for a defined period and in a defined geographical area, but the ownership remains with the provider. The license will include some form of financial consideration to the provider such as a lump sum on signature and a royalty on sale of products based on the intellectual property rights. An assignment document is signed by both parties. Again there would be a financial consideration, probably a lump sum on signature plus a continuing royalty on sales.

Who is responsible for leading the exploitation effort?

Formally it is the IP office, but in practice the creators of the intellectual property will need to be deeply involved in almost every case. The professional skills in intellectual property management and licensing which the IP office possesses, or more generally has access to, will provide an essential complement to the scientific and technical skills of the researchers. Experience has shown that a surprising amount of work, often spread over 5 or more years, has to be put in to most exploitation projects. The best way to organize the effort is for the IP office to be the main point of contact with the external world, and for the researchers to be brought in to the discussions as appropriate.

IP INFRASTRUCTURE IN KEMRI

KEMRI has put in place an appropriate intellectual property and technology transfer infrastructure towards promoting the development and commercialization of biotechnological innovations. The infrastructure consists of an Intellectual Property and Technology Transfer Committee composed of senior research scientists, Marketing, Intellectual Property and Technology Transfer Office and, the Institute Intellectual Property Policy.

The Policy forms the foundation of the intellectual property and technology transfer system in KEMRI and provides clear guidelines on ownership, responsibilities of the various stakeholders and available incentives in the management of intellectual property. The Committee plays an oversight and advisory role in regard to intellectual property and technology transfer management including the development and where necessary review of the policy while the Office is responsible for the implementation of the policy and the day to day management of intellectual property and technology transfer activities within the Institute including identification, protection and utilization of intellectual property. The Office is also responsible for the coordination of all revenue generation activities within the Institute.

The Institute collaborates with various local and international organizations, in various initiatives, towards the protection and effective utilization of its intellectual property among them participation in WIPO Re: Search. The Institute also has representation on the Board of Directors of the Kenya Industrial Property Institute – KIPI. KIPI is the organization responsible for grant and registration of Industrial Property Rights in Kenya.

The Marketing, IP & TT Office is housed within the KEMRI Production Unit Building located within KEMRI Headquarters in Nairobi, Kenya.

Contacts: Extensions 3423 / 3429 / 3430 marketing@kemri.org

Annual Renewal of Research Protocols: What you need to Know

All proposal and protocols approved by the KEMRI Scientific and Ethics Review Unit (SERU) are subject to annual review and approval. Researchers are therefore required to submit an application requesting for permission from the SERU to continue with the research each year until the study is completed. Researchers must notify the SERU when they intend to close out the study. SERU reviews the annual renewal request before determining whether to grant it approval. Below are some of the facts that a Principal Investigator (PI) must take note of when requesting for annual renewal from the SERU.

1. What should accompany a request for annual renewal?

- A duly signed explanatory cover letter
- The annual or status report (Filled using the CRR template on KEMRI Website)
- One copy of the current approval letter
- Any publications and/or abstracts

2. Which type of studies are subject to annual renewal

- A study that that has completed recruitment but research participants arein the follow-up phase.
- A study that has no direct contact with study participants but activities such as data analysis, report writing or manuscript preparation are still ongoing .
- A proposed study that has not been initiated within twelve (12) months from the date of ethical approval provided that valid reasons for not undertaking the research in the initial approval period have been provided.

3. When should a PI file for annual renewal

- SERU requires a PI to file a request for annual renewal six weeks before lapse of the one year approval period
- The study reports submitted shall be reviewed at the next available SERU meeting provided that the request has been received by the deadline for submission.

4. What happens when a PI does not request for annual renewal on time

- The study will automatically expire. The PI shall be required to stop all study activities, to immediately submit a list of research participants for

whom the postponement of research would cause harm within five (5) days of expiration

- The PI should also submit a request for annual renewal together with aprotocol deviation report explaining the reason for failure to apply for renewal.
- The Chairperson in consultation with the SERU committee members shall issue an appropriate course of action.
- The PI may only resume the study once continuing review and approval by the SERU committee has taken place.

5. How long does it take for the PI to receive status of the application for annual renewal

- The SERU Secretariat shall communicate to the PI, in writing, the outcome of its deliberations on the request within six (6) working days of the meeting at which the request was discussed.

6. How many times is a PI allowed to renew a continuing study?

- All approved research protocols have a life span of sixty (60) months after which a new research proposal should be developed and submitted for review or an extension be submitted with appropriate justification.
- A final study report should be submitted and notice of closure must be issued on or before the expiry date of approval at month sixty (60).
- The SERU committee makes special consideration for research that is designed for longer study period as indicated in the approved study documents.

SOUTH AFRICAN RESEARCH ETHICS TRAINING INITIATIVE (SARETI)

MASTERS Degree Programme in Health Research Ethics 2017

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To enable trainees to train others in providing this review
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To prepare African professionals to assume leadership positions in health research ethics in Africa, to pursue a career or further doctoral studies in this field
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