BIODIVERSITY, BIOTECHNOLOGY AND ENVIRONMENTAL JUSTICE IN MALAWI

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1. INTRODUCTION

The concept of environmental justice has for a considerable period of time been the focus of commentary on an extensive scale worldwide. Innumerable definitions have been ascribed to this concept which vary considerably and most of which are customized with references to particular jurisdictions and groups¹. One commentator defined the concept as the equitable environmental policy making and enforcement to protect the health of all persons². More recently, this concept has registered on the radar screens of a number of environmental, civil rights and social groups because of the potential dangers that the numerous techniques that are being developed in the field of biotechnology pose on the individual's right to a clean and healthy environment. On the other hand, biotechnology has revolutionalized the search for new product lines in different industries. Agricultural biotechnology alone, for instance, has been touted by some as the best solution to the shortcomings of chemical agriculture. It has been argued that it possibly constitutes the only available avenue for raising yields fast to be able to feed an ever-increasing world population³. Albeit that the techniques being developed in the new field of biotechnology hold great promise and new opportunities for the human community as a whole, we need to contain the potential risks that are concomitant with bioengineering. In striking the appropriate balance, it is imperative that we must consider the impact of biotechnology on all relevant aspects such as food security, public health, access and benefit sharing within the context of environmental justice.

The regulation of biotechnology under environmental law brings to the fore issues of environmental justice and sustainable development. The major concern under both heads is the intra and inter-generation distribution of costs and benefits of biotechnology products by improving the quality of life and enhancing access to resources. Put succinctly, environmental justice and sustainable development seek to fulfill the basic needs of people by improving access to and benefit sharing of resources without compromising the capacity of the environment to provide similar benefits to future generations. Environmental justice alone seeks to draw the necessary balance between conservation and economic development.

A serious and comprehensive environmental agenda in this respect must also examine and analyze the regimes of nature management and identify what kinds of politics and governance are imagined and implemented in order to assess the consequences meticulously. We further need to examine the civil rights implications of intellectual property rights vis-à-vis access and benefit sharing of the products of biotechnology.

¹ It has been argued that, "the pursuit of stable, consensual definitions of such terms as *environmental justice* and *environmental racism* is misguided. We must accept that people in different geographic, historical, political, and institutional contexts understand the terms differently. Instead of regarding the lack of universal definitions as a barrier to progress, however, we need to treat the breadth and multiplicity of interpretations as guides to more relevant and useful new research. See Ryan Holifield, <u>rholifi@arches.uga.edu</u>.Generally, the concept of justice has three facets, viz. facets - <u>interpersonal adjudication</u>, law based on standards and <u>fault</u> and an emphasis on <u>procedures</u> http://www.ecojustice.net/

² John Hoyte, "Biotechnology and Environmental Justice," http://www.ecojustice.net/

³ See Schaal, B.A, "Biodiversity, Biotechnology and the Environment," http://schaal@biology2.wust.edu

This paper recognizes that Malawi like most developing countries is facing severe environmental crises that are impacting on its economic development due to, *inter alia*, deforestation and a decline in biodiversity. Hand in glove with the concept of environmental justice, this paper will critique the current legal regime on environmental protection in respect of biotechnology and recommend the possible courses of action to ensure sustainable economic development whilst minimizing environmental risks.

2. ENVIRONMENT LAW AND HUMAN RIGHTS

Environmental justice and human rights are inextricably intertwined. This is because both fields strive to achieve better living conditions on mother earth. The nexus between environmental law and human rights becomes more patent when we acknowledge that the preservation, conservation and restoration of the environment are a necessary and integral part of the enjoyment of human rights such as, the right to health, to food and life. One cannot claim protection against acts that endanger the environment without adducing the basis for such a claim. In fact most formulations that seek to protect nature and individuals against harmful effects to the environment are couched in a human rights language such that they are claimed as of right. The unending interrelationship of environmental law protection and human rights becomes even more apparent when we understand environmental protection as an instrument for the realization of almost all human rights⁴. For instance, the implementation of certain projects largely depends on them passing the assessment of their environmental destructive potential⁵. The right to life will be unrealistic and virtually non-existent if the emission of fatal toxins were unregulated by sanctions.

3. INTER- AND INTRA--GENERATIONAL EQUITY

Inter-generational equity has to do with fairness between current and future members of a community. It does not mean that we neglect our current needs, but that we try to achieve a reasonable balance between satisfying our needs now and setting aside enough to provide for needs of the future⁶. We are currently living unsustainable lives and if we are not careful with how we use and dispose of resources, our children, grandchildren, and great-grandchildren will have a poorer, more polluted world to live in. Aiming for intergenerational equity means we want to give equal consideration to our own immediate needs, our own future needs, and our children's and grandchildren's future needs⁷.

There are regular and seemingly obligatory references to the rights and interests of "present and future generations" in contemporary international legal instruments dealing with sustainable development⁸. They indicate that the global society has come to recognize the use of natural resources in an inter-temporal context. Intergenerational equity, as employed in current international instruments, contains two distinct

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⁴ See Cullet, P, "Definition of an Environmental Right in a Human Rights Context," http://www.ielrc.org/content/a9502.pdf

⁵ See section 24 (1) of the Environmental Management Act No.23 of 1996, (hereafter the EMA).

⁶ Inter-generational equity denounces cupidity. We must not rush into accepting new forms of technology that can spur economic development and satisfy our pressing needs now in total disregard to their long-term effects on future generations.

⁷ This need is recognized by the Constitution of the Republic of Malawi of 1994 under section 13 (d) (iii).

⁸ See, for instance, Principle 1 of the Stockholm Declaration 1972.

components which have inter-temporal implications regarding the utilization of resources. The first calls for fairness in the utilization of resources between human generations past, present and future. This requires that a balance be attained between meeting the consumptive demands of existing societies and ensuring that adequate resources are available for future generations. The inter- temporal aspect of resource distribution and consumption has become an increasingly important issue, especially in view of growing threats of environmental degradation and resource depletion arising out of current consumption patterns. The second concept is referred to as "intra-generational equity," that is fairness in utilization of resources among human members of present generations, both domestically and globally.

Law and policy makers, therefore, must define appropriate criteria to balance equitable, environmental and economic considerations in an inter-temporal context. This task is very critical in the wake of biotechnology as some problems might not appear daunting today but may cause irreparable damage to generations yet unborn.

4. BIODIVERSITY AND BIOTECHNOLOGY

Biological diversity⁹ contributes directly to meeting the basic food, health and energy needs of people. The increase in population and static food production makes sustainable management of biological resources a must if the fight against poverty in Malawi is to have any impact at all¹⁰. Thus, the significance of biodiversity calls for the need to put in place elaborate policies and legal mechanisms for use and conservation of biological resources. However, such policies and legal mechanisms should not undermine the great potential of modern biotechnology¹¹ to spur production in different fields and hence promote development. There is, therefore, need to first acknowledge that biodiversity today is the result of millions of years of the evolution of living organisms¹². The organisms we know today have been developed from one original micro-organism through the processes of mutation and selection. In developing the regulatory framework we must, therefore, balance the benefits of modern biotechnology in so far as it can boost crop yields and hence food security and the danger that genetically engineered varieties might be marred by a number of caveats that may cause irreparable damage.

The development of genetically modified varieties for a developing country like Malawi presents a number of economical challenges in assessing their environmental impact. For instance, Malawi might not have the economic muscle and requisite capacity to assess the

⁹ The Convention on Biological Diversity of 1992 defines biological diversity as the variability among living organisms from all sources including, inter alia, terrestrial marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. The Convention entered into force in December 1993.

¹⁰ The Malawi Poverty Strategy Paper recognizes that science and technology are crucial to the socio-economic development of Malawi. See the Malawi Poverty Reduction Strategy Paper, 2002, p.i

¹¹ Article 2 of the CBD defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

¹² The Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture in clause 7 (a) that, "many plant genetic resources for food and agriculture today are the result of human intervention: that is they have been consciously selected and improved by farmers since the origins of agriculture."

potential harm of biotechnology products on humans and other non-target organisms¹³. But a reduction in the use of insectides which biotechnology is capable of offering, among other things, is of great benefit not only for human health but also for native biodiversity. In summary, it must be emphasized that biotechnology not only has potential liability for native biodiversity but also potential benefits for biodiversity.

5. INTERNATIONAL LEGAL FRAMEWORK ON THE MANAGEMENT OF BIODIVERSITY

This section examines the different international legal instruments that regulate the management and conservation of biological resources and their impact on domestic law. There are a number of international legal instruments which regulate species conservation and management. However, the central instrument in the field of biodiversity is the Convention on Biological Diversity ("the CBD") which seeks to promote the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of resources and transfer of relevant technologies¹⁴. A radical change brought about by the CBD is the recognition that States have a sovereign right over biodiversity within their own territory¹⁵, while previously living organisms were considered the common heritage of mankind. Under the terms of the CBD, living organisms or their products may only be removed from a country under mutually agreed conditions. Action is delegated to national level obliging States to assess biodiversity, enact legislation for its conservation *in situ* and *ex situ*, and to enforce legislation within their national boundaries.

Biotechnology is particularly affected by Articles 16 and 19 of the CBD. The Articles require a fair and equitable sharing of benefits derived from the use of genetic resources. This includes providing facilities and financial means for technology transfer and open access to scientific and technical information¹⁶.

The Agreement on Trade-Related Aspects of Intellectual Property Rights¹⁷ also has a great impact in so far as it requires all member States to protect products of technology and plant varieties, either by patents or by an alternative system (*sui generis*).

Another instrument of considerable significance is the Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) which focuses on the conservation and sustainable use of agricultural biodiversity and attempts to give an international legal definition to farmers' rights. It also sets up an access and benefit sharing regime.

¹³ Banda, G.Z, "Review of Policy and Legal framework for Modern Biotechnology in Malawi," Paper Submitted to CTDT, Harare, Zimbabwe for the Regional Modern Biotechnology Networking and Lobbying Project, p.2

¹⁴ These are the three main objectives that the CBD pursues. See Article 1 of the CBD

¹⁵ See Article 3 of the CBD

¹⁶ As a matter of fact, the European Court of Human Rights has recently held that not only do States have the obligation to prevent environmental pollution and hazards but also where the risks to health are severe, they are under the obligation to provide information to the affected individuals. The European Court held in a case where the applicants were living near to a factory which suffered an explosion in the past and fell short of safety standards that Article 8 of the European Convention on Human Rights had been violated because the State had failed to provide the applicants with essential information about the risks posed. See *Guerra v Italy*, Judgment of 19 February 1998.

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights of 15th April 1994 (hereafter, TRIPS Agreement)

The conclusion of these landmark environmental agreements to which Malawi subscribes has a significant influence on the development of policy and the enactment of laws on natural resource conservation and management.

5.1 BIOSAFETY

Although the new field of biotechnology holds great promise and new opportunities for the human community, it poses a number of challenges on environmental protection. Of particular concern are the uncertainties concerning the long-term environmental impacts on the introduction of genetically modified organisms into the environment. Just like any other powerful technology, biotechnology raises significant ethical and equity questions stemming from the manner in which this technology is designed, developed and implemented 18. Central to these issues is the concept of biosafety which seeks to ensure environmental justice and sustainable development. In other words, biosafety seeks to ensure the safe application of biotechnology in order to optimize the potential benefits of biotechnology whilst minimizing and containing any adverse effects on human health and the environment 19.

One of the three objectives of the CBD is the conservation of biodiversity. Under Articles 8 and 19 of the CBD member states are required to maintain, among other things, the means to regulate, control and manage risks associated with the use and release of LMOs resulting from biotechnology. Thus the management of environmental impacts on the conservation and sustainable use of biodiversity, including risk to human health, is a primary concern of biosafety.

The Biosafety Protocol calls for member States to develop rules on liability and redress of damage resulting from transboundary movements of living modified organisms. This blank cheque freedom gives States the liberty to develop such rules that are considered appropriate for the management and assessment of environmental damage arising from biotechnology in accordance with domestic priorities. Such liability rules should, however, contribute towards the implementation of the precautionary approach which constitutes the central paradigm around which the protocol is articulated. This is because liability schemes have traditionally been used to compensate injury to property and humans. The regimes must, however, perform a preventive function to induce operators to adopt measures that minimize the risks of damage and not to wait until damage has occurred and then try to remedy it²⁰.

The conclusion of the Biosafety Protocol has been hailed as a significant step forward on biosafety regulation in that it provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing industry of biotechnology²¹. The Biosafety Protocol carries on the duty charged on States by Articles 8 and 19 of the Convention on Biological Diversity which require

¹⁸ Some of the questions that occur include: Who will be the primary beneficiaries of this technology? What are the costs? Who will bear the costs if they cause unanticipated and unintended environmental damage to other organisms, species or ecosystems?

¹⁹ Kameri-Mbote, P, "The Development of Biosafety Regulation in Africa in the Context of the Cartagena Protocol: Legal and Administrative Issues," IELRC Working Paper, see: http://www.ielrc.org/content/

²⁰ It is better to err to on the side of caution. This is the basis on which the precautionary principle is founded.

²¹ Kameri-Mbote, P, *supra* note 20 at p.62

parties to maintain the means to regulate, control and manage risks associated with the use of living modified organisms, LMOs, resulting from biotechnology²².

5.1.1 BIOSAFETY LEGISLATION IN MALAWI

Biosafety is about risk assessment, risk management and risk communication which are the focal points of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Biosafety Protocol)²³ as set out in Articles 7-9, 15 and 16. Thus the framework and efficacy of biosafety laws and institutions in Malawi will be judged by her capacity to put in place elaborate mechanisms for risk assessment and management. Risk assessment has been defined as the identification of potential environmental adverse effects or hazards, and when a hazard has been identified, a determination of the probability of it occurring²⁴. Risk management refers to the methods applied to minimize potential hazards or adverse effects which have been identified during a scientifically based risk assessment²⁵.

5.1.1.1 THE BIOSAFETY ACT OF 2002

Malawi, after signing the Biosafety Protocol in 2000 enacted a Biosafety Act in 2002 which provides for the management of biotechnological activities. There are, however, other Acts which complement the regulation and management of biotechnology.

5.1.1.1.1 LICENCES AND PERMITS

Part IV of the Biosafety Act deals with licences and permits. Under the Act, the Minister is the licensing authority responsible for the granting, renewal, variation, suspension and revocation of licences²⁶. Section 17 makes it unlawful for a person to engage in (i) genetic modification of organisms, (ii) importation, development, production, testing, release use and application of GMOs, and (iii) the use of gene therapy in animals and human beings, unless such a person has been granted a licence or permit. The regulation of the importation of GMOs under the Act relates to persons only and the Act does not regulate the position when the government is importing GMOs and/or their products²⁷. In fact, there is no regulatory body established to check government's actions when importing, producing, testing or any kind of involvement in GMOs. This lacuna runs counter to the stipulations of the CBD and the Biosafety Protocol which requires States to put in place measures and mechanisms for the wholesale regulation of LMOs. The need for a regulatory body to check government's dealings in this respect cannot be overemphasized. The flexibility that the Biosafety Protocol proffers is capable of being

²² The Biosafety Protocol aims at comprehensively addressing concerns raised about biotechnology. These concerns include those that are captured in the preambular paragraphs and Article 1 of the Protocol namely; the safe-handling, use and transfer of living modified organisms.

²³ See the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal, 20 January 2000), (hereafter, Biosafety Protocol)

²⁴ See, Kameri-Mbote, P, "The Development of Biosafety Regulation in Africa in the context of the Cartagena Protocol: Legal Administrative Issues," IELRC Briefing Paper, RECIEL 11 (1) 2002, p. 64.

²⁵ Ibid. p.64

²⁶ See Section 16.

²⁷ Cf the Public Procurement Act No. 8 of 2003. The Act generally regulates the public procurement of goods, works and services. However, under section 5 of the Act the Director General of Public Procurement who is responsible for the regulation and monitoring of public procurement is accountable to the President. This law in this regard fails to put in place appropriate checks in the exercise of such power.

abused. For instance, a Party is not barred from taking a decision to import LMOs intended for direct use as food or feed merely because there is a lack of scientific certainty due to insufficient relevant scientific information and knowledge²⁸. Such powers undoubtedly demand the establishment of a controlling machinery to ensure that government does not subject its citizens to LMOs whose scientific certainty is questionable.

Section 22 lists down matters to be considered by the Minister before issuing a licence. The Act, however, does not have a similar list of considerations in respect of permits authorising a person to do the acts prohibited under section 17. We argue that this legislative inertia to provide guidelines for the Minister is unhealthy in this delicate area of law as it is capable of being abused. To crown it all, the Act does not state the person responsible for supplying the expert information under section 22 that the Minister must consider before issuing a licence.

5.1.1.2 THE ENVIRONMENTAL MANAGEMENT ACT OF 1996

The Environmental Management Act of 1996 (the EMA) is another piece of legislation of considerable significance on biosafety. The fundamental tenets of environmental protection and management namely, precaution and polluter pays, lie at the heart of this piece of legislation. The embodiment of these principles coupled with Parliament's bold attempt to include risk assessment and management measures in part fulfils Malawi's obligations as provided by Article 16 of the Biosafety Protocol.

The EMA is an Act that makes provision for the protection and management of the environment and the conservation and sustainable utilization of natural resources²⁹. The Act recognizes that the natural and genetic resources of Malawi are the property of the people of Malawi³⁰, and casts a duty "on every person to take all necessary and appropriate measures to protect and manage the environment and to conserve natural resources and promote the sustainable utilization of natural resources."³¹ The Act further guarantees every person a right to a clean and healthy environment³².

Part V of the EMA deals with Environmental Impact Assessments³³. Environmental Impact Assessment is increasingly used as a mechanism to implement the precautionary principle that the Biosafety Protocol articulates. Under section 24 (1) of the EMA, the Minister has powers, on recommendation from the council, to issue a notice published in a gazette, specifying types and sizes of projects amenable to EIAs before implementation. A notice issued under the said provision by the Ministry of Mines, Natural Resources and the environmental Affairs Department³⁴, does not specifically list biotechnology projects. However, it can be argued that clauses 13 and 14 of the notice impliedly cover this area in so far as it involves the introduction of exotic species which in turn may affect natural resources.

²⁸ See Article 11 of the Biosafety Protocol.

²⁹ This is the objective that the EMA seeks to pursue.

³⁰ See Section 4 EMA.

³¹ See Section 3 (1) of the EMA.

³² See Section 5 of the EMA

³³ Hereafter "the EIA".

³⁴ See Government Notice No. 42 of 1998

Section 24 (2) requires a developer of such a listed project to submit to the Director³⁵, a project brief stating, inter alia, the description of the project activities to be undertaken and their impact in the implementation of the project, and the segment (s) of the environment likely to be affected in the implementation of the project. If such information is sufficient, the Director shall require the developer to conduct an EIA. Section 25 (1) lists down the details that the EIA report must encompass. One shortfall of the Act is that it leaves the developer to his own devices to conduct an EIA and compile the report and makes no attempt to involve an independent expert to make an independent assessment at the expense of the developer. The Act, therefore, fails to put in place elaborate mechanisms and measures to check the veracity of the contents of an EIA report. The Act attempts to do this by requiring the Director to call for public comments on EIA reports. This attempt is, however, inane as projects on biotechnology involve issues of scientific intricacy and such an exercise might not benefit any probative endeavor by the laity in terms of constructive criticism. Further still, the attempt to establish a penal regime by criminalizing the giving of false information in EIA reports³⁶ in a way defeats the very essence upon which the principle of precaution is founded as harm and damage might have already been done at the time it would become apparent that the information is false.

Part VII of the Act deals with environmental management. Section 31 mandates the Minister to determine fiscal incentives necessary for 'promoting the protection and management of the environment and the conservation and sustainable utilization of natural resources'. It also mandates the Minister to take such measures as are necessary for preventing the unsustainable use of natural resources. This section gives the Minister unfettered powers to determine necessary measures to be adopted in preventing the unsustainable use of natural resources. This unfettered power is fundamental as it gives a leeway to the Minister to regulate scenarios that are unforeseeable at the moment but may arise in future.

Sections 32 to 35 provide mechanisms for the conservation of biological diversity. Under section 32, a Minister can declare an area to be an environmental protection area. And under section 33 the Director has powers to issue environmental protection orders against a person whose acts or omissions have or are likely to have adverse effects on the protection of the environment³⁷. This section as read together with section 34 attempt to establish a liability and redress regime as they embody the polluter pays principle. As a

³⁵ The office of the Director General is established under section 9 of the EMA. The duties of the Director include, inter alia, carrying out the duties specified by the Act and "the implementation of policies relating to the protection, management, of the environment and the conservation and sustainable utilization of resources that the Minister may determine".

³⁶ Section 63 criminalizes the inclusion of false information in IEA reports with the knowledge that such information is false. Any person convicted under the section can be jailed for 2 years or fined K200, 000.00.

³⁷ In Malawi problems of deliberate environmental degradation are rampant because of the poverty levels which in part explain low agricultural production. This forces farmers to subsidize their diets by hunting animals. Economic stability and GM agriculture can reduce the harvest pressure on native biodiversity.)The cutoff poverty line, which is defined in terms of having enough income for a specified amount of food, was in 1998 estimated to be at K10.47 per day. See Government of Malawi, The Malawi Poverty Reduction Strategy Paper, Final Draft, (2000) at p. 5, the exchange at the time was MK 31.1 to U\$ 1)

matter of fact, subsection 2 of section 33 provides that the environmental protection order may require the person against whom it is issued to, inter alia, take measures to restore, stop, remove or pay compensation. If the person fails to comply with the EPO, the Director can fulfill the requirements set out in the EPO and the expenses so incurred are recoverable by the government from the defaulter as a civil debt.

7. ACCESS AND BENEFIT SHARING 7.1 INTERNATIONAL LEGAL REGIMES

As pointed out earlier, the regulation of biotechnology under environmental law brings to the fore issues of environmental justice and sustainable development. The major concern under both heads is the intra and inter-generation distribution of costs and benefits of development by improving the quality of life and enhancing access to resources³⁸. Put succinctly, environmental justice and sustainable development seek to fulfill the basic needs of people by improving access to and benefit sharing of resources without compromising the capacity of the environment to provide similar benefits to future generations.

Environmental justice alone seeks to draw the necessary balance between conservation and economic development. In respect to biotechnology, which holds great promise to improve peoples' lives and spur economic development, environmental justice seeks to balance States' obligations to progressively realize peoples' rights to economic development³⁹ with other civil rights of environmental concern such as the right to a clean and healthy environment. In this regard, any attempt to formulate measures and mechanisms entails the effective consideration of all factors.

In fact the International Treaty on Plant Genetic Resources for Food and Agriculture, the ITPGRFA⁴⁰, recognizes that the management of genetic resources is a meeting point of different sectors such as commerce, agriculture and the environment and recommends that there should be synergy amongst them⁴¹.

This section reviews the issues associated with access to genetic resources and the equitable distribution of resulting benefits accruing from biotechnology. We also rashly examine the implications of different international instruments that regulate and impact the regulation of access to genetic resources and benefit sharing.

One of the principal tenets of the CBD is the equitable sharing of any benefits derived from the development of biological resources. Benefits accruing from biotechnology may be realized in the short-term and long-term, and may either be monetary or non-monetary, direct or indirect. Direct benefits are those that accrue to participants in research programs, such as royalties for discoveries or opportunities to participate in research. Indirect benefits are those that arise from infrastructure used in discovery

³⁸ Kameri-Mbote, P, and Cullet, P, "Environmental Justice and Sustainable Development", http://www.ielrc.org/content/f0204.htm

³⁹ Under Article 2 of the International Covenant on Economic, Social and Political Rights of 1966 Malawi undertook to take such steps to achieve progressively the full realization of the rights recognized under the Covent, such as those under Article 11, viz. the right of everyone to an adequate standard of living, including adequate food, clothing, and housing. Malawi ratified the Covenant on the 22nd March 1994.

⁴⁰ FAO Doc. C 2001/LIM/17, Rome, 13 November 2001.

⁴¹ See the preamble to the Treaty.

programs which upon completion of the program may be used for educational and other research programs⁴². The public largely benefits from the contribution that new pharmaceutical, agricultural or nutritional products may provide by improving human health and the availability of new drugs. Access to developed medicines is of great importance to a country like Malawi where health care options are limited.

The CBD encourages source countries to promote access to their biological resources in a regulated manner in exchange for an equitable share of the benefits. But the duty to regulate access rests with national governments and is subject to national legislation⁴³. However, the CBD and the ITPGRFA set out prescriptions that State parties must adopt in such legislation. For instance Article 16 (4) of the CBD prescribes that State parties should adopt appropriate legislative, administrative or policy measures to ensure that the private sector facilitates access to joint development and transfer of technology for the benefit of both governmental institutions and the private sector. This prescription flows from the recognition by Contracting parties that issues of trade (patents and intellectual property rights) have an influence on the implementation of the Convention in so far as access and benefit sharing is concerned. Presently, there is a raging debate over the granting of intellectual property rights over biological diversity as required by the TRIPS agreement. This controversy is attributed to the existence of parallel international processes and instruments that have implications on access and benefit sharing of genetic resources, particularly, the WTO and the TRIPS agreement. Put succinctly, the WTO and TRIPS Agreement which pursue commercial objectives stifle the realization of the objectives formulated by the CBD whose establishment was prompted by the need to regulate access to and the sharing of benefits from the conservation and sustainable use of biodiversity⁴⁴.

A cursory look at the recognition by the CBD of States' sovereignty over their natural resources and the freedom that Article 15 (1) bestows on States to enact legislation gives a leeway to States to determine the regulation of access to genetic resources without restriction⁴⁵. However, such freedom must be exercised in the light of the States' obligations under equally binding treaties instruments like the TRIPS.

It appears, however, that member States under the TRIPS agreement are under a strict obligation to meet TRIPS' recommendations without regard to their level of development, needs and priorities. State parties would, therefore, be seen to renege on their undertakings under the agreement if they chose to priotise particular needs in disregard to these recommendations.

Notwithstanding various safeguards that exist in the TRIPS agreement, it also provides a lot of flexibilities to member States to maneuver. Albeit members are obliged to formulate laws and regulations and take such measures that are consistent with the provisions of the agreement 46, the recognition under Article 7 of the agreement that the

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⁴² Miller, J.S, "Impact of the Convention on Biological Diversity: The Lessons of Ten Years of Experience with Models for Equitable Sharing of Benefits," james.miller@mobot.org

⁴³ See Article 15 of the CBD.

⁴⁴ See the Preamble to the CBD.

⁴⁵ Cf the Procedures and Guidelines for Access and Collection of Genetic resources in Malawi of October 2002.

⁴⁶ See Article 8

protection of and enforcement of IPRs are not ends in themselves, enables States to establish a balanced regime of protection to producers and users of technological knowledge in a manner conducive to their social and economic welfare.

7.1.1 PATENTABILITY: INDIVIDUAL RIGHTS VERSUS COMMUNITY RIGHTS

7.1.1.1 INTELLECTUAL PROPERTY RIGHTS (IPRs) AND PATENTS

Intellectual property rights are intangible rights which grant an exclusive right to impede others to freely exploit an invention or creation. IPRs were originally established as a way to reward creativity and promote innovation. Under the TRIPS agreement, patent protection must be available for inventions for at least 20 years, and requires that patent protection must be available for both products and processes in almost all fields of technology. Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic and surgical methods, plants and animals and biological processes for the production of plants or animals.

Under the TRIPS plant varieties can be protectable either by patents or by a special system such as the breeder's rights. Plant variety protection provides protection to new plant varieties that have previously not been commercialized, are distinct from existing varieties, are uniform in their main characteristics and stable over the years for those characteristics. Unlike patented material, protected varieties can be used for the development of new varieties without the authorization of the rights holder.

One major drawback to the quest for improved access to products of technology is the TRIPS' extension of patent protection to both products and processes. The extension has negative impacts on the realization of human rights⁴⁷. The regulation of patent protection and the promotion of access to products of technology, therefore, demands the striking of an appropriate balance between the broader social and humanitarian goals of the community and the need to ensure that patent holders are not discouraged from invention and innovation. In other words, the protection of innovation and invention must not be given greater prominence over the needs of the community. In so doing, we will avert the usual concomitants of a strict patent protection regime that render products of technology such as medicines, prohibitively expensive. Such measures would fail to stall States' efforts to progressively realize peoples' rights to health, development and even the right to education as espoused by the International Covenant on Economic, Social and Cultural Rights and the Universal Declaration of Human Rights of 1966⁴⁸.

Under Article 27 (3) (b) of the TRIPS member States to the World Trade Organization (WTO) agreements have the obligation to provide a form of intellectual property rights protection for plant varieties. This requirement raises concerns that advocate for the exclusion from patentability of plants and animals and the protection of plant varieties either by patents or through a *sui generic* system. Proponents of exclusion are concerned with the danger that patent protection of plant varieties will lead to monopoly rights in

⁴⁷ Especially the right to development which is advocated by many international legal instruments and to which many States are parties.

⁴⁸ See Article 11, 12 and 13 of the Covenant.

the area of agricultural production which is of substantive importance to human beings in so far as the quest for food security is concerned. The protection of patent plant varieties under a patent is capable of perpetrating environmental injustice on innocent people because under patent liability rules, any user, conscious or unconscious of an invention may be held liable for damages to the patent holder for using a patented invention without approval⁴⁹. In the case of GMOs the patent holder can ensure that farmers who buy GM seeds also sign a contract stopping them from using the seeds for more than one crop and stopping them from saving, distributing and selling the same. The patent holder, however, is not in the position to stop GM seeds intentionally introduced into the environment from contaminating other fields and the environment in general. Recently, a novel situation concerning the question of patent liability where seeds contaminate the fields of other farmers who have not purchased seeds from the patent holder was the subject of litigation before the Supreme Court of Canada. In the case of Schmeiser v Monsanto⁵⁰, Monsanto Company was claiming damages from Mr. Schmeiser because he was found in possession of genetically modified canola seeds even though he never purchased seeds from Monsanto. It was Monsanto's contention that Mr. Schmeiser used, reproduced and created genes, cells, plants and seeds containing the genes and cells claimed in Monsanto's patent without authorization. Finding for Monsanto, the Court had this to say on liability of farmer who is responsible for the presence of patented seeds on his land.

"...a farmer whose field contains seed or plants originating from seed spilled into them, or blown as seed, in swaths from a neighbor's land or even growing from germination by pollen carried into his field from elsewhere by insects, birds, or by the wind, may own the seed or plants on his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene, or of the seed or plant containing the patented gene or cell". 51

The Court went on to suggest that Mr. Schmeiser had to pay a licence fee even though he did not benefit from the specific characteristics of the patented product.

The *Schmeiser* case has significant implications for the development of liability regimes in the field of biotechnology especially patent protection of plant varieties. The regulation of plant varieties under patents has serious negative impacts on property rights of individuals as well as the relationship with other rights such as the fundamental right to food.

7.1.1.2 IPRS AND PUBLIC HEALTH

The protection of both processes and products of technology has lately been the subject of controversy in respect to pharmaceuticals especially in the wake of the Aids pandemic. Patent protection of life-saving drugs has seen such drugs being prohibitively priced hence being virtually inaccessible to individuals living in countries with struggling economies.

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⁴⁹ See Cullet, P, "Liability and Redress in Biotechnology," http://www.ielrc.org/content/w0401.pdf

^{50 29} March 2001, 2001 FCT 256

⁵¹ *ibid*.

This has forced most developing countries to issue compulsory licences and use the mechanism of parallel market importation. A compulsory licence is a licence issued by a government to a third party for the right to use or exploit a patent without the patent holder's consent. And parallel imports involve the importation and resale in a country without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder.⁵²

Compulsory licences do promote competition and prevent abuse of patent rights and monopolies. Article 31 makes specific mention of five possible grounds under which a compulsory licence can be granted, namely; refusal to deal, emergency and extreme urgency, public non-commercial use, anti-competitive practices and dependent patents. This article, however, places no restrictions on the grounds or purposes for the granting of compulsory licences. This has been extolled by many as giving States the requisite freedom to maneuver and promote accessibility of medicines by using the compulsory licensing mechanism⁵³.

Parallel imports are premised on the principle of exhaustion of rights by the patent holder. The rationale is to prevent an incessant reward process for the patent holder by striping the patent holder of the right to control the use or resale of the product after the first sale. The importance of parallel imports in the pharmaceutical industry cannot be overemphasized. It allows consumers to import goods from countries of choice where a patented medicine is sold at a lower price. This enables patients in the importing country to gain access to cheaper medicines and be able to answer to the exigencies of health crises⁵⁴.

Furthermore, the allowance given to States by article 30 of the TRIPS to "provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the rights of third parties," help States to contain the unreasonable exercise of monopoly rights by patent holders and promote accessibility of products.

7.1.2 ACCESS TO INFORMATION VERSUS COMMERCIAL CONFIDENTIALITY

The legal protection of inventions demands that commercially sensitive information should not be kept in confidence. Generally, the General Agreement on Trade in Services, the GATT and the Trade-Related Aspects of Intellectual Property Rights, the TRIPS, prohibit Member States from providing "confidential information, the disclosure of which would impede law enforcement, or otherwise be contrary to the public interest, or which would *prejudice legitimate commercial interests of particular enterprises*, public or private"⁵⁵. This is intended at promoting the enjoyment of intellectual property rights protected under a patent against competitors. These requirements have serious

⁵² Mwakyembe, H, and Kanja, G.M, "Implications of the TRIPS Agreement on the Access to Cheaper Pharmaceutical Drugs by Developing Countries." Diploma in Intellectual Property, Dissertation, (University of Turin, November 2001) ⁵³ *ibid*.

⁵⁴ ibid.

⁵⁵ See in particular Article III of the GATT

implications on the extent to which the civil right to access information can be enjoyed and claimed by an individual. As a matter of fact, section 33 of the Biosafety Act which prohibits the disclosure of information with respect to any manufacturing process or trade secrets obtained by a person who enters any premises pursuant to the powers conferred under the Act, stifles the extent to which an individual can make a free and informed decision whether to consume a particular product or not⁵⁶. Under the EMA the non disclosure of commercial information tapers off the extent to which the public can participate in scrutinizing risk assessment exercises compiled in EIA reports⁵⁷.

Parts V and VI of the Biosafety Act deal with labelling. Section 26 outlaws the sell or supply or possession of GMOs or its products which have not been labeled in accordance with regulations made under section 41. This area is at the moment unregulated as the responsible Minister has not invoked his powers conferred on him under section 41 of the Act to make regulations on labeling information and contents of advertisements. This lacuna is scantly taken care of in part by the Consumer Protection Act of 2003 which in a way complements the Biosafety Act. Under section 35, the Act imposes an obligation on the seller to indicate to the consumer whether the goods are genetically modified or not, and if they are, the manufacturer is duty bound to have them labeled as such. The supplier is obliged to provide the consumer with a manual showing the technical characteristics, application of the technology and safety precautions. However, like the Biosafety Act, it omits to state the essential standard particulars that a label must have albeit prohibiting the sale of GMOs without properly labeling them. The Act also leaves the task of making regulations for the particulars that a label must have to the relevant Minister.

8. ACCESS TO COURTS/ JUSTICE 8.1 ENFORCEABILITY OF RIGHTS AGAINST PUBLIC FUNCTIONARIES

The Constitution guarantees every individual the right to access to courts and the right to have an effective remedy before a court of law for acts violating the rights and freedoms under the Constitution or any other law⁵⁸. The question of justiciability of certain environmental claims has been attacked on a number of fronts. It has been argued that most claims lack a substantive content. In fact, it is contended that there can be no substantive right to environment because the quality of the environment cannot be defined universally *a priori*. However, several jurisdictions have adopted formulations that avoid imprecision in order to avoid non-enforceability by putting environmental protection claims in a human rights setting⁵⁹. It is recognized that such claims can only be realized through specific procedural rights such as the right to environmental information⁶⁰.

⁵⁶ The argument that is likely to be advanced is that the Constitutional right to access to information under section 37 being a limitable right, the extent to which an individual can exercise this right is limited under the Biosafety Act. Cf Article 10 of Rio Declaration of 1992.

⁵⁷ Under section 26 of the EMA

⁵⁸ Section 41 of the Constitution of Malawi 1994

⁵⁹ The perceived necessity to bring environmental considerations into the human rights sphere stems from the need to assert environmental preoccupations as a fundamental consideration and to benefit from the more elaborate machinery offered to citizens by the human rights instruments. See, Cullet, P, "Definition of an Environmental Right in a Human Rights Context," http:// www.ielrc .org/content /a9502.pdf ⁶⁰ *ibid*.

In Malawi, the starting point is section 5 of the Environmental Management Act which guarantees every person a right to a clean and healthy environment⁶¹. This right flows from the Constitutional principles of national policy in respect to the environment. Section 13 (d) of the Constitution which spells out the principles in this respect is in the following terms;

"The State shall actively promote the welfare and development of the people of Malawi by progressively adopting and implementing policies and legislation aimed at achieving the following goals-

(d) The Environment

To manage the environment responsibly in order to-

- (i) prevent the degradation of the environment;
- (ii) provide a healthy living and working environment for the people of Malawi;
- (iii) accord full recognition to the rights of future generations by means of environmental protection and the sustainable development of natural resources;
- (iv) conserve and enhance the biological diversity of Malawi."

However, the law on the protection of the environment and the health of people does not provide enough confrontational rights to individuals despite the fact that most pieces of legislation confer untrammeled powers on public officers to do acts that might have adverse effect on the enjoyment of the right to a clean and healthy environment and even endanger human health⁶². It is the nature of the decision made or not made that will result in the performance or non-performance of duties by public functionaries. The recognition by the Constitution that, "all persons responsible for the exercise of power do so on trust and shall exercise such power to the extent of their lawful authority and in accordance with their responsibilities to the people of Malawi"⁶³, has the effect of putting public functionaries in a fiduciary position. This is because the people of Malawi have reposed faith in them and public officers have undertaken to discharge their duties with the welfare of the citizenry at heart. According to Kasambara, in the context of Malawi, what becomes apparent is that the framers of the Constitution were prepared to have rulers who would be trustees and that should these "politician trustees" act outside their trust, they

⁶¹ The qualification adopted by the Constitution to the general right to environment guarantees its enforceability. The terminology used in most legal instruments is qualified in order to ensure enforceability. Some bolder formulations peak of a right to a decent environment encompassing social and cultural needs. Other instruments, like of the African Charter on Human and Peoples Rights recognize the link between the protection of the environment and development. See Article 24.

⁶² We note that most pieces of legislation on environmental protection do not guarantee confrontational rights to individuals. As a matter of fact it is only section 5 of the EMA that guarantees a right in respect of the environment. However, most pieces of legislation confer untrammeled powers on public officers whose decisions affect individuals' right to a clean and health environment. We argue that the enforcement of this right can require such public officers to account for the exercise of such power as fiduciaries to ensure good governance and effective public participation on environmental issues.

⁶³ See Section 12 (ii) of the Constitution of Malawi.

would be fired⁶⁴. Although the law does not expressly declare public functionaries as fiduciaries, this conclusion is inescapable. The recognition of someone as a fiduciary renders him amenable to fiduciary obligations in the discharge of his given duties. Firstly, the fiduciary must not place himself in a position where personal interest might conflict with duty. The second principle of fiduciary management requires the fiduciary to manage resources of his/her principal prudently.⁶⁵

These principles of fiduciary management when applied to public functionaries have the potential of bringing about a more efficacious discharge of duties by the public functionaries as people would sue on the basis of section 5 of the EMA to enforce fiduciary obligations charged by other pieces of legislation.

Having regard to the fact that the welfare of the citizenry is largely dependent on the manner in which public functionaries discharge their duties, it should be apparent that an improvement in the manner in which public functionaries discharge their duties should lead to amelioration of the living standards of the citizenry. It is, therefore, one necessary consequence of observing the concept of good governance that there should be an efficacious discharge of public duties ⁶⁶. Such a discharge of public duties would in turn lead to a more prudent and efficient management of the environment and ensure that individuals have access to its resources.

8.1.1 ENFORCEABILITY OF FIDUCIARY OBLIGATIONS

English law has lagged behind many progressive jurisdictions on the enforceability of a fiduciary relationship that has political overtones⁶⁷. English law regards such a trust as involving the discharge of public law duties hence the denial of enforcement through the courts. The argument is premised on the fact that the enforcement of such a fiduciary relationship through the courts would amount to according private law remedies in a public domain⁶⁸. We must hasten to add that the fact that the relationship between certain parties does not suffice to be called a trust relationship as recognized within private law does not negative the fact that such a relationship may nevertheless create enforceable fiduciary duties⁶⁹. Central to this finding is the fact that the performance of public law duties by the government and the various public functionaries inevitably involves the exercise of discretion on their part. The allowance for the exercise of discretion in the

⁶⁸ See *Tito* v *Waddell et al* (No. 2) [1977] Ch 106.

⁶⁴ See Kasambara, R.Z.M, "Constitutionalism and Democratic Accountability During the Multiparty Decade in Malawi: Challenges and Opportunities for the Civil Society," Paper Presented at a Workshop on Constitutionalism and Democratic Accountability in Malawi and South Africa: Ten Years After Change", Blantyre; 12th-13th July 2003 (unpublished)

⁶⁵ See Pearce, R and Stevens, J, "The Law of Trusts and Equitable Obligations,"2nd edn. (1998) Butterworths, London, p.281-2

⁶⁶ This in turn ensures the progressive realization of such rights as the right to development, housing e.t.c

⁶⁷ Notably Canada, Philippines and Australia

⁶⁹ See *Minors Oposa* v *Secretary of the Department of Environment and Natural Resources*, reprinted in 33 International Legal Materials 173 (1994). In this case a number of Filipino children brought an action for the enforcement of their right to a balanced and healthful ecology. They claimed that their right was being threatened by the timber logging licences that a government officer was granting. The court held that as long as the petitioners could prove before the court a specific legal right which could be violated by the government's actions or failure to act, the court could validly vindicate the rights prayed for notwithstanding that such rights are found under the declaration of principles and state policies.

discharge of duties by public functionaries far from ousting the jurisdiction of the courts to regulate the relationship thereby transforms the government into a fiduciary.

It, therefore, becomes apparent that the existence of a public law duty does not exclude the fact that in the discharge of public law duties the duty bearer may undertake to discharge obligations in the nature of a private law duty. This position has recently been reaffirmed by the Supreme Court of Canada in *Wewaykum Indian Band v Canada*⁷⁰. The case involved two competing claims over a reserve by rival Indian Bands. Both bands alleged that they would be entitled to the disputed reserve but for the breach of duties by the federal crown. In expounding the fiduciary facet of the case, the court stated that the existence of a public law duty did not exclude the possibility that the crown undertook in the discharge of that public law duty obligations in "the nature of private law duty". The court further stated that a fiduciary duty where it exists it is called into existence to facilitate supervision of the high degree of discretionary control assumed by, in this case the crown, over the lives of aboriginal people. It is, therefore not plausible to assert that the existence of a public law duty in the discharge of fiduciary obligations excludes the possibility of enforcing such a relationship through the courts.

It is patent from the foregoing that fiduciary relationships that traditionally have been declared unenforceable for involving the discharge of duties are now enforceable before courts of law as long as one can prove before a court of law a specific legal right which could be violated by the public functionary. Thus the citizenry as beneficiaries have the right to enforce the exercise of public duties on the strength of the fiduciary relationship that has been created by the reposition of trust into public functionaries to act on behalf of others. Primary among the ways in which the citizenry can enforce the fiduciary relationship is the right to demand an account or obtain a restraint order⁷¹ restraining a public officer from exercising his powers in a particular way. One can, therefore, challenge the exercise of a Minister's powers under section 20 of the Biosafety Act if the exemption from importation of GMOs is propelled by extraneous considerations than matters of environmental protection even though the Act does not specifically provide a right to challenge such a decision.

It is evident from the foregoing that the enforcement of fiduciary obligations of public functionaries by the courts would help in checking the abuse of power by public officers who have been entrusted with the duty of managing the environment especially where the law does not provide adequate confrontational rights.

9. CONCLUSION AND RECOMMENDATIONS

The international legal system for the management of biological diversity and the regulation of biotechnology has had a dramatic influence on the development of domestic environmental laws and policies. The contribution of international law is and large progressive and has championed significant initiatives especially in the new field of

^{70 (2002-12-06)} Supreme Court of Canada, http://www.canlii.org/ca/scc/2002scc79.html

⁷¹ The question whether an injunction can be validly granted against the government or a public officer is unsettled and shrouded in uncertainty as the High Court of Malawi of Malawi has delivered conflicting rulings on the same. See section 10 of the Suits by or Against the Government or Public Officers Act Cap. 6:04 of the Laws of Malawi

biotechnology. Malawi, has responded to its international obligations by enacting legislation to improve the advancement of science and technology. However, the broad nature of the international framework fails to appropriately address the concerns, problems and priorities of specific jurisdictions according to their pressing needs and challenges. This has an impact on the fulfillment of States' obligations under international instruments. Having analyzed the law on biodiversity management and biotechnology, we make the following observations and recommendations.

9.1 BIOSAFETY

9.1.1 RISK ASSESSMENT AND MANAGEMENT

We note the Biosafety Act does establish a regime of risk assessment, management and communication which regime is however available under the EMA. We recommend for the establishment of a special regime under the Biosafety Act to ensure that all decisions made under the Act in respect of handling, transfer of GMOs are based on assessments. We further recommend that such a regime should provide that the assessment of such risks should be done in accordance with sound science based on the available information. We also recommend the establishment of a national committee of experts on biosafety which should have the mandate to conduct risk assessments and control the exercise of powers conferred on the Minister and public officers by the Biosafety Act.

9.1.2 ACCESS TO INFORMATION (PUBLIC AWARENESS AND PARTICIPATION)

We recognize that Malawi has lagged behind in the fulfillment of its obligations under Article 23 (1) of the Biosafety Protocol which focuses on public awareness and participation. The Protocol calls parties to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMO's Biosafety guidelines should articulate the issue of dissemination of information regarding biotechnology risks and benefits. We further recognize that the rapid pace of technological advancement and the wide ranging nature of the perceived effects of biotechnology necessitate much greater public participation. The public controls the fate of biotechnology in its willingness or refusal to accept products produced through genetic engineering. Thus it is essential to inform the public about all aspects of biotechnology. We therefore recommend that the national committee on biosafety that should be established should be charged with the duty of publishing expert reports on safety considerations after conducting appropriate scientific studies including the assessment of relative risk, measures of gene flow, determining the fitness of hybrids, assessing the effects on non-target species and ecological monitoring for things gone wrong. The reports will help in gaining public confidence in accepting these technologies. Another way of enhancing public access to information is through workshops, symposia, seminars e.t.c

9.2 ACCESS AND BENEFIT SHARING

9.2.1 INTELLECTUAL PROPERTY RIGHTS (PLANT VARIETY PROTECTION)

We notice that under the Patents Act, the government can use a patent without compensating the patent holder. We recommend the revision of this provision as it runs

counter to the Constitutional provision under the Republican Constitution of 1994 that proscribe the arbitrary deprivation of property. We observe that the provision under the Patents Act does perpetrate injustice to patent holders and would hamper innovative and inventive efforts by inventors of technology and incentives that come with exclusive commercial rights.

In fulfilling its obligations under Article 27 (3) (b) of the TRIPS, we recommend that the national law that will be developed should seek to implement the agricultural needs of this country by setting priorities according to domestic needs. We further recommend the development of a special legal regime that would protect traditional knowledge in order to promote incentives that come with commercial rights.

9.3 ACCESS TO COURTS AND JUSTICIABILITY OF FIDUCIARY OBLIGATIONS

We observe that access to courts in Malawi is quite open and there have never been any cases arbitrary denial of access. We, however, observe that much of the legislation on environmental protection does not offer sufficient confrontational rights to individuals albeit that the law grants untrammeled powers to managers of the environment. We also observe that Malawian courts have not had the opportunity to determine the enforceability of fiduciary obligations that have traditionally been regarded as unenforceable. We can only express hope that Malawian courts will not lag behind like English courts in opening up to enforce such fiduciary obligations that will play a supplementary role in promoting good governance.