

**INTELLECTUAL PROPERTY RIGHTS, BIODIVERSITY AND  
MODERN BIOTECHNOLOGY IN MALAWI**

By Gracian Zibelu Banda, Centre for Environmental Policy and Advocacy, P O Box  
5062, Limbe

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## 1. Background, issues and introduction

### 1.1. The case for intellectual property rights

Intellectual property rights refer (IPRs) to the monopoly rights granted to innovators in recognition of the creativity. The inventor is given financial incentives whose impact is to benefit those who have knowledge and inventive power and to increase costs of access to those without. The only cost to the inventor is that she/he makes the knowledge ‘freely’ available to society<sup>1</sup>. Other potential inventors are therefore able to take leads from the specification and either improve on the invention or use it to invent other related products or processes.

The main argument advanced by those who promote IPRs, especially in international trade, is that IPRs provide incentives for these researchers to invest more in their research activities and therefore produce even better products that ultimately benefit society as a whole. In essence this suggests, not in so many words, that society owes these innovators at least the curtsey of an enabling policy and legislation framework to protect their innovations not only as a ‘thank you’ but also in the best interest of society as a whole. This perhaps explains the significance of the territoriality principle in IPR law. A patent is a monopoly granted by the state and is only effective in that state and it is the state that limits its applicability, duration as well as exceptions<sup>2</sup>.

While there is some merit in the incentives offered by IPRs to benefit society several commentators have pointed out a number of contrary indications. In the first place, they have not found any cogent evidence that strong IPR protection does indeed stimulate more innovation<sup>3</sup>. They also point to the potential of IPRs to stifle innovations, especially improvements, to existing products since in many cases they will need licenses to work the patent and therefore innovate. There is evidence that some of the staunch supporters of IPRs benefited from less stringent IPR regimes that enabled them to copy and later create better and more competitive products<sup>4</sup>. Further, it is unlike in the past when innovators were individuals with small scale industries, today hardly any patents are owned and or worked by individuals; they will invariably be registered in the name of and be worked by private enterprises, mostly multinational companies, who wield immense influence in terms of resources, information and expertise. The advantages of IPRs are thus even more uncertain for developing countries because of the monopolistic

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<sup>1</sup> Intellectual Property legislation including Malawi’s Patents Act (section 14) require that the inventor must provide complete specifications which fully disclose the invention and the manner in which it may be performed as well as the best method of performing the invention.

<sup>2</sup> This is one reason for the growing opposition to the standardization promoted by TRIPs. Apart from a few regional instruments such as, for Malawi, the African Regional Intellectual Property Organization (ARIPO), no IPRs registered elsewhere are enforceable in Malawi. For a discussion of the territoriality principle see UNCTAD (1975) *The role of the Patent System in the transfer of Technology to developing countries* (UNCTAD, Geneva)

<sup>3</sup> See Commission on Intellectual Property Rights (2002) *Integrating Intellectual Property Rights and Development Policy* (DFID, London); and F Yamin (2004) *Intellectual Property Rights, Biotechnology and Food Security* (Institute of Development Studies, Brighton, England).

<sup>4</sup> Yamin, *supra* pp. 11-13

tendencies promoted by multinational companies: unlike developed countries which have sophisticated anti-trust laws to ensure that abuse of monopolies do not harm the public interest, developing countries do not have such workable mechanisms and are therefore vulnerable<sup>5</sup>.

## **1.2 Intellectual property rights and development**

For most developing countries at the moment, whose main preoccupation is sustainable livelihoods, the critical issue is affordability of the patented products such as medicines, seeds, fertilizers, chemicals and pesticides on which much of the livelihoods of vulnerable local communities depends. Competition on the global market, on which much of the debates in the World Trade Organization (WTO) are based, is not a primary concern of developing countries. Hence, though membership of the entails that developing countries enact standardized IPR regimes, the primary beneficiaries are multinational companies who are shielded from the requirement to work patents where they are registered while at the same time afforded the privilege of a protected market in developing countries. The end result is that developing countries have to import these products at very high prices, in the process draining scarce foreign exchange earnings.

But the WTO requirements have gone further after the adoption of the Agreement on Trade Related aspects of Intellectual Property Rights. TRIPs now requires biological resources hitherto not subject of international IPR regimes to be subject to IPR protection of one form or another. Hence although the Convention on Biological Diversity (CBD) requires that countries determine access to and benefit sharing of technological exploitation of biological resources, IPRs pose a real threat to this most important of sovereign entitlements. Monopoly IPR rights can easily dilute the value of a country's biological resources.

The dilemma for developing countries such as Malawi is that the TRIPs requirement may extend to the patenting of life forms to which most developing countries, including Malawi, strongly object. Yet the prospect of protecting biological resources and the knowledge associated with it appears attractive in the face of allegations of piracy of such resources and indigenous knowledge by western multinational companies and research organizations that have been highlighted in recent times. It may be better to embrace IPRs for this purpose. Yet the requirements for registering IPRs under TRIPs and current legislation are so prohibitive that most IKS would be disqualified. Further, western institutions have an arsenal of information and expertise at their disposal that can easily overwhelm providers of genetic resources and IKS in developing country institutions making it extremely difficult for these local institutions to obtain value for their products and information.

In addition, technological advances are making it very easy for western institutions to replicate active ingredients in collected materials and indeed to store for future use; making it difficult for valorisation of samples for purposes of determining royalties

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<sup>5</sup> Ibid, p. 5, Malawi's Competition and Fair Trading Act, 1998 remains on the statute book without implementation some six years after its enactment.

payable thereon<sup>6</sup>. The challenge therefore is how Malawi and other developing countries can formulate IPR legislation that ensures compliance with WTO/TRIPS as well as the CBD. A number of international and regional initiatives have provided guidelines for such an assignment and provide insight into possible directions. These include the Bonn Guidelines on Access to and Benefit Sharing of Biological resources and their Utilization adopted by the Conference of the Parties of the CBD and the African Model Law on Community, Farmers and Breeders Rights. This paper reviews Malawi IPR laws as they affect biological resources and sustainable livelihoods and considers how the various international instruments can be effectively domesticated to promote the country's core needs in general and the conservation and sustainable utilization of biological resources in particular.

## **2. Intellectual property rights and international human rights**

IPRs confer monopoly private rights to protect the material and moral rights of authors; these are in turn inextricably related to private material benefits of these individuals. These private material benefits may and, often are, exercised at the expense of the consumer who, for developing countries, is a poor villager suffering from hunger or disease for which has little or no control. Here is the potential conflict between the human rights of the creators and those of the consumers. There are however no circumstances in which fundamental human rights such as the right to life can be subordinated to the economic rights promoted by IPRs<sup>7</sup>. Several international human rights instruments make this quite clear.

The International Covenant on Economic Social and Cultural Rights<sup>8</sup> (ICESCR) (1966), for example, confers on individuals the right 'to enjoy the benefits of scientific progress and its application' and 'to benefit from the protection of the moral and materials interests arising from the literary and artistic production' of which they are the creators<sup>9</sup> (Article 15.1.2, 15.1.3). It also imposes an obligation on state parties 'to respect the freedom of indispensable scientific research' and to 'recognise the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields' (Article 15.2, 15.3). Nevertheless it clearly stipulates that developing countries may, with due regard to human rights and their national economies, determine the extent to which they would grant the economic rights recognized in the covenant (Article 2.3). Most importantly, for biodiversity related matters, Article 1.2 states that 'all people may, for their own ends, freely dispose of their natural wealth and resources, without regard to any obligations arising out of international economic cooperation, based upon the principle of mutual benefit, and international law. *In no case may a people be deprived of its means of subsistence*'. (Emphasis supplied).

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<sup>6</sup> Zerner, C (ed) (2000) *People, Plants and justice*, Columbia, University Press, New York.

<sup>7</sup> Commission on Intellectual Property Rights, *supra*, p. 6.

<sup>8</sup> Malawi ratified the International Covenant on Economic, Social and Cultural Rights together with the International Covenant on Political and Civil Rights on 22 March 1994 and is therefore part of the law of Malawi in accordance with section 211 of the Constitution.

<sup>9</sup> This provision repeats Article 27.2 of the Universal Declaration of Human Rights, 1948, to which Malawi is a party. In *Chihana -vs- Republic* (Criminal Appeal No. 90f 1992) the Supreme Court declared that the Declaration is part of the Law of Malawi since the 1966 Constitution had specifically referred to it.

The above instruments clearly provide the direction for which general policy questions relating to peoples livelihoods should be resolved. No economic (human) rights can supersede the principle of sustainable development or sustainable livelihoods. International instruments relating to biodiversity have including the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) have followed this principle and seek to elevate its facilitation. The problem however is that of implementation and enforceability at national level. There remains the gap that, though fundamental human rights instruments enforceable by individual citizens should take priority, quite often there are no effective machinery for their realisation.

In the first place, the struggles of every day life and growing poverty make it difficult for ordinary people to enforce these rights. Secondly, there is so much reliance on state resources that it becomes difficult to promote independent action. Civil society in most developing countries, including Malawi, is overwhelmed with welfare bread and butter as well as relief issues to alleviate hunger, HIV and natural calamities so much so that policy related action is very minimal. Here is therefore the challenge for funding institutions to provide support for these activities so as to contribute to realization of internationally recognized rights.

### **3. Human Rights, Food Security and Health in Malawi**

The Malawi Constitution is the supreme law and policy instrument in Malawi and even international law is subject to the Constitution (section 211). This is already an expression of sovereignty as enshrined in various international instruments including the United Nations Charter. In the context of biodiversity the principles of national policy in section 13 provides for the responsibility of Government to conserve and enhance the biological diversity of Malawi (paragraph d) while paragraph (d) calls upon the state to achieve adequate nutrition for all in order to promote good health and self-sufficiency in food. The effect of the principles of national policy in the Constitution is to provide direction for Governments action and is therefore not binding; but courts may take them into account in determining the validity of executive decisions and in interpretation of the Constitution.

It follows therefore that the Constitution does not provide for a readily enforceable right to food. However two provisions in the bill of rights may be interpreted as providing for a right of access to food or health facilities. The first is section 16 which provides for the right to life. It does not require too much analysis to conclude that the right to life is not confined to the physical aspects of a person's well being. It also includes the material aspects that enable a person realize that right. In that respect deprivation of food and health facilities would violate such a right and so would violation of a clean and healthy environment.

In addition section 30 provides for the right to development which, though at first glance appears communitarian in nature, is essentially intended to address individual needs. Subsection (2) is particularly relevant in relation to access to food and health facilities. It states that:

*“The State shall take all necessary measures for the realization of the right to development. Such measures shall include, amongst other things, equality of opportunity for all in their access to basic resources, education, health services, food, shelter, employment and infrastructure.”*

The services mentioned in the above provision are to be provided for all Malawians and for the benefit of individuals that require them. It therefore provides the right of access to food and health to ensure that the material requirements for realizing that right should be provided and facilitated. Commentators have considered these measures as including land reform, ensuring physical and economic access to credit, natural resources, new technologies, rural infrastructure, irrigation and provision of explicit farmers’ rights through legislation<sup>10</sup>.

The state needs to deliberately put in place mechanisms to ensure that cash crops do not replace food crops at the expense of food security; that the private sector is regulated to prevent them violating farmers rights and that there is sufficient R & D with respect to under utilized crops of high nutritional value (bid). On the other hand, the enforceability of these so-called ‘third generation’ socio-economic rights has been subject to several doubts. However the South African Constitutional Court<sup>11</sup> has come out quite clear and held these enforceable; though consideration need to be taken of availability of state resources in determining the type of executive or legislative action to be undertaken in fulfilling these rights. These rights would be quite instructive for Malawi; though it may be essential to strengthen the rights of access to food and health further under our Constitution.

#### **4. Globalisation, biotechnology and biodiversity**

Commentators have characterized the current process of globalisation as taking twin tracks. The developed world with their technological, financial, economic and trade muscle have emphasized trade liberalization, free flow of information and removal of restrictions on investments. They have concentrated their efforts on institutions that promote and champion these, especially the IMF and the WTO. On the other hand, the developing world feel marginalized in the financial, technology and trade areas; they have tended to support efforts to promote sustainable development and have concentrated on institutions, instruments and processes that support the poor and vulnerable in society. The United Nations bodies and secretariats of international instruments such as the

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<sup>10</sup> See Phillip Cullet (2004) *Human Rights and Intellectual Property Rights: Need for a New Perspective* ([www.ielrc.org](http://www.ielrc.org)).

<sup>11</sup> In *Minister of Public Works and Others –vs- Kyalami Ridge Environmental Association* (case No CCT 55/00); *Government of Republic of South Africa –vs- Grootboom* (case CCT 11/00); and *Minister of Health –vs-Treatment Action Campaign* (case CCT 8/02), the Constitutional Court held that access to housing and access to health are enforceable under the South African Constitution. The South African Constitution of course is much more clear and direct than the Malawi Constitution; nevertheless the fact that the rights of access to food and health facilities appear in the bill of rights the reasoning in the above cases can be applied to Malawi for Government to provide core minimum to the plight of those suffering from deprivation and healthy problems.

Convention on Biological Diversity constitute the main forum for these developing country efforts<sup>12</sup>.

The dilemma for developing countries however is that there is a tendency to shift ‘goal posts’ by developed countries in that they are quite happy to dump liberalization when it hurts their interests; and yet demand it from developing regardless of the consequences. TRIPs is such a typical example; not only did the developed countries remove the debate on TRIPs from World Intellectual Property Organization, a specialist United Nations body, they succeeded in giving IPR jurisdiction to the WTO, a trade body with no track record in IPRs; but has binding dispute procedures in which they have a much stronger voice. It is now widely acknowledged that developing countries had barely time to digest the complex Uruguay Round trade negotiations culminating in the establishment of the WTO when TRIPs was foisted on them<sup>13</sup>. Nevertheless they must now comply; and even though developing countries were given grace periods ranging from 5 to 10 years (and now, after the Doha declaration, up to 2016) most are ill prepared<sup>14</sup> but need to comply as required, otherwise trade sanctions may be imposed on them that can have devastating effects on their already weak economies.

Globalisation is therefore polarising debate and development making it increasingly difficult for most developing countries to concentrate on promoting their core business, promotion of livelihoods. The lack of capacity to negotiate, follow up and clearly articulate national positions makes them weaker and provides ammunition for developed countries to push their agendas with little or no resistance. In addition, most developing countries rarely consult their people such as the private sector and civil society in these issues from whom they could get insights and positions that may have positive influence on their negotiations whether at bilateral or multilateral level.

Most developed countries have well equipped departments of trade, justice, health and agriculture to enable them keep up to date with global negotiations. In addition they often use expertise from academia, think tank organizations and civil society to enable them formulate national positions. Not only has Malawi inadequate capacity in these departments but also there is no strategy to incorporate inputs from non-state actors in its international negotiations. This weakens the country’s ability to respond to and follow up on international issues for the benefit of the country. There is therefore clear need for developing countries such as Malawi to develop strategies for incorporating issues, concerns and participation of non state actors in its international processes

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<sup>12</sup> See F Yamin, *supra* p. 4

<sup>13</sup> Developing countries generally signed up to TRIPs not because they thought it was a priority for them; rather because they considered it was part of a larger package such as reduction in trade protectionisms. As it turned out WTO did not reduce protectionist tendencies, nevertheless TRIPs was adopted: Commission on Intellectual Property Rights, *supra*, p.8

<sup>14</sup> See Robert Lewis Lewington & Chikosa Banda (2004) *A survey of Policy and Practice on the Use of Access to Medicines-Related TRIPs Flexibilities in Malawi* (DFID Health Systems Resource Centre, London): [www.odi.org](http://www.odi.org). The authors point out that their survey revealed that there is very little awareness and or appreciation of impact of TRIPs deadlines and no appreciable action to respond to it.

## 5. IPRs in Malawi

IPRs can be divided into two broad categories: industrial property comprising patents, trademarks, geographical indications and trade secrets; and literary and artistic ones comprising copyright. Patents are awarded to an inventor to prevent others from making, selling, distributing, importing<sup>15</sup> or using the invention or its products without a license for a fixed period. Section 29 of the Patents Act provides that the patent will be valid for a period of 16 years from the date of providing the complete specification of the invention, and is renewable.

Trademarks provide exclusive rights to use distinctive signs such as symbols, colours, letters, shapes or names to identify a product and protect its associated reputation. A mark must be distinctive to identify the proprietor's goods or services. It is valid for a period of seven years subject to renewal (section 25 of the Trade Marks Act). A geographical indication identifies geographical origins of a product and protects the associated reputation, qualities or other characteristic of the product.

There is no specific legislation protecting geographical indications but they could easily be protected as trademarks under Malawi law. Trade secrets consist of commercially valuable information about production methods, business plans or customer lists. These are protected under the common law in Malawi. The Copyright Act grants exclusive rights to creators of original literary scientific and artistic works and is valid for the life of the author plus 50 years (section 13).

While most of these IPRs would apply to biodiversity and biotechnology products, we shall concentrate on patents that regulate products and processes most related to biodiversity.

## 6. Patentable subject matter

The Patents Act, 1958 does not define directly what processes or products may be registered. Section 2 however defines a patent as a '*new and useful art* (whether producing a physical effect or not), process, machine, manufacture or composition of matter *which is not obvious*, or any new and useful improvement thereof *which is not obvious, capable of being used or applied in trade or industry* and includes an alleged invention' (emphasis supplied). The underlined words are key in the definition. An invention will be 'new' according to section 2 if, *inter alia*, it was 'not known or used anywhere in Malawi by anyone other than the applicant or his agent, or the person or persons through whom such applicant has derived his right or title (secret knowledge or secret user otherwise than on a commercial scale being excluded)' or it was not worked anywhere in Malawi otherwise than by way of technical trial or experiment by the applicant or any person or persons from or through whom such applicant has derived his right or title'.

The terms 'trade or industry' are not defined in the Act. This may invite uncertainty as to whether village 'cottage' industries or traditional knowledge that is not in the

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<sup>15</sup> See TRIPs Agreement; the Malawi Patents Act as we shall later does not explicitly cover imports though perhaps a general reading of the Act gives the sense that they should be covered.

mainstream science are covered in the Act. Further, it is not clear in the Act whether the Registrar of patents will have the necessary information to enable him scrutinize applications to ensure they contain information that is not already being utilized. The well publicized cases of the *neem* tree and *texmat* rice in which United States multinationals companies used already existing indigenous knowledge and genetic resources in India to patent medicinal and rice inventions. It had to take legal action to have these patents cancelled. It follows therefore that the Patents Act is not the suitable framework for protecting indigenous knowledge since it is quite possible for the Registrar to refuse registration of a local knowledge patent on the basis that it is not new, has not legal owner or is not capable of industrial application. Further, the Registrar may easily register the claims of a multinational based on our local knowledge merely because he does not know the knowledge already exists in Malawi or simply that it represents the first industrial application of the knowledge and that the manufacture has given it newness.

The definition of invention clearly shows that any invention to be registered as a patent must be new, not obvious and must be capable of industrial application. This is the universal definition of and contains essential elements for patents. Article 27.1 of TRIPs, for example, requires that an invention must be *new, involve an inventive step and must be capable of industrial application*; these terms correspond directly to those in the Patents Act. However the definition of invention in the Patents Act does not show whether an invention includes both processes and products. In fact the definition is more descriptive of the technology than products thereof. The question of course would be whether the Act would be effective to protect patents if it does not products from such patents. In the first place the protection of the technology is critical; not many people and perhaps none in Malawi would have the facilities to work the patents; on the other hand the patent would remain vulnerable to products coming from outside Malawi either authorized by the patentee or not.

## **7. Parallel Importation**

It is important to determine whether the patent protects products because it has bearing on whether a patent holder can be protected from parallel imports<sup>16</sup> or whether Malawi can enact a legal requirement that all patents should be worked in Malawi in order for the patent to be granted. Further, the clarity is necessary in order to determine whether Malawi can, for certain essential products such as medicinal drugs and agricultural inputs that are key to livelihoods, exempt from product patent protection.

In the first place the definition of an invention suggests that the invention may produce a 'physical effect' and further that it will be used in trade or industry, for some purpose, presumably. Section 28.4 of the Patents Act provides further leads. It defines the legal

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<sup>16</sup> Parallel imports are defined as imports or resale in a country, without the consent of the patent holder, of a product of a patent that was put on the market by the patentee or with his consent. It is premised on the concept of exhaustion of rights under which who has been rewarded through the first sale or distribution of a patented product has no longer the right to control use or resale of the product: See Harrison Mwakymbe and George Kanja, *infra*, pp. 15-20

right that a patent holder gets under the Act. Subject to the Act and the conditions in the patent the patentee has:

*'full power, sole privilege...during the term of the patent to make, use, exercise and vend the invention within Malawi...so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention during the terms of the patent'.*

This is a sweeping provision that, though not covering imports, would seem to cover products that are the result of working the patent whether these are produced in or outside Malawi. The patentee can therefore obtain an injunction restraining such imports into Malawi. In sum, patents registered in Malawi protect markets for patentees; and there is no requirement that the patent should be worked in Malawi. This is in compliance with TRIPs. Malawi may need to revisit this provision to determine whether it is in the interest of the national economy or may fall foul of fundamental human rights provisions already alluded to above. It is not difficult to envisage a situation where a manufacturer of essential life serving drugs prohibits cheaper generic drugs on the basis of a registered patent that he has never and has no intention to work in Malawi<sup>17</sup>. No economic rights whether internationally agreed can justify such a restriction.

Article 27. 1 of TRIPs however puts it beyond doubt that parallel imports are illegal subject to exhaustion of rights under Article 6. It requires member states to make patent rights available for any invention, whether products or processes, and whether products are imported or locally produced. Article 28.1 emphasizes the rights of the patentee. It confers exclusive rights:

- a. *Where the subject matter of a patent is a product, to prevent third parties not having the owner's consent for the acts of: making, using, offering for sale, selling, or importing from these purposes that product;*
- b. *Where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.*

These provisions are important for two main reasons. First they indicate the extent to which Malawi patent law should be revised in order to comply with TRIPs. Secondly, they show the mischief that TRIPs seeks to deal with in matters of trade related IPRs. Articles 27 and 28 seek to remove the restrictions and exceptions that most countries had prior to TRIPs. This is perhaps why the Malawi Government in spite of the provisions of section 28.4, maintains that it allows parallel imports<sup>18</sup>. As they are now in violation of TRIPs what should Malawi's response be?

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<sup>17</sup> In fact the importation of generic ARVs into Malawi may already be in violation of the Patents Act: See Robert Lewis-Lewington & Chikosa Banda, *supra*, at p. 19 who point out that Malawi authorities interpret section 28. 4 as not prohibiting parallel importation.

<sup>18</sup> *Ibid*

In the first place Malawi should have recourse to its Constitution and ensure that the values therein are upheld. Section 211 clearly gives Malawi mandate to uphold the Constitution first and foremost. Secondly, TRIPs itself provides for a number of flexibilities. Thus, although the Patents Act provisions on compulsory licensing and government use<sup>19</sup> have intrinsic problems such as in relation to issues of non-negotiation and non-payment of compensation and may be TRIPs non-compliant<sup>20</sup>, Article 31.d of TRIPs allows member states to authorize third parties to use patents for public non commercial use without negotiation with the patentee in cases of emergency. Many developed country patent legislation have this exception even prior to TRIPs<sup>21</sup>. Though this provision does not mention parallel imports it may be assumed to authorize these; Malawi will need to reflect this clearly. And perhaps more importantly Article 8 of TRIPs allows members states:

*to adopt measures necessary to protect health and nutrition, and to promote public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'*

When this provision is read together with the ICESCR already dealt with above, Malawi has adequate room to move her policy and legislation position to primarily consider the public interest. There is however need to sound a caution. Developed country multinational firms have been very adept at lobbying their government to solicit favourable investment and market opportunities across the globe. They are therefore using bilateral measures rather than multilateral frameworks to extort compliance with the strict letter of TRIPs. Bilateral investment agreements slip in restrictive terms including exclusive IPR rights that tie the hands of developing countries<sup>22</sup> to formulate general policy positions in the public interest

## **8. IPRs Food Security and Health**

Food security has been defined in different ways by different agencies, groups or individuals. The FAO defined food security at the World Food Summit in 1996 as food that is available at all times, that all persons have means of access to it, that it is nutritionally adequate in terms of quantity, quality and variety, and it is acceptable within a given culture. Academics and NGOs on the other hand emphasize that the term entails a guarantee of livelihoods that would generate sufficient food at the household level<sup>23</sup>. The biotechnology industry together with the Breton Woods financial institutions and the

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<sup>19</sup> Sections 37, 38 and 40 of the Patents Act

<sup>20</sup> See Robert Lewis-Lewington & Chikosa Banda, *supra*, pp. 21-40

<sup>21</sup> See James Love (2001) *Compulsory Licensing: models for state practice in developing countries, Access to Medicine and compliance with WTO/TRIPs accord* (UNDP) [www.cptech.org](http://www.cptech.org).

<sup>22</sup> See Carlos M Correa (2004) *Bilateral Investment Agreements: Agents of New Global Standards for the protection of Intellectual Property Rights* ([www.grain.org](http://www.grain.org)). These agreements define IPRs as 'investments' making it therefore unnecessary to work them where they are registered or indeed to disseminate the technology protected.

<sup>23</sup> F. Yamin, *supra*, p. 3.

WTO use the term to denote increased food production: availability, quality, variety and cultural issues are not relevant in their context.

Despite these differences it is clear that what is crucial is guaranteeing access to food at household level. Achieving this is a challenge the nations of the world committed themselves at the Earth Summit in 1992 and more recently at the World Summit for Sustainable Development in 2002.

For developing countries, though gene rich in terms of plant genetic resources necessary for food production, the major challenge is for them to acquire and establish the necessary technological and institutional capacity to harness such genetic resources. These happen to be concentrated in developed country centres whose priorities and interests are driven more by corporate private interests than social goals that the developing world are more concerned with. The dilemma is that developing countries do need the services of developed country dominated forums such as WTO and are therefore easily coerced into accepting and implementing policies that do not effectively address pressing social issues. They also need instruments in their countries and so end up signing agreements that impose more stringent obligation than perhaps the minimum.

Thus although TRIPs requires that plant animal varieties may be exempted from patenting but that they be protected by *sui generis* IPRs, bilateral investment agreements, trade and aid conditionalities with developed countries may coerce them to patent these. In addition the 20 year minimum required by TRIPs for all products and processes of technology without discrimination as to place of invention and whether products are imported or locally produced effectively curtails freedom of government to promote cheaper agriculture imports, pharmaceuticals or other chemicals. Payment of IPRs related royalties and market concentration brought about by IPRs would push up prices and make it difficult for small scale farmers to afford<sup>24</sup>.

Further, there is concern that IPR plant varieties promote monoculture and emphasis on cash crops. The result being loss of biodiversity and threat to sustainable livelihoods. It is therefore necessary for policy and legislation to deliberately target small-scale farmers and provide incentives for them to conserve and protect agro-biodiversity. This will promote local food varieties that have stood the test of time, climate change and pests and diseases with minimum or no outlays for chemicals. In addition, incentives should be given to commercial breeders to promote research and development of local varieties with a view to conserving agro-biodiversity.

This equally applies in relation to access to medicines and medical care that has become a contentious issue in recent times not least because of life threatening illnesses such as HIV/Aids that have reached epidemic levels in most developing countries. The patent protection under TRIPs clearly runs counter not only to the basic tenets of economic liberalization but more significantly the moral and humanitarian interest that is closely

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<sup>24</sup> It is interesting to note that despite the exceptions provided by most legislation for dealing with government use of patents or compulsory incensing (such as sections 37, 38 of the Patents Act), most of which are allowed by TRIPs, no developing country has taken advantage of the flexibilities.

associated with public health and healing. While almost everyone agrees that pharmaceutical companies that spend billions in research and development of new drugs should be adequately compensated to enable them recoup their investments and incentives them to conduct further research, there is little justification for withholding life saving drugs from impoverished people in developing countries using patents monopoly. Many of these patents are just 'parked' in developing country patents registry with no intention to work there or transfer the technology associated with them.

In the same vein developing countries have given little support to the promotion of traditional medicines and the protection of the knowledge associated with them though it is widely agreed that these provide essential services to the majority in the rural areas. Policy initiatives have been undertaken in Malawi in form of a draft Traditional Medicines Policy and a draft Traditional Healers bill but these do not provide for protection of the knowledge associated with traditional medicines and traditional healers<sup>25</sup>. Piracy of traditional knowledge is being perpetrated due largely to weak monitoring mechanisms and lack of protection for such knowledge.

## **9. Exemption from Patentability**

Article 27.2 of TRIPs provides for patentability of all technologies whether biological processes or otherwise. The following are however excluded.

- (a) Inventions contrary to *Ordre public* or morality including inventions that are dangerous to human, animal or plant life or health or seriously prejudicial to the environment. What is contrary to *Ordre public* morality is contentious and TRIPs has not defined these. However it is generally understood that technologies that are offensive or abhorrent to existing culture, tradition or values may be caught cases decided by the European Patent Office (EPO) on this point suggest there is no clear answer. This is much more so because biotechnology by its very nature is pushing the boundaries of nature.
- (b) Plants and animals other than microorganisms and essentially biological processes, plants and animal are excludable for patenting, however, member states are obliged to provide some form of protection for plant varieties. These could be under UPOV or *sui generis* IPR. On the other hand microorganisms and essentially biological process for plants and animals are subject to mandatory patenting. The definition of microorganisms is not provided for in TRIPs and neither is there any for 'essentially biological processes'. The lack of definition of these terms and the objection of most people to patenting life forms has generated more controversy. A broad definition as adopted by developed countries such as US and European Union narrows the scope of excludable organisms and therefore little or no effect to plant/animal exclusion and bans the patenting of naturally occurring organisms. The same can be said with regards to 'essentially biological processes'. The boundary should be the extent of human intervention so that

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<sup>25</sup> See Environmental Affairs Department (2004) *Policy, legislation and Mechanisms on Access and Benefit Sharing in Malawi* (Lilongwe)

where it is less pronounced then it is a naturally occurring process and therefore excludable.

The Patents Act provides for exclusion of certain inventions from patentability under section 18. Section 18.1.b provides that the Registrar can refuse an application if he determines that the use of the invention in respect of which the application is made will be contrary to law or morality. This partly conforms to Article 27.2 which allows exemptions on the ground of *ordre public* or morality; however exemptions on the ground merely that there is a law that prohibits the invention is not TRIPs compliance. The question would be whether TRIPs would override a national constitution if it so provided or provided for the exemption indirectly. The answer to this clearly depends on the context. In as far as Malawi's international relations are concerned Malawi must comply with TRIPs but domestically the Constitution would apply and the courts would have to give expression to such a provision and not TRIPs. This is clear from section 211 of the Constitution. Malawi's international relations would further determine what response her partners would make and whether the conduct of Government would be considered in the interest of the public. The case brought but subsequently abandoned by pharmaceutical companies in South Africa over the alleged non-compliance with TRIPs is instructive. These companies challenged the South African Government on the ground that amendments to the Medicines Act that allowed parallel imports of generic drugs into South Africa were contrary to TRIPs. The challenge did not go far as the pharmaceutical companies bowed to public pressure and withdrew the case<sup>26</sup>.

## **10. IPRs and Competition**

Patents may be abused by their holders because of the technological and market monopoly rights they provide. The Patents Act regulates the abuse of monopoly rights granted by patents in various ways. Section 37.1 provides for compulsory licensing to be granted by the Registrar of patents if an applicant can show that the reasonable requirements of the public with regard to the invention have not been or will not be satisfied. In terms of section 37.6 the reasonable requirements of the public may be proved by the applicant showing:

- a. that a patent that is capable of being worked in Malawi is not being so worked without any satisfactory reason; or
- b. that the working of the patent in Malawi is being prevented by the importation of the patented article by the patentee or persons authorized by the patentee; or
- c. that demand for the patented article is not being met on reasonable terms
- d. that the refusal of the patentee to grant a license or unfair terms or conditions attached by the patentee are prejudicing the trade or industry of Malawi or of any person contrary to public interest; or
- e. that any condition that is void as being in restraint of trade has been attached by the patentee to the license to work or use the patent or work any article.

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<sup>26</sup> For a full analysis of the case and its likely ramifications see Harrison Mwakyembe & George Kanja (2001) *Implications of the TRIPs Agreement on the Access to Cheaper Pharmaceutical Drugs by Developing Countries: Case Study of South Africa –vs- Pharmaceutical Companies* ([www.hurid.org](http://www.hurid.org)).

In determining whether there has been abuse of monopoly rights the Registrar shall have due regard to the fact that patents are granted 'not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Malawi without undue delay: proviso to section 37.6 (f). This seems to be in conformity with Article 40 that allows member states to control anti-competitive practices in their legislation. However these controls must be read together with Article 27 that allows imports and prohibits discrimination of such imports on the basis that the patent is not being worked in Malawi. The solution to this potential conflict could lie in ensuring that the legislation should target patents that are capable of being worked in Malawi and are deliberately not being so worked and that such practice is merely intended to secure monopoly markets but prevents transfer and dissemination of technology which is a key objective of TRIPs.

Finally, the Competition and Fair Trading Act 1998 seeks to facilitate competition in the economy by prohibiting anti-competitive trade practices. It establishes a Competition and Fair Trading Commission to regulate and monitor monopolies and protect consumer welfare. The Commission has not been established yet and the Act is not yet operationalized. It would however provide the relevant institutional presence to check anti-competitive behaviour by use of IPRs in trade and business. However section 3.d specifically excludes

*'those elements of any agreement which relate exclusively to the use, license or assignment of the rights under, or existing by virtue of, any copyright, patent or trade mark'.*

The reason for this exclusion seems to be that these IPR agreements are provided for under their respective legislation. On the other hand, it is possible to invoke the provisions of the Competition and Fair Trading Act where anti-competitive behaviour is being committed in the name of enforcing a patent when the main objective is to secure market power and monopoly. In that respect the elements of an agreement not exclusively relating to IPRs will be amenable to the Commission.

## **11. Recommendations for policy and legislation reform**

The following are some of the recommendations based on the foregoing analysis. They are given here in order of their priority.

### *12.1 IPRs human rights and local livelihoods*

- Government policy relating to food security and public health must give meaning and give expression to fundamental human rights protected under basic instruments of international human rights;
- The provisions of the CBD and ITPGRFA should be fully integrated in relevant policies because they form the basis of realizing these fundamental human rights;
- Such expression should be reflected in the Constitution by providing for the right of access to food and health;
- Such policy positions should guide government response to TRIPs compliance. Full advantage should be taken of flexibilities under TRIPs.

### *12.2 IPRs community and farmers rights*

- The Patents Act is not appropriate for regulating traditional knowledge. It is necessary to enact a separate piece of legislation to protect community and farmers rights;
- Such rights could be registered at local level, either at district or traditional authority level; they may be in form of community registers where local knowledge that is useful to the community may be recorded;
- Benefits arising from exploitation of local knowledge may be invested in a community trust fund for the benefit of the community; and
- Farmers' rights to save and exchange seed should be protected; these may be protected under the Plant Variety Bill being drafted or under legislation protecting community rights;
- Provide rewards to farmers who conserve landraces and commercial breeders that conserve and improve on local varieties.

### *12.3 IPRs, food security and public health*

- In revising IPR legislation the policy issues outlined in paragraphs 12.1 and 12.2 above should guide the process;
- Clear provisions on parallel imports or indeed specifically the right to import generic drugs whatever their origin (in case of health) should be specifically protected; this is important in view of the inadequate capacity to work patents in the country.
- Malawi is not a party to UPOV and should remain as such; it should take advantage of the flexibilities under TRIPs to exempt plant and animal IPRs though some aspects of *sui generis* policy and legislation can be utilized;
- Government use of a patent for public non-commercial use should be protected by clear unambiguous legislation.
- The right to compensation for use of a patent for public non commercial should be respected subject to a proviso that such compensation should be reasonable due regard being had to the inability of the patentee to undertake working of the patent in the country and therefore to transfer technology and also to the profits already recouped by the patentee.
- While the period for validity of patents may be increased to comply with TRIPs, such increase should contain necessary conditions that can be monitored and enforced including the condition to effect technology transfer, where possible, within a certain period.

## **12. Concluding Remarks**

The main reason for granting patents is to encourage innovation as much as it is to facilitate technology transfer in Malawi. More often than not the former is claimed and enforced at the expense of the latter. In some cases, of course, inadequate infrastructure makes it impossible for technology to be transferred. Nevertheless it is necessary that policy and legislation should reflect this balance so as to avoid the current situation where this country is a seller's or patentee's market. Deliberate policies to encourage local innovation including copying the patents should be promulgated. Further, there is the

danger that in the pursuit of profit and markets, fundamental human rights and sustainable management of biodiversity will be given scant regard. Malawi needs to reflect these rights in her international negotiations as well as critical policy instruments such as those relating to food security and public health. TRIPs provides adequate flexibilities to accommodate these. Rights of farmers, local communities and local knowledge should be protected; this will ensure that biodiversity and knowledge associated with it also protected. Commercial breeders should be give incentives to promote indigenous varieties and farmers preserving landraces should be rewarded.