

## The Conflict between intellectual property rights of pharmaceutical companies and the right to health of AIDS victims in South Africa

© Lisa Anderson<sup>1</sup>

### Introduction

South Africa has more people living with HIV/AIDS than any other country in the world: 4.1 million South Africans, one in nine of the population are living with the disease.<sup>2</sup>The inflated price of essential drugs puts effective treatment beyond the reach of many, as more than 60% of employed people in South Africa earn less than US \$ 250.00 monthly.<sup>3</sup>

In 1997 the South African government passed the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (Medicines Act). The new law contains measures that will increase economic availability certain antiretroviral drugs for people with HIV/AIDS in need of (safe) effective medication and improve the functioning of the National Medicines Control Council with regard to its constitutional duty to realise the right to health<sup>4</sup>. The following year in an attempt to halt the Medicines Act, the Pharmaceutical Manufacturers Association and forty multinational drug companies filed

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<sup>2</sup> It is the poorest countries where budget resources are most limited, and where household poverty is most prevalent that face the gravest threat from rising drugs prices. Oxfam (2000) 'Patent Injustice: How the World Trade Rules Threaten the Health of Poor People', p. 3.

<sup>3</sup> Achmat, Z. (1999) 'We can use compulsory licensing and parallel imports a south African case study' for Treatment Action Campaign (TAC) at URL page: <http://www.hri.ca/partners/alp/tac/license.shtml>

<sup>4</sup> Treatment Action Campaign Fact Sheet, at URL page: <http://www.tac.org.za/pmavsggov.txt>

a lawsuit against the South African government<sup>5</sup>. They have argued that the law would undermine their intellectual property rights, by permitting the South African health minister to use parallel importation of drugs, compulsory licensing and generic substitution and that such measures would contravene the governments obligations under the World Trade Organisation's (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Since the passage of the Medicines Act, it has been reported that 400,000 HIV/AIDS sufferers have died whilst the pharmaceutical industry has prevented the implementation of reforms<sup>6</sup>, prompting the rebuke of several non-governmental organisations at the apparent prioritisation of company profits over the right to health and life.

Both the right to intellectual property and the right to health are articulated in international human rights instruments. Whilst the relationship between these rights have been declared as interdependent, indivisible and interrelated<sup>7</sup>, the South African constitutional court case exemplifies the challenge of achieving this aspiration in the context of the divergent economic and political motives and interests that exist between pharmaceutical companies and states. Furthermore it also serves to highlight the global ramifications of the resulting conflict of rights with regards to the ability of a developing country to effectively confront the AIDS epidemic.

This essay will examine the right to health of South African HIV/AIDS sufferers enshrined in international and domestic human rights law, and the obligations this right confers upon the state. It will also consider the economic, political and human rights function of intellectual property rights within the pharmaceutical industry in relation to those drugs that have been deemed essential for the treatment of HIV/AIDS. It will critically analyse the degree to which TRIPS and concurrent obligations may undermine the ability of a state to fulfil its duty to effectively realise the right to health, by considering the scope of this duty with specific reference to AIDS. Ultimately in recognition of AIDS as a 'global issue', this essay will address the capacity of the international human rights framework to articulate the duties conferred on state and non-state actors with regards to the realisation of the right to health of AIDS/HIV.

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<sup>5</sup> Case 4183/9: Pharmaceutical company lawsuit (forty-two applicants) against the Government of South Africa (ten respondents), at URL page: <http://cptech.org/ip/health/sa/pharmasuit.html>.

<sup>6</sup> TAC (2001) TAC Fact Sheet 'The Medicines and Related Substances Act 90 of 1997: A Step Towards Ending Apartheid in Healthcare', at URL page: <http://www.tac.org.za/pmavsgov.txt>

<sup>7</sup> See 'The 1993 Vienna Declaration and Programme of Action' Section 1 (5) A/CONF.157/23 12 July 1993.

## The right to health and obligations arising from this right

General Comment No.14 on 'the right to the highest attainable standard of health conducive to living a life in dignity' affirms, "Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The realisation of the right to health may be pursued through the formulation of health policies, or the implementation of health programs developed by the World Health Organisation or the adoption of specific legal instruments."<sup>8</sup>

The right to health is recognised in numerous international instruments. Article 25.1 of the Universal Declaration of Human Rights asserts, " Everyone has the right to a standard of living adequate for the health of himself and of his family including food, clothing, housing and medical care and necessary social services". The International Covenant on Economic Social and Cultural Rights (ICESCR) provides the most comprehensive article on the right to health in international human rights law. In accordance with article 12(1) of the Covenant, states parties recognise "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", while article 2 enumerates, by way of illustration, a number of "steps to be taken by states parties...to achieve the full realisation of this right"<sup>9</sup>

South Africa has yet to ratify the ICESCR to which it became signatory in October 1994. However the state is party to the following covenants where the right to health is recognised *inter alia*; in article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in articles 11.1 (f) and 12 of the International Convention on the Elimination of Discrimination of All Discrimination Against Women of 1979 and in article 24 of the Convention of the Rights of the Child of 1989. In addition South Africa is also party to the African Charter on Human and Peoples Rights of 1981, in which the right to health is provided for in article 16<sup>10</sup>.

The right to health in South Africa is also defended in the 1997 constitution, which formulates both a right to health and a right to social security. During the drafting of

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<sup>8</sup> General Comment No. 14 (2000) 'The right to the highest attainable standard of health', Committee on Economic and Social and Cultural Rights, Twenty Second session, Agenda item 3, E/C.12/2000/4, 11 September 2000.

<sup>9</sup> Ibid.

<sup>10</sup> It is often argued that the crippling problems forced by many African states does not allow for them to contemplate programs of the welfare state. Accordingly Article 16 does not provide for the progressive realisation with respect to the progressive realisation of the right to health, and with respect to the resource constraints to which the rights are subject, as does Article 21 of the ICESCR. Steiner, H and Alston, P.,

the economic and social provisions in the constitution, a technical committee advised that the grouping of certain social and economic rights be kept to a minimum. The subsequent decision to group the related provisions on health, food, water and social security together, separate from provisions on education, access to land and children's rights in order to was guided by the priority to maximise the importance of these rights on a symbolic level. Accordingly the South African constitution includes 'health care, food, water and social security':

'Health care, food, water and social security

27. (1) Everyone has the right to have access to –

- (a) health care services, including reproductive health care;
- (b) sufficient food and water; and
- (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.

(2) The state must take reasonable legislative and other measures within its available resources, to achieve progressive realisation of each of these rights.

(3) No one may be refused emergency treatment.<sup>11</sup>

This same technical committee held that the right to access of health care services should not be restricted to those without adequate resources, but would also apply to persons living in areas where health care services are underdeveloped (e.g. rural areas), and those with special needs (e.g. the elderly, persons with disabilities and HIV patients). Finally it was suggested that the right not to be refused emergency medical treatment is an obligation that is immediately enforceable.<sup>12</sup>

The right to health like all human rights imposes three levels of obligations on States Parties: the obligations to respect protect and fulfil<sup>13</sup>. In turn each level necessitates the duty to facilitate, provide and promote. The stipulation of the right to health in the constitution, concerning its equal accessibility, is an indicator of the will of the state regarding its negative duty to protect this right. However it is the positive obligation to

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(2000) *International human rights in context: law, politics, morals: text and materials*, Oxford: Oxford University Press, p.355.

<sup>11</sup> Constitution of the Republic of South Africa, Act No. 108, 1996, at URL page: <http://www.polity.org.za/govdocs/constitution/saconst02.html#27>

<sup>12</sup> Toebes, B. (1999) *The Right to Health as a Human Right in International Law*, London: Intersentia, p. 83.

<sup>13</sup> Henry Shue developed this tripartite typology of duties. In Toebes, B. (1999) 'Towards an Improved Understanding of the International Human Right to health', in *Human Rights Quarterly* Vol. 21: p. 677.

'respect' and 'fulfil' this right that is highlighted by the South African states' defensive stance towards pharmaceutical companies. The obligation to 'respect' requires the state to *ensure* equal access to health services of the population. In this regard it can be argued that sufferers of AIDS/HIV are unfairly discriminated against by the prohibitive prices of essential drugs, which (amongst other reasons) limits their access to health care. The obligation to 'fulfil' requires states to adopt appropriate legislative administrative, budgetary judicial promotional and other measures towards the full realisation of the right to health<sup>14</sup>. With regard to the treatment of AIDS/HIV sufferers this obligation relates directly to the passing of the Medicines Act; the government's attempt to implement progressive legislation concerning it's ability to provide effective basic health care. However it also relates to the performance of the state regarding the allocation of sufficient budgetary resources crucial to fulfilling the substance of such legislation.

The scope of the latter aspect of this obligation is of critical importance as it provides for the means to the end of realising the right to health. Bridgit Toebes has commented that the limitation of the right to health does not necessarily lie in its international codification but rather its lack of conceptual clarity and probably as a result of that, its weak international and national implementation<sup>15</sup>. This limitation can be understood with regards to the health of HIV/AIDS sufferers as being inextricably linked to their right to life *inter alia*, and the corresponding difficulty of defining sufficient state obligations with respect to equating the necessary (often expensive) treatment with basic health care owed to all.

Consequently, considerable attention has been given to the challenge posed by the programmatic nature of the obligations related to the right to health, for its effective implementation. Article 2(1) of the ICESCR provides that "state parties must take steps...to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights."<sup>16</sup> In General Comment 3, the Committee on Economic, Social and Cultural Rights express that the concept of progressive realisation constitutes a recognition of the fact that full realisation of all economic and social rights will generally not be able to be achieved in a short period of time. It emphasises that on the one hand it is a necessary flexibility device, which rather than providing a 'loophole' for countries to exploit in order to evade obligations, reflects the realities of the real world and the difficulties in ensuring full realisation of

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<sup>14</sup> Toebes, B. (1999) The Right to Health as a Human Right in International Law, London: Intersentia, p. 338.

<sup>15</sup> Ibid, p. 86.

economic and social rights. Hence, the committee asserts that the provision also imposes a clear obligation for states to move as expeditiously and effectively as possible towards that goal<sup>17</sup>.

As a developing state, provision of health care in South Africa is constrained by structural economic problems. In light of these difficulties and the negative implications for the standard of life of the most vulnerable sectors of the population, it is essential that the government maximise its efforts in the regard of healthcare. However, in the absence of this obligation framed in the language of the ICESCR, the South African constitution obliges the state in similar yet muted terms to take 'reasonable measures' within its 'available resources'. In this domestic translation, the constitutional court has the power to discern the value of 'reasonableness' with regards to its allocation of resources. In the event of the states' failure to adequately fulfil its duties in this regard, an applicant would need to prove state actions 'unreasonable' to establish his/her right to health and the states corresponding duty.

The fine line between the state's duty to provide healthcare to those in urgent need, whilst fulfilling its duties to realise the right to health of everyone within its available resources has already been tested in the South African context. In *Soobramoney v. Minister of Health (Kwazulu-Natal)*<sup>18</sup> the South African constitutional court used a utilitarian argument to uphold the states' decision to refuse treatment of a man who was terminally ill and in effect employed a restrictive understanding of the scope of the right to health. The ruling expressed that the government had insufficient resources to provide the vital services that would improve his health and thereby prolong his life, and that his circumstances could not be considered under the provision for 'emergency treatment'.

This example illustrates the way that state discretion in the interpretation of the scope of health care and its obligation to fulfil this duty is problematic for the realisation of the fundamental right to health as a universal human right. In view of the obligations conferred by the ICESCR, General Comment 3 provides that States are obliged, regardless of their level of economic development to ensure respect for minimum subsistence rights for all<sup>19</sup>. With regard to the right to health care, Teobes comments

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<sup>16</sup> Article 2(1) of the ICESCR

<sup>17</sup> General Comment No. 3, (2000) 'The nature of state parties obligations (Art. 2, par. 1 of the Covenant) Committee on Economic and Social and Cultural Rights, Fifth session, E/1991/23, 14 December 1990.

<sup>18</sup> Case CCT 32/97, 27 November 1997 in Teobes, 1999, p. 228

<sup>19</sup> General Comment 3

that this, *inter alia* includes the obligation to provide the basic health care services. Whilst international case law exists that supports the inclusion of the (justiciable right and corresponding) duty to grant emergency care under this criterion, there is also a precedent provided by a Colombian constitutional court case for the duty to grant health services that are fundamental in character, considered to be more important than services of a more general character<sup>20</sup>. However where states draw the line is difficult to determine. Whereas in the Colombian case the ruling provided for the treatment of an indignant HIV sufferer, it is unclear whether this would be the case in South Africa.

Ultimately the obligation imposed by the right to health confers positive duties upon the state. Effective legislation is one important aspect of the governments' obligation in this respect; adequate resources and effective management and leadership are necessary to adequately fulfil this obligation. Toebes has adopted a progressive interpretation of state obligations, which stresses the need for governments to ensure the availability, geographic financial and cultural accessibility, equality and quality of such services, while paying due attention to vulnerable groups in society, irrespective of their economic capacity.<sup>21</sup> Although the South African government has yet to ratify the International Covenant on Economic Social and Cultural Rights, its recognition of a constitutional right to health, and its ratification of other human rights instruments reflects its support for the existence of an international human right to health. In this vein its case against the pharmaceutical companies on the grounds of the right to health, is a 'healthy' indicator of its regard for this right. However, recognition of this right does not ensure systematic, consistent respect of corresponding duties; it remains to be seen whether fulfilment of the Medicines Act will release the resources necessary to realise the health care of HIV/AIDS sufferers.

## The International Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) – an obstacle to the realisation of the human right to health?

International human rights law provides the normative framework for intellectual property rights, where intellectual property is understood as a generic term that refers

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<sup>20</sup>The court ruled that the right to health is fundamental when it relates to the right to life and that the state is required to provide health services that are fundamental in nature as opposed to those of a more general character. Toebes, B. (1999) The Right to Health as a Human Right in International Law, Oxford: HART, p.225

<sup>21</sup> Ibid, p.350.

to intangible objects that acquire their value primarily from creative efforts. Beginning with the provisions of the Universal Declaration of Human Rights (UDHR), international human rights instruments have enumerated the right of an author, creator or inventor to some form of recognition and benefit from their intellectual products. Article 27 of the UDHR states that "Everyone has the right to the protection of the moral and material interests resulting from any scientific literary or artistic production of which he is author". This right is linked to another provision of Article 27: "Everyone has the right to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancements and benefits." From this customary source of law the right is rearticulated in the ICESCR, which contains similar provisions. Article 15 (1) (c) requires states parties to recognise the rights of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author. Also like UDHR, other components of UDHR link this obligation to rights to "enjoy the benefits of scientific progress and its applications."<sup>22</sup>

Patents are the legal means of protection for pharmaceutical inventions. They are the titles conferred by the state that attest to the grant of exclusive rights to the inventor for the exploitation of his/her invention. As such they serve two functions: an inducement to invent and as an essential factor in scientific and technological progress by providing companies with an advantage over competitors<sup>23</sup>. International and domestic legal regimes defining the nature of intellectual property and the types of protection that accrue to its creators effectively shape the realisation of these rights<sup>24</sup>.

The TRIPS agreement of 1995 is the result of the culmination of the Uruguay Round of Trade Negotiations and reflects an effort on the part of industrialised states to increase global protection of intellectual property and the establishment of a global intellectual property regime. In addition to the standard functions of intellectual property rights cited as motivations for its establishment, governments are using intellectual property rights as a means to improve the country's competitive edge and this has subsequently become an increasingly dominant motive in the global economy.

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<sup>22</sup> Chapman, A. 'Approaching Intellectual Property as a Human Right', Committee on Economic, Social and Cultural Rights, Twenty-fourth session, Item 3 of the provisional agenda, E/C.12/2000/12, 3 October 2000, p. 2.

<sup>23</sup> Salazar, S., (2000) 'Intellectual Property and the Right to Health' in World Intellectual Property Organisation WIPO/UNHCR Intellectual Property and Human Rights: A Panel Discussion to commemorate the 50<sup>th</sup> anniversary of the Universal Declaration on Human Rights, Publication NO. 762 (E), Geneva: WIPO, p. 68.



The WTO has stressed the economic importance of intellectual property in the recent decades with the increasing significance of information and knowledge based industries. It claims that a number of studies showed that by the 1980s contribution to gross domestic product of certain countries made by copyright industries was in the order of 3-5%, and that the number of people employed in these industries also grew. With the growing interdependence of national economies, the WTO argues that it became clear that there no longer existed a functioning multilateral rule of law to regulate the relations and differences between countries, and that this was the main reason for the incorporation of intellectual property matters into the GATT Round Negotiations<sup>25</sup>. However, opponents of the TRIPS regime argue that subsequent policies often favour major economic interests, particularly large multinational firms, to the detriment of promoting public access and benefits in the home country and promoting development in countries in the South.

The TRIPS agreement sets mandatory minimum standards for the national protection of intellectual property, including the right to exclusively market a patented product for at least 20 years, which accordingly requires states to implement a common and often expanded set of intellectual property protections. It also imposes enforcement measures, including potential trade sanctions against nations that do not comply with these standards. Thus it has been argued that provisions of the TRIPS agreement make it more difficult for countries to set intellectual property standards and policies to fit domestic economic conditions, as well as to protect the human right to health and life.<sup>26</sup> Furthermore, some northern countries are using bilateral and regional trade agreements to negotiate even more stringent protection for patents under so-called 'TRIPS plus' agreements.<sup>27</sup>

The principal obstacle for public health care imposed by the patent rights conferred by the TRIPS agreement is manifest in the cost for pharmaceutical drugs. Patented drugs are often considerably more expensive than their generic counterparts, because patent holders, which are usually corporations have the freedom to price their products at arbitrary, often inflated levels that make essential drugs beyond the means of poor people lacking health insurance. With regards to the HIV/AIDS sufferers in the developing world, particularly South Africa, the consequence of patents on the drugs

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<sup>24</sup> Chapman, A., E/C.12/2000/12, p. 3

<sup>25</sup> Secretariat of the WTO, 'Protection of Intellectual Property Under the TRIPS Agreement' Committee on Economic Social and Cultural Rights, Twenty-fourth Session, Item 3 of the provisional agenda, 29 November 2000, E/C.12/2000/18.

<sup>26</sup> Oxfam Policy Papers (2001), 'Patent Injustice: How World Trade Rules threaten the health of Poor People' available at, <http://www.oxfam.org.uk/policy/papers/safrica2.htm> p. 5.

that are necessary for the effective care of HIV/AIDS is that the vast majority of them do not have economic access to medicines that are prolonging or improving the lives of people with HIV/AIDS industrialised countries.

Organisations such as Medicins Sans Frontieres (MSF) have highlighted the high cost of the fluconazole in South Africa, which is crucial for the treatment of cryptococcal meningitis that affects one in ten of people with AIDS. This is one of the drugs that have been identified as essential<sup>28</sup> for HIV/AIDS care in less developed countries, and falls into the category of drugs that are effective in the prevention and treatment of life threatening and frequent opportunistic infections. However, prohibitive prices of anti-retrovirals, which limit the damage that HIV causes to the immune system and mother to child transmission of the virus, also pose a significant challenge to the realisation of the South African governments' ability to realise it's duty to provide health care. Some idea of the cost of the magnitude of potential price shifts can be derived from the evidence of past developments. Bayer introduced the patented anti-infective drug ciproflaxin in India in the mid 1980s. Within seven years it was being produced and marketed by 4 local firms at a fraction of the initial import prices<sup>29</sup>.

In reaction to the growing international controversy concerning the limiting effect of patents on the ability of governments to provide effective healthcare, the WTO has presented an interpretation of the TRIPS argument that stresses the need to balance the interests of the authors of intellectual property with the benefit of their products to society in compliance with the scope of related human rights provisions. It asserts "the challenge of the national and international rule-maker is to find the optimal balance between various competing interests with a view to maximising the public good, while meeting also the human rights of authors and inventors"<sup>30</sup>. In addition the organisation acknowledges the dynamic nature of this balance in view of variable national and international economic and political conditions. Thus, regarding the issue of patent protection for pharmaceutical goods, the WTO emphasise that the Agreement contains a substantial number of provisions that take account of immediate as well as longer term health considerations. These provisions include those relating to patentability, the possibility to make limited exceptions to exclusive rights, compulsory licensing

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<sup>27</sup> Ibid, p.6

<sup>28</sup> MSF have developed certain criteria, linked to both available scientific data and MSF experience, for the selection of drugs that are essential for HIV/AIDS sufferers in developing countries. Perez-Casas, C., (2000) HIV/AIDS Pricing Report. Setting Objectives, is there political will?' at URL page: <http://msf.org/advocacy/accessmed/reports/2000/07/aidspricing/>

<sup>29</sup> Oxfam Policy Papers (2001) 'Patent Injustice', p.21

<sup>30</sup> Secretariat of the WTO, E/C.12/2000/18.

(Article 31<sup>31</sup>), parallel importation (Articles 28 and 6<sup>32</sup>) and the recognition that member countries may adopt necessary measures protect public health (Article 8<sup>33</sup>), e.g. through 'generic substitution', whereby patented products are substituted by their generic counterparts<sup>34</sup>.

This line of argument purportedly legitimises the actions taken by the South African government that seek to implement such provisions. However, the vehement resistance of the pharmaceutical industry to the efforts of developing countries to make full effect of these provisions throws the inconsistency between the legal theory and the practical implementation of the TRIPS agreement into relief<sup>35</sup>. Pharmaceutical companies have argued that the practice of parallel importation, whereby a distributor without any concession or license from the owner of the patent, purchases patented products in countries where higher prices are charged (in spite of the fact that there are companies in the latter countries that have been licensed to distribute the products by the owner of the patent) is capable of weakening their position in the world market<sup>36</sup>. Similar economic arguments are advanced in opposition to compulsory licensing. In addition to such arguments, the industry has warned that the cost of lower competitiveness will necessarily reduce the incentive for future research and development into 'thirdworld' diseases. Moreover they assert that significant reductions in price have been offered to developing countries in line with tiered pricing schemes such as the UNAIDS 'Accelerated Access to HIV/AIDS Care and Treatment Initiative'<sup>37</sup>.

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<sup>31</sup> Article 31 of the TRIPS sets out the framework for national laws on use without authorisation of the patent owner and provides broad discretion on government use of compulsory licensing. The general rules are that governments consider cases on their individual merits and that prior to authorising third party use there should be an effort to negotiate a voluntary license on reasonable commercial terms must provide for adequate remuneration taking into account the economic value of the authorisation. Another important rule is 31 (f) which states "use shall be authorised predominantly for the supply of the domestic market." 'Health care and IP: International Law and Compulsory Licensing' at URL page: <http://www.capttech.org/ip/health/cl/cl-ilaw.html>

<sup>32</sup> Article 28 of the TRIPS gives the patent owner the exclusive rights to import a good into a country, that right is subject to article 6 which concerns the doctrine of 'exhaustion' of intellectual property rights, which relates to the fact that the owner of intellectual property can not control the resale of a legally purchased good.

<sup>33</sup> Article 8 of the TRIPS allows for states to adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and economic welfare.

<sup>34</sup> Secretariat of the WTO, E/C.12/2000/18.

<sup>35</sup> The inconsistency of their stance is further highlighted by the fact that various developed countries have already taken full advantage of the permissive rules of the TRIPS agreement, e.g. compulsory licenses have been extensively used in North America, Japan and Europe for a variety of purposes, furthermore, the US has broad patent rights, it is not obliged to negotiate for licenses and does not authorise any injunctive relief to the patent owner. Love, J. (2001) Access to Medicines and Compliance with the WTO TRIPS Accord: Models for States Practice In Developing Countries.

<sup>36</sup> Salazar, S. (2000) p.74.

<sup>37</sup> This initiative brings together five companies, all of which have pledged to supply cut-price anti-retrovirals to developing country governments.

In response to these claims advocates of TRIPS compliant measures to ensure affordable medicines have countered that the cost to the pharmaceutical industry of parallel imports and compulsory licensing is sustainable. Prices in developed countries remain significantly higher despite the global disparities, and evidence of significant discounts already available on medicines in Africa implies that they believe it possible to manage the threat of parallel imports back into the US or Europe<sup>38</sup>. With regards to the availability of discounted drugs, it is argued that reliance on preferential pricing or donations renders governments dependent on companies' good will, providing an ad hoc, disease specific approach to the problem rather than a systematic solution<sup>39</sup>.

The tenuous argument supporting a restrictive interpretation of TRIPS also avoids confrontation with the real implications of the economic and historical context of their oppositions' stance. Developing countries in the past have necessarily avoided stringent patent regimes on medicines in the interests on public health. Whilst developed countries extended patent protection to pharmaceutical goods at the end of the 20<sup>th</sup> century, developing countries in response to the belief that such intellectual property would pose a threat to the prospect of the right to health, took steps to exclude essential drugs from patentability. This context was instrumental for the subsequent emergence of highly sophisticated generic industries with a specialisation in the development of low cost equivalent of expensive patented medicines for low-income populations.

High-profile conflicts involving anti-HIV drugs have highlighted the cost-advantage enjoyed by generic producers. Generic companies in Thailand market the drug flucanazole, which is used for the treatment of HIV patients who have contracted meningitis, for US \$0.29 and in India for US \$0.64. This compares with market prices for brand name drugs of US \$10.50 in Kenya US \$27 in Guatemala, and (until recently) US \$8.25 in South Africa. In Thailand, Pfizer enjoyed exclusive marketing rights on the drug until these were withdrawn in 1999. The price fell within a period of nine months to a little over three percent of its previous level, as generic competitors entered the market<sup>40</sup>.

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<sup>38</sup> Oxfam policy papers (2001) 'Implausible denial why the drug giants arguments on patents don't stand up', at URL page: <http://www.oxfam.org.uk/policypapers/trips2.htm>

<sup>39</sup> Oxfam Policy Papers (April 2001) 'Oxfam update on South African Court Case: South Africa vs. the drugs giants', at URL page: <http://www.oxfam.org.uk/policy/papers/safrica2.htm>

<sup>40</sup> Ibid.

Countries willing to produce generics despite existing patent protection or engage in compulsory licensing have sometimes made dramatic breakthroughs in health care policy. Brazil has become a model in the fight against AIDS because of the government's decision to produce generic AIDS medicines and distribute them to patients free of charge or at a subsidised rate. Presently government laboratories produce five generic US antiviral AIDS medications. Brazil has countered opposition from the US pharmaceutical industry, arguing that WTO rules permit it to manufacture generic medications in a 'national emergency'<sup>41</sup>.

The unconditional withdrawal of 39 pharmaceutical applicants from the lawsuit against the South African government after widespread international condemnation, further corroborates a progressive interpretation of the TRIPS agreement, which permits governments to implement patent laws in a way that will enable them to realise their duties towards healthcare. It also potentially strengthens the plans of the Kenyan and other governments to assert the rights of their AIDS/HIV population to affordable healthcare in the same fashion as the South African government<sup>42</sup>.

However, the continuing trade dispute between the US and Brazil, signifies that the future risks to health care latent in the implementation of TRIPS provisions. Audrey Chapman comments; "In the years ahead the provisions of TRIPS are likely to reshape intellectual property law and relationships within and across countries. Unless human rights advocates provide an effective intellectual and organisational counterweight to economic interests, the intellectual property landscape will be reshaped in the years ahead without adequate consideration of the impact on human rights".<sup>43</sup>

In recognition of the potential conflict existing between the implementation of the TRIPS Agreement and the realisation of economic, social and cultural rights, the Sub-Commission on the Promotion and Protection of Human Rights adopted a resolution addressing this topic at its 2000 session. It declares:

That since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS

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<sup>41</sup> Chapman, A., EC, p. 23

<sup>42</sup> See BBC World Service (6 March 2001) 'Kenya pushes for cheap AIDS drugs' at URL page: [http://news.bbc.co.uk/1/hi/english/world/africa/newsid\\_1205000/1205777.stm](http://news.bbc.co.uk/1/hi/english/world/africa/newsid_1205000/1205777.stm)

<sup>43</sup> Chapman, A., E/C.12/2000/12, p.3

Agreement on the one hand, and international human rights law on the other<sup>44</sup>.

In addition, the resolution reminds all governments of the primacy of human rights obligations over economic policies and agreements. And it makes a number of recommendations, among them that the WTO and particularly its council on TRIPS take existing state obligations under international human rights fully into account during its ongoing review of the TRIPS Agreement. The resolution also requests governments to protect the social function of intellectual property in accordance with international human rights obligations when shaping national and local legislation<sup>45</sup>.

### Reappraisal of government obligations

In response to the success of the South African government against the pharmaceutical companies attempting to block the implementation of the Medicines Act, campaigners were optimistic on the future of the availability of essential HIV/AIDS medicines, Ellen 't Hoen MSF legal advisor exclaimed; "Now nothing should stand in the way of countries who want to ensure long term access to affordable medicines."<sup>46</sup>

However, although the prices of essential drugs constitute a barrier to the achievement of their wider availability, other factors that facilitate effective healthcare must be considered. Inadequate and inequitable public spending on health infrastructure, weak planning, and failure to prioritise preventive interventions and ineffective service provision also limit the realisation of the symbolic rights enshrined in the constitution.

The fulfilment of effective health care requires a comprehensive effort that cannot be confined to the narrow issue of the cost of essential drugs. As well as ensuring economic availability of healthcare the government is obliged to a 'progressive' realisation of this right. In order to facilitate access to essential drugs and ensure their effectiveness, the government has to be able to monitor the use of drugs and supply adequate nutritional and medical infrastructure<sup>47</sup>. However, in the latest World Health Statistics on the health system attainment and performance, South Africa ranked

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<sup>44</sup> 'Intellectual Property Rights and Human Rights', Sub-Commission on the Promotion and Protection of Human Rights, Fifty-second, agenda item 4, E/CN.4/Sub.2/2000/7, adopted 17 August 2000, in Chapman, A., E/C.12/2000/12 p. 4

<sup>45</sup> Ibid

<sup>46</sup> 'Drug Companies In South Africa Capitulate Under Barrage of Public Pressure', TAC Press Release 19 April 2001.

<sup>47</sup> Thomas, S., Muheki, C., (2000) 'Public Sector Health financing' in South African Health Review, at URL page: <http://www.hst.org.za/sahr/2000/chapter5.htm>

poorly. In a measurement for the fairness of the financial contribution to its health system, it achieved a rank of 142-143 out of 191 countries. Similarly, in a measurement of the overall health system performance it achieved a worse score of 175 out of 191 countries included<sup>48</sup>.

The latest South African Health review reported that the funding of public health in South Africa had reached a critical juncture. It claimed that whilst what was done to improve equity in the funding of public health care in the first few years of democratic government, this trend appears to have reversed. Data on public health expenditure and human resources, from a recent National Health Accounts Projects revealed that from 1997 there have been declines in public per capita public funding of health care, increased inequity in provincial resource of the public health sector.<sup>49</sup>

This picture reflects a failure on the part of the government to realise its duty to provide 'progressive' realisation of its duties towards healthcare within its available resources. In addition the South African government has suffered criticism on its initial response to the AIDS crisis on two fronts. First, for its' initial scepticism towards the causal link between HIV and AIDS the subsequent lack of attention that had been paid to the prevention of mother to child transmission with regard to curbing the spread of HIV.

These criticisms have serious implications for the governments' ability to ensure that AIDS sufferers, the majority of whom rely on the public health sector have 'equal' access to the basic health care it requires. In response the government has recently developed a national HIV/AIDS strategy and accepted donations of fluconazole from Pfizer for use against opportunistic infections and of nevirapine from Boehringer Ingelheim for a programme to reduce mother to child transmission of HIV<sup>50</sup>. These are positive developments, however it is clear that the governments success against the pharmaceutical companies constitute, the means rather than the end of realising its duties regarding the health of HIV/AIDS sufferers.

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<sup>48</sup> The WHO's assessment system was based on five indicators: overall level of population health; health disparities within the population; overall level of health system responsiveness; how well people of varying economic status were served by the system, and the distribution of the health systems financial burden throughout the population. World Health Report at URL page; <http://filestore.who.int/~who/whr/2000/en/pdf/AnnexTable0.1.pdf>

<sup>49</sup> Thomas, S., Muheki, C., (2000) 'Public Sector Health financing' in *South African Health Review*, at URL page: <http://www.hst.org.za/sahr/2000/chapter5.htm>

## 'HIV/AIDS, an issue of domestic health care or a international emergency?'

The United States one of the strongest supporters of the intellectual property protection regimes recently capitulated in the face of international pressure on the issue in 1999, acknowledging its recognition of AIDS as an issue of global proportions with implications for international security<sup>51</sup>. Accordingly, the US under the Clinton administration, proclaimed its support for efforts on the part of African countries to secure affordable drugs for HIV/AIDS sufferers. Surprisingly, this line was reaffirmed by the Bush administration after issuing a statement that it would not seek sanctions against poor countries overwhelmed by the AIDS epidemic that try to force down the price of patented anti-AIDS drugs by legalising the manufacture of generic versions<sup>52</sup>.

International political developments accompanied by the swell of public and intellectual support global support for effective approaches towards the AIDS epidemic help to elucidate the complexity of the right to health. In respect of intellectual property rights it is clear that the implementation of the TRIPS agreement differs significantly from the substance of provisions which in theory reflect the requirement, in line with international human rights law to balance the right to intellectual property protection and the potential health benefits that property may provide to society. The recent success of the South African government seems likely to encourage some progressive refinements with regard to the future implementation of the TRIPS provisions and its implications for the international human right to health. Furthermore the question of international obligations concerning the right to health of HIV/AIDS suffers victims has been elevated on the international political agenda given the acknowledgement of AIDS as an issue of international security by the Security Council<sup>53</sup>. These developments corroborate the interdependent nature of these obligations at the national and international level forwarded in the Report of the Secretary General. States are encouraged to adopt a multi-sectoral approach, which includes greater

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<sup>50</sup> Oxfam Policy Papers (April 2001) 'Oxfam update on South African Court Case: South Africa vs. the drugs giants', at URL page: <http://www.oxfam.org.uk/policy/papers/safrica2.htm>

<sup>51</sup> By overwhelming Africa's health and social services, by creating millions of orphans, and by decimating health workers and teachers, is claimed that AIDS is causing social and economic crises which threaten political stability. See UNAIDS Press Release, (2001) AIDS Now Core Issue at United Nations Security Council, at URL page: [http://www.unaids.org/whatsnew/press/eng/pressarc01/newyork\\_190101.html](http://www.unaids.org/whatsnew/press/eng/pressarc01/newyork_190101.html)

<sup>52</sup> Mc Neil, G. (22 February 2001) 'Bush keeps Clinton Policy on Poor Lands need for AIDS Drugs' at URL page: <http://lists.essential.org/pipermail/pharmpolicy/2001-february/00709.html>.

<sup>53</sup> Security Council Resolution 13008 was adopted as a means to urge countries to address the HIV/ AIDS in the context of human security. See UNAIDS Press Release, (2001) AIDS Now Core Issue at United Nations Security Council, at URL page: [http://www.unaids.org/whatsnew/press/eng/pressarc01/newyork\\_190101.html](http://www.unaids.org/whatsnew/press/eng/pressarc01/newyork_190101.html)



awareness of their interconnected obligations regarding health, education as well as social services in the realisation of HIV/AIDS sufferers right to health and life. At the international level combination of approaches is advanced which requires: strengthening leadership, alleviating the social and economic impacts of the epidemic, reducing vulnerability, intensifying prevention, increasing care and support, providing international public goods (such as essential anti AIDS/HIV drugs)<sup>54</sup>. However ultimately, at both the national and international level resistance to the adoption of a holistic approach and the commitment of the required resources constitute more of an overt barrier to the realisation of health and associated obligations regarding HIV/AIDS than the highly politicised intellectual property protection. To overcome these connected obstacles requires both international and national political will in word and deed that complies with the various in obligations implicated in realising the human right to health *inter alia* of AIDS sufferers.

The principal issue is whether a human rights framework can help South Africa and all affected states to confront the AIDS crisis. More importantly this leads to the question of how such a framework can help to secure the urgent challenge of securing the vast resources needed for treatment and prevention. In an address to the plenary session of the International Conference on AIDS, the executive director of Human Rights Watch, Mr. Kenneth Roth posited that a human rights framework requires governments to address the crisis with appropriate urgency and transparency, which necessitates a participatory policy process. Furthermore it implies that obligations rising from the AIDS epidemic differ from those arising from other public health issues or from the general need for health care because of the magnitude of its potential international impact<sup>55</sup>.

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<sup>54</sup> Special Session on the General Assembly on HIV/AIDS, Fifty-fifth session, Agenda item 179, 'Review of the problem of human immunodeficiency syndrome Report of the Secretary General' A/55/779.

<sup>55</sup> Garbus, L., (2000) 'Human Rights and the AIDS crisis the debate over resources' in 13<sup>th</sup> International AIDS Conference Report, HIV In Site at URL page;  
[http://hivinsite.ucsf.edu/medical/conference\\_updates/3098.0711.html](http://hivinsite.ucsf.edu/medical/conference_updates/3098.0711.html)

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