

# **A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPs Flexibilities in Malawi**

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September 2004

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# Acronyms and abbreviations

AIDS – Acquired Immune Deficiency Syndrome  
APIs – active pharmaceutical ingredients  
ARIPO – African Regional Intellectual Property Office  
ARVs – anti-retrovirals  
CHAM – Christian Health Association of Malawi  
CMS – Central Medical Stores  
DFID – Department for International Development  
FDC – fixed-dose combination (primarily in the context of ARV triple therapy)  
FPPs – finished pharmaceutical products  
GFTAM (or Global Fund) – Global Fund to Fight Tuberculosis, AIDS and Malaria  
GMP – good manufacturing practices  
HIV – Human Immunodeficiency Virus  
IPRs – intellectual property rights  
MSF – Médecins sans Frontières  
NGOs – non-governmental organisations  
TRIPs – Uruguay Round Agreement on Trade Related Aspects of Intellectual Property Rights  
UNICEF – United Nations’ Children’s Fund  
WB – World Bank  
WHO – World Health Organisation  
WTO – World Trade Organisation

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## Key words

- Drug registration
- Procurement
- Public health
- Legislation



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# 1 Executive Summary

Malawi is a least developed country with poor socio-economic indicators, particularly in public health. It has a limited pharmaceutical manufacturing base and thus depends significantly upon the importation of products from foreign-based manufacturers. In the case of relatively newer medicines, some of which are covered by intellectual property rights, Malawi must import from brand name manufacturers. Where a patent bar does not exist, Malawi relies on manufacturers based in India and, to some extent, in China and South Africa. With respect to anti-retrovirals, Malawi's HIV/AIDS treatment programme, funded by the Global Fund, relies almost exclusively on fixed-dose combinations generics imported from India. This reliance is potentially problematic because some of the component medicines are still patent protected in Malawi.

Malawi's patent legislation must become generally compliant with the Uruguay Round Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) by January 2006, but this will require a comprehensive review to meet this deadline. With respect to medicines, Malawi has some flexibility to extend its date of compliance until 2016 under paragraph 7 of the Doha Declaration and under subsequent action by the World Trade Organisation General Council. This extension does not obviate the need for prospective domestic legislative reform to take advantage of existing TRIPs flexibilities, including the extended transition period. Moreover, given Malawi's current system for granting pharmaceutical patents, the right to extend the transition period re medicines will not necessarily suspend the effect of previously granted patents. Thus, provision will need to be made for granting compulsory licences and/or authorising government use with respect to existing on-patent medicines. In addition, Malawi's underlying patent legislation reflects few of the available TRIPs public health safeguards with the exception of some provision for compulsory licences and government use. However, even where these are available, there is little, or no, capacity to implement them and thus no experience in their use.

In sum, there is minimal awareness of the approaching 2005 and 2006 deadlines and, where awareness does exist, almost no knowledge of the technical details at issue. Malawi's current efforts to regularise its intellectual property rights affecting access to medicines are *ad hoc*, problematic and reflect a limited technical capacity. Nonetheless, the apparent political will to revise the Malawian Patents Act and make best efforts to ensure maximum access to medicines should be capitalised upon and key ministries and institutions, particularly the Ministries of Health and Commerce and the Patents Office, should be supported in their access to medicines-related and broader TRIPs-related initiatives. However, this intellectual property reform will not be possible without the assistance of development partners in increasing the availability of specialist skills on issues such as intellectual property law and international drug procurement and



further assistance in facilitating the thorough review of legislation and associated policies.



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# 1 Introduction

## 1.1 Political Context

Malawi was ruled by Britain from 1891 to 1964, attaining its independence on 6 July 1964. After independence, Malawi slid into a one party dictatorship with a President for Life.<sup>4</sup> This state of affairs lasted for almost 30 years until 1993 when Malawi changed from a single party to a multiparty system of government. The political transition was legally marked by a new Constitution, which became completely effective in 1995.<sup>5</sup>

The Constitution prescribes two sets of fundamental principles that were designed to guide the interpretation of other Constitutional provisions and to inform subsequent legislation, policy initiatives, and executive action. The first set of principles is constitutional and the second governs national policy. With respect to health, the principles affecting national policy impose an obligation on government:

*...to actively promote the welfare of the people of Malawi by progressively adopting laws and policies aimed, inter alia, at providing adequate health care commensurate with the health needs of the Malawian society and international standards of health care.<sup>6</sup>*

Section 30 provides for the right to development and obliges the state to take all necessary measures to provide equality of opportunity for all in their access to basic health services.<sup>7</sup> “Access” includes physical access and economic access. One of the core minimum obligations of the state towards this end is the provision of essential drugs to its people.<sup>8</sup>

Among the major obstacles to the provision of some newer essential medicines in Malawi and in other developing countries is the enforcement of intellectual property rights.<sup>9</sup> This is due to the fact that patent protection, in the short run, effectively confers upon the patent holder a monopoly over the manufacture, sale and importation of the patented drug. In Malawi, the Patents Act grants the holder of a patent full power, sole privilege and authority, during the term of a patent, to make, use, exercise and vend an invention within Malawi in such a manner as he deems fit. The holder also has a right to enjoy the whole profit and advantage accruing by reason of the invention during the term of the patent.<sup>10</sup> The effect of this exclusivity is to reduce competition and increase market prices meaning that patented drugs are often not registered, or sometimes even physically available, in poor countries or are sold at prices that are unaffordable to the majority of Malawians. As a result, poor people do not have access to treatment for many diseases or are vulnerable to fake products of suspect quality.<sup>11</sup>

Anti-retroviral drugs for the treatment for HIV/AIDS have been the focus of the debate over intellectual property rights and access to medicines both in Malawi and elsewhere. They are relatively new inventions, and many are protected under the patent laws of Malawi and other developing countries, thereby limiting access to life-saving treatment for millions of mostly poor Africans. There are other diseases for which the prohibitive cost of medicines denies people the right to safe and affordable medicines,<sup>12</sup> including malaria, meningitis, tuberculosis, and other opportunistic infections.<sup>13</sup> According to the World Health Organisation (WHO), most patented drugs are sold at 20–100 times the marginal cost.<sup>14</sup> Consequently, patents pose a serious challenge for developing and least developed countries in accessing essential medicines.

Any country seeking to provide adequate health care for its citizens needs to carefully revisit its intellectual property laws in the light of the current global developments. It is in this context that we consider the extent to which the government's legislative and policy programme has furthered access to essential medicines in Malawi and, in particular, has taken advantage of the flexibilities under the TRIPs agreement.

## 1.2 Socio-economic Context

Malawi remains one of the poorest countries in the world, with a per capita GNP of US\$ 210 (1999 estimate).<sup>15</sup> The last population and housing census indicates that Malawi has a population of 9.9 million<sup>16</sup> with an annual growth rate of 2% per year.<sup>17</sup> 11% of the population lives in the major urban areas, the rest is rural based. Malawi is a landlocked country and has a narrow economic base with no significant mineral resources and high costs of external trade.<sup>18</sup> Consequently, it is heavily dependent on donor support.

Approximately 50% of Malawi's population is below the age of 15 years, thus presenting a huge dependency burden.<sup>19</sup> Over 60% of Malawians live below the absolute poverty line.<sup>20</sup> Literacy in Malawi is extremely low. According to the 1998 population census results, 58% were basically able to read and write in a particular language. Literacy rates among males and females stood at 64% and 51% respectively.<sup>21</sup> Up to 80% of rural women can neither read nor write.<sup>22</sup>

Since the formulation of the first National Health Plan in 1964, and subsequent plans in 1973 and 1986, Malawi has made some impressive strides in the health sector.<sup>23</sup> The number of health units the government put in place and the immunisation coverage on communicable diseases evidences this expanded commitment. Despite these improvements to health care delivery, the health status of the population remains relatively poor. This is due to a lack of financial and human resources, reduced donor support, increased demand for health services, the resurgence of diseases such as TB and malaria, and the escalation of the AIDS pandemic.

Among the major challenges is the consistent shortage of essential drugs and medical supplies at service delivery points. This is partly because of the chronic under funding

of the health sector. Health expenditure as a percentage of GNP in Malawi is among the lowest in Sub-Saharan Africa.<sup>24</sup> Problems are often compounded by mismanagement, pilferage, and less than efficient drug procurement and distribution procedures.<sup>25</sup>

Health indicators are amongst the worst in the world and have shown little improvement in recent years:<sup>26</sup>

	Year	Kenya	Malawi	Zambia
Life expectancy at birth (years)	2002	50.9	40.2	39.7
Maternal mortality rate (per 100,000 live births)	2000	1,000	1,800	750
Under 5 mortality rate (per 1,000 live births)	2000	113	197	185
Infant mortality rate (per 1,000 live births)	2000	79	117	111

Source: WHO (2004).<sup>27</sup>

The Malawi social indicators survey of 1995 showed that approximately 70% of in-patients deaths in Malawian health institutions are due to malnutrition, pneumonia, anaemia, malaria, AIDS-related diseases and tuberculosis.

Much of the gains in terms of life expectancy expected from expanded access to health care services appear to have been eroded by the impact of HIV/AIDS.<sup>28</sup> According to the National AIDS Commission, the analysis of results from sentinel surveillance collected in 2003 indicates that HIV prevalence among all adults is 12–17%,<sup>29</sup> which implies that some 700,000 to 1,000,000 Malawians are infected. This epidemic has mainly affected the most productive age group in that approximately 75 % of AIDS cases are found between ages of 20 and 40.<sup>30</sup> Considering that this is the most economically active segment of the population, deaths in this age group impose a significant economic burden.<sup>31</sup> HIV/AIDS also accounts for over 40% of the in-patient admissions, placing major burdens on health care services and on limited health budgets.<sup>32</sup> AIDS has tripled the number of adult deaths to nearly 80,000 a year.<sup>33</sup> Apart from the resulting decline in life expectancy, HIV/AIDS has adversely affected the national economy.

The other commonly reported cause of morbidity in both adults and children is malaria. Resistance to commonly used anti-malarial drugs is increasing.<sup>34</sup> Studies indicate that the sulfadoxine-pyrimethamine parasitological failure rate is about 25% and that the overall treatment failure rate has increased from 5% in 1991 to a national average of 13%. The above indicators depict the enormous public health problems facing the health sector.<sup>35</sup>

These problems are aggravated by the fact that the majority of people cannot afford to pay for quality care and that free health services are not adequately resourced.<sup>36</sup> This is

especially so in the area of drugs. For instance, despite the remarkable therapeutic effect of anti-retrovirals (ARVs) in developed countries, the vast majority of HIV infected people in Malawi do not have access to ARVs.<sup>37</sup>

Additional factors contributing to lack of access to medicines in Malawi include inadequate capacity to administer and monitor complex and potentially toxic drugs, including laboratory testing, patient follow-up and treatment of drug side-effects.<sup>38</sup> The relatively high cost of drugs, most of which are imported, in the context of a stagnant economy and increased public awareness of the existence of these drugs has resulted in a situation where a substantial amount of the health budget has been devoted to the acquisition of drugs.

Considering that access to medicine is an essential element of an effective response to pandemics, the Malawi government has devised strategies to ensure the availability and accessibility of essential drugs.<sup>39</sup> More specifically the government intends to negotiate for reduced prices to enable poor people to afford essential medicines, including ARVs.<sup>40</sup> In some cases, action has already been taken to reduce the cost of drugs or to provide them free of charge.<sup>41</sup>



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## 2 Sources of Supply

The providers of formal health care services in Malawi can generally be classified into two, namely public and private. The public health sector comprises the Ministries of Health and Population, Local Government, Education and Agriculture; and the armed forces,<sup>42</sup> police and prisons.<sup>43</sup> Private health care providers can be classified into three. The first one is the non-profit category within which fall the Christian Health Association of Malawi (CHAM).<sup>44</sup> The second category includes profit making private practitioners and hospitals. The last category is of traditional healers and traditional birth attendants.<sup>45</sup> The Ministry of Health and Population provides about 60% of the total national health care services; CHAM and non-governmental organisations (NGOs) 37%; the army and the police 2%; and the Ministry of Local Government 1%.<sup>46</sup>

The Ministry of Health and Population regulates hospitals. It sources its funding from the Ministry of Finance (primarily from internal revenue and donors).<sup>47</sup> CHAM receives annual financial support from the Ministry of Health and Population, primarily in terms of payment of staff salaries.<sup>48</sup> It also gets its funding from a variety of local and foreign sources. For instance, CHAM implements user fees for a wide range of its health services<sup>49</sup> and also gets revenue from drug sales.

The above health service providers procure essential medicines from both similar and varying<sup>50</sup> sources in both developed and developing countries depending on their internal procurement policies, government procurement regulations, individual institutional needs, and availability. Policies set by funding agencies also determine the sources of essential medicines. In terms of volume, the majority of drugs consumed in Malawi's public and private sectors appear to be sourced from generic manufacturers in the developing world.<sup>51</sup>

The Ministry of Health and Population centrally procures medicines for all government hospitals through the Central Medical Stores (CMS). CMS stores and distributes the bulk of drugs and supplies used in the health system. The sources of essential medicines for public hospitals are varied and depend on the type of drug to be procured. Nonetheless, pharmaceutical industries based in developing countries, such as India, have been a valuable source of essential medicines supplied to public hospitals in Malawi.<sup>52</sup> The major procurement agent for government for ARVs and other drugs under the Global Fund is UNICEF.<sup>53</sup> The Government also procures drugs through local suppliers like Pharmavet, Pharmachemie and YB Enterprises, who have links with Indian pharmaceutical companies such as CIPLA and Ranbaxy.<sup>54</sup> The Government used to procure brand-name drugs<sup>55</sup> but is gradually giving preference to generics, so long as they are pre-qualified by WHO and are registered by the Pharmacies, Medicines and Poisons Board. This growing preference for generics has substantially increased



the affordability of the drugs.<sup>56</sup> Domestic generic manufacturers also supply the Ministry of Health albeit on a small scale. The Public Procurement Act seems to reflect deliberate government policy to encourage domestic manufacturers/suppliers to supply goods to the government. Section 31(17) of the Act stipulates that “in the evaluation of tenders, a procuring entity may apply the margin of price preference in favour of domestic bidders.”

Mission hospitals and NGOs are not bound by the government procurement regulations. CHAM procures its essential drugs mainly through the International Dispensary Association (IDA)<sup>57</sup> and the CMS.<sup>58</sup> Some drugs, however, are sourced from local pharmacies.<sup>59</sup> In terms of ARVs, the preference of mission hospitals has been generics supplied by manufacturers in India. However, whether a mission hospital procures branded drugs or generics is dependent on need, conditions set by funding agencies, and availability. NGOs either procure from local suppliers like Pharmachemie, Chemicals and Marketing and Pharmavet, or import directly. Medecins Sans Frontieres (Luxembourg) (MSF), for example, sources about 90% of its drugs from Europe and has been very restrictive in buying medicines from the developing world.<sup>60</sup> There are however specific medicines for which MSF has a different policy. These include malaria drugs, ARVs<sup>61</sup> and drugs for the treatment of opportunistic infections. When it comes to these drugs MSF’s policy is to promote the use of FDCs produced generically.<sup>62</sup> These are primarily imported from India through local suppliers.<sup>63</sup>

Unlike public and mission hospitals, private hospitals procure medicines as individual institutions. This means that they usually hold small stocks of drugs. Because private hospitals are profit-making entities, they do not engage in sourcing for essential medicines directly from manufacturers partly for efficiency and human resource reasons and partly because of their policy of concentrating on their core business – treatment. Private hospitals normally go through local suppliers who have links with pharmaceutical industries in developed<sup>64</sup> and developing countries. These suppliers include Indian and Chinese generic manufacturers.

It should be noted, however, that local private-sector importers import in response to the wishes of their customers. Private sector customers who are price conscious generally opt for generics from the developing world, whereas those who are more affluent and quality conscious frequently opt for brand name medicines. Consequently, on-patent drugs produced by proprietary manufacturers in the developed world are also part of their stock. Most of the drugs sold by Chemicals and Marketing Company Ltd., for example, come from Western brand manufacturers. In terms of volume, Pharmachemie imports more from Indian companies, but in terms of value the amount of money spent on importing generics is more or less equivalent to the sum spent on brand products from the West. Pharmavet also imports most of its drugs from India.

The level of supply to the private sector from local manufacturers is quite low. This is partly because these manufacturers produce a limited range of drugs on a very small scale.

## 2.1 Domestic Supply

As a least developed country, Malawi is deemed not to have a sophisticated pharmaceutical industry, has no innovative capabilities, and can only manufacture a small array of finished products from imported ingredients and/or repackage finished products. The pharmaceutical manufacturing industry is characterised by a small number of registered pharmaceutical manufacturers. Only four pharmaceutical companies are actively engaged in the manufacture of a limited range of drugs, particularly those that are in great demand on the local market.<sup>65</sup> These are Pharmanova Ltd. and its sister company SADM, Malawi Pharmacies (Pharmaceuticals Limited)<sup>66</sup> and Kentam Pharmacies<sup>67</sup>. These manufacturers primarily target the domestic market and they manufacture what the domestic market can absorb. Owing to the small size of the domestic market, they have low production capacity.<sup>68</sup>

Research and development in the pharmaceutical manufacturing sector is limited to manufacturing processes rather than in primary research on innovative pharmaceutical products. According to some manufacturers it is even cheaper to import certain drugs than to invest in research and technology, considering the size of the market. Most of these manufacturers have small research departments that mainly concentrate on the reformulation of simple proven elements. These companies have no capacity to invest in primary research partly due to the huge infrastructure investment required compared to the small and impoverished domestic market. Malawi therefore does not have the capacity to make most essential drugs, including ARVs, unless it deliberately develops that capacity.

Production costs for domestic producers are generally high due to the non-availability of locally produced primary, secondary and tertiary ingredients. Thus, almost all active pharmaceutical ingredients (APIs) are imported from India and China. Even though no duty is payable on APIs, surtax is payable subject to refund. Unfortunately, the process of claiming refunds from the Malawi Revenue Authority is unduly long with the result that money which would have been usefully invested in drug manufacturing is tied up with the revenue authority. The cost of electricity, the only source of industrial energy, is also high. Additionally, electricity supply is very erratic in Malawi due to frequent power cuts. As a landlocked country, the cost of transport remains a serious constraint to industrial development with over 40% of Malawi's total importation bill attributable to transportation costs. The high cost of telecommunications is also a factor. Consequently, generic pharmaceutical products manufactured in Malawi are generally more expensive than those imported from elsewhere, for example from India.<sup>69</sup>

“Lack of a guaranteed market”<sup>70</sup> is also a factor. Government tenders are not predictable and when available the orders are in small volumes. Local manufacturers are, therefore, reluctant to make major investments in materials and research in the absence of a ready market. Also the small number of private medical institutions does not warrant major investments in drug manufacturing. Related to this is the fact that none of the local



generic manufacturers are on the World Health Organisation (WHO) pre-qualified list of suppliers. Thus even with Malawi being a beneficiary of the Global Fund to Fight Tuberculosis, Malaria and AIDS (GFTAM) and World Bank (WB) programmes, the Ministry of Health and Population cannot source drugs for treatment of these diseases from the local generic manufacturers using funds from these multilateral programmes.

As a source of supply of essential medicines, local production has a limited effect on availability and a negative impact on affordability. With regard to availability, the fact that most of the essential medicines have to be imported means that even in the event of the relatively frequent shortages from foreign sources local industries are not a factor in ameliorating the shortage. The impact on affordability is easier to discern – the lack of capacity to manufacture pharmaceutical ingredients and high production costs negatively impact on price.

## 2.2 International Supply

In general terms, the international supply of essential medicines into Malawi can be classified into two: as a source of supply of APIs for the generic manufacturers, and secondly as a source of finished pharmaceutical products (FPPs), whether branded or generics. As stated earlier, APIs are not locally available. Thus, all pharmaceutical generic manufacturers in Malawi rely on outside sources, mostly from India and China. This ultimately has a cost and price effect on the generic FPPs manufactured locally because they must compete for a smaller market share against a more technologically advanced and efficiently scaled set of competitors.

International supply of FPPs is the main source of supply of essential medicines in Malawi. As a source of supply, its effect is felt often, either price-wise or when shortages occur. The price at the market for imported FPPs is based on several factors including cost, insurance and freight (C.I.F.), taxes and duties<sup>71</sup> paid at the point of entry, distribution, and storage costs related to importation. This problem is compounded by the fact that Malawi is a landlocked country. As a result, the affordability of essential medicines is greatly affected.

Shortages of essential medicines, particularly ARVs, occur often, particularly in government hospitals. For example, on 14 April 2004, local newspapers reported that the biggest referral hospital in the country had run out of ARVs and the hospital administrator was quoted as saying the money allocated for ARVs was not sufficient to meet the growing demand.<sup>72</sup> For HIV/AIDS patients, constant availability of ARVs is central to ARV therapy treatment, primarily because resistance to particular courses of drugs can develop quickly in the absence of consistent treatment.



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## 3 Existing Legislation

Malawi is a founding member of WTO and thus agreed to be bound by its various agreements, including TRIPs, in 1995. Malawi is also party to a number of other international treaties, agreements and conventions. Of these, its membership of the World Intellectual Property Organisation (WIPO) is perhaps the most relevant, with Malawi having ratified both the Paris Convention for the Protection of Industrial Property (1883) and the Patent Co-operation Treaty (1970). However, Section 211 of the Malawian Constitution provides that:

*...any international agreement entered into after the commencement of the Constitution shall form part of the law of the Republic if so provided by or under an Act of Parliament.*

This means that Malawi does not recognise the self-execution of international agreements and thus any obligations are only domestically enforceable to the extent that they are recognised by national legislation.

The following section of this paper examines several elements of national legislation in terms of their relevance to access to medicines. First, it considers a number of sections of the Patents Act,<sup>73</sup> one of the three elements<sup>74</sup> of Malawi's industrial property<sup>75</sup> regime, which was first established by the colonial authorities in 1958.<sup>76</sup> The section closes by considering the impacts of procurement and competition legislation.

### 3.1 TRIPs Compliance

Malawian patent law is contained in its Patent's Act. Malawi was formerly a member of the federation of Rhodesia and Nyasaland and its patent legislation is based on the old Federation Patents Act. The Patents Act provides for a nationally independent system of patent protection and establishes the Patents Office, which falls under the umbrella of the Registrar General and is responsible for the registration of patents.<sup>77</sup> The Patents Act substantially predates TRIPs and, to date, there has been no deliberate attempt to make it TRIPs compliant. The Act has been subject to minor amendments, primarily to bring it in line with the African Regional Intellectual Property Office (ARIPO) agreement (see section 3.11, below).

Malawi is a least developed country and, as such, is due to comply with the general provisions of TRIPs by 1 January 2006 pursuant to TRIPs Article 66.1.<sup>78</sup> However, as discussed further below, Malawi has flexibility under recent WTO decisions to reverse its legislation and delay the granting of pharmaceutical product patents until 2016.<sup>79</sup> Regardless of these potential flexibilities, the discussion here focuses on the existing

binding provisions of the Patents Act (1992),<sup>80</sup> which are far from compliant with the provisions of TRIPs. As detailed below, there are numerous incompatible provisions in the Malawian legislation, ranging from broad issues, such as the term of patents granted,<sup>81</sup> to more specific questions such as *ordre publique* and morality exceptions to patentability.<sup>82</sup> The National Science and Technology Policy recognises the need to review the existing Patents Act and other related laws to bring them into compliance with the TRIPs agreement and to make them consistent with international practice.<sup>83</sup> However, this study is not intended to address the general question of Malawi's forthcoming obligation to become TRIPs compliant and thus does not provide any form of comprehensive analysis in this area.<sup>84</sup> The study focuses on issues of relevance to access to medicines and notes where provisions of the Malawian legislation vary from the standards provided for under TRIPs and, in particular, where it fails to take advantage of TRIPs flexibilities.

In this latter regard, Malawi's legislation does not take advantage of key flexibilities available under TRIPs or the subsequent Doha Declaration or the August 30 Paragraph 6 Implementation Agreement,<sup>85</sup> although it does have some potential flexibilities built in. In fact, in relation to access to medicines, Malawi's entire patent regime can be described as TRIPs-plus because it prematurely provides patent protections for medicines.<sup>86</sup> Nonetheless, on the plus side, some of its provisions could be exploited to promote access to medicines.

There is some evidence of limited technical assistance to public agencies in relation to intellectual property rights and access to medicines issues.<sup>87</sup> However, this appears to have been almost exclusively focused on Global Fund proposals<sup>88</sup> and has not considered the broader picture. Civil society, and other non-profit, organisations have established some links with groups active in other countries and access information and ideas through these relationships. However, these relationships have yet to develop to a point that they are able to provide anything that might be described as technical assistance to public agencies.<sup>89</sup>

If Malawi intends to fulfil its general TRIPs obligations by, or soon after, 2006 and if it intends to amend its patent scheme to make maximum use of TRIPs flexibilities for ensuring access to medicines, it will need at least some level of technical assistance from local, regional and international sources.<sup>90</sup> To effectively inform government policy, access to expertise from other fields also will be needed. In particular, assistance in assessing local manufacturing and international procurement options could be critical. Finally, underlying any efforts at technical assistance there will need to be a programme of awareness-raising, as very few public agencies or officers are currently aware<sup>91</sup> of the interactions between intellectual property rights and access to medicines.

## 3.2 Exclusions from Patentability

- Potentially allows for over-broad exclusions, one of which, on the face of it, violates TRIPs 27.2
- Probably prohibits new formulation and process patents
- May prohibit new use patents, but unlikely
- May prohibit FDC patents

The provisions of the Patents Act relating to patentability are simple and potentially very broad. There are two elements of Section 18, “Refusal of application in certain cases”, which are of potential relevance to the question of access to medicines. The first is subsection 18.1(b),<sup>92</sup> which provides that the Registrar of Patents may refuse an application where he determines, “that the use of the invention in respect of which the application is made would be contrary to law or morality” (emphasis added). Subsection 18.1 clearly relates to TRIPs Article 27.2, which allows for the exclusion of inventions from patentability on the grounds of *ordre public* or morality, but not on the basis of mere illegality. Article 27.2 expressly includes the protection of human health within its scope, so Malawi would be within its rights to invoke subsection 18.1(b) in addressing access to essential medicines issues. However, subsection 18.1(b), in its current form, may be in violation of TRIPs Article 27.2, which permits Member states to exclude some inventions from patentability, “provided that such exclusion is not made merely because the exploitation is prohibited by their law”.<sup>93</sup> Because mere illegality is insufficient, the challenged patentability and exploitation of the product must be specifically linked to public order or morality.

The second element of Section 18 of potential relevance to access to essential medicines is subsection 18.1(c), which is a provision that potentially impacts several intellectual property rights strategies commonly employed by the major brand name pharmaceutical companies to extend the life of their patents beyond the TRIPs mandated 20 year term:

18.1 If it appears to the Registrar in the case of any application for a patent – ...  
(c) that it claims as an invention a substance capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients, or that it claims as an invention a process producing such a substance by mere admixture, he may refuse the application.

Subsection 18.1(c) could be invoked to prohibit a range of pharmaceutical patents, in particular those relating to new compositions or formulations of known ingredients and new processes based solely on admixture. New use patents might also be prohibited, although this would be a somewhat strained interpretation.<sup>94</sup> Similarly, the reference to “a mixture of known ingredients possessing only the aggregate of the known properties” might also suggest a ban, or at least limitation, on the patenting of products such as FDC drugs.



Subsection 18.1(c) is probably TRIPs compatible on the basis that it primarily relates to the definition of the term “invention”, a subject where member states have considerable flexibility. However, the fact that the text refers to “food or medicine” raises concerns regarding the possibility of discrimination as to technical field, in violation of TRIPs Article 27.1. These concerns can probably be addressed with the argument that subsection 18.1(c) addresses problem areas, rather than technical fields, but this argument would be stronger if the text referred to “an invention of relevance to food security or public health rather than a substance capable of being used as food or medicine”.

In addition to the substantive issues, there are two procedural questions raised by Section 18. The first is that subsection 18.3 provides that, “[a]n appeal shall lie from any decision of the Registrar under this section”, something that is discussed further in part 3.8 of this study, below. A second procedural point relates to the enforcement of Section 18.1, potentially expanding its scope beyond immediately interested parties and allowing for judicial review.<sup>95</sup> Pursuant to subsection 22.1(m), the grant of a patent may be opposed on the grounds that it should have been refused under Section 18.1. Section 22.8 provides that the Patents Tribunal is competent to hear applications for opposition by “[a]ny person interested, including the Government”. Orders or decisions of, and presumably a failure to act by, the Patents Tribunal may, as discussed below, be appealed to the High Court. This effectively means that any person that might be affected by the grant of a patent has the option to oppose its grant as far as the courts.<sup>96</sup>

### 3.3 Parallel Importation

- No provisions specific to import or export
- Parallel importation, in any form, apparently illegal but accepted on the basis of administrative interpretation

Parallel importation, or more accurately the underlying concept of the exhaustion of rights, is usually provided for as a limitation of, or an exclusion from, a patent holder’s rights. The Patents Act contains no provisions fitting this description and relies instead on Section 28, ‘Extent, effect and form of patent’. Section 28.4 is the primary section iterating the extent of a patent holder’s rights:

The effect of a patent shall be to grant to the patentee, subject to this Act and the conditions of the patent, full power, sole privilege and authority by himself, his agents and licensees during the term of the patent to make, use, exercise and vend the invention within Malawi in such a manner as to him seems meet, so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention during the terms of the patent.

Section 28.4 does not specifically address rights of import or export, rights that are not explicitly addressed anywhere in the Patents Act. At first glance, this would appear not to grant any exclusive rights to import or export on the basis of the well-established legal

principle that what is not specifically prohibited is permissible.<sup>97</sup> However, the closing language of Section 28.4 appears designed to provide comprehensive rights addressing all activities, and thereby specifically prohibiting unauthorised import and export, as not providing for exclusive rights to import and export would appear to take away from “the whole profit and advantage accruing by reason of the invention”. As a result of this language, the Patents Act does not, on the face of it, allow for a theory of international exhaustion and, therefore, prohibits parallel importation.

Despite the presence of the closing language of Section 28.4, the Malawian authorities have adopted an interpretation based on the assertion that there is no explicit reference to rights of importation, meaning that parallel importation is permissible and would not infringe Section 28.4 patent rights.<sup>98</sup> This extremely broad interpretation effectively means that any understanding of the scope of parallel importation<sup>99</sup> might be acceptable, since there is no indication of the particular understanding adopted. Too broad an interpretation of Section 28.4 of the Malawian Act, however, would be incompatible with Article 28.1 of TRIPs if it did not provide for the minimum rights to be available to patent holders pursuant to that Article. In addition, the adoption of the principle of interpretation that only the most explicit mention of a right may be considered, while it may promote access to medicines under Section 28.4, may also restrict Malawi’s options under other sections of the Patents Act, as discussed in part 3.5 of this study, below.

### **3.4 Voluntary Licences**

- Limited specific text allowing maximum flexibility
- Less restrictive than commonly accepted standards

The Patents Act contains only very limited provisions relating to the regulation of voluntary licences. The terms and conditions of licensing contracts are, in general, left to standard contract law without the imposition of additional government regulation or supervision. The few qualified restrictions that are imposed are contained in Section 49, “Avoidance of certain restrictive conditions in contracts”. Section 49.1 provides that contracts must:

- not unreasonably restrict the licensee’s use of products or processes owned by others than the licensor
- not unreasonably require the licensee to purchase any product that is not the subject of the licence.

However, these restrictions do not apply where there is evidence that a licensee had a reasonable choice as to whether to accept them or not and the contract contains a three-month termination clause. Section 49.2 is, perhaps, the most restrictive of the provisions of Section 49 in that it contains a mandatory requirement. However, this requirement is only that contracts may not enforce periods for notice of termination of longer than three

months once the patent rights that are the subject of the contract have expired. Section 49.3 includes several general provisions related to the independence of contracts and allowing for contracts to provide for the physical maintenance of patented products.

Overall, the provisions of Section 49 constitute minimal regulation of voluntary licences and would be unlikely to negatively impact the opportunities of Malawian companies and institutions to obtain such licences. Indeed, the provisions of the Malawian Patents Act are less restrictive than those the legal systems of some developed countries, such as the United States, impose on their citizens when licensing technologies abroad.

### 3.5 Compulsory Licences for Food and Medicines

- No clear grounds for grant
- Implied, but not explicit, purpose of availability at lowest possible price
- Unclear whether allows for import, perhaps implicitly
- No explicit bar to use for export

The Patents Act provides for the granting of compulsory licences in Sections 37 and 38. Section 37 provides for the grant of compulsory licences generally, while Section 38 specifically refers to the grant of licences for food and medicines. Given its specific relevance to this paper, Section 38 is considered in detail while Section 37 is considered only to the extent that Section 38 is dependent upon, or related to, it. The one exception is Section 37.6 licences granted on the grounds of anti-competitive practices. The reasons for focusing on Section 38 are threefold. First, where medicines are concerned, the specific provisions imply, although they do not explicitly state, that Section 38 is to be applied to the exclusion of Section 37. Second, the key differences between Sections 37 and 38 do not suggest any reason why an applicant might wish to apply for a licence pursuant to 37 and not 38, except in the instance of anti-competitive practices. Third, the greater flexibility under Section 38 would seem to reflect a legislative intent that the authorities should view compulsory licence applications for medicines more favourably on the basis that they are in the national interest.

#### Section 38 – Inventions relating to food or certain other commodities

(1) Subject to section 37(14) and without prejudice to the other foregoing provisions of this Act, where a patent is in force in respect of –

- (a) a substance capable of being used as food or medicine, or in the production of food or medicine;
- (b) a process for producing such a substance as aforesaid; or
- (c) any invention capable of being used as or as part of a surgical or curative device,

the Patents Tribunal shall, on application made to it by any person interested, order the grant to the applicant of a licence under the patent on such terms as it thinks fit unless it appears to such Tribunal that there are good reasons for refusing the application.



(2) In settling the terms of licences under this section the Patents Tribunal shall endeavour to secure that food, medicines, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(3) A licence granted under this section shall entitle the licensee to make, use, exercise and vend the invention as a food or medicine, or for the purposes of the production of food or medicine or as part of a surgical or curative device, but for no other purposes.

The first flexibility of Section 38, as opposed to Section 37, eliminates any waiting period for filing an application for a compulsory licence. Under Section 37.1 an application may only be submitted three years from the grant of a patent or four years from an initial application, whichever is later. This requirement reflects the requirements of Article 5.A(4) of the Paris Convention for the Protection of Industrial Property (1883), which is also incorporated into TRIPs by Article 2.1 of the latter agreement. Section 38 includes no comparable restrictions and thus potentially allows for the submission of applications for compulsory licences at any time from the grant of a patent. The one exception to this is Section 38.1's cross-reference to Section 37.14, which primarily relates to the requirement that the grant of compulsory licences only be considered where a patent is not "endorsed 'licences of right' under section 35."<sup>100</sup> However, given that Section 37.14 also refers, in turn by reference, to a number of other elements of Section 37, Section 38.1's cross-reference potentially risks confusing the distinctions between Sections 37 and 38.

The second flexibility found in Section 38 relates to the grounds for the grant of a compulsory licence. Section 37.1 provides that compulsory licences may generally be granted where the "reasonable requirements of the public...have not been or will not be satisfied". Section 37.6 expands upon these basic grounds by providing a non-exclusive list of examples that revolve around local working requirements<sup>101</sup> and the prohibition of anti-competitive practice. In contrast, Section 38.1 allows for the grant of licence "unless it appears to [the Patents] Tribunal that there are good reasons for refusing the application." While Section 37.1 gives broad scope for the grant of licences, Section 38.1 can accurately be described as completely discretionary.

Section 38 provides little guidance as to the minimum terms and conditions that shall apply to licences granted pursuant to it. The basic provision is found in the concluding text of Section 38.1, where the Patents Tribunal is given powers to grant licences under "such terms as it thinks fit." However, three more specific terms and conditions can be found in Sections 38.3 and 38.2. Section 38.3 contains the explicit condition that the licence shall be limited to particular purposes, namely use in food and medicine. Section 38.2 is more ambiguous but appears to implicitly contain two terms to be included in any licence. The first relates to the general meaning and intent of the text. The requirement that the Patents Tribunal shall endeavour to construct the terms of any licence such that its object "shall be available to the public at the lowest prices" implies that licences could and perhaps even should include terms restricting the price of products manufactured

under the licence.<sup>102</sup> This clause could also be read as relating to the grounds for the grant of a licence, meaning that the cost of products to consumers could be a determining factor in such a grant. The second implicit term found in Section 38.2 is derived from the language “consistent with the patentees deriving a reasonable advantage from their patent rights.” This could be read as meaning one, or both, of two things. First, is again in relation to the grounds for the grant of the licence and implies that, where cost to consumers is a determining factor in a grant, the reasonable cost of a product should be judged in terms of reasonable profits for patent holders. Second, the text may imply a requirement that any licence require some form of compensation for the patent holder who is deprived of their rights by the grant of the licence. This latter meaning is reinforced when one considers that Section 44.4 of the Malawian Constitution provides that “expropriation of property shall be permissible only...when there has been...appropriate compensation”. Therefore, given that patents are widely recognised as an element of personal property under common law, if a right to compensation for patent holders is not recognised under Section 38.2 then the whole of Section 38 may be found to be unconstitutional. Of course, non-compensation would also violate Article 31(h) of the TRIPs Agreement.

The final substantive point regarding Section 38 is the question of whether it allows for the import and export of products that are the objects of licences since it does not explicitly address either option. Instead, Section 38.3 merely allows for rights to “make, use, exercise and vend”. The right to import could be implied in the rights to “use, exercise and vend”. However, applying the authorities’ principle of interpretation where parallel importation is considered non-infringing because it is not explicitly listed as an exclusive right (see 3.3. above), it would seem that a compulsory licence might not be granted for importation because it is not explicitly referenced under Section 38.3. A similar situation applies as regards rights to export under a compulsory licence, although this is more likely to be deemed acceptable on the basis that, where Section 38.3 refers to the right to vend, it does not specify whether this is domestically or internationally and thus both might be presumed to be permissible. Vending/exporting predominant amounts would, however, violate Article 31(f) of the TRIPs Agreement.

The procedural aspects of Section 38 are provided for in Rule 12 of the Patents Tribunal Rules rather than in the principal statute. In simple terms, Rule 12 provides for several steps in any application for a compulsory licence under Section 38:

- the application must specify the particulars of the grounds claimed for a grant and be submitted in a prescribed form to the Registrar of Patents (12.1 and 12.2)
- the application must be served on the patentee and other officially recognised interested parties (the latter primarily being registered licensees) (12.3)
- the application must be published in the Gazette in a form approved by the Registrar (12.3)

- an opposition to the application may be made within two months of its advertisement in the Gazette provided that it specifies particulars of the opposition and is served on the applicant (12.4).

Once the Registrar of Patents is satisfied that the above steps have been completed he shall forward the application and all related documents to the Tribunal for adjudication pursuant to Section 38.1 of the statute. It is important to note that these procedural requirements do not require the licensee to negotiate for a voluntary licence with the patent holder on commercial terms and for a commercially reasonable period of time. Thus, this feature of Section 38 is also non-TRIPs-compliant.

A final point to note regarding the distinctions between Sections 37 and 38 is the relationship between Section 50.2 and Section 37.6. Section 50 provides procedures for the revocation of patents and Section 50.2 specifically refers to the right of “any person interested” to apply to the Patents Tribunal for the revocation of a patent that has been the subject of a compulsory licence granted upon any of the grounds specified in Section 37.6. There are three conditions for the consideration of such an application:

- two years must have passed from the grant of the licence under Section 37
- that any of the grounds specified in 37.6 are established, and
- that the purpose of an order under Section 37 could not be achieved.

Given that Section 37 allows for the transfer of any of a patent holder’s rights to the licensee, up to and including exclusivity, it is not immediately clear in what conditions the third of these conditions might be met. Additionally, it is important to note that Section 50.2 does not apply to Section 38. Given the general relationship between Sections 37 and 38, where Section 38 provides for greater flexibility, this is a somewhat anomalous situation.

The above discussion highlights a number of points under Section 38 that are open to varying interpretations. These ambiguities are exacerbated by the broad scope of discretion allowed to the authorities, particularly the Patents Tribunal, under this section. The primary problem is that there has been no experience, to the extent that the authors have been able to determine, in the implementation of Section 38 and there is no officially stated policy regarding its implementation. Indeed, as noted in 3.7 below, the Patents Tribunal is not known to have ever been convened in the recent past. As previously noted, several provisions of Section 38 are incompatible with the minimum standards of TRIPs and thus the section should, theoretically, be comprehensively reviewed and amended, or repealed, by January 2006. More positively, where the authorities have the political will to issue compulsory licences to improve access to medicines, the ambiguous and discretionary nature of Section 38 provides considerable scope for the grant of compulsory licences for a range of activities.



The last form of compulsory licensing worth discussing is a licence issued under Section 37 to remedy practices that are anti-competitive. In this regard, it is important to note that there is a waiting period. Moreover, there is no jurisprudence whatsoever concerning what behaviour by a patent holder might be considered anti-competitive. Nonetheless, the advantages of a competition-based compulsory licence are many, especially to the extent that Section 37 eventually is interpreted or amended to include all of the flexibilities of Article 31(k) of the TRIPs Agreement. These flexibilities would permit reduced compensation, would obviate the necessity of prior negotiations, and would permit exportation of unlimited quantities. However, the use of Section 37 compulsory licences for medicine may, as noted above, be subject to challenge on the basis that Section 38 exclusively provides for such licences, potentially meaning that compulsory licences for medicines may not be granted exclusively on the basis of anticompetitive practices.

### 3.6 Governmental Use

- Not TRIPs compatible
- Not clear whether import and export permissible – probably not
- Significant discretion to the Minister
- Compensation provisions may violate Constitution and TRIPs
- Limited, or non-existent, accountability to patent holders

The provisions of the Patents Act relating to government use of patented inventions are found in Sections 40 through to 42 of the Act. These provisions are particularly significant due to the fact that Section 28.1 specifies that “[s]ubject to this Act, a Patent shall have the same effect against the Government as it has against a subject.” The Government cannot, therefore, claim any special privilege or immunity in regard to the implementation of the Patents Act.

Section 40.1 provides the Minister<sup>103</sup> with broad powers to authorise “any Government department or any person” in writing to “make, use or exercise any invention... for the service of the Government”. There are several points to note regarding this language. First is that the Minister may authorise any institution or individual, whether public or private sector, foreign or national. Second is the point, noted in 3.5 above, that it is not clear whether the Minister’s powers include rights to import and export. Under the principle of interpretation stated by the Patents Office (discussed variously in 3.3 and 3.5 above), they might not, but given Malawi’s limited domestic drug manufacturing capacity and limited market, it would be completely illogical to exclude rights of importation. Third, the reference to “the service of the Government” could be extremely broad or relatively narrow depending upon one’s understanding of that term. The role of government is a subjective matter depending upon prevailing political theory. For example, if one took the position that one role of government is to promote the economic development of the country and to enhance the wealth of citizens, then almost any government use order could be said to be in “the service of the Government” provided it created benefits for

any Malawians at the expense of non-Malawians. This problem of subjective interpretation is the basis of TRIPs' use of the more specific, and limited, language, "public non-commercial use", rather than "the service of Government" or other more ambiguous terms. Related to this third point, is the fact that under Sections 40.6 through to 40.8 the Minister may authorise rights equivalent to those of a patent holder, including as regards the rights of third parties and sales to foreign governments.

Section 40.4 provides that the Minister may make such an authorisation "either before or after the patent is granted." In addition, Section 40.4 provides that the Minister may make an authorisation either prospectively or retroactively. Although the retroactivity provision would seem to conflict with the basic common law principle of non-retroactivity of the law, its scope is relatively clear. The point relating to authorisation pre- or post-patent grant is less clear. Prior to the grant of a patent, a patent applicant holds no rights and is merely accruing a potential right of priority that may become enforceable upon the actual grant of the patent. Thus, the basis of the need for an authorisation is uncertain.<sup>104</sup> However, if this power is read in the sense that the Minister is empowered to issue an authorisation predicting the grant of a patent, and thereby extinguishing priority rights as soon as they are realised at the grant of that patent, it may serve some purpose.

The remaining elements of Section 40 provide for various terms and conditions for government use orders that may be issued. Section 40.2 provides that no royalty or payment shall be made to the patent holder where the Government, or an authorised agent thereof, has made use of the object of a patent without the relevant information having been provided, either directly or indirectly, by the patent holder:

(2) If and so far as the invention has, before the effective date of the relevant claim of the completed specification, been duly recorded by or tried by or on behalf of a Government department or a person authorized in terms of subsection (1) otherwise than in consequence of the communication thereof directly or indirectly by the patentee or any person from whom he derives title, any use of the invention by virtue of this section may be made by such Government department or person free of any royalty or other payment to the patentee.

The reference to direct or indirect provision of information makes Section 40.2 reminiscent of trade secrets law, where independent discovery or invention does not violate a trade secret. Its use here raises two questions. First, in terms of the reference to government agents, it is difficult to see how a person could be an agent pursuant to subsection 40.1 without having received communication of the invention at least indirectly from the patent holder. They are the beneficiary of a government use order overriding the rights provided for in a patent and it seems hard to imagine how they would not be aware of the contents of that patent at the point of their authorisation. Second is a constitutional point. The use of the object of a patent "free of any royalty or other payment" almost undoubtedly conflicts with Article 44.4 of the Malawian Constitution, as referred to in 3.5 above. It would also violate Article 31(h) of the TRIPs Agreement.



Section 40.3 provides for situations where Section 40.2 does not apply. It requires the Minister and the patent holder, subject to the approval of the Minister of Finance, to agree on terms for the government use or, in the absence of an agreement, for the Patents Tribunal to establish terms. Two points under Section 40.3 should be noted. First, the Minister has the option of only seeking to agree terms after the use has occurred. How long after the use is not specified and thus the language is open to abuse or, at the least, places the patent holder in a highly prejudiced negotiating position. Second, the meaning of “in default of an agreement”, allowing for the establishment of terms by the Patents Tribunal, is not clear. The Minister’s decision not to negotiate with the patent holder at all could be said to create a situation “in default of an agreement” and thus the Minister could directly request the Patents Tribunal to establish terms, obviating the need to negotiate with the patent holder at all.

Section 40.5 has some implications for Sections 40.2 and 40.3, in that it requires the Minister to notify a patent holder of any government use, “as soon as is practicable after the use is begun.” Terms for use could thus be established before the patent holder is even aware of the use, or the patent holder could be informed of the use long before they are made aware of the terms. The exception to Section 40.5 is that, where the Minister determines that notification would be “contrary to the public interest”, notification is not required.

Section 41 supplements Section 40 and provides for government use during emergencies. Section 41.1 provides the definition of emergency and requires that any period of emergency, including its duration, be officially gazetted by the Minister.<sup>105</sup> Section 41.2 lists a range of activities that shall, in the event of an emergency, be considered as within the scope of “for the service of the Government”:

- (a) for the efficient prosecution of any war in which Malawi may be engaged;
- (b) for the maintenance of supplies and services essential to the life of the community;
- (c) for securing a sufficiency of supplies and services essential to the well-being of the community;
- (d) for promoting the productivity of industry, commerce and agriculture;
- (e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade;
- (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community;
- or
- (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Malawi or any other countries that are in grave distress as the result of war;

There are no other provisions, whether as regards streamlined procedures or exemptions or otherwise, under Section 41 and, thus, its only substance is in the above list. As a consequence, either Section 41 is redundant or the interpretation of “for the



service of the Government” in Section 40 is intended to be sufficiently restrictive so as to exclude the activities listed in Section 41.2 under normal circumstances. While the latter interpretation would normally be preferred, on the basis that a substantive interpretation is always preferable to one that is redundant, some of the activities listed in Section 41.2 would appear to be classic functions of government and, thus, it would seem to be unusually restrictive.

Section 42 provides for disputes as to the implementation of Sections 40 and 41. Section 42.1 provides for the primary mechanism where disputes regarding activities under a government use order and terms and compensation may be appealed to the Patents Tribunal. This essentially ties government use provisions into the main framework of appeals under the Act, discussed in 3.7 below. However, there are key distinctions to be noted. First, is that the basic discretion of the Minister to issue orders, and the grounds therefor, appears not to be a potential subject for appeal. Subsection 42.1(a) refers to the exercise of powers under the order but not to the issuance of the order itself. This is distinct from the situation where decisions of the Registrar of Patents and the Patents Tribunal are potential subjects of appeal under other sections of the Act. Section 42.1 may therefore violate Article 31(i) of TRIPs. The second distinction is that the role of the Patents Tribunal as the appellate body for the implementation of Sections 40 and 41 means that it could be called upon to review its own actions, specifically where it has established the terms of government use under Section 40. This may not have major consequences as any decision of the Patents Tribunal may be appealed to the courts as of right, but it appears to be something of an anomaly nonetheless. The third, and final, distinction is Section 42.2, which provides that where a government department is party to a dispute the Minister may query the validity of a patent as an affirmative defence or, where the patent holder is a party to the proceedings, apply for the revocation of the patent. The exact purpose of Section 42.2 is unclear but it would certainly act as a deterrent to the raising of, or participation in, disputes by patent holders.

### **3.7 Appeals Procedure and the Patents Tribunal**

- Three tiers:
  - Registrar of Patents
  - Patents Tribunal
  - High Court
- Patents Tribunal non-functional

Several of the substantive provisions of the Patents Act discussed in this study allow for appeals from decisions made pursuant to them. The administrative-judicial structure established by the Patents Act consists of three tiers. The first is the Registrar of Patents, who is given considerable discretion in a number of areas. Appeals from decisions of the Registrar are, pursuant to Section 73, made to the Patents Tribunal, which is established by Section 74:



#### Patents Tribunal

(1) For the purposes of hearing and determining appeals in accordance with Section 73 and of exercising the other powers conferred upon it by this Act, there is hereby established a Patents Tribunal, which shall consist of a Chairman appointed by the Minister.

The Patents Tribunal is essentially defunct, not having sat in recent times and a Chairman not having been appointed.<sup>106</sup> In this situation, it is assumed that, where the Tribunal was required to address any matter, the Solicitor General would be requested to appoint an *ad hoc* tribunal that would include a Chairman of the Tribunal other than the Registrar General.

Pursuant to Section 78, orders and decisions of the Patents Tribunal may be appealed to the High Court. There are two points to note regarding appeals to the High Court. The first is that both orders and decisions of the Patents Tribunal may be appealed, suggesting that specific points, or in the case of licences terms and conditions, may be appealed as well as decisions *in toto*. The second point concerns the defunct nature of the Patents Tribunal. Presumably, the failure to appoint the Tribunal means that decisions of the Registrar of Patents may be appealed directly to the High Court for want of other recourse to justice.

### 3.8 Extension of Patent

- Clearly TRIPs-plus
- Extensions granted due to hostilities or "inadequate remuneration"
- Extensions of 5 or 10 years
- No provisions regarding multiple extensions – may be possible

Section 30, "Extension of patent", provides for the extension of patent terms beyond the basic term of 16 years provided for in Section 29.<sup>107</sup> As previously noted, Section 29 violates the provisions of TRIPs Article 33, which requires that the term of a patent "shall not end before the expiration of a period of twenty years counted from the filing date". However, Section 30 exceeds the requirements of TRIPs,<sup>108</sup> as the Agreement does not require any extension of patents beyond their basic term. Section 30 ultimately affects access to medicines because extending the life of pharmaceutical patents prevents early entry of cheaper generic equivalents.<sup>109</sup>

Pursuant to Section 30.1, there are two grounds upon which a patent holder, or its exclusive licensee, may request the extension of a patent. Subsection 30.1(b) covers infrequent situations involving hostilities between Malawi and a foreign state and is thus relatively restricted in its scope. Subsection 30.1(a) is potentially much more common in that it covers circumstances of inadequate remuneration:

30.1 A patentee or an exclusive licensee may, after advertising in the prescribed manner, apply to the Patents Tribunal for an extension of the term of the relevant patent on any one or more of the following grounds, namely –  
(a) that he has not derived adequate remuneration from that patent;

Any application under Section 30.1 must, pursuant to Section 30.2, be made between twelve and six months prior to the expiration of the patent, with the exception that the Patents Tribunal may, at its discretion, allow for applications during the final six months of a patent. Section 30.3 provides that applications may be opposed by *any person*,<sup>110</sup> while Section 30.4 empowers the Patents Tribunal to make determinations as to the grant or refusal of extensions,<sup>111</sup> whether opposed or otherwise. Subsection 30.4(a) provides for the length of extensions:

30.4 The Patents Tribunal may...order the extension of the term of the patent in question for such period and subject to such conditions as it may deem fit ...:  
Provided that no such extension shall be granted –  
(a) on the grounds mentioned in subsection (1) (a) for a term exceeding five years or, in what the Patents Tribunal may deem to be exceptional circumstances, ten years;  
or ...

Apart from the general question of its utility and desirability in the economic and industrial context of Malawi, Section 30 raises specific questions regarding its implementation. First, there is no explicit language relating to the precise meaning, or perhaps more importantly context, of “adequate remuneration”. Subsection 30.1(a) refers specifically to “that patent”, meaning that granted by Malawi, and therefore the context would appear to be restricted to Malawi. However, how might “adequate remuneration” from a particular patent in Malawi be calculated? In the case of medicines, recent events may make such a calculation more or less complex depending upon one’s perspective. For example, a number of international “brand name” pharmaceutical companies have made repeated statements that they provide key products, particularly anti-retroviral drugs, at cost. Does this mean that “adequate remuneration” from patents on these products is effectively zero, meaning that companies may extend their exclusivity based on unilateral discount-pricing alone? Alternatively, if the company has not even attempted to recoup the costs of obtaining a patent in Malawi, may the patent holders be barred from submitting applications under subsection 30.1(a) due to the doctrine of estoppel?<sup>112</sup> The issues raised by the question of adequate remuneration might not be expected to appear in primary legislation. However, in jurisdictions where there is minimal case law<sup>113</sup> or precedents in administrative practice, and where there is little prospect of change in this regard, some guidance, perhaps in the form of regulations or a policy, might seem advisable.

A second question regarding the implementation of Section 30 is raised by the length of such extensions. Section 30.4 specifically states that, where an extension is granted



pursuant to subsection 30.1(a), a patent is extended and thus it is the original grant of a patent that is still in force and that will expire after a period of 21 or 26 years, rather than the standard 16. The question is whether a patent holder may apply for a further extension between twelve and six months prior to the expiration of the extended patent upon demonstrating that they have not derived the adequate remuneration that was basis of the grant of the first extension. Section 30 does not explicitly allow for such repeat extensions. However, an argument in favour of them could be made on the basis that a patent holder approaching the expiry of a patent extended under subsection 30.1(a) would still fulfil the general requirements for an applicant under Section 30.1.

### 3.9 “Submarine” Patents

- Apparently non-infringing activities could subsequently become infringing
- No evidence this is a problem and unlikely to become one

“Submarine” patents<sup>114</sup> are the result of a manipulation of the application procedures for the grant of a patent. In simple terms, a patent applicant seeks to keep their application hidden, or “submarine”, until another party makes use of, or becomes reliant on, the subject of the application and then brings the application into the open and uses it as the basis of an infringement claim. In most instances, the basis of the manipulation is that jurisdictions provide for patent terms that are counted from the grant of a patent but allow for priority rights to be established from the date of application and do not publish all applications.

Under the Patents Act a slightly different basis for the “submarine” manipulation, producing the same results, is possible. Under Section 29, the term of a patent runs from “the date of lodging the *complete* specification” [emphasis added].<sup>115</sup> However, pursuant to Section 15.2, a patent holder may claim priority rights from the date of an application accompanied by a provisional specification that is later amended to provide a complete specification. Pursuant to Section 21.2, there is no requirement for publication prior to the provision of a complete specification. A patent applicant could, therefore, lodge an application accompanied by a provisional specification and intentionally delay the completion of the specification until another party makes use of the subject of the patent application or a dependent technology. At this point they would provide the complete specification, claim priority rights under Section 15.2, and sue the party making use of the subject of the patent for infringement, demanding damages, future royalties and placing conditions on the use.

In the context of access to medicines, this strategy could be used to affect both the local manufacture and importation of medicines in Malawi. What are apparently non-infringing activities could be found to be infringements of patent applications after they are already well established.<sup>116</sup> However, while this strategy appears to be technically feasible, it should be noted that there is no evidence that the Patents Act has been manipulated in this manner in the past. The scale, sophistication and politics of the Malawian market for

medicines and intellectual property rights framework may also suggest that few potential applicants for pharmaceutical patents would be interested in attempting it.

### **3.10 The African Regional Intellectual Property Organisation (ARIPO)**

- Does not currently affect national standards
- May represent a *de facto* emerging regional standard
- Facilitates more widespread applicability of patents in member countries

The most significant amendments to the Patents Act were those provided for in the Statute Law (Miscellaneous Amendments) Act No. 9, April 1985, which incorporated section 10 A into the Patents Act recognising the domestic applicability of patents granted under the African Regional Industrial Property Organisation (ARIPO) Harare Protocol. Malawi is a party to the Lusaka agreement creating ARIPO. ARIPO was established to promote, among other objectives, the harmonisation and development of the Industrial Property Laws, and related matters appropriate to the needs, of its members and the region at large.<sup>117</sup> Subsequent to the Lusaka agreement, ARIPO adopted the Harare Protocol on Patents and Industrial Designs, which empowers ARIPO to grant and administer patents on behalf of member states.<sup>118</sup> Applications for patents can either be lodged with the ARIPO secretariat or, where the law of the contracting state permits, with the Industrial Property Office of the Contracting State.<sup>119</sup> Under Article 10(A) of the Patents Act, a patent granted under the Harare Protocol has effect in Malawi as if it were granted under Malawi's Patent Act.

The Harare Protocol empowers the ARIPO office to receive and examine patent applications, and to grant regional patents on behalf of the 15 ARIPO member states. Patents granted by the ARIPO office have the same effect as national patents in each ARIPO country that has been designated in the patent application.<sup>120</sup> The ARIPO office only undertakes the formal and substantive examination of the application and formally notifies designated member states. The decision whether to accept the patent or not ultimately rests with the designated Member State. Silence is understood as acceptance, with each designated state having six months to inform ARIPO that the patent shall have no effect on its territory, according to its own law.<sup>121</sup>

Until recently, ARIPO patents, once granted, were subject to the national patent law of each designated state with regard to the patent term, compulsory licences, or the use of the patent in the public interest. As a result ARIPO patents used to expire at different dates in different countries. Following the entry into force of the TRIPs agreement, the Harare Protocol was revised on 16 November 1999 and the duration of all ARIPO patents was extended to 20 years starting from the date of the application was filed. Since the entry into force of the Harare Protocol, foreign pharmaceutical companies seem to prefer the regional procedure, which is cheaper and easier than applying for patents in each respective country of the region.<sup>122</sup>



Given that the ARIPO standards are, in most instances, subject to the national standards of each member state, they do not really affect the latter. However, the tendency of a number of member states to routinely accept ARIPO applications may mean that the ARIPO standards are *de facto* emerging as a uniform regional standard that may, in the future, need to be examined in its own right. Of particular significance would be the implied acceptance of a 20-year patent term.

### 3.11 Procurement Legislation

- Applies to public procurement of medicines
- No intellectual property rights related provisions
- Provides adequate flexibility depending upon circumstances
- Reasonable interpretation legally requires a preference for generic drugs of proven quality due to price

The principles and procedures regulating public procurement of goods are provided for under the Public Procurement Act, 2003.<sup>123</sup> The Act applies to all procurement carried out by procuring entities using public funds.<sup>124</sup> The Act establishes the office of the Director of Public Procurement, who is responsible for the regulation of public procurement in Malawi under the general supervision of the President.<sup>125</sup> The Act also provides for the establishment of internal procurement committees by respective ministries and departments of government.<sup>126</sup>

Public procurement is, save for a few exceptions, done by means of open tender proceedings.<sup>127</sup> Under Section 30 of the Act public procurement is realised by means of open tendering proceedings. The Act also allows for restricted tendering, two-stage tendering, single source procurement, and request for quotations. The Ministry of Health does utilise these procurement procedures depending on its particular needs, urgency, and purpose.

As previously discussed, drugs and medical supplies required by public hospitals are procured through the Central Medical Stores, which in turn supplies them directly to public health facilities and centres.<sup>128</sup> Section 21 of the Public Procurement Act is of particular relevance to the issue of access to essential medicines. It stipulates that “procurement entities shall plan procurement with a view to achieving maximum value for public expenditures....”<sup>129</sup> This provision, in other words, requires public officers to be prudent in their use of public funds. Consequently, it requires them to seek the most favourable market price. In the case of procurement of medicines achieving the maximum value might mean procuring generics instead of more expensive proprietary brands.

### **3.12 Competition Legislation**

- Applicability to patents unclear – definitely not applicable to use, assignment, or licensing agreements
- May apply to pricing and availability of patented products
- Could allow for compulsory licences as a remedy

Malawi has relatively recently enacted competition legislation in the form of the Competition and Fair Trading Act (Act No. 43 of 1998). With one exception, the Act does not refer specifically to patents, or industrial or intellectual property more generally. The exception is Section 3(d), which provides that “nothing in this Act shall apply to: those elements of any agreement which relate exclusively to the use, licence or assignment of rights under, or existing by virtue of, any copyright, patent or trade mark.” On the face of it this could be interpreted as meaning that the Act applies generally to patents, for example to pricing decisions, but that it does not apply to use, assignment, or licensing agreements. Given that such agreements are important features of patent rights in many countries and given the prevalence of abusive licensing, the wisdom of this exclusion could certainly be questioned. Moreover, anti-competitive remedies for refusals to licence may also be important for compulsory licensing schemes and the Act may be interpreted not to cover such refusals since they involve “licensing of patent rights”.

However, to the extent that the Competition Act provides remedies for other patent abuses, it may still be a valuable public policy tool for accessing medicines especially if remedies thereunder include issuance of compulsory licences that simultaneously permit access to registration data and some degree of technology transfer. In the case that patents are considered as within the scope of the Act, the activities of patent holders would be subject to the review and action of the Competition and Fair Trading Commission, which has a broad mandate typical of such bodies.



## 4 Registration Issues

The registration of medicines in Malawi is governed by the Pharmacy, Medicines and Poisons Act (Cap 35:01) of the Laws of Malawi, dated 15 January 1991. The Act established the Pharmacy, Medicines and Poisons Board and provides for the licensing of traders in medicines and poisons, for the control and regulation of the profession of pharmacy, and for matters incidental and connected therewith.

The Board comprises eight members appointed by the Minister. These include the Chief of Health Services, the Chief Pharmacist, three members representing pharmacists, three members representing medical practitioners, one member representing veterinary surgeons, and one member representing nurses and midwives. The Board, among other things, advises the licensing authority on matters relating to medicinal products and poisons pursuant to Section 11(f) of the Act.

The Minister is responsible for granting product licences under Section 34 of the Act. Section 35 prohibits the manufacture, sale, supply, export, or import of any medicinal products except in accordance with a licence granted under the Act. Any application for such a licence should be made to the licensing authority in the prescribed form. The application should contain a description of medicinal products to which the licence will relate, Section 37 (1) and (2). Section 38 spells out the factors which the licensing authority shall take into consideration before issuing a licence:

- (a) In the case of an application for a product licence
  - (i) the safety of the medicinal products of each description to which the application relates.
  - (ii) The efficacy of the medicinal products...for the purposes for which the medicinal products are proposed to be administered.
  - (iii) The quality of the medicinal products...according to the specification and the method of or proposed method of manufacture of the medicinal products, and the provisions proposed for securing that the medicinal products when sold or supplied will be of that quality.
- (b) In the case of an application for a manufacturer's licence
  - (i) the operations proposed to be carried out pursuant to the licence.
  - (ii) The premises in which those operations are to be carried out.
  - (iii) The equipment which is or will be available on those premises...
  - (iv) The qualifications of the person or persons under whose supervision the operations will be carried out.
- (c) In the case of a dealer's or a wholesaler's licence
  - (i) the premises on which medicinal products... will be stored.

- (ii) The equipment which is or will be available for storing medicinal products on those premises.
- (iii) The equipment and facilities that will be available for distributing medicinal products...
- (iv) The qualifications of the persons under whose supervision the operations will be carried out.
- (v) The arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

A licence will be issued only if the licensing authority, the Registrar of the Board, is satisfied that the applicant is a fit and proper person to manufacture, import, export and sell medicinal products. The licence is issued subject to certain conditions [Section 39(1)].

Under the Pharmacy, Medicines and Poisons Regulations, an applicant is required to submit the following information when applying for a product licence: particulars of the applicant, particulars of the medical product, pharmaceutical data (formulation), chemical data (active and inactive ingredients), manufacturing data (summary of procedures/in-process controls), raw materials data, final products data, container and packaging data, stability data (degradation, deterioration, active ingredients, etc.), packaging insert and labelling data, foreign registration data, distribution and promotion data, pharmaceutical and biological availability data, toxicological data, efficacy (preclinical and clinical), pharmacological data.

After the application dossier is submitted to the Pharmacies, Poisons and Medicines Board for approval, members of staff at the Board examine the dossier and ingredients for conformity with the act and pharmacy best practices.<sup>130</sup> As part of this process, samples of the drug go to a quality control lab for testing. For generic ARVs and other generic products, the Board requires bio-equivalence data, performed by a well-known research laboratory. The Board confirms that the bioavailability of the two products is therapeutically equivalent. Only after establishing such bio-equivalence is a generic submitted to the Board for final approval. Most of the ARVs, including key generics, on the international market have already been approved by the board and registered (Nevirapine and Triomune).

The Board is empowered to seize drugs that are not registered. In case of donations, the Board requires the organisation to prove that the drugs were manufactured by a company that has a certificate of good manufacturing practices (GMP) by the WHO before dispensing the product.

The efficiency of the Board depends on a number of factors, including how well the dossier is drafted and whether inspectors have to travel abroad to inspect manufacturing

sites. However, for ARVs coming from WHO pre-qualified manufacturers, the process does not take too long because the dossiers are more often than not well written. Consequently, it is not necessary to expedite their applications. For some companies, registration takes longer because dossiers are not well drafted, hence Board staff have to clarify omissions and discrepancies before passing the dossier to the Board for approval. Another cause of delay might be the fact that calendared Board meetings may not necessarily coincide with the dates of submission of dossiers.

It does not appear that registration of generics is currently affected by data exclusivity rules, as the Board is willing to compare generic dossiers against those previously supplied by proprietary companies.<sup>131</sup> Likewise, it does not appear that there are any regulations linking registration of generic medicines to the patent status of a proprietary product. Malawi is not yet subject to any proposed bilateral or regional trade agreement that may negatively impact on either of these current registration flexibilities, both of which will ease access to medicines.



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# 5 Future Access Scenarios

## 5.1 Post-2005 Impacts

- Similar, or identical, to situation in other developing countries
- May affect existing imports but impacts unknown due to lack of information regarding patent and mailbox status in other countries
- Will affect access to any new products that are developed
- No formal assessment of impacts undertaken or planned
- Limited awareness or coordination between agencies/ ministries
- 2006 likely to have a more significant impact

As is the case in many other sub-Saharan countries, Malawi's primary concern in relation to intellectual property rights and access to medicines involves anti-retroviral and related drugs for the treatment of HIV/AIDS and opportunistic infections and to the future development of new drugs for the treatment of resurgent public health problems such as malaria and TB. An additional concern may be the supply of active ingredients for the limited manufacturing base that does exist in the country. While Malawi's current strategies to combat HIV/AIDS are completely dependent on the supply of generic drugs from India, Malawian institutions and authorities have not sought to collect the information necessary to assess what the situation in that country will be post-2005. Similarly, concerned NGOs and other groups have not considered the issue in detail and it is thus difficult to go beyond broad generalisations.

Most government ministries and agencies and most civil society organisations have no awareness of the issue. Those that are minimally aware have virtually no capacity, or access to such capacity, to analyse what the implications may be.<sup>132</sup> However, given that Malawi's current strategies to deal with immediate and post-2005 intellectual property rights-affected drug imports are, as discussed in 5.2 below, somewhat flawed, problems emerge under existing national law and under impending TRIPs deadlines, in particular the 2006 TRIPs deadline for least developed countries to enforce the full provisions of the Agreement.

## 5.2 Current Strategies for Post-2005

Malawi's strategy for dealing with the post-2005 situation is not specifically directed at the TRIPs deadline but rather on expediting the current<sup>133</sup> roll-out of anti-retroviral therapy using funding provided by the Global Fund. The roll-out is presently based exclusively on CIPLA's Triomune fixed-dose combination product being imported from India. With respect to the Global Fund grant, UNICEF acts as the procurement agent

rather than Malawi's Central Medical Stores. Recognising that Triomune infringes patents valid in Malawi (see Annex I), UNICEF and the Government of Malawi sought the assistance of an international legal consultant in regularising the programme. The consultation resulted in a letter being issued by the Government of Malawi, the relevant portion of which reads as follows:

**UNICEF,**

Malawi invokes paragraph 7 of the Doha Declaration on TRIPS and Public Health to request UNICEF to procure generic versions of the attached list of pharmaceutical products, diagnostic kits and related medical supplies. Malawi notes that footnote 6 to paragraph 2(a)(iii) of the 30th August decision of the General Council of the WTO on the implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health provides that the subparagraph is without prejudice to article 66(1) of TRIPS. Article 66(1) of TRIPS provides that Malawi and other least developed countries have a transitional period of 10 years to comply with TRIPS, which has been extended to 2016. This means that Malawi is not currently required to grant a compulsory licence in relation to any products which may be subject to patent within its territory.

As required, Malawi will notify the WTO TRIPS Council of the attached list.

Ministry of Health

This letter is problematic as it involves a fundamental misconception regarding the meaning of paragraph 7 of the Doha Declaration. The first point regarding this misconception is that paragraph 7 extends Malawi's general TRIPs implementation grace period from 2006 to 2016, which it does not:

7. ...We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these sections until 1 January 2016...

The paragraph 7 grace period extension only relates to pharmaceutical product patents and not to Malawi's general TRIPs obligations, which become enforceable in January 2006. Under TRIPs Article 66.1, Malawi could request the TRIPs Council to extend the general LDC transition period but it has not done so to date. Accordingly, Malawi remains obligated to amend its non-pharmaceutical product patent scheme to be TRIPs compliant by 2006.

In addition, paragraph 7 allows for national legislation that does not comply with TRIPs requirements and is not self-executing: i.e. where legislation prohibiting the patenting of pharmaceutical products does not exist, paragraph 7 does not automatically create it or otherwise override existing national laws. Finally, even if least developed countries such as Malawi amend existing legislation to cease granting patent protection for

pharmaceutical products, this amendment would not necessarily retroactively affect vested patent rights.

Given that Malawi is only currently obligated to fully implement its TRIPs related obligations by January 2006, and is not required by TRIPs obligations to enforce its national law on pharmaceutical product patents until 2016, the UNICEF letter is primarily problematic in terms of national law. Due consideration should be given to the provisions of Malawi's Patents Act and perhaps also some potentially relevant constitutional provisions. If the current legal arrangements were reviewed from this perspective it should be a relatively straightforward task to put an effective long-term framework in place to provide for the needs of the ARV roll-out and UNICEF's role as procurement agent.

However, even if Malawi establishes an effective legal framework for existing public sector projects, it is still going to need to amend its national law so as to be able to take advantage of the August 30 Paragraph 6 Implementation Agreement. Even though it is a least developed country and thus automatically eligible to use the Paragraph 6 Implementation Agreement to import medicines, the Implementation Agreement imposes obligations on it both with respect to notifications and with respect to issuing compulsory licences for import. To the extent that Malawi intends to source newer medicines from countries like India that must become TRIPs-compliant in 2005, those countries will ordinarily need to issue Paragraph 6 Implementation Agreement compulsory licences for export but can only do so if Malawi likewise abides by the Agreement. Admittedly, non-predominant quantities might be imported via orthodox compulsory licences granted in India and unlimited quantities might be imported via competition-based licences, but the major route of future importation may well be pursuant to Paragraph 6 Implementation Agreement provisions.

### **5.3 Related Initiatives**

Participants at a national stakeholders' ARIPO Sensitisation Workshop on Intellectual Property Rights and Its Role in Socio-Economic Development (2003)<sup>134</sup> recommended that the National Research Council of Malawi and the Registrar General should initiate the formulation of an intellectual property policy for Malawi. It was also agreed that the Research Council should collaborate with relevant stakeholders to review intellectual-property-related legislation for conformity with applicable regional and international agreements.

However, according to the Patents Office the process of revising the Patents Act has not yet begun even though plans are in the pipeline. This has been due to a lack of technical expertise both within the Patent Office, and in the Government more generally, to undertake the proposed revision. Also related to this is the fact that, at the ministerial level, there is a clear lack of defined leadership amongst the various ministries relevant to the review process. However, it is clear from the Government that there is an intention to review the Patent Act and develop an intellectual property policy should the necessary human and financial resources be made available.



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## 6 Conclusion

While discussion in the various elements of this paper has reached a number of specific conclusions, several more general conclusions are considered here. First, is the fact that the Government needs to review the mechanisms regularising its current roll-out programme for anti-retroviral therapy. Second, there is a short-term need to comprehensively review the Patents Act in preparation for the 2006 TRIPs deadline and to ensure that Malawi has expressly included the maximum range of flexibilities for accessing medicines. These flexibilities include: (1) prospective repeal of patent protection for pharmaceutical products at least through 2016, (2) rights of parallel importation re presently patented medicines, (3) explicit rights to import and to export under a compulsory licence or under government use re presently patented medicines, (4) procedures for utilising Paragraph 6 Implementation Agreement flexibilities, including necessary notifications, and (5) even revocation of existing pharmaceutical product patents, though this revocation would probably be subject to compensation demands. In addition, Malawi will need assistance in developing its capacity to implement the revised legislation once enacted, as current practice suggests that the country's ability to make use of available flexibilities is highly prejudiced by a lack of specialist skills within the country.

Finally, consideration might also be given to assisting Malawian generic manufacturers to develop their capacity, in particular to develop the requisite infrastructure and skills to apply for WHO GMP certification, as a means of insuring against unforeseen events beyond the Government's jurisdiction and facilitating the local private sector's ability to take advantage of programmes such as the Global Fund. However, given the small market and limited existing manufacturing base in Malawi, this option might be more usefully considered within a regional, or sub-regional, approach to avoid small-scale duplication of efforts and consequent waste of resources resulting in inefficient production.



# Annex I

## PATENT STATUS of ARVs in MALAWI

APRIL 2004

Generic name	Patent number	Protection of:	Foreign priority date	Filing date	Expiry date	Patent status in Malawi	Most recent renewal fee payment <sup>135</sup>
abacavir	AP196 MW/17/91	basic substance	22/12/89	21/12/90	21/12/10	in force	21/12/2003
AZT+3TC	AP652 MW/124/98	new composition	30/03/95	28/03/97	28/03/14	in force	28/03/2004
didanosine							
efavirenz							
indinavir							
lamivudine	AP136 MW/34/90	basic substance	08/02/89	08/02/90	08/02/10	in force	08/02/2004
	AP182 MW/33/91	new form	02/05/90	02/05/91	02/05/11	in force	02/05/2000
	AP321 MW/84/92	new process and use	01/08/91	31/07/92	31/07/12	in force	31/07/2004
nelfinavir	AP600 MW/85/96	basic substance	07/10/93	07/10/94	07/10/14	in force	7/10/2003
nevirapine	AP189 MW/66/90	basic substance	28/06/89	28/06/90	28/06/10	in force	16/11/2003
	AP179 MW/27/91	new form	17/11/89	16/11/90	16/11/10	in force	
ritonavir							
saquinavir	Roche patent application filed, not clear whether granted			11/12/89			
stavudine	no patent						
zalcitabine	no patent						
zidovudine	AP11	composition and use	16/03/85	14/03/86	14/03/06	not found in the registry	

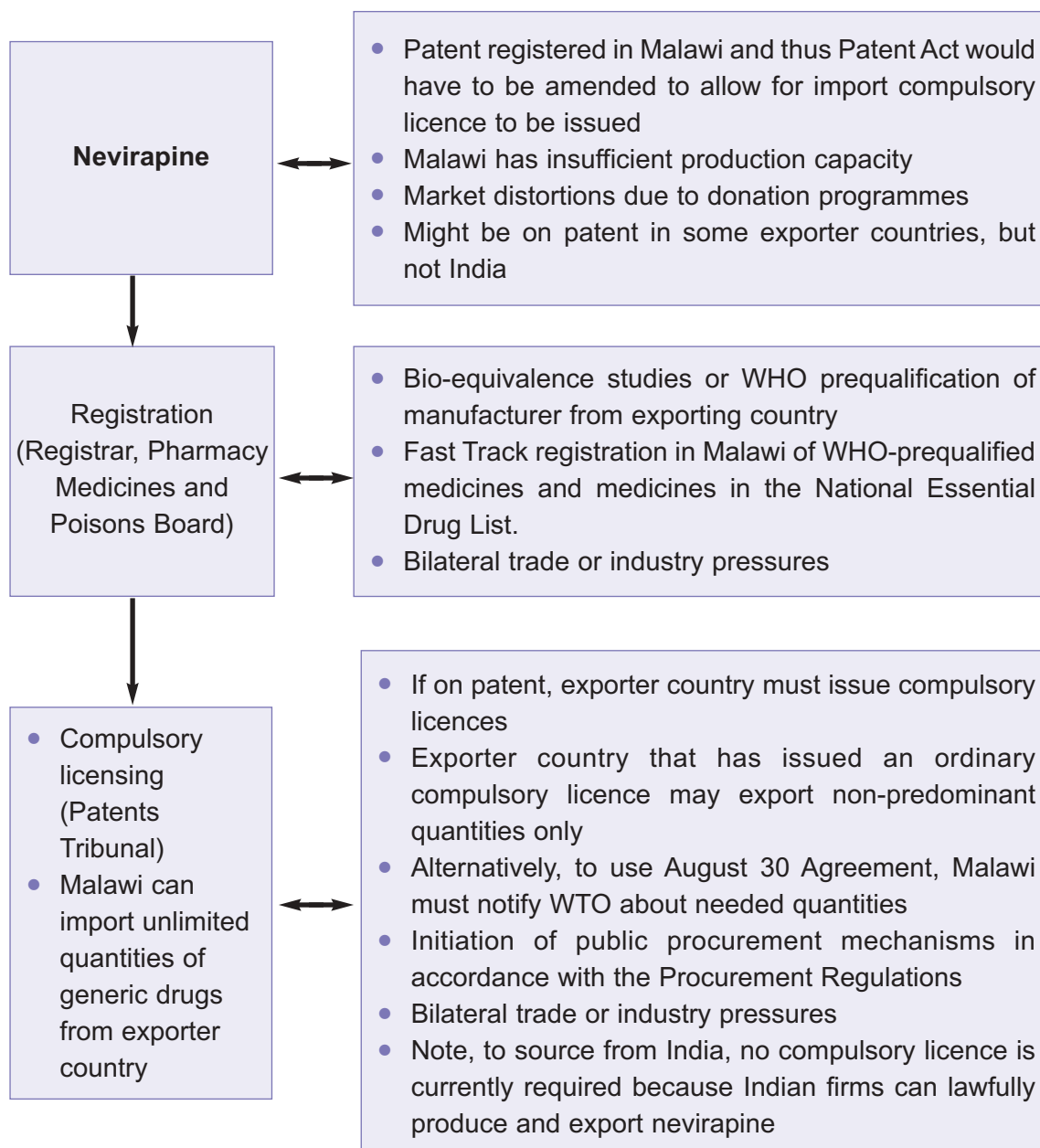


# Annex II

## Decision tree 1 – Importation of a patented drug in Malawi in a post-2005 scenario

### Nevirapine<sup>136</sup>

Two patents with respect to nevirapine are currently in force in Malawi: one on new form that is in force until 16 November 2010, and another with respect to basic substance that is in force until 28 June 2010.

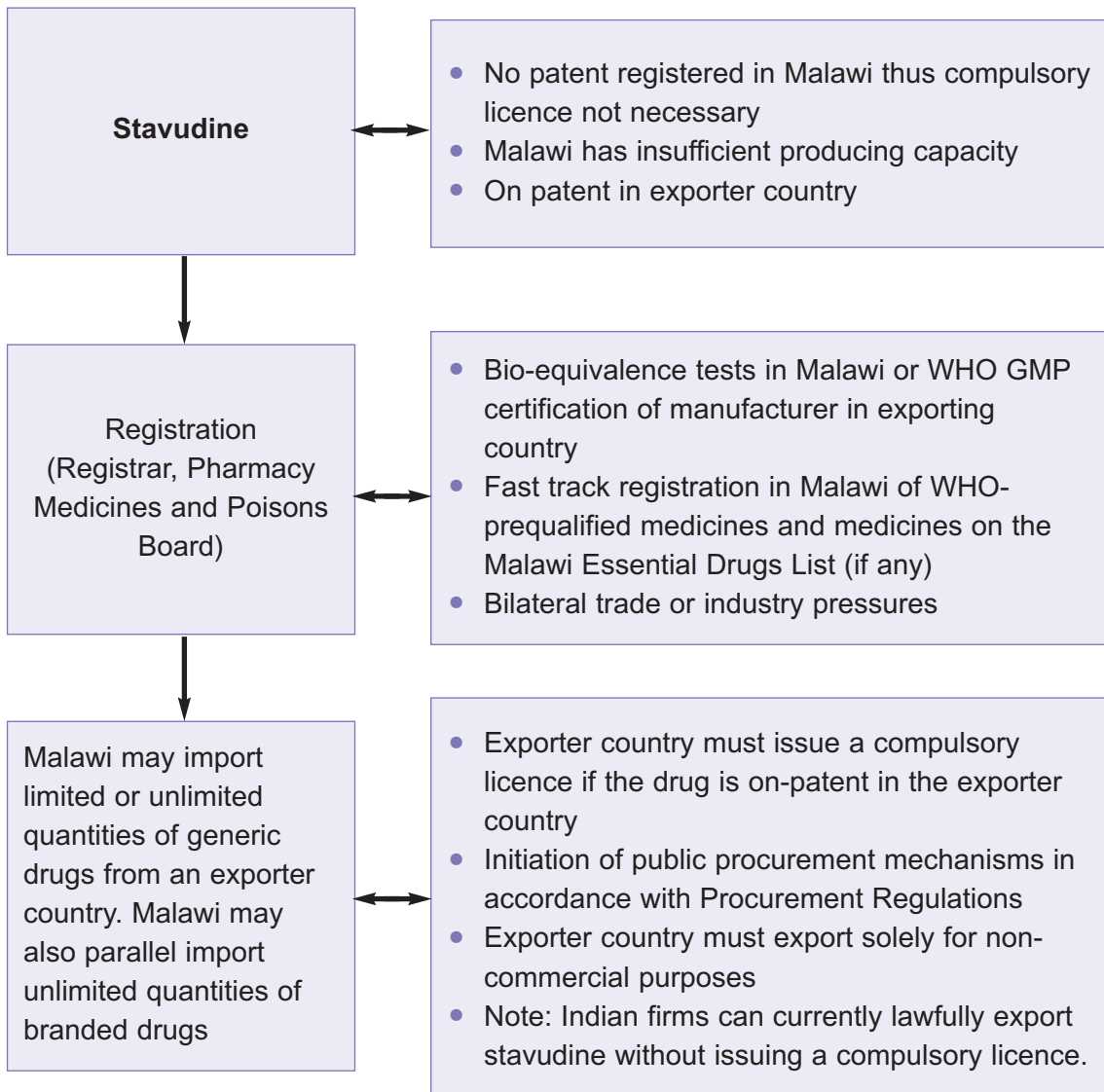




## Decision tree 2 – Importation of a non-patented drug in Malawi in a post-2005 scenario

### Stavudine

Stavudine is not on patent in Malawi.



Note: Whereas it is important for the patent status of drugs in Malawi to be known in the analysis of a post-2005 importation scenario, establishing the patent status of the drug in the exporter country is also critical.

## Notes

1 The views and opinions expressed in this case study are those of the authors and do not represent the positions or policies of the Government of Malawi, SEAPRI or DFID.

2 Robert Lewis-Lettington is Deputy Director of the Southern Environmental and Agricultural Policy Research Institute (SEAPRI), an initiative of the International Centre of Insect Physiology and Ecology (ICIPE).

3 Chikosa Banda is a lecturer in law at Chancellor College, University of Malawi.

4 University of Keele, The Centre for Health Planning and Management, (1996), "Malawi Health Sector Reform and Policy Implementation 1997–2000", p. 1.

5 By Act No.7 of 1995. It initially operated provisionally for one year effective from 18 May 1994.

6 Section 13(c) of the Constitution.

7 Section 30(2) of the Constitution.

8 General comment number 14 of the Committee on Economic Social and Cultural Rights.

9 Gillespie-White, Lee, (2001), *Patent Protection and Patient Access to HIV/AIDS Drugs in Sub-Saharan Africa*, p. 2.

10 Section 28(4) of the Act.

11 Some of the prescription drugs are purchased illegally from the open market.

12 This is particularly the case as resistance to older treatments necessitates the use of newer treatments that are more likely to be affected by intellectual property rights.

13 Williams, Mariama, (2001), "The TRIPS and Public Health Debate: An Overview", International Gender and Trade Network, p. 2.

14 Ibid.

15 National Aids Control Programme, (2000), *Malawi Strategic Framework for National Response to HIV/AIDS 2000–2004: Technical Cooperation Document*, p. 2.

16 National Statistical Office, (1998), "Malawi Population and Housing Census Final Results", press release.

17 National Statistical Office and ORC Macro (USA), (August 2001), *Demographic and Health Survey, 2000*.

18 University of Keele, (1996), p. 1.

19 National Aids Control Programme, (2000).

20 Ibid.

21 National Statistical Office, (1998), and *Weekend Nation*, 23–24 December 2000.

22 Ministry of Health and Population, (1999a), *Fourth National Health Plan, 1999–2004*, p. 3.

23 Ministry of Health and Population, (1999b), "To the Year 2020: A Vision for the Health Sector in Malawi", p. 9.

24 Ibid, p.11.

25 Ibid, p.17 and Ministry of Health and Population (1999a). Newspaper reports of recent events have highlighted drug management problems in the Central Medical Stores (CMS). During a campaign rally on 20 March 2004, the State President informed the public that he had heard reports that most public facilities, including main

referral hospitals, had serious shortage of drugs. He directed the Minister of Health to ensure the availability of drugs in all government hospitals, failing which he would be sacked. This declaration was widely publicised by the state-owned radio stations and Television Malawi. Additionally, it has on several occasions been reported in the media that the drugs procured by the CMS fail to reach the intended beneficiaries because of pilferage and bottlenecks within the system (*The Chronicle*, Vol.11, No 469, 26 April 2004). In order to curb the problem the Minister of Health directed that the CMS distribute drugs directly to the health centres instead of going through the District Health Officers (*Daily Times*, Monday 5 April 2004). He also directed that CMS should regularly publish reports for public information of the consignments it sent out. Pursuant to this directive the CMS published a list of public health facilities to which the CMS directly delivered drugs and medical supplies during the period of January to March 2004 (*Daily Times*, 2 April 2004). This notwithstanding, the Programme Manager of the Malawi Health Equity Network was quoted as saying that most rural health centres had not received drugs as reported in the papers (*The Nation*, 13 April 2004).

26 University of Keele, (1996), p. 2.

27 Data for Kenya and Zambia are provided to facilitate relative assessment. All data provided in this table has been derived from the World Health Organisation's 2004 Epidemiological Fact Sheets for the respective countries. These are available at the following URLs:

Kenya: <[http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS\\_PDFs/EFS2004\\_KE.pdf](http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS_PDFs/EFS2004_KE.pdf)>;

Malawi: <[http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS\\_PDFs/EFS2004\\_MW.pdf](http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS_PDFs/EFS2004_MW.pdf)>;

Zambia :<[http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS\\_PDFs/EFS2004\\_ZM.pdf](http://www.who.int/GlobalAtlas/PDFFactory/HIV/EFS_PDFs/EFS2004_ZM.pdf)>;

28 United Nations System in Malawi, (2001), *United Nations Development Assistance Framework, Malawi, 2002-2006*, p. 24.

29 National Aids Commission, (October 2003), "HIV/AIDS in Malawi: Estimates of the Prevalence of Infection and the Implications", p. 4.

30 AIDS is responsible for almost three out of every four deaths in the age group 15–49.

31 National AIDS Commission, (2003), p. 9.

32 Ministry of Health and Population, (1999a), p. 5.

33 National AIDS Commission, (2003), p. 12.

34 Ministry of Health and Population, (1999a), p. 4.

35 Ministry of Health and Populatio, (1999b), p. 11.

36 Ministry of Finance, (2002), *Malawi Poverty Reduction Strategy Paper*, p. 86.

37 Given estimates of 700,000 to 1,000,000 infected, the general rule of thumb that 10–20% of those infected require anti-retroviral therapy means that between 70,000 and 200,000 Malawians are in immediate need of treatment. Estimates of the current number of Malawians receiving treatment vary from 4,000 to 6,000. Personal communications to the authors, Sister Nympha Que, Christian Health Association of Malawi, and Dr. Erik Schouten, Ministry of Health (April 2004). In May 2004, the Ministry of Health, with support from the Global Fund for AIDS, TB and Malaria, rolled out a treatment programme targeting 36,000 patients by June 2005. The project

depends on the use of the generic fixed-dose combination (FDC), Triomune, produced by CIPLA of India. Personal communication to the authors Dr. Erik Schouten, Ministry of Health (April 2004).

38 Gillespie-White, (2001). Most of our interviewees confirmed that it is not easy to administer these drugs due to operational constraints, e.g., lack of qualified staff and support systems to prepare people for treatment and to monitor adherence to the same.

39 Ministry of Finance, (2002), p. 87.

40 Ibid.

41 Ibid.

42 The army has currently started providing free ARVs to HIV positive soldiers albeit on a small scale. George Ntonya, "Free ARVs for Soldiers", *The Nation*, Wednesday, 28 April 2004, p. 3.

43 National Aids Control Programme, (2000), p. 4.

44 Made up of religious agencies.

45 National Aids Control Programme, (2000), p. 4.

46 Ministry of Health and Population, (1999a), p. 7.

47 National Aids Control Programme, (2000), p. 5.

48 Ministry of Health and Population, (1999b), p. 54.

49 Office of the President and Cabinet, (May 1999), *Policy Analysis Initiative*, p. 276.

50 For example, while all health service providers procure significant amounts of foreign manufactured generic medicines, only a limited number procure them directly from these foreign sources rather than through local distributors.

51 Personal communications to the authors, Mehul Shah, Pharmacist, Pharmavet Ltd. (12 May 2004) and J. Siva Kumar, Pharmacist and General Manager, Pharmachemie Ltd. (23 April 2004).

52 India appears to be the largest supplier of essential drugs to Malawi and the general perception is that this results from a combination of favourable prices and reliable quality. Personal communication to the authors, Mehul Shah, Pharmacist, Pharmavet Ltd. (12 May 2004).

53 This has been done pursuant to a memorandum of understanding between the government and UNICEF. The initial period for this procurement agreement is one year.

54 Local wholesalers procure medicines from India, South Africa, Tanzania, Zimbabwe, Holland and other countries.

55 Boehringer and Glaxosmithkline. Companies like Boehringer Ingelheim at one time offered free Nevarapine to the government.

56 Patients are now paying K2,500 per month for first-line triple therapy instead of K10,500 for brands. Notwithstanding this being a quarter of the cost, the majority of the people still cannot afford generics. US\$1 = approx. K105 to K110.

57 IDA is an international not-for profit NGO based in Holland that provides procurement services to other NGOs especially in developing countries.

58 It was observed that only a very small percentage of drugs is sourced by CHAM from CMS.

59 Inter-Med.

60 According to Roger Teck MSF is cautious about the quality of the drugs it procures, hence it avoids buying drugs from places where counterfeit drugs may be difficult to detect.

61 MSF supplies free ARVs in Thyolo and Chiradzulu districts.

62 MSF uses its own assessments of quality and price and the registration status of drugs in Malawi as its primary guides in the choice of drugs for its programmes; it regards intellectual property rights (IPR) issues as of secondary concern. This has been reinforced by the perception that Malawi does not need to enforce pharmaceutical product patents until 2016. Personal communication to the authors by Dr. Roger Teck, MSF Luxembourg, (23 April 2004).

63 MSF does not procure drugs from local manufacturers.

64 Chemicals and Marketing, for example, sources its medicines from Denk Pharma in Germany, Glaxo Smithkline from South Africa and the United Kingdom. It sources anti-malarial drugs e.g Arinate from Dafra Belgium. Some drugs are procured from Scanpharma in Denmark and Astra Zeneca Pharma.

65 These include over the counter drugs and some prescription-only drugs.

66 Malawi Pharmacies Ltd. makes aspirin, Paramol, Anadin and Asco 30 (pain killers) and repacks a range of products for foreign pharmaceutical companies, e.g., Fansidar for Roche, and Good Morning Lung Tonic for Beta.

67 Kentam makes Kilpain (paracetamol), Ketaprin (aspirin), and Bufen (ibuprofen).

68 As a least developed country Malawi is deemed to have little or no manufacturing capacity in the pharmaceutical sector (Decision of 30 August 2003).

69 The retail price for ibuprofen from India, for example, is K15 per strip of 10 tablets whereas the cost of its counterpart from Malawi is between K9.95 and K10.95 per strip of two.

70 Lack of a market is dependent on the price of the medicines and their affordability, cost of production, the actual number of patients, and competition.

71 There is no duty on APIs, even though refundable surtax is payable.

72 The alternative for patients was to buy drugs at private pharmacies or clinics at K4,000 instead of K2,500. See *Daily Times*, 14 April 2004.

73 Chapter 49:02, Laws of Malawi.

74 Similar to the situation in other countries, the other two elements of the industrial property regime are the Trademarks Act (Cap 49:01) and the Registered Designs Act (Cap 49:05).

75 As opposed to “intellectual property rights”, which includes copyright.

76 Namelo, C. and Chavula, S.W.D., (2003), *Aspects of Non-conformity in Malawi's Intellectual Property Legislation vis a vis International Agreements Conventions and Treaties on Intellectual Property*, p. 2.

77 *Ibid*, p. 5. The Office of the Registrar General falls under the Ministry of Justice.

78 Malawi has not requested any extension of the general grace period for the implementation of its TRIPs obligations, i.e. that beyond pharmaceutical product patents, pursuant to Article 66.1 of TRIPs.

79 Pursuant to paragraph 7 of the WTO Ministerial's Doha Declaration.

80 Chapter 49:02 of the Laws of Malawi.

81 Section 29 of Malawi's legislation provides for a term of 16 years while TRIPs Article 33 requires a minimum term of 20 years.

82 Section 18.1 of the Malawian legislation allows for declarations of the non-patentability of certain products whose use is contrary to law, something that on its face violates TRIPs Article 27.2.

83 Office of the President and Cabinet, (August 2002), *National Science and Technology Policy*, par. 3.4.12.

84 Although this must be considered a crucial first step of immediate importance if Malawi is to achieve compliance with TRIPs within a reasonable time after its obligations accrue.

85 For example, pharmaceuticals could be excluded from patentability until 2016 pursuant to paragraph 7 of the Doha Declaration.

86 Under Article 66 governing transitional periods, Malawi is not obliged to implement any of the provisions of TRIPs, except for Articles 3 and 4, prior to 2006. However, its premature and thus TRIPs-plus patenting scheme is a result of Malawi's colonial legacy rather than of any bilateral or multilateral trade agreements or pressure.

87 It does appear that some form of informal technical assistance is being received through the attendance of public officers at NGO side-sessions at formal events such as the World Health Assembly and global HIV/AIDS conferences.

88 Essentially the ARV roll-out supported by the Global Fund and facilitated by UNICEF.

89 Further development of the non-profit sector's capacities in this area is something that could be usefully considered by the relevant organisations and by donors.

90 It is assumed that this technical assistance would be focused on the implementation of flexibilities as much as on meeting TRIPs obligations. The sources and nature of technical assistance have, on occasion, given cause for concern.

91 There are a few isolated instances of individuals who are aware of the issues in general terms but almost no examples of awareness of the specifics, despite the impending 2005 and 2006 deadlines.

92 Section 18.2 provides for situations where the legality of the use of an invention is in doubt, requiring disclaimers for any illegal uses on the part of applicants.

93 The Malawian authorities do not, despite the plain meaning of the disjunctive "or", consider this text to be in violation of TRIPs on the basis that it is a generally qualifying provision found in the comparable legislation of other countries. Personal communication to the authors, Mr. Chikumbutso Namelo, Assistant Registrar General (22 April 2004). Apparently, the Malawian authorities read the disjunctive "or" as a conjunctive "and" in order to be in compliance with Article 27.2.

94 The Malawian authorities do not interpret the text as excluding new use patents, preferring to apply a generally inclusive principle, where everything that meets the basic requirements is presumed patentable unless explicitly excluded. Personal communication to the authors, Mr. Chikumbutso Namelo, Assistant Registrar General (22 April 2004).

95 I.e. the patent holder or applicant and any person whose commercial interests

might be directly affected by the grant of the patent.

96 Thus the fact that patent-granting is not simply left to the discretion of administrative or political authorities, but can be challenged in the courts, effectively gives citizens and lobby groups a potential tool to oppose the granting of particular patents affecting them and thereby encourage wider access to the objects of those patents.

97 The theory of exhaustion has been applied in the absence of explicit mention in other jurisdictions, including the European Union.

98 Personal communications to the authors, Mr. Chikumbutso Namelo, Assistant Registrar General (22 April 2004) and Mr. Vincent Jeremy Mzumara, Registrar General (23 April 2004).

99 Whether based on a narrow or broad theory of international exhaustion.

100 Where a patent holder endorses a patent 'licences of right,' licensees may take up licences upon accepting stated minimum terms and conditions and without the need to negotiate individual terms and conditions with the patent holder.

101 This focus on local working requirements violates TRIPs Article 27.1's requirement that "patents shall be available and patent rights enjoyable without discrimination as to...whether products are imported or locally produced."

102 An alternative way to realise lowest prices might be to issue multiple licences thereby promoting competition between several licensees, assuming, of course, that the aggregate market can support several competitors.

103 According to Section 2 of the General Interpretation Act (Cap 1:01 of the Laws of Malawi), "the minister" means the minister for the time being charged with the responsibility for the matter in question, and includes the President when he has assigned to himself or is exercising such responsibility. Therefore, the minister referred to in the Patent Act is the one responsible for the administration of patent law, namely the Minister of Justice.

104 Although, in practice, Ministries of Health, non-profit organisations and other similar agencies may be reluctant to proceed with procurement of generics if they are aware that a patent application for the brand name is pending.

105 This once again raises the question of ministerial competence discussed in note 103. Does whichever Minister has responsibility for the Patents Act have the power to gazette an emergency and, if so, are there broader implications for such a notification?

106 Personal communication to the authors, Mr. Chikumbutso Namelo, Assistant Registrar General (22 April 2004).

107 Although, as discussed in 3.10 below, this is calculated from the "lodging of a complete specification" rather than from initial application or grant and thus may actually be longer than 16 years.

108 Or, as it has become popularly known, "TRIPs plus".

109 See, for example, Lettington, R. and Musungu, S., *In Defence of Kenya's Health: Proposed Amendments to the Industrial Property Bill 2000*, Kenya Coalition for Access to Essential Medicines, July 2000. Report on file with the authors.

110 "Any person" is highlighted here as the language may have implications for

questions of locus standi. The Patents Act frequently refers to “any interested person” or specific parties and the change in language here may be interpreted to suggest a broadening of locus standi to all persons, whether legally defined as interested or not, or, at a minimum, to persons with only remote interests.

111 As discussed in part 3.8, above, the fact that the Patents Tribunal makes such determinations means that they may be appealed to the High Court.

112 Estoppel is a common law legal doctrine that, in this context, means that a party may not seek to benefit from changing their position in a matter. Once a patent holder has argued that they are intentionally not making a profit from a product in Malawi should they then be prohibited from arguing that they have not received adequate remuneration?

113 Most common law countries, such as Malawi, do allow for reference to decisions from other common law jurisdictions, particularly England. However, the fundamentally different English socio-economic situation would seem to reinforce the argument in favour of local interpretations of terms such as adequate remuneration.

114 The term derives from patent practice in the United States prior to the amendment of US legislation in accordance with TRIPs.

115 Section 25.2 provides for some restrictions on the period to be allowed from the lodging of an application to the grant or rejection of a patent but it is unclear whether an incomplete specification may be considered an “application” and extensions are allowed upon the payment of a fee.

116 Interestingly, the potentially retroactive powers of the Minister in granting governmental use orders could be invoked to address such situations.

117 Article III (a).

118 Section 1 of the Protocol on Patents and Industrial Designs Within the Framework of the African Regional Industrial Property Organisation, 1982.

119 Section 2 (1).

120 Boulet, Pascale, (2000), *Patent Protection for Medicines in Kenya and Uganda* (Report for discussion at the MSF conference on Improving Access to Essential Medicines in East Africa – Patents and Prices in the Global Economy, April 2000), p. 1.

121 Section 3(6). Boulet, (2000), p. 1.

122 Boulet, (2000), p. 2.

123 Act No. 8 of 2003.

124 Section 3 of the Public Procurement Act, 2003. “Public funds according to section 2 means any monetary resources appropriated to procuring entities through budgetary processes, aid grants and credits put at the disposal of procuring entities by foreign donors or revenues of procuring entities.”

125 Section 4 and 5 of the Act.

126 Section 8 of the Act. The Internal Procurement Committee for the Ministry of Health is presided over by the Principal Secretary.

127 Section 30 of the Public Procurement Act; the exceptions may include procurements of a sensitive nature (for example national-security related procurements).

128 The list of public health facilities to which the CMS supplied drugs and medical

supplies between the months of January and March 2004 was published in the *Daily Times*, Friday 2 April 2004, pp. 10–12. The press release also urged the general public to assist the Ministry of Health in the monitoring of the usage of these supplies through their local Health and Hospital Advisory Committees and report any abuse to the police and the Ministry.

129 This requirement is similar to the Global Funds lowest cost-pricing requirement. This means that grant recipients will be obliged to procure the lowest cost medicines that meet other standards concerning quality and legality (Baker, Brook, (2003), *Analyses and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, p. 50).

130 The procedures described in this and the following two paragraphs summarise telephone interviews with Mrs Nyirenda of the Pharmacies, Medicines and Poisons Board.

131 Indeed, pursuant to paragraph 7 of the Doha Declaration Malawi is not required to implement Article 39.3 of TRIPs until 2016.

132 The Ministry of Health has a task force on TRIPs but it appears the task force has not met.

133 The roll-out began in May 2004, just subsequent to the research undertaken for this paper.

134 13 –15 August 2003.

135 In most jurisdictions, the payment of periodic renewal or maintenance fees is a statutory requirement for the maintenance of rights. If fees are not paid, a patent may be deemed to have lapsed or have been abandoned if legally challenged.

136 Nevirapine is the generic version of Boehringer Ingelheim's Viramune , a non-nucleoside analogue reverse transcriptase inhibitor. The drug is used in the prevention of mother to child transmission (PMTCT) of HIV and in first-line ARV triple therapy



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