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**PATENTS AND THE HIV/AIDS DRUGS CRISIS  
IN DEVELOPING COUNTRIES: A HUMAN  
RIGHTS-BASED APPROACH TO ACCESS TO  
HIV/AIDS TREATMENT.**

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**ABSTRACT**

The first three parts of this research paper analyses the balance between the competing human rights, namely the right to health (also the right to life and development) of the individuals affected by the lack of access to HIV/AIDS drugs, as against the property rights of the pharmaceutical companies manufacturing such drugs. In particular, the paper firstly explores whether the access to treatment and HIV/AIDS drugs, namely ARV medications, is a human rights issue and whether it forms part of the international human right to health. Secondly, the paper considers whether lawful actions by pharmaceutical corporations, acting within their property rights, such as blocking access to or making it difficult to access such treatment and drugs in developing nations, are in violation of the international human right to health. In respect to this, the paper looks at a case study and analyses the arguments advanced by the pharmaceutical industry in support of its stand on this issue. Finally, the paper shows how a balance may be struck between both those rights. The next part of this research paper considers the role of the World Trade Organisation (WTO) in relation to the right to health (including access to HIV/AIDS treatment) and patent matters. In particular, this section of the paper studies the WTO agreements, especially the TRIPS Agreement, and its dispute settlement process. Recent decisions declared by the WTO with regards to the interpretation of the TRIPS Agreement and public health matters are also considered here. Lastly, the paper attempts to show that a relationship between human rights and the WTO can be formed. The final part of this research paper looks at the role of the World Health Organisation (WHO) in improving access to HIV/AIDS treatment to developing countries. In particular, the steps already taken by the WHO and the steps to be taken to improve access to such treatment are considered, including having input in future WTO international trade agreements involving international public health matters.

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The text of this paper (excluding cover page, abstract, table of contents, footnotes and bibliography) comprises approximately 14,774 words.



## I. INTRODUCTION

The access to pharmaceutical drugs and treatment needs of the human immunodeficiency virus (HIV)<sup>1</sup> infected and acquired immunodeficiency syndrome (AIDS)<sup>2</sup> diagnosed persons in the developing part of the world provides an emotional battleground for fundamental human rights issues, such as the right to life and the right to health of those persons against the intellectual property rights of pharmaceutical companies that own the patents to those various HIV/AIDS medication. In most discussions about HIV and AIDS today, particularly about HIV/AIDS and intellectual property, human rights receive very little attention. Human rights law is a recognised body of law, just like intellectual property law. However, despite its power, a human rights framework is seldom used to analyse the forces fuelling the pandemic and to devise appropriate responses to them.<sup>3</sup>

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organisation's (WHO's) December 2003 Global Summary of the HIV/AIDS Epidemic,<sup>4</sup> forty million people in the world today are living with HIV/AIDS. Sub-Saharan Africa remains by far the region worst-affected by the HIV/AIDS epidemic. In 2003, an estimated 26.6 million people in the sub-Saharan region were living with HIV, including the 3.2 million who became infected during the year 2003 itself. AIDS killed approximately 2.3 million people in 2003. In sub-Saharan Africa, HIV prevalence has remained relatively steady, generally at high levels, for the past several years across much of the region. This is due to the fact that high levels of new HIV infections are persisting and are now matched by high levels of AIDS mortality.

<sup>1</sup> HIV is a retrovirus spread by the exchange of bodily fluids through non-casual contacts, such as intrauterine contact, contact during birth, breastfeeding, intravenous needle contamination and sexual intercourse. It attacks the immune system of its host, crippling the body's defense mechanisms over time and rendering it susceptible to various opportunistic infections. See <<http://www.cdc.gov/hiv/general.htm#cause>> (last accessed 20 December 2003).

<sup>2</sup> AIDS is a diagnosis made by a physician using certain clinical criteria, like presence of AIDS indicator illnesses or specific CD4+ counts. See <<http://www.cdc.gov/hiv/general.htm#cause>> (last accessed 20 December 2003).

<sup>3</sup> See generally Leonard S Rubenstein "Human Rights And Fair Access To Medication" (2003) 17 *Emory Int'l L Rev* 525.

<sup>4</sup> UNAIDS/WHO AIDS Epidemic Update, December 2003, available at <[http://www.who.int/hiv/pub/epidemiology/en/epiupdate2003\\_1\\_en.pdf](http://www.who.int/hiv/pub/epidemiology/en/epiupdate2003_1_en.pdf)> (last accessed 7 February 2004).



Many of the AIDS related deaths in sub-Saharan Africa could have been prevented through the provision of comprehensive HIV/AIDS care, in particular antiretroviral treatment. Since the advent of Highly Active Antiretroviral Therapy (HAART) in 1996, antiretroviral (ARV) medicines have dramatically reduced AIDS mortality and morbidity in developed countries, where such drugs are widely accessible.<sup>5</sup> The drugs are not a cure but they prolong life, suppress or prevent the entry of the virus into cells, and allow people living with HIV to continue their productive lives, to contribute to their families, their communities, and the social and economic life of their societies. Unfortunately, the vast majority of people living with HIV do not have access to HAART or even to more basic HIV care services. In Africa today, only 50,000 people, representing about one percent of the four million in urgent need of HAART, are on treatment.<sup>6</sup>

There is a raging debate about why these people, who are in dire need of life saving medicines, are not receiving HAART. Underdeveloped healthcare infrastructure, lack of HIV testing, lack of trained medical personnel, lack of education and lack of prevention and follow-up programmes are amongst the many arguments proffered. However, the largest single debate is focused on whether patent protection of those life saving pharmaceuticals in those developing countries (that is, the issue of affordability) is the primary or key obstacle to access to ARV drugs.

Patent protection plays a key role in promoting economic growth by offering incentives for investment in the development of new products. In fact, one of the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the most comprehensive multilateral international instrument on intellectual property, is that all member nations grant patents for any invention in all fields of technology, including pharmaceutical drug inventions. A patent grants its owner certain exclusive rights, such as the right to prevent third parties from making, using, offering for sale,

<sup>5</sup> Dr Timothy Mastro "The Global Fight Against HIV and AIDS – Current State Of The Global Epidemic" (2003) 17 *Emory Int'l L Rev* 413, 418.

<sup>6</sup> Julian Fleet "UN Approach To Access To Essential Aids Medications, Intellectual Property Law And The WTO TRIPS Agreement" (2003) 17 *Emory Int'l L Rev* 451, 452 & 453.



selling or importing the invention without the patent holder's consent.<sup>7</sup> Patents, thus, create temporary monopolies for their owners. This outcome is justified as a means to allow investors to recoup the costs of product development.

Patents serve as a barrier to market entry. One of the key determinants of pharmaceutical costs is the patent-status of a product. The TRIPS Agreement significantly altered the status quo of the patentability of pharmaceuticals. Before the TRIPS Agreement came about, many developing countries, who are now signatories to the TRIPS Agreement, did not have patent protection laws for pharmaceuticals. Developing countries which had the manufacturing capacity to produce pharmaceuticals, for example India and Brazil, were thus able to supply their populations with generic drug products, pre-TRIPS. However, with the introduction of pharmaceutical patent protections into these formerly unrestricted markets, drug prices significantly increased, inevitably blocking access to essential drugs, as they were no longer affordable.<sup>8</sup>

The ARV drugs that are widely patented in Africa tend to be those for which demand is highest for reasons of both cost and efficacy. For example, the World Health Organisation (WHO) highly recommends using AZT and 3TC drugs together, branded as Combivir by GlaxoSmithKline (GSK), as the first two of a standard "first-line" three-drug combination in developing countries. According to a study, the Attaran-White paper,<sup>9</sup> this is the most frequently patented ARV medicine in Africa, covered by patents in thirty seven African countries. As for the third drug in the cocktail, the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine (NVP), branded Viramune by Boehringer Ingelheim (BI), it is the cheapest in generic form. According to the Attaran-White paper, that key medicine (Viramune) for poor countries is blocked by patents in twenty-five African countries.<sup>10</sup>

<sup>7</sup> Agreement On Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 28.

<sup>8</sup> Kelley A Friedgen "Rethinking The Struggle Between Health & Intellectual Property: A Proposed Framework For Dynamic, Rather Than Absolute, Patent Protection Of Essential Medicines" (2002) 16 *Emory Int'l L Rev* 689, 695.

<sup>9</sup> Amir Attaran & Lee Gillespie-White "Do Patents For Antiretroviral Drugs Constrain Access To AIDS Treatment In Africa?" (2001) 286 *JAMA* 1886-1892.

<sup>10</sup> Sean Flynn "Legal Strategies For Expanding Access to Medicines" (2003) 17 *Emory Int'l L Rev* 535, 540.



According to a non-profit United States (US) based organisation, the Consumer Project on Technology (CPTech), in South Africa, a combination of AZT + 3TC + NVP costs over US\$2,000 a year at private sector wholesale prices (about US\$750 for public sector). Generic versions can be purchased for US\$200-\$400, including in three-drug fixed dose combinations (FDC) with all the medicines in a single pill. Such a three-drug FDC is not available from the brand companies because they do not cross license their products. South Africa has a gross domestic product per person of about US\$3000 a year and a HIV prevalence rate of about 4.7 million people (about ten percent of the population). The median household income is only about US\$1000 a year. It is fair to say that the US\$2000 price tag for ARV drugs in South Africa, and the US\$750 public sector price, puts the drugs far out of reach of most people in need.<sup>11</sup>

The first three parts of this research paper analyses the balance between the competing human rights, namely the right to health (also the right to life and development) of the individuals affected by the lack of access to ARV drugs, as against the property rights of the pharmaceutical companies manufacturing such drugs. In particular, the paper firstly explores whether the access to treatment and HIV/AIDS drugs, namely ARV medications, is a human rights issue and whether it forms part of the international human right to health. Secondly, the paper considers whether lawful actions by pharmaceutical corporations, acting within their property rights, such as blocking access to or making it difficult to access such treatment and drugs in developing nations, are in violation of the international human right to health. In respect to this, the paper looks at a case study and analyses the arguments advanced by the pharmaceutical industry in support of its stand on this issue. Finally, the paper shows how a balance may be struck between both the rights, that is, between the right to health (encompassing the right to access HIV/AIDS treatment) and the right to property (intellectual property rights).

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<sup>11</sup> Sean Flynn "Legal Strategies For Expanding Access to Medicines" (2003) 17 *Emory Int'l L Rev* 535, 540 & 541.



The next part of this research paper considers the role of the World Trade Organisation (WTO) in relation to the right to health (including access to HIV/AIDS treatment) and patent matters. In particular, this section of the paper studies the WTO agreements, especially the TRIPS Agreement, and its dispute settlement process. Recent decisions declared by the WTO with regards to the interpretation of the TRIPS Agreement and public health matters are also considered here. Lastly, the paper attempts to show that it is possible to form a relationship between human rights and the WTO.

The final part of this research paper looks at the role of the World Health Organisation (WHO) in improving access to HIV/AIDS treatment to developing countries. In particular, the steps already taken by the WHO and the steps to be taken to improve access to such treatment are considered, including having input in future WTO international trade agreements involving international public health matters.

## **II. ACCESS TO HIV/AIDS DRUGS AND HUMAN RIGHTS**

The International Bill of Human Rights consists of the Universal Declaration of Human Rights and the two primary human rights conventions, the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Social, Economic and Cultural Rights (ICESCR) and its two Optional Protocols.<sup>12</sup>

Adopted on 10 December 1948, the Universal Declaration of Human Rights (Universal Declaration) contains the whole range of human rights within one consolidated text. While it is not a formal treaty, the Universal Declaration has a special legitimacy in international law. The ICCPR and the ICESCR are

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<sup>12</sup> Details of the International Bill of Human Rights can be found at the website of the Office of the High Commissioner for Human Rights <<http://www.unhchr.ch/html/menu6/2/fs2.htm>> (last accessed 12 February 2004).



legally binding on those states that ratify them, obligating those states to respect, protect and fulfil the rights enshrined in the conventions.<sup>13</sup>

#### A. *The Specific Human Rights at Issue*

Human rights activists and commentators argue that access to affordable HIV/AIDS drugs is a human right or is a component of other internationally guaranteed human rights, such as the rights to health, life, development and enjoying the benefits of scientific progress. In 1946, WHO declared the right to health a fundamental human right. Subsequently, the Universal Declaration enshrined the right to health as a fundamental human right, and the ICESCR later legally obligated signatory States to respect, protect and fulfil the right to health.<sup>14</sup>

The preamble to the WHO Constitution provides, among others, that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."<sup>15</sup> Article 25(1) of the Universal Declaration affirms that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services ..."<sup>16</sup> The ICESCR, by virtue of Article 12, obligates State parties to "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."<sup>17</sup>

As the contours of the right to health are ill-defined in international law, it is unclear whether the right to health under international law specifically encompasses the right to access HIV/AIDS medications/affordable drugs. As stated above, the Universal Declaration recognizes that "Everyone has the right to

<sup>13</sup> See <<http://www.unhchr.ch/html/menu6/2/fs2.htm>> (last accessed 12 February 2004).

<sup>14</sup> See generally Lissett Ferreira "Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations Of Multinational Pharmaceutical Corporations" (2002) 71 Fordham L Rev 1133, 1162.

<sup>15</sup> See <[http://policy.who.int/cgi-bin/om\\_isapi.dll?hitsperheading=on&infobase=basicdoc&record={9D5}&softpage=Document42](http://policy.who.int/cgi-bin/om_isapi.dll?hitsperheading=on&infobase=basicdoc&record={9D5}&softpage=Document42)> (last accessed 15 December 2003).

<sup>16</sup> See <<http://www.unhchr.ch/udhr/lang/eng.htm>> (last accessed 18 February 2004).

<sup>17</sup> See <[http://www.unhchr.ch/html/menu3/b/a\\_ceschr.htm](http://www.unhchr.ch/html/menu3/b/a_ceschr.htm)> (last accessed 18 February 2004).



... medical care.” Additionally, the ICESCR requires States to take necessary steps to achieve full realisation of the right to health, such as “the prevention, treatment and control of epidemic ... diseases”<sup>18</sup> and “the creation of conditions which would assure to all medical service and medical attention in the event of sickness.”<sup>19</sup> Thus, many activists and scholars argue that “access to medicines is an essential part of access to health”.<sup>20</sup>

Several recent developments suggest that the right of access to medical treatment may be a component of the right to health. For example, the United Nations (UN) Committee that supervises the implementation of the ICESCR has interpreted the right to health guaranteed in the ICESCR to include the rights to treatment of epidemic diseases, access to affordable health services, and the provision of essential drugs. In its General Comment 14, the Committee further specifies that States’ duties to protect the right to health include “the duties ... to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties”, as well as to “ensure that third parties do not limit people’s access to health-related information and services.”<sup>21</sup> Whilst the committee’s interpretations are not legally binding, they may, however, be said to have considerable legal weight. Thus, some scholars argue that State signatories to the ICESCR have a binding obligation to protect and promote the right to health by guaranteeing affordable health care, including providing access to drugs.<sup>22</sup>

Furthermore, the UN Commission on Human Rights has passed a resolution recognising that access to HIV/AIDS medications is “one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.<sup>23</sup>

<sup>18</sup> International Covenant on Economic, Social and Cultural Rights, Article 12(2)(c).

<sup>19</sup> International Covenant on Economic, Social and Cultural Rights, Article 12(2)(d).

<sup>20</sup> Lissett Ferreira “Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations Of Multinational Pharmaceutical Corporations” (2002) 71 *Fordham L Rev* 1133, 1162 & 1163.

<sup>21</sup> See E/C.12/2000/4, CESCR General Comment No. 14, paragraph 35, available at <<http://www.unhchr.ch/tbs/doc.nsf/8e9c603f486cdf83802566f8003870e7/40d009901358b0e2c1256915005090be?OpenDocument#3>> (last accessed 12 February 2004).

<sup>22</sup> Lissett Ferreira “Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations Of Multinational Pharmaceutical Corporations” (2002) 71 *Fordham L Rev* 1133, 1163.

<sup>23</sup> Resolution entitled “Access to medication in the context of pandemics such as HIV/AIDS” E/CN.4/RES/2002/32



The resolution further calls on States to pursue policies to ensure the availability of HIV/AIDS medications.

Most recently, the UN revised and updated its International Guidelines on HIV/AIDS and Human Rights "to reflect new standards in HIV treatment and evolving international law on the right to health."<sup>24</sup> The new revised Guideline 6 specifically asserts that States should "take measures necessary to ensure for all persons ... the availability and accessibility of quality goods, services and information for HIV/AIDS prevention, treatment, care and support, including antiretroviral and other safe and effective medicines ..."<sup>25</sup>

In addition to these developments under international law, there is also recent domestic case law defining the right to health to include the right to access HIV/AIDS drugs/treatment. In *Cruz Bermúdez, et al v Ministerio de Sanidad y Asistencia Social*, the Venezuelan Supreme Court held that the national government violated the right to access HIV/AIDS drugs by failing to provide its citizens with those drugs.<sup>26</sup> In that case, the court reached its holding that the right to health included the right to access to treatment by taking into account both the Venezuelan Constitution and unspecified "international legal principles."<sup>27</sup>

Similarly, the South African High Court held that the national government breached the right to health by failing to provide HIV/AIDS treatment to pregnant women who are HIV positive, in order to prevent mother-to-child HIV transmission.<sup>28</sup> However, unlike the court in *Cruz Bermúdez*, the South African court reached its holding that access to HIV/AIDS drugs was a right to health on

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<[http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/E.CN.4.RES.2002.32.En?Opendocument](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.RES.2002.32.En?Opendocument)> (last accessed 12 February 2004).

<sup>24</sup> HIV/AIDS and Human Rights International Guidelines, Third International Consultation on HIV/AIDS and Human Rights, Foreword, page 5 <<http://www.unhchr.ch/hiv/g6.pdf>> (last accessed 12 February 2004).

<sup>25</sup> HIV/AIDS and Human Rights International Guidelines, Third International Consultation on HIV/AIDS and Human Rights, Revised Guideline 6, page 14 <<http://www.unhchr.ch/hiv/g6.pdf>> (last accessed 12 February 2004).

<sup>26</sup> See generally Mary Ann Torres "The Human Right To Health, National Courts, And Access To HIV/AIDS Treatment: A Case Study From Venezuela" (2002) 3 Chi J Int'l L 105.

<sup>27</sup> Mary Ann Torres "The Human Right To Health, National Courts, And Access To HIV/AIDS Treatment: A Case Study From Venezuela" (2002) 3 Chi J Int'l L 105, 111.

<sup>28</sup> See *Treatment Action Campaign & Others v The Minister of Health & Others*, No. 2182/2001 (unreported) <<http://www.tac.org.za>> (last accessed 2 November 2003).



the basis of the South African constitution alone, and did not explicitly recognize access to HIV/AIDS treatment as an internationally guaranteed right.<sup>29</sup>

According to one commentator, in addition to the right to health, other internationally guaranteed human rights may be linked to access to affordable HIV/AIDS treatment.<sup>30</sup> During the controversy in South Africa, for example, human rights activists linked the right to access HIV/AIDS drugs to the right to life. Under Article 3 of the Universal Declaration, "Everyone has the right to life, liberty and the security of person."<sup>31</sup> Further, Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR) states that "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life".<sup>32</sup> In its general comment interpreting the right to life in the ICCPR, the UN Human Rights Committee noted that the:<sup>33</sup>

[R]ight to life has been too often narrowly interpreted. The expression 'inherent right to life' cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for State parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.

Access to HIV/AIDS drugs may also be tied to the right to development. The right to development is guaranteed in the Universal Declaration, which specifies that "Everyone is entitled to a social and international order in which the rights ... set forth in this Declaration can be fully realised."<sup>34</sup> Moreover, the Declaration on the Right to Development<sup>35</sup> further defines the right to

<sup>29</sup> Ferreira, above, 1164.

<sup>30</sup> Ferreira, above, 1165.

<sup>31</sup> Universal Declaration of Human Rights, Article 3 <<http://www.unhchr.ch/udhr/lang/eng.htm>> (last accessed 12 February 2004).

<sup>32</sup> International Covenant on Civil and Political Rights, Article 6(1) <[http://www.unhchr.ch/html/menu3/b/a\\_ccpr.htm](http://www.unhchr.ch/html/menu3/b/a_ccpr.htm)> (last accessed 12 February 2004).

<sup>33</sup> Sixteenth Session (1982), General Comment No. 6, Article 6 of the ICCPR <[http://www.hshr.org/General%20Comment%20Files/ICCPR\\_GC6.htm](http://www.hshr.org/General%20Comment%20Files/ICCPR_GC6.htm)> (last accessed 15 February 2004).

<sup>34</sup> Universal Declaration of Human Rights, Article 28.

<sup>35</sup> Declaration on the Right to Development, GA res 41/128, annex, 41 UN GAOR Supp (No 53) at 186, UN Doc A/41/53 (1986) <<http://www1.umn.edu/humanrts/instree/s3drd.htm>> (last accessed 15 February 2004).



development, recognizing the right to development as “an inalienable human right,”<sup>36</sup> and giving States the right and duty “to formulate appropriate national development policies ... on the basis of ... the fair distribution of the benefits resulting.”<sup>37</sup> Specifically, the Declaration on the Right to Development urges States to take all of the necessary steps to ensure “equality of opportunity for all in their access to ... health services.”<sup>38</sup>

Similarly, some argue that “to give effect to [the rights to share in scientific advancement and its benefits] dictates, at the very least, the need for reasonable exceptions to protection that allow for research and development by third parties.”<sup>39</sup> The right to share in scientific progress is also guaranteed under international law. For example, Article 27(1) of the Universal Declaration states that “Everyone has the right ... to share in scientific advancement and its benefits.” Similarly, the ICESCR guarantees all persons the right “To enjoy the benefits of scientific progress and its applications.”<sup>40</sup> Access to HIV/AIDS drugs and treatment, which exist as a benefit of scientific progress, is thus necessary for the realisation of the right to health and the highest attainable standard of health.<sup>41</sup>

#### ***B. Counter Arguments to the View that the Right to Health Includes Access to HIV/AIDS Drugs***

The development thus far of the interpretation of the right to health, as an international legal principle, to include access to HIV/AIDS drugs and treatment has not been without controversy. Arguments have been advanced to reject the notion that the right to health includes access to medications. These arguments are analysed below.

<sup>36</sup> Declaration on the Right to Development, above, Article 1(1).

<sup>37</sup> Declaration on the Right to Development, above, Article 2(3).

<sup>38</sup> Declaration on the Right to Development, above, Article 8(1).

<sup>39</sup> Ferreira, above, 1166.

<sup>40</sup> International Covenant on Economic, Social and Cultural Rights, Article 15(1)(b).

<sup>41</sup> Barbara Cochrane Alexander “Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health? (2001) 8 Hum Rts Br 12, 13.



In the Venezuelan case mentioned above (the *Cruz Bermúdez* case), the Venezuelan Ministry of Health rejected the accusation that the government violated the plaintiffs' rights to life, health and access to scientific advances protected under Venezuelan law. The Ministry's main defence rested on economics, that is, that the government could not pay for ARV therapy and related medicines for all Venezuelan people living with HIV and/or AIDS because such expenses would be impossible to sustain. The Ministry pointed to programmes on HIV/AIDS prevention it had started, for example, distributing information booklets and condoms and implementing a 'safe sex' initiative, as evidence that it was fulfilling its obligations toward health under Venezuelan law given its financial constraints.<sup>42</sup>

In the *Cruz Bermúdez* case, however, the Ministry of Health's arguments regarding the financial difficulties of increasing access to ARV therapies did not hold water, as with arguments frequently advanced by governments in connection with questions about their commitment to the right to health under international law. Under the ICESCR, the right to health is to be achieved progressively, and the determination about how resources are allocated in this progressive project is left to the responsible individual governments. In the *Cruz Bermúdez* case, the Ministry of Health argued that it was progressively achieving improvements in connection with HIV/AIDS under the budget constrains it faced as a health ministry in a developing country.<sup>43</sup>

According to one commentator, the Ministry of Health's arguments in the *Cruz Bermúdez* case echo much of what experts have faced in dealing with the HIV/AIDS pandemic since the 1980s. This pandemic highlights the problems that economic, social and cultural rights confront as elements of contemporary international law. Inadequate financial resources, unequal and uneven economic development, poverty, social injustice and other problems endemic in the developing part of the world have fuelled the HIV/AIDS pandemic and severely

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<sup>42</sup> Mary Ann Torres "The Human Right To Health, National Courts, And Access To HIV/AIDS Treatment: A Case Study From Venezuela" (2002) 3 Chi J Int'l L 105, 110.

<sup>43</sup> Mary Ann Torres "The Human Right To Health, National Courts, And Access To HIV/AIDS Treatment: A Case Study From Venezuela" (2002) 3 Chi J Int'l L 105, 111.



constrain what the governments of developing countries can do to respect, protect and fulfil the right to health.<sup>44</sup>

There are several reasons why governments in developing countries are reluctant to equate access to HIV/AIDS drugs as a right to health and therefore slow to implement proven public health strategies to respect, protect and fulfil the right to health. Absence of committed political leadership and inadequate funding are some of the examples.

The South African President, Thabo Mbeki, as pointed out by one commentator,<sup>45</sup> exemplifies the inaction of some leaders. Mbeki has questioned whether HIV actually causes disease, stating, “[y]ou cannot attribute immune deficiency solely and exclusively to a virus.” Such scepticism of science by a respected political leader seriously undermines HIV/AIDS education and prevention. President Mbeki has also openly doubted the accuracy of his own Department of Health estimates of the national HIV prevalence among pregnant women. The data, based on annual unlinked, anonymous HIV surveys among women attending antenatal clinics, demonstrate a thirty-fold increase in HIV prevalence, from 0.7% in 1990 to 22.4% in 1999. For several years, the Ministry of Health, under President Mbeki, resisted full implementation of UNAIDS guidelines for short-course antiretroviral therapy for pregnant women, even though it had been demonstrated to be cost effective in South Africa.<sup>46</sup>

Fortunately, as further pointed out by the same commentator, there have been competing voices about the dangers of political inaction from the African National Congress.<sup>47</sup> Former South African President Nelson Mandela observed: “Nothing threatens us more today than HIV/AIDS. AIDS is a scourge threatening to undo all the gains we made in our generations of struggle.” More radically, the Premier of KwaZulu-Natal, the South African province most affected by

<sup>44</sup> Torres, above, 111.

<sup>45</sup> Lawrence O Gostin “The Global Reach of HIV/AIDS: Science, Politics, Economics, And Research” 17 *Emory Int’l L Rev* 1, 23.

<sup>46</sup> Lawrence O Gostin “The Global Reach of HIV/AIDS: Science, Politics, Economics, And Research” 17 *Emory Int’l L Rev* 1, 23.

<sup>47</sup> Lawrence O Gostin “The Global Reach of HIV/AIDS: Science, Politics, Economics, And Research” 17 *Emory Int’l L Rev* 1, 23 & 24.



HIV/AIDS, declared that he would distribute drugs to pregnant women with AIDS, in direct violation of central government policy. Further, the Constitutional Court of South Africa drastically altered government policy in the 2002 court case, *Minister of Health and Others v Treatment Action Campaign and Others (TAC)*, when it upheld a request by TAC to provide nevirapine (NVP), an antiretroviral drug available to the government free of charge, to pregnant mothers at public hospitals.<sup>48</sup>

### **III. ACCESS TO HIV/AIDS DRUGS AND INTELLECTUAL PROPERTY RIGHTS**

As pointed out above, access to HIV/AIDS drugs and treatment, or lack thereof, highlights the tension that exists between the protection of intellectual property rights and the rights of HIV/AIDS victims to be provided with access to the drugs/treatment. Manufacturers of essential medicines hold patents on the drugs they produce and are able to charge unreasonable and unaffordable prices for their products. Patent protection also leads to the untenable situation where governments cannot ensure that these drugs are produced at a cheaper price in their own countries (via compulsory licenses and/or voluntary licenses). In other cases, patent protection makes it difficult for countries to purchase these drugs where they are sold at a cheaper price (that is, through parallel importation).<sup>49</sup>

This section focuses on the stand taken by the pharmaceutical industry in respect of the issue of patents and the lack of access to HIV/AIDS drugs. In particular, the legal action taken by the pharmaceutical industry against the South African Government is studied below. The section further analyses the arguments advanced by the pharmaceutical industry in support of its stand. Lastly, the section considers whether the actions of the pharmaceutical industry in blocking access to HIV/AIDS drugs constitutes a breach of international human rights, in particular the right to health.

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<sup>48</sup> Gostin, above, 24.

<sup>49</sup> Jennifer Joni "The Global AIDS Crisis: Access to Treatment for HIV/AIDS: A Human Rights Issue in the Developing World" (2002) 17 *Conn J Int'l L* 273, 275.



*A. Access to HIV/AIDS Drugs and the Pharmaceutical Industry's Stance: the South African Case Study*<sup>50</sup>

The issues at stake in the debate over developing countries' efforts to make HIV/AIDS drugs more accessible are well-illustrated by South Africa's attempts to widen access to HIV/AIDS drugs and by the lawsuit that the pharmaceutical industry brought against the government to challenge that law. The post-apartheid Constitution guarantees South Africans the right to health care. To meet its constitutional duty, South Africa adopted a national policy of promoting access to essential drugs. In 1997, to further that policy, the South African Parliament passed the Medicines Act Amendment, granting the Minister of Health broad power to ensure access to affordable drugs.<sup>51</sup>

Among other provisions to make HIV/AIDS drugs more affordable, the new law authorised the Minister of Health to adopt regulations requiring pharmacists to prescribe generic versions of drugs. The amendment further authorised the Minister to form a pricing committee, which is empowered to recommend a transparent pricing system for medicines. This provision would force pharmaceutical companies to justify the prices they charge and prevent pharmacists from over pricing drugs.<sup>52</sup>

The most controversial provision of the amendment is section 10, which provides:<sup>53</sup>

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may:

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any

<sup>50</sup> The facts and chronology of events of this case study is available at <<http://www.tac.org.za/>> (last accessed 20 February 2004).

<sup>51</sup> See generally Lissett Ferreira "Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations Of Multinational Pharmaceutical Corporations" (2002) 71 Fordham L Rev 1133, 1148.

<sup>52</sup> Ferreira, above, 1149.

<sup>53</sup> Medicines and Related Substances Control Amendment Act, No. 90 of 1997, available at <<http://www.gov.za/acts/97index.html>> (last accessed 17 February 2004).



medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

There has been considerable debate over the scope of the Health Minister's powers and the precise meaning of the provisions of section 10. On the one hand, the South African Government intended the law only to provide for parallel importing and generic substitution. On the other hand, the pharmaceutical industry interpreted the amendment to give the government much broader power. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the law appears to allow the Minister of Health to revoke pharmaceutical patents in violation of South African law and the TRIPS Agreement. The pharmaceutical industry considered the amendment a violation of both the South African Constitution and the TRIPS Agreement, and thus brought a suit against the South African government.<sup>54</sup>

The next few sections analyse the arguments advanced by both the pharmaceutical industry and the South African Government in the said legal action.

### *1. Constitution arguments*

The pharmaceutical industry attacked the new South African amendment as unconstitutional because it interpreted Section 10 to give the Minister of Health overly broad powers of implementation, thereby effectively allowing the

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<sup>54</sup> Ferreira, above, 1150.



government to deprive the pharmaceutical companies of their constitutional right to property. The pharmaceutical industry also specifically attacked the constitutionality of, among other provisions, the law's sections providing for generic drug substitution and a drug pricing committee, in that the industry was unfairly being discriminated against in favour of the generic manufacturers. In reply to those allegations, the South African government argued that it had an express constitutional duty to provide health care to its citizens, and that the Medicines Act Amendment is critical to meeting that duty.<sup>55</sup>

## 2. *TRIPS and intellectual property arguments*

The pharmaceutical industry also claimed that the South African law violated the TRIPS Agreement on several grounds. In their complaint, the pharmaceutical companies asserted that the new South African law was inconsistent with Article 27 of the TRIPS Agreement, because it discriminated against pharmaceutical patents by providing lesser protections for pharmaceuticals than for other inventions.<sup>56</sup> Article 27 of the TRIPS Agreement provides that "...patents shall be available for any inventions, whether products or processes, in all fields of technology, ..." Therefore, the industry was of the opinion that their pharmaceutical patents should not be treated differently from any other patents.

To counter this argument, it is important to note that Article 27 of the TRIPS Agreement must be interpreted in light of the objectives and principles of the TRIPS Agreement, as laid out in Articles 7 and 8 of the TRIPS Agreement respectively. The objectives outlined in Article 7 call for the protection and enforcement of intellectual property rights to contribute to the "promotion of technological innovation ... to the mutual advantage of producers and users ... and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".<sup>57</sup> The Medicines Amendment Act may be viewed as a mechanism employed by the South African Government to ensure intellectual property rights are protected and enforced in a manner conducive to social (in

<sup>55</sup> Ferreira, above, 1150 & 1151.

<sup>56</sup> Ferreira, above, 1151.

<sup>57</sup> Agreement On Trade-Related Aspects Of Intellectual Property Rights, Article 7.



view of the HIV/AIDS epidemic conditions in South Africa) and economic welfare.<sup>58</sup>

Furthermore, Article 8 provides that member States "may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition ... provided that such measures are consistent with the provisions of this Agreement".<sup>59</sup> The new South African law also represents a measure necessary to protect public health, in light of South Africa's public health crisis. Article 8 also highlights the potential need for appropriate measures, consistent with TRIPS, "to prevent the abuse of intellectual property rights by right holders". According to one commentator,<sup>60</sup> it is not impossible, given the present epidemic conditions in South Africa, that pharmaceutical company patent rights holders may be abusing their intellectual property rights in South Africa. The limited supply of drugs produced or imported into South Africa, and the exorbitant South African prices on HIV/AIDS drugs demonstrate abuse of intellectual property rights under present conditions.<sup>61</sup>

The pharmaceutical industry further argued that, as written, the new law delegated broad powers to the Minister of Health that would enable the government to import generic versions of patented drugs, as well as to issue compulsory licenses for the local manufacture of generics under conditions beyond those that the TRIPS Agreement specifies.<sup>62</sup> Article 31 of the TRIPS Agreement allows member countries to participate in compulsory licensing. However, this licensing will be permitted only if the proposed user makes reasonable efforts to obtain authorisation from the right holder of the patent.<sup>63</sup> The proposed user must satisfy several other conditions, including making a showing that the authorisation will only be used to supply the country's domestic market.<sup>64</sup>

<sup>58</sup> See Kara M Bombach "Can South Africa Fight AIDS? Reconciling The South African Medicines And Related Substances Act With The TRIPS Agreement" (2001) 19 B U Int'l L J 273, 293.

<sup>59</sup> Agreement On Trade-Related Aspects Of Intellectual Property Rights, Article 8.

<sup>60</sup> Kara M Bombach "Can South Africa Fight AIDS? Reconciling The South African Medicines And Related Substances Act With The TRIPS Agreement" (2001) 19 B U Int'l L J 273, 294.

<sup>61</sup> Kara M Bombach "Can South Africa Fight AIDS? Reconciling The South African Medicines And Related Substances Act With The TRIPS Agreement" (2001) 19 B U Int'l L J 273, 294.

<sup>62</sup> Ferreira, above, 1151.

<sup>63</sup> Agreement On Trade-Related Aspects Of Intellectual Property Rights, Article 31(b).

<sup>64</sup> Agreement On Trade-Related Aspects Of Intellectual Property Rights, Article 31(f).



Prior to the passage of the Medicines Act Amendment, South Africa already had limited power to issue compulsory licenses under the South African Patents Act of 1978. Section 4 of the Patents Act of 1978 provides that:

[A] Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.

Thus, the South African government argued that its existing Patents Act of 1978 already provided for compulsory licensing, that the amendment introducing the new law was not designed to permit compulsory licensing, and that the government only intended to use the new law for parallel importing.<sup>65</sup>

In any event, even if the South African Government did intend the new law to cover compulsory licensing, it is submitted that the new law, contrary to the pharmaceutical industry's argument, would not be inconsistent with the TRIPS Agreement. This is because Article 31(b) of the TRIPS Agreement allows the requirement for gaining the right holder's authorisation to be waived in "the case of a national emergency or other circumstances of extreme urgency". Even though South Africa had not officially declared the AIDS crisis a national emergency at that time, the HIV/AIDS pandemic may constitute a national emergency for the purposes of the TRIPS Agreement. Moreover, the TRIPS Agreement does not seem to require a legal declaration of a "state of national emergency". However, if it did, then this case could at least qualify for the broader "circumstance of extreme urgency" language of Article 31. The rapid rate of HIV infection and AIDS death in South Africa is recognised as a case of extreme urgency.<sup>66</sup>

Outside the courtroom, the industry also levelled broader challenges to the law's validity under the TRIPS Agreement, claiming, for example, that the amendment violated Article 28 of the TRIPS Agreement by allowing parallel

<sup>65</sup> Ferreira, above, 1152.

<sup>66</sup> Bombach, above, 289 & 290.



importing.<sup>67</sup> This argument may, however, be countered by the fact that Article 6 of the TRIPS Agreement allows member States to engage in parallel importing by specifically abstaining from the issue of exhaustion, thus allowing member States to adopt whatever national policy they deem appropriate on the issue of exhaustion. Therefore, by permitting member States to adopt the principle of international exhaustion of patent rights, member States' Governments could allow parallel imports.<sup>68</sup> Hence, it may be argued that there is no violation of Article 28 of the TRIPS Agreement.

South Africa appears to have kept its promise that the new law was intended only for parallel importing and not to permit compulsory licensing, since in the proposed regulations that the government later issued pursuant to the amended law, the government only provided for parallel importing.<sup>69</sup>

The debate over the law's validity under the TRIPS Agreement spilled out of the courtroom and into the global community, and was taken up by scholars, activists, government officials, and multilateral organisations. The United States (US) government initially adopted the industry's stance, opposing the law because it was "potentially" in violation of the TRIPS Agreement (see arguments advanced by the pharmaceutical industry as discussed above), was overly broad, and gave the Minister of Health excessive power. Consistent with its TRIPS-plus policy, the US repeatedly sought assurances from South Africa that the Medicines Act Amendment would not be implemented to allow parallel imports or compulsory licensing of pharmaceuticals. According to a group of organisations that met with representatives of the US government, however, the United States failed to articulate the precise provisions of the TRIPS Agreement it believed that South Africa's law violated.<sup>70</sup>

Eventually, the pharmaceutical companies dropped their claim that the Medicines Act Amendment violated the TRIPS Agreement and limited their legal

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<sup>67</sup> Ferreira, above, 1151.

<sup>68</sup> Bombach, above, 289.

<sup>69</sup> Ferreira, above, 1152.

<sup>70</sup> Ferreira, above, 1152 & 1153.



action to challenging the law on constitutional grounds.<sup>71</sup> In April 2001, however, after widespread negative publicity, the pharmaceutical companies withdrew their lawsuit all together and reached an out-of-court settlement with the South African Government. The pharmaceutical companies agreed to cooperate with South Africa to provide HIV/AIDS drugs at lower costs, and the South African Government agreed both to honour the TRIPS Agreement and to consult with the pharmaceutical industry on the proposed amendment. While PhRMA claims that the legal challenge was dropped because the South African Minister of Health promised to redraft the law, many commentators attribute the resolution of the legal challenge to the negative publicity that surrounded the lawsuit.<sup>72</sup>

Although the South African lawsuit was resolved and some programmes have been implemented since to provide wider access to HIV/AIDS drugs in developing countries, HIV/AIDS drugs still remain inaccessible and unaffordable to the majority of HIV-infected people in developing countries. The drug donations and discounts offered by pharmaceutical companies are not permanent solutions to the lack of access to affordable HIV/AIDS drugs.<sup>73</sup>

Furthermore, the pharmaceutical corporations and the American government continue to exert their substantial influence to prevent developing countries from implementing laws like South Africa's Medicines Act Amendment. For example, the pharmaceutical industry recently opposed the enactment of Kenyan legislation that would allow compulsory licensing and parallel importing to make HIV/AIDS drugs cheaper. Despite enacting laws permitting compulsory licensing, developing countries are reluctant to follow through and issue compulsory licenses for HIV/AIDS drugs because of pressure from the pharmaceutical industry and the American government it lobbies. Thus, developing nations continue to struggle with the problem of ensuring affordable HIV/AIDS drugs to their populations, while the pharmaceutical industry and the United States continue to challenge these efforts by such developing countries,

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<sup>71</sup> Ferreira, above, 1153.

<sup>72</sup> Ferreira, above, 1156 & 1157.

<sup>73</sup> Ferreira, above, 1157.



arguing that the efforts undermine intellectual property rights and international obligations under the TRIPS Agreement.<sup>74</sup>

### ***B. Other Arguments Advanced by the Pharmaceutical Industry***

Besides the arguments raised by the pharmaceutical industry in the case against the South African Government (as pointed out above), there are other arguments proffered by the pharmaceutical industry in further support of their stand. These arguments are considered in general below.

#### *1. Patents not a barrier*

The pharmaceutical industry denies that patents are responsible for the lack of access to HIV/AIDS drugs in developing countries. The pharmaceutical industry, instead, blames other barriers for the lack of access to HIV/AIDS medications. (Other barriers the pharmaceutical industry points to are poverty, poor health infrastructure, the lack of government commitment to combating HIV/AIDS and other cultural barriers in the developing part of the world.<sup>75</sup>) Whilst both advocates and opponents of HIV/AIDS treatment access agree that high prices or protectionist laws are not the only barriers to providing high quality HIV/AIDS care in the developing part of the world, they do, nevertheless, recognise that it is an important barrier.

According to one article,<sup>76</sup> the problems of fair and efficient methods of dissemination of HIV/AIDS drugs in developing countries may, compared to the price barrier, be an even more difficult problem or bigger barrier to overcome. Allocation and distribution of drugs within crowded cities, among homeless people, and in remote villages requires organised transportation and communication systems. In some developing countries, the health care system

<sup>74</sup> Ferreira, above, 1157 & 1158.

<sup>75</sup> Ferreira, above, 1139.

<sup>76</sup> Lawrence O Gostin "The Global Reach of HIV/AIDS: Science, Politics, Economics, And Research" 17 Emory Int'l L Rev 1, 38.



may not be capable of accurately diagnosing HIV, monitoring viral load and checking for adverse reactions. Patients must also be educated correctly about the strict regimen of taking medications, especially the ARV drugs.

Further, notwithstanding the fact that even if distribution is achieved in developing countries, ARV drugs may not be prescribed or taken appropriately. Incorrect or intermittent use of ARV medications could create serious health risks for individual patients and pose a wider risk to the population. One of the principal concerns of pharmaceutical companies is that the HIV virus could become resistant to existing medicines, rendering them less effective. The problems of resistance to ARV medications already exist and they would be exacerbated by large scale distribution to patients in developing countries who do not have the health care and support systems needed to ensure appropriate use.<sup>77</sup>

## 2. *Inflated prices justified*

According to the pharmaceutical industry, the drug development process is lengthy, costly, and risky. Patent rights, which allow the inventors of new drugs to charge high prices, are necessary to provide incentives for the research and development of new drugs to treat diseases such as HIV/AIDS. Without patent protection, pharmaceutical companies will no longer allocate their resources to finding new HIV/AIDS drugs.<sup>78</sup>

However, according to one commentator,<sup>79</sup> since the pharmaceutical industry traditionally has failed to disclose its research and development investments, many accuse the pharmaceutical industry of inflating the research and development costs that form the basis for the industry's justification to artificially high prices. The industry's critics assert that the pharmaceutical industry spends twice as much on marketing rather than on research and development efforts. Some critics also assert that the industry's very high profitability itself belies any claims about the risks involved in the development of

<sup>77</sup> See generally Gostin, above, 39.

<sup>78</sup> See generally Ferreira, above, 1142.

<sup>79</sup> Ferreira, above, 1142.



new drugs. Additionally, they point out that the development of new drugs is frequently subsidised heavily by the taxpayer's money and performed in publicly-funded laboratories. Thus, critics not only question the research and development claims that the industry uses to justify its inflated prices, but some also argue that it is unfair for pharmaceutical companies to reap huge profits from the inflated prices they charge for products developed using taxpayer's money.<sup>80</sup>

**C. *Pharmaceutical Industry's Actions in Blocking Access to HIV/AIDS Drugs: A Violation of the International Human Right to Health?***

By their actions in blocking access to HIV/AIDS drugs, do these patent holders (that is, the pharmaceutical corporations) violate the international human right to health? According to one commentator,<sup>81</sup> two international legal instruments help formulate strong legal arguments for corporate human rights liability. The first is the Universal Declaration of Human Rights (Universal Declaration), which states in its Preamble that "every organ of society ... shall strive ... to promote respect for these rights and freedom and ... to secure their universal and effective recognition." A pharmaceutical corporation may be argued to be an "organ of society". This argument may be supported by the notion that if the drafters of the Universal Declaration intended to limit the scope of who should promote and recognise human rights to just public bodies and/or member States, the phrase "every State" instead of "every organ of society" would have been used by the said drafters.

The second international instrument, which affirms the Universal Declaration, is the United Nations Declaration on the Rights and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognised Human Rights and Fundamental Freedoms (Human Rights Defenders Declaration).<sup>82</sup> According to the Human Rights Defenders Declaration,

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<sup>80</sup> Ferreira, above, 1142.

<sup>81</sup> Barbara Cochrane Alexander "Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health? (2001) 8 Hum Rts Br 12, 14.

<sup>82</sup> See Barbara Cochrane Alexander "Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health? (2001) 8 Hum Rts Br 12, 14.



“individuals, groups, institutions and non-governmental organisations have an important role to play and a responsibility in safeguarding democracy, promoting human rights and fundamental freedoms and contributing to the promotion and advancement of democratic societies, institutions and processes.”<sup>83</sup>

However, the commentator concludes that although the two international legal instruments outlined above lend some legal precedent in setting forth the possibility of corporate responsibility for human rights violation, pharmaceutical corporations are unlikely to agree that they have any legal responsibility in respect of an international human right to health.<sup>84</sup>

Sources of corporate responsibility for human rights can also be found in other international instruments/documents such as, the International Labour Organisation’s Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy (the ILO Declaration)<sup>85</sup> and the Organisation for Economic Co-Operation and Development’s guidelines (OECD Guidelines) for multinational companies.<sup>86</sup> Presumably, the obligations in the ILO Declaration and OECD Guidelines would be applicable to major pharmaceutical corporations (operating as multinational companies), that own patents to HIV/AIDS drugs around the world.

The ILO Declaration recommends that governments and multinational corporations operating in member States observe a set of principles. It calls on trans-national corporations to “take fully into account established general policy objectives of the countries in which they operate”.<sup>87</sup> Moreover, the ILO Declaration also asserts that multinational corporations should “respect the sovereign rights of States, obey the national laws and regulations, give due

<sup>83</sup> United Nations Declaration on the Rights and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognised Human Rights and Fundamental Freedoms, Article 18, Paragraph 2.

<sup>84</sup> Alexander, above, 14.

<sup>85</sup> Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, available at <<http://www.ilo.org/public/english/standards/norm/sources/mne.htm>> (last accessed 20 February 2004).

<sup>86</sup> The OECD Guidelines for Multinational Enterprises (Revision 2000), available at <<http://www.oecd.org/dataoecd/56/36/1922428.pdf>> (last accessed 20 February 2004).

<sup>87</sup> Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, above, paragraph 10.



consideration to local practices and respect relevant international standards.”<sup>88</sup> The ILO Declaration specifically calls on trans-national corporations to respect the International Bill of Rights.<sup>89</sup>

The OECD Guidelines (Revision 2000) obligate corporations to “Respect the human rights of those affected by their activities consistent with the host government's international obligations and commitments.”<sup>90</sup> The OECD Guidelines also specify that multinational corporations should “take fully into account established policies in the countries in which they operate” and, specifically, ensure that their activities are consistent with their host country's technology policies.<sup>91</sup>

Additionally, the OECD Guidelines exhort corporations to contribute to economic and social progress, and specify the affirmative obligations of multinational corporations in the area of science and technology. Thus, they suggest that when practicable or appropriate, multinational corporations should “contribute to the development of local and national innovative capacity”<sup>92</sup> and “Adopt ... practices that permit the transfer and rapid diffusion of technologies and know-how, with due regard to the protection of intellectual property rights.”<sup>93</sup> The commentary to the OECD Guidelines further specifies that “When selling or licensing technologies ... the terms and conditions negotiated [should] be reasonable.”<sup>94</sup>

The international standards outlined above also impose simultaneous obligations on corporations to respect the human rights obligations of countries and to themselves respect and support international human rights. Reading these multiple obligations together, therefore, suggests that corporations have a duty to

<sup>88</sup> Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, above, paragraph 8.

<sup>89</sup> Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, above, paragraph 8.

<sup>90</sup> The OECD Guidelines for Multinational Enterprises (Revision 2000), Part 1, II, paragraph 2.

<sup>91</sup> The OECD Guidelines for Multinational Enterprises (Revision 2000), Part 1, VIII, paragraph 1.

<sup>92</sup> The OECD Guidelines for Multinational Enterprises (Revision 2000), Part 1, VIII, paragraph 1.

<sup>93</sup> The OECD Guidelines for Multinational Enterprises (Revision 2000), Part 1, VIII, paragraph 2.

<sup>94</sup> The OECD Guidelines for Multinational Enterprises (Revision 2000), Part 3 (Commentaries), paragraph 54.



respect those national laws and policies which are consistent with international human rights standards. In the case of South Africa, for example, the Medicines Act Amendment (and similar legislations elsewhere in the world) is an effort by the South African Government to actively promote important human rights, and thus should be respected by the pharmaceutical corporations.<sup>95</sup>

Furthermore, in view of the staggering magnitude of the HIV/AIDS epidemic in developing nations, State policies and laws that seek to make life-saving drugs available to those dying of HIV/AIDS reflect particularly legitimate and weighty goals worthy of the respect and cooperation of the pharmaceutical corporations. Additionally, since the right to affordable HIV/AIDS treatment is a human right that States are obligated to protect, laws to promote access to life-prolonging medications accord with international human rights law. The South African Medicines Act Amendment (and similar laws), for example, directly promote human rights by more equitably distributing life-prolonging medications among HIV positive people.<sup>96</sup>

According to one commentator,<sup>97</sup> some may argue that pharmaceutical companies do not have any obligation to respect laws to increase access to HIV/AIDS drugs because such laws violate developing countries' international obligations under the TRIPS Agreement. While the pharmaceutical industry and its supporters continue to oppose laws such as South Africa's Medicines Act Amendment, the consensus is that the Medicines Act Amendment is valid under the TRIPS Agreement – see arguments in Part III(A)(2) above. Additionally, in the recent Doha Declaration,<sup>98</sup> the World Trade Organisation (WTO) interpreted the TRIPS Agreement to allow developing countries to make HIV/AIDS drugs more affordable, including through the use of compulsory licensing and parallel importing. As a WTO ministerial pronouncement, the Doha Declaration is a “persuasive authority” that asserts that the TRIPS Agreement does indeed allow such practices, which laws like the Medicines Act Amendment seek to introduce

<sup>95</sup> See generally Lissett Ferreira “Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations Of Multinational Pharmaceutical Corporations” (2002) 71 *Fordham L Rev* 1133, 1174.

<sup>96</sup> See generally Ferreira, above, 1174.

<sup>97</sup> See Ferreira, above, 1175.

<sup>98</sup> Doha WTO Ministerial 2001: TRIPS, WT/MIN(01)/DEC/2 (20 November 2001).



in order to make HIV/AIDS drugs more broadly accessible.<sup>99</sup>

Furthermore, the pharmaceutical industry's interpretation of those laws is based on a TRIPS-plus approach (that is, interpretation on issues such as compulsory licensing and parallel importing - see arguments in Part III(A)(2) above), which seeks to force developing countries to offer their products greater patent protection than the minimum standards the TRIPS Agreement requires. The WTO member States, however, signed on to the standards in the TRIPS Agreement, not the TRIPS-plus obligations that the pharmaceutical industry seeks to impose. Pharmaceutical companies are not obligated to respect laws that violate the TRIPS Agreement, but the pharmaceutical industry has failed to prove that laws like the South African Medicines Act Amendment violate the TRIPS Agreement. As such, there is little merit to the argument that pharmaceutical companies do not have an obligation to respect laws like South Africa's Medicines Act Amendment because they violate the TRIPS Agreement.<sup>100</sup>

Additionally, there is some suggestion in the international codes of conduct that corporations have an affirmative obligation to cooperate with their host states. The ILO Declaration specifically recommends that corporations affirmatively harmonise their activities with their host States' social and development policies. The pharmaceutical companies' multi-faceted attack on laws such as the South African Medicines Act Amendment is inconsistent with this obligation to cooperate with, and conform their activities to, State efforts to make HIV/AIDS drugs affordable and thus more accessible.<sup>101</sup>

Moreover, the pharmaceutical companies may also violate their obligation to respect and cooperate with State policies to promote the right to medical treatment when they charge prices so high that only one-tenth of one percent of worldwide HIV/AIDS sufferers can buy their drugs.<sup>102</sup> The consistently high prices pharmaceutical companies charge directly conflict with the shared goal of many developing states to ensure treatment to those dying of HIV/AIDS. As such,

<sup>99</sup> See generally Ferreira, above, 1175.

<sup>100</sup> See generally Ferreira, above, 1175.

<sup>101</sup> See generally Ferreira, above, 1175 & 1176.

<sup>102</sup> See generally Ferreira, above, 1176.



the prices pharmaceutical corporations charge for their patented drugs in the developing world may not only be unreasonable and unethical, but also a violation of their obligations under the international codes of conduct not to interfere with the legitimate policies of host governments.<sup>103</sup>

#### *IV. Balancing the Right to Health and the Right to Property*

The tension between developed and developing world perspectives is reflected in the Universal Declaration of Human Rights (Universal Declaration). On the one hand, the Universal Declaration guarantees the right to property and the protection of material interests resulting from scientific discovery.<sup>104</sup> On the other hand, it guarantees the right to health, education, and to share in scientific advancement and its benefits, as discussed above. Developed countries seek the right to protection of their proprietary interests resulting from scientific discovery, whilst least developed countries seek the right to share in scientific discoveries and to the health of the population.<sup>105</sup>

It is important to note that the WTO rules do provide limited methods of circumventing intellectual property rules where necessary to protect the public's health. Firstly, as pointed out earlier, Article 8 of the TRIPS Agreement provides a general public interest exception to the protection of intellectual property that allows member States to adopt necessary measures to protect public health and to promote public interest. Secondly, whilst Article 28 of the TRIPS Agreement confers exclusive rights on the inventor to manufacture, use, sell or import its invention, Article 30 of the TRIPS Agreement allows member States some room to limit such exclusive rights and to take into account "the legitimate interests of third parties". Thirdly, with regards to parallel imports, although the TRIPS Agreement does not directly address it, Article 6 leaves the issue of exhaustion to the discretion of the WTO members, thus, in effect, sanctioning parallel importing. Lastly, Article 31 of the TRIPS Agreement allows for domestic

<sup>103</sup> See generally Ferreira, above, 1176.

<sup>104</sup> Universal Declaration of Human Rights, Articles 17 & 27(2).

<sup>105</sup> Lawrence O Gostin "The Global Reach of HIV/AIDS: Science, Politics, Economics, And Research" 17 *Emory Int'l L Rev* 1, 33.



legislation permitting compulsory licensing, subject to certain conditions. "National emergency" or "circumstances of extreme urgency" are major exceptions to fulfilling the conditions where compulsory licensing is allowed.<sup>106</sup>

As argued earlier as well, although the use of compulsory licenses is enshrined in TRIPS, pharmaceutical companies, supported by developed nations (in particular by the United States of America), have strongly resisted claims of a national health emergency, preferring instead to maintain their patents. For example, Thailand, under intense pressure from the United States (pressure of being imposed with trade sanctions), amended its law to provide patent protection for drugs and to limit compulsory licensing and the importation of patented drugs. This occurred against a backdrop of an epidemic in which one million people are infected with HIV and where AIDS is the leading cause of death.<sup>107</sup>

According to one article,<sup>108</sup> the US Census Bureau estimates that the HIV/AIDS epidemic has reduced life expectancy in South Africa by fifteen years and in Zimbabwe by thirty-two years and compares these justifications for compulsory licenses with those made by political leaders in the United States in response to the intentional release of anthrax in 2001 even though there were only a half dozen deaths from anthrax. Politicians suggested that the United States exercised its compulsory licensing privilege under the TRIPS Agreement to permit cheap production of the antibiotic Cipro, without the consent of Bayer Pharmaceuticals.<sup>109</sup>

There are creative ways to relax rigid trade rules to allow less developed countries to obtain essential medicines at a more affordable cost.<sup>110</sup> Through the innovative thinking of political leaders in developed and less developed countries, the criteria for the issuance of compulsory licenses under Article 31 of the TRIPS Agreement could be clarified. The international trade system should recognise the

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<sup>106</sup> Agreement On Trade-Related Aspects Of Intellectual Property Rights, Article 31(b).

<sup>107</sup> Gostin, above, 34.

<sup>108</sup> Gostin, above, 34.

<sup>109</sup> Gostin, above, 34 & 35.

<sup>110</sup> Gostin, above, 35.



devastating public health effects of HIV/AIDS in resource poor countries.<sup>111</sup>

A joint study conducted in 2002, by the World Trade Organisation (WTO) and the World Health Organisation (WHO) on the relationship between trade rules and public health, revealed that the WTO Agreements are sensitive to health issues. In fact, the study affirms that health concerns take precedence over trade issues and that if necessary, governments may put aside WTO commitments in order to protect human life. Furthermore, the then Deputy Director General of the WTO affirmed that according to the WTO jurisprudence, human health has been recognised as being "important in the highest degree".<sup>112</sup>

The Doha WTO Ministerial Declaration of 14 November 2001, as further discussed below, clarified that patent protection does not and should not prevent member nations from taking measures to protect public health.<sup>113</sup> In other words, when weighing public health against property rights, public health should always be heavier.

All of the above indicate that the right to health can be interpreted consistently, and thus balanced, with intellectual property rights. Intellectual property rights are important to the research and development of HIV/AIDS drugs and deserve protection. However, intellectual property rights do not, and should not trump human rights. Through its various public interest exceptions to patent protections, the TRIPS Agreement makes it clear that, under certain circumstances, it is legal and appropriate to limit intellectual property rights to achieve broader societal goals. This is further fortified by the recent WTO Doha Declaration (discussed further below) clarifying the ability of WTO member nations to use the flexibilities that are built into the TRIPS Agreement to protect public health. Given the magnitude of the HIV/AIDS pandemic in developing countries and the widespread lack of access to HIV/AIDS drugs in those countries, laws increasing access to HIV/AIDS drugs like the South African

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<sup>111</sup> Gostin, above, 35.

<sup>112</sup> WTO News: 2002 Press Releases, Press/310 (20 August 2002).

<sup>113</sup> Doha WTO Ministerial 2001: TRIPS, WT/MIN(01)/DEC/2 (20 November 2001).



Medicines Amendment Act, are an appropriate limitation on intellectual property rights.

## **V. ROLE OF THE WORLD TRADE ORGANISATION AND EFFECT OF TRIPS IN RELATION TO THE RIGHT TO HEALTH AND PATENT MATTERS**

This section of the paper provides an introduction to the World Trade Organisation (WTO), its agreements and its dispute settlement system. This section also analyses the steps taken by the WTO to address the problems posed by the TRIPS Agreement to developing country members of the WTO, in particular, the negative influence the TRIPS Agreement has exerted on developing country members' domestic public health policies (as discussed above). The relationship between the WTO and human rights is also examined in this section.

### **A. An Overview of WTO and Its Dispute Settlement Process**

The World Trade Organisation (WTO) was formed as a result of the need to ensure that world trade flowed as smoothly, predictably and freely as possible.<sup>114</sup> Although the WTO began life on 1 January 1995, its trading system is half a century older. Since 1948, the General Agreement on Tariffs and Trade (GATT) had provided the rules for the system. In fact, the second WTO ministerial meeting, held in Geneva in May 1998, included a celebration of the 50th anniversary of the system. It did not take long for the General Agreement to give birth to an unofficial, de facto international organisation, also known informally as GATT. Over the years, GATT evolved through several rounds of negotiations. The last and largest GATT round, was the Uruguay Round which lasted from 1986 to 1994 and led to the creation of the WTO. Whereas GATT had

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<sup>114</sup> See explanation of the WTO, its role and its functions, at the WTO website, available at <[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact1\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm)> (last accessed 14 February 2004).



mainly dealt with trade in goods, the WTO and its agreements now cover trade in services, and in traded inventions, creations and designs (intellectual property).<sup>115</sup>

There are a number of ways of looking at the WTO. Firstly, the WTO is an organization for liberalising trade. Where countries have faced trade barriers and wanted them lowered, the negotiations have helped to liberalise trade. However, the WTO is not just about liberalising trade. In some circumstances, its rules support maintaining trade barriers, for example, to protect consumers or to prevent the spread of diseases.<sup>116</sup>

Secondly, it is a forum for governments to negotiate trade agreements. In fact, the WTO was born out of negotiations, and everything the WTO does is as a result of negotiations. The bulk of the WTO's current work comes from the 1986-1994 negotiations, called the Uruguay Round, and earlier negotiations under the General Agreement on Tariffs and Trade (GATT), as discussed above. The WTO is currently the host to new negotiations, under the "Doha Development Agenda" launched in 2001. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations. These documents provide the legal ground rules for international commerce. They are essentially contracts, binding member governments to keep their trade policies within agreed limits. Although negotiated and signed by member governments, the goal is to help producers of goods and services, exporters, and importers conduct their business, while allowing governments to meet social and environmental objectives.<sup>117</sup>

Thirdly, the WTO is a place for governments to settle trade disputes, via the operation of a system of trade rules. Essentially, the WTO is a place where member governments go, to try to sort out the trade problems they face with each other. The first step, of course, is to talk. Trade relations often involve conflicting interests. Furthermore, agreements, including those painstakingly negotiated in

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<sup>115</sup> See explanation of the WTO, its role and its functions, at the WTO website, available at <[http://www.wto.org/english/thewto\\_e/whatise\\_e/tif\\_e/fact1\\_e.htm](http://www.wto.org/english/thewto_e/whatise_e/tif_e/fact1_e.htm)> (last accessed 14 February 2004).

<sup>116</sup> See explanation of the WTO, its role and its functions, on the WTO website, available at <[http://www.wto.org/english/thewto\\_e/whatise\\_e/tif\\_e/fact1\\_e.htm](http://www.wto.org/english/thewto_e/whatise_e/tif_e/fact1_e.htm)> (last accessed 14 February 2004).

<sup>117</sup> See the WTO website, as above.



the WTO system, often need interpreting. The most harmonious way to settle these differences is through some neutral procedure based on an agreed legal foundation. That is the purpose behind the dispute settlement process written into the WTO agreements.<sup>118</sup>

The system's overriding purpose is to help trade flow as freely as possible, so long as there are no undesirable side effects. That partly means removing obstacles and ensuring that individuals, companies and governments know what the trade rules are around the world; and giving them the confidence that there will be no sudden changes of policy. In other words, the rules have to be "transparent" and predictable.<sup>119</sup>

The Uruguay Round Understanding on Rules and Procedures Governing the Settlement of Disputes (the Understanding on Dispute Settlement or DSU) established "an integrated, rules-based dispute settlement process with a right of appellate review."<sup>120</sup> Only member States can initiate complaints and intervene in proceedings and the DSU is the only mechanism available for resolving disputes, unless parties agree otherwise. The DSU assures "that all panel or Appellate Body reports will be adopted expeditiously and without modification."<sup>121</sup>

The DSU also prohibits members from acting unilaterally on the following issues: "(1) whether an Uruguay Round agreement has been violated, (2) whether another member has failed to implement a Dispute Settlement Body (DSB) recommendation within a reasonable period of time, or (3) whether the level of suspension of concessions is appropriate."<sup>122</sup> The purpose of this commitment is to ensure that government-sanctioned barriers do not impede trade.<sup>123</sup>

<sup>118</sup> See the WTO website, as above.

<sup>119</sup> See the WTO website, as above.

<sup>120</sup> See the WTO website page on dispute settlement, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm) (last accessed 20 February 2004).

<sup>121</sup> See generally Johanna Kiehl "TRIPS Article 31(B) And The HIV/AIDS Epidemic" (2002) 10 J Intell Prop L 143, 154.

<sup>122</sup> See generally Johanna Kiehl "TRIPS Article 31(B) And The HIV/AIDS Epidemic" (2002) 10 J Intell Prop L 143, 154.

<sup>123</sup> See generally Johanna Kiehl "TRIPS Article 31(B) And The HIV/AIDS Epidemic" (2002) 10 J Intell Prop L 143, 154.



After a country petitions the WTO to settle a dispute, the member States involved in the dispute undergo negotiations. If these discussions are not fruitful, the parties decide the composition of the panel of experts to consider the case. Panels only base findings on cited agreements, and they only address claims and issues necessary to reach a decision. They can accept amicus briefs, though they are not required to do so.<sup>124</sup> One commentator suggests that when amicus briefs are attached to a party's submission, the information appears to be "treated as part of the government's materials for purposes of accepting the information and having the opportunity to respond to it."<sup>125</sup> The WTO's General Council, acting as the Dispute Settlement Body (DSB) under the DSU, then accepts or rejects a panel's conclusion. Rejection, however, must be by consensus, making panel decisions virtually impossible to overturn. After a ruling of the DSB, both sides can appeal.<sup>126</sup>

Three members of a permanent seven-member Appellate Body hear the appeal. Members of the Appellate Body, like panels, can only base findings on cited agreements, but they can substitute a panel decision with a de novo decision of their own. After the Appellate Body gives a report, the DSB again decides whether to accept or reject it. Like panel reports, Appellate Body reports can only be rejected by a consensus of the DSB.<sup>127</sup>

In this system, the panel and Appellate Body reports are not judgments; they are legal advice given to the DSB, which makes the actual decision. The adoption of reports, however, is "quasi-automatic," due to DSB's voting system. Therefore, the WTO dispute settlement "in practice ... functions as a judicial system of settling international disputes ... The direction taken by the WTO system has set it firmly on route to becoming recognised de facto as an international court ..."<sup>128</sup>

<sup>124</sup> See the WTO website page on dispute settlement, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/displ\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm) (last accessed 20 February 2004).

<sup>125</sup> Kiehl, above, 155.

<sup>126</sup> See the WTO website page on dispute settlement, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/displ\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm) (last accessed 20 February 2004).

<sup>127</sup> See the WTO website page on dispute settlement, as above.

<sup>128</sup> Kiehl, above, 155 & 156.



According to one commentator,<sup>129</sup> many people characterize the WTO as a secretive and powerful organisation, which is isolated from non-governmental influence, and which limits state sovereignty. To some extent, these descriptions are accurate. Hearings are private; governments that petition the DSB do not have to make public their full submissions; and the WTO only recently began publishing certain materials. Its panels and Appellate Body are not required to consider amicus briefs presented by non-governmental organisations. And finally, the organisation has a highly effective, enforceable dispute settlement mechanism that prohibits States from acting unilaterally.<sup>130</sup>

Probably the most important characteristic of the WTO, however, is that its primary aim is to facilitate trade liberalisation. The DSU was primarily designed to promote that goal, not other social policies such as development, environment, security, and labour standards. Though many critics argue the WTO is an isolated organisation that acts against the important policy objectives of its member states, the fact that the WTO favours free trade objectives over other social policy objectives may be a reflection of the national interests of its member states.<sup>131</sup>

Non-governmental organisations (NGOs) have become increasingly active in the area of human rights and international trade law, especially where the WTO is concerned. However, while other international forums have embraced the participation of NGOs in policy-making or legislative activities, the WTO has been far less hospitable to NGO involvement and does not permit NGOs attendance at WTO General Council or WTO committee meetings.<sup>132</sup>

The WTO has, however, showed some encouraging signs of change. For example, since 1998, the WTO has allowed NGOs to submit amicus curiae briefs for some cases entering the dispute settlement process, and has taken steps to

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<sup>129</sup> Kiehl, above, 156.

<sup>130</sup> Kiehl, above, 156.

<sup>131</sup> Kiehl, above, 156.

<sup>132</sup> See generally Rona Nardone "Like Oil And Water: The WTO And The World's Water Resources" 19 (2003) Conn J Int'l L 183, 194.



address its relationship with NGOs.<sup>133</sup> In fact, in November 2001, at the Doha Ministerial Conference, member governments agreed to negotiate to improve and clarify the DSU.<sup>134</sup> Amongst one of the proposals submitted was to open up the WTO's dispute settlement mechanism to public scrutiny, and to allow NGOs to offer unsolicited briefs as friends of the court (*amicus curiae*) to the dispute settlement panels and the Appellate Body. The United States, which championed the cause of NGOs, made a three-page proposal related to transparency, calling for complete public access to hearings, unrestricted access to *amicus curiae* briefs, timely access to submissions and timely access to final reports.<sup>135</sup>

However, the US proposal to open up the WTO's dispute settlement mechanism to public scrutiny and to allow NGOs to offer unsolicited briefs as *amicus curiae* to the dispute settlement panels and the Appellate Body met with resistance from some WTO members, in particular, by two ASEAN trade diplomats.<sup>136</sup> According to one commentator,<sup>137</sup> southern countries oppose *amicus* submissions, arguing that such submissions erode the rights of governments without access to legal resources and tilt the dispute resolution system against them. The commentator further argues that, for developing countries, the issue is not one of resource reallocation because the necessary resources are either non-existent or severely limited; these governments are burdened by personnel and financial constraints, which preclude effective participation in dispute panel hearings and other WTO events.<sup>138</sup>

According to the Doha Declaration,<sup>139</sup> by May 2003, the WTO members were required to agree on a set of reform proposals to improve the functioning of

<sup>133</sup> Rona Nardone "Like Oil And Water: The WTO And The World's Water Resources" (2003) 19 *Conn J Int'l L* 183, 194.

<sup>134</sup> See the WTO's website page on dispute settlement, available at <[http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm#negotiations](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#negotiations)> (last accessed 20 February 2004).

<sup>135</sup> See article entitled "ASEAN Rejects US Call For NGO Access To WTO Dispute Process", Global Policy Forum website, available at <<http://www.globalpolicy.org/ngos/role/globalact/int-inst/2002/0917asean.htm>> (last accessed 20 February 2004).

<sup>136</sup> See article on Global Policy Forum website, as above.

<sup>137</sup> Rona Nardone "Like Oil And Water: The WTO And The World's Water Resources" (2003) 19 *Conn J Int'l L* 183, 194.

<sup>138</sup> Nardone, above, 194.

<sup>139</sup> Doha WTO Ministerial 2001: Ministerial Declaration WT/MIN(01)/DEC/1 (20 November 2001), available at <[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm)> (last accessed 13 December 2003).



its dispute settlement understanding. The amicus curiae issue, which involves NGOs in environment or industry lobbies submitting briefs directly to panels or the Appellate Body, has divided the WTO. Therefore, on 24 July 2003, acknowledging the fact that the DSB special session needed more time to conclude its work, the General Council agreed to extend the special session's timeframe by one year, to May 2004.<sup>140</sup>

### **B. TRIPS and Its Affect in General**

In 1994, the World Trade Organization (WTO) adopted the Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement).<sup>141</sup> The TRIPS Agreement emerged from the Uruguay Round, one of the rounds of negotiations, forming part of the GATT.<sup>142</sup> Over one hundred countries, including the United States and South Africa, signed the treaty. The purpose of the TRIPS Agreement, and arguably its effect, is to set minimum requirements for the protection of intellectual property rights to which all member nations must adhere. The TRIPS Agreement covers copyrights, trademarks, geographic indications, industrial designs, and patents.<sup>143</sup>

Compliance with the requirements of the TRIPS Agreement provides member countries with two advantages; that is, firstly, the benefit of national treatment<sup>144</sup> and secondly, most-favoured-nation treatment.<sup>145</sup> National treatment ensures that imported goods receive the same intellectual property protections as goods produced within the importing country. For example, because both the United States and South Africa signed the TRIPS Agreement, the United States is assured that South Africa will provide the same patent protections to HIV/AIDS

<sup>140</sup> See the WTO's website page on dispute settlement, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm#negotiations](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#negotiations) (last accessed 20 February 2004).

<sup>141</sup> Information obtained from WTO website, available at [http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm) (last accessed 13 December 2003).

<sup>142</sup> See discussion of TRIPS, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (last accessed 13 December 2003).

<sup>143</sup> See overview of TRIPS, [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last accessed 13 December 2003).

<sup>144</sup> Agreement On Trade-Related Aspects Of Intellectual Property Rights (TRIPS), Article 3.

<sup>145</sup> TRIPS, Article 4.



drugs imported from the United States as it does to HIV/AIDS drugs made in South Africa. Most favoured nation treatment means that all WTO member countries will receive the same custom rates or duties. No country can give reduced duties to one WTO member nation without giving the same reduced duties to all other WTO member countries.<sup>146</sup>

If a member country violates the provisions of the TRIPS Agreement, then that nation risks losing its "general market access entitlements under the WTO."<sup>147</sup> The nation also opens itself up to trade sanctions from other member nations. The TRIPS Agreement allows developing countries five years to comply with the provisions of the treaty. It allows "least developed" countries a ten-year period before they must apply the provisions of the TRIPS Agreement. Therefore, developing countries such as South Africa had to be in compliance by 1 January 2000. Other less developed countries, including nations in sub-Saharan Africa, have until 1 January 2005, to come into full compliance with the TRIPS agreement.<sup>148</sup>

### C. *TRIPS and Public Health*

It has been said that the TRIPS Agreement has exerted negative influence on the implementation of domestic public health policies in many developing country members of the WTO by adversely affecting their access to medicines. One commentator states:<sup>149</sup>

Africa is suffering the anguish and plight of the HIV/AIDS epidemic, loud protests rise high into the sky above Seattle squares, and heated debates occur among the attendees of many international conferences; these are all examples of the heavy pressure aimed at the TRIPS Agreement. Appeals that the WTO undertake to reform the Agreement with respect to public

<sup>146</sup> See generally Angela G Thornton-Millard "Intellectual Property Rights and the AIDS Epidemic in Sub-Saharan Africa" (2001) 11 *Transnat'l L & Contemp Probs* 517.

<sup>147</sup> Angela G Thornton-Millard "Intellectual Property Rights and the AIDS Epidemic in Sub-Saharan Africa" (2001) 11 *Transnat'l L & Contemp Probs* 517, 523.

<sup>148</sup> Angela G Thornton-Millard "Intellectual Property Rights and the AIDS Epidemic in Sub-Saharan Africa" (2001) 11 *Transnat'l L & Contemp Probs* 517, 523.

<sup>149</sup> Haochen Sun "A Wider Access To Patented Drugs Under The TRIPS Agreement" (2003) 21 *B U Int'l L J* 101,102.



health issues have never been so loud and clear.

This view is further exemplified by the legal action taken by the pharmaceutical industry against the South African Government, as discussed in Part III(A) above.

1. *The Doha Declaration on TRIPS and public health*

Recognizing the gravity of the public health problems afflicting many developing countries, WTO members at the Doha Ministerial Conference attempted to integrate the TRIPS Agreement into part of the international action to address public health problems.<sup>150</sup> Although there were some conflicting views regarding the conditions under which the flexibility of the TRIPS Agreement could be used, the Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by consensus at the Doha Ministerial Conference (Doha Declaration) helped to prevent situations where developing country members could not avail themselves fully to the flexibility provided in the TRIPS Agreement due to pressure from interested groups. The Doha Declaration marked a turning point for political and legal relations at the WTO.<sup>151</sup>

The Doha Declaration states that whilst the protection of intellectual property is important for the development of new medicines, the TRIPS Agreement, however, does not and should not prevent members from taking measures to protect public health.<sup>152</sup> Accordingly, the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of a WTO member's right to protect public health and, in particular, to promote access to medicines for everyone. Applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement should be read in the

<sup>150</sup> See Doha Declaration explained on the WTO website, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/healthdecl\\_expln\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/healthdecl_expln_e.htm) (last accessed 14 February 2004).

<sup>151</sup> Haochen Sun "A Wider Access To Patented Drugs Under The TRIPS Agreement" (2003) 21 B U Int'l L J 101,104.

<sup>152</sup> Doha WTO Ministerial 2001: TRIPS, WT/MIN(01)/DEC/2 (20 November 2001) [Doha Declaration], available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (last accessed 14 February 2004).



light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.<sup>153</sup>

The Doha Declaration clearly outlines all the key flexibilities available in the TRIPS Agreement, including: the right of member nations to use compulsory licensing and to determine the grounds upon which such licenses are granted;<sup>154</sup> the right of member nations to determine what constitutes a national emergency or other circumstances of extreme urgency, which can ease the granting of compulsory licenses;<sup>155</sup> the right of member nations to determine their own parallel import regimes, "subject to the MFN and national treatment provisions of Articles 3 and 4;"<sup>156</sup> and the right of least developed country members to postpone providing pharmaceutical patents until at least 1 January 2016, and possibly longer.<sup>157</sup>

In addition, the Doha Declaration reaffirms the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members pursuant to Article 66.2 of the TRIPS Agreement.<sup>158</sup> Moreover, since the granting of exclusive marketing rights will materially impair the additional extension accorded by the Doha Declaration to the least developed country members by delaying the application of providing patent protection to pharmaceutical products for ten years, paragraph 7 of the Doha Declaration instructs the TRIPS Council to take the necessary action to give effect to this extension.<sup>159</sup>

Considering that obligations of granting exclusive marketing rights, where applicable, should not prevent the attainment of the objectives of paragraph 7 of the Declaration, the General Council adopted a waiver decision on 8 July 2002. Pursuant to this decision, the obligations of least-developed country members under paragraph 9 of Article 70 of the TRIPS Agreement are waived with respect

<sup>153</sup> Doha Declaration, above, paragraph 5(a).

<sup>154</sup> Doha Declaration, above, paragraph 5(b).

<sup>155</sup> Doha Declaration, above, paragraph 5(c).

<sup>156</sup> Doha Declaration, above, paragraph 5(d).

<sup>157</sup> Doha Declaration, above, paragraph 7.

<sup>158</sup> Doha Declaration, above, paragraph 7.

<sup>159</sup> Haochen Sun "A Wider Access To Patented Drugs Under The TRIPS Agreement" (2003) 21 B U Int'l L J 101,105.



to pharmaceutical products until 1 January 2016. The decision is part of the WTO members' ongoing efforts to ensure that intellectual property protection supports, and does not obstruct, a poorer nation's need to tackle serious public health problems. As pointed out by the former Director-General of WTO, Mike Moore:<sup>160</sup>

I am pleased that WTO members have acted promptly to implement this important part of the Doha Declaration on TRIPS and public health, and have seen fit to go beyond the strict reading of that declaration by also approving a draft waiver on exclusive marketing rights.

This waiver indicates that the reform in the TRIPS Agreement concerning public health will take the developing country members' essential needs into account, and the remaining unsolved issue of how to assist some developing members to make effective use of compulsory licensing under the TRIPS Agreement will have more optimistic prospects.<sup>161</sup>

The Doha Declaration also recognises that there are WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector and thus could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. In respect of that, the Doha Declaration instructed the TRIPS Council to find an expeditious way to facilitate effective use of compulsory licensing to address public health needs and to report to the General Council before the end of 2002.<sup>162</sup> This has been referred to as the "Paragraph 6" issue, as it comes under that paragraph in the Doha Declaration on TRIPS and public health. Although the original deadline of 31 December 2002 to solve the Paragraph 6 issue was missed, it has now been solved, and is discussed below.

<sup>160</sup> See WTO NEWS: 2002 PRESS RELEASES, Press/301 (28 June 2002), available at <[http://www.wto.org/english/news\\_e/pres02\\_e/pr301\\_e.htm](http://www.wto.org/english/news_e/pres02_e/pr301_e.htm)> (last accessed 23 February 2004).

<sup>161</sup> Haochen Sun "A Wider Access To Patented Drugs Under The TRIPS Agreement" (2003) 21 B U Int'l L J 101,106.

<sup>162</sup> Doha Declaration, above, paragraph 6.



2. *Implementation of paragraph 6 of the Doha Declaration on TRIPS and public health*

Article 31(f) of the TRIPS Agreement states that products made under compulsory licensing must be “predominantly for the supply of the domestic market”. This applies directly to member countries that can manufacture drugs. It limits the amount that those countries can export when the drugs are made under compulsory licence. Article 31(f) also has an indirect impact on member countries unable to make medicines and therefore intend to import generics. Such member countries would find it difficult to find other member countries willing to supply them with drugs made under compulsory licensing.

On 30 August 2003, the TRIPS General Council agreed to allow WTO member countries to export pharmaceutical products made under compulsory licences within the terms set out in the decision.<sup>163</sup> All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.

The decision takes the form of an interim waiver, which allows countries producing generic copies of patented products under compulsory licenses to export the products to eligible importing countries. This waiver would last until the TRIPS Agreement is amended.<sup>164</sup> The General Council chairperson stressed that the decision “should be used in good faith to protect public health and ... not be an instrument to pursue industrial or commercial policy objectives.”<sup>165</sup>

**D. *WTO and Human Rights***

<sup>163</sup> See decision of WTO General Council, WT/L/540 (1 September 2003) – Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, available at <[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)> (last accessed 14 February 2004).

<sup>164</sup> See WTO NEWS: 2003 Press Releases, Press/350/Rev 1 (30 August 2003), available at <[http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm)> (last accessed 20 February 2004).

<sup>165</sup> See WTO NEWS: 2003 News Items (30 August 2003), available at <[http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm)> (last accessed 20 February 2004).



It has been said that although international trade agreements, including the WTO Agreements such as the TRIPS Agreement and others, explicitly recognise the need for trade efforts to promote human rights and general welfare, in practice, trade negotiations and applications have often been characterised by widespread disregard for human rights and the welfare of the poorest and most vulnerable group.<sup>166</sup> A clear example of this can be seen from the South African case study discussed above.

According to one scholar,<sup>167</sup> international finance, trade and human rights have developed their own systems of monitoring and adjudication. It is the failure to coordinate these systems, and to integrate the obligations that states have taken on in the field of human rights into agreements reached regarding trade, that would continue to perpetuate the unintended subordination of human rights. Advocates should pursue efforts to coordinate those systems and to include specific human rights representation and criteria in the standards of those other bodies. Advocacy that seeks to address areas traditionally considered outside the scope of human rights, such as trade, intellectual property, or the environment, must utilise both human rights provisions and innovative strategies. The Treatment Action Coalition (TAC) in South Africa employed a mixed approach that may serve as a useful possible example. TAC drew upon national law, incorporated human rights norms, and utilised a strong public health justification in its substantive claims. It mobilised national and international attention on the arguments put forward by the pharmaceutical companies, which ultimately resulted in their withdrawal of their suit challenging South Africa's 1997 law.<sup>168</sup>

The Doha Declaration and its subsequent decisions, as discussed above, clearly indicate that the WTO is able to balance humanitarian as well as trade concerns. The fact that WTO members have managed to find a compromise in such a complex issue (that is allowing the poorer member nations to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with

<sup>166</sup> See generally Zita Lazzarini "The Global AIDS Crisis: Access to HIV Drugs: Are We Changing the Two World Paradigm?" (2002) 17 Conn J Int'l L 281, 289 & 290.

<sup>167</sup> See generally Zita Lazzarini "The Global AIDS Crisis: Access to HIV Drugs: Are We Changing the Two World Paradigm?" (2002) 17 Conn J Int'l L 281, 291.

<sup>168</sup> Zita Lazzarini "The Global AIDS Crisis: Access to HIV Drugs: Are We Changing the Two World Paradigm?" (2002) 17 Conn J Int'l L 281, 291 & 292.



the diseases that ravage their people) bears testimony to their goodwill. Although not specifically acknowledged by the WTO in the Doha Declaration or its subsequent decisions, these positive steps taken by the WTO seem to signify that intellectual property rights are not meant to trump international human rights, such as the right to health, life and development. In fact, to the contrary, they show willingness on the WTO's part to harmonise the two international rights.

However, notwithstanding the Doha Declaration and its subsequent decisions, one scholar is of the view that these efforts by the WTO to reconcile the TRIPS Agreement and human rights are merely rhetorical. The scholar is further of the opinion that:<sup>169</sup>

No body has gone so far as to say that trade law generally, or the TRIPS Agreement, must defer to human rights laws, but some headway has been made on the need at least to reconcile the two. The Doha Declaration that followed the World Trade Organization's meeting in Doha, Qatar, generally made reference to protecting public health. It does not state, as it should have, the WTO would interpret trade law consistently with human rights law. But the United Nations Commission on Human Rights, which also consists of country representatives, has passed resolutions stating that that members of international organizations - which would of course include the WTO - should interpret the TRIPS agreement so that it is "part of the wider national and international action" to address the grave public health problems in developing countries, including HIV/AIDS, tuberculosis and malaria."

The scholar also opines that it is clearly incumbent on the WTO to take the next step beyond a vague commitment to public health to assure that its interpretations of trade agreements are consistent with international human rights law, including the right to health and its requirement of making essential medicines available. These interpretations should both harmonise the right to have access to essential medications with the protection of patent rights and, more broadly, assure that trade agreements are consistent with human rights

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<sup>169</sup> Leonard S Rubenstein "Human Rights And Fair Access To Medication" (2003) 17 *Emory Int'l L Rev* 525, 533.



obligations.<sup>170</sup>

## **VI. ROLE OF THE WORLD HEALTH ORGANISATION IN IMPROVING ACCESS TO HIV/AIDS TREATMENT**

The World Health Organisation (WHO) was established on 7 April 1948 by the United Nations (UN), in furtherance of the UN's mission to promote peace, human right and social justice. The WHO's goal, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health.<sup>171</sup> In order to achieve that objective, many functions of the WHO are promulgated in the Constitution, including functions such as: i) to promote cooperation among scientific and professional groups which contribute to the advancement of health;<sup>172</sup> ii) to propose conventions, agreements and regulations, and make recommendations with respect to international health matters;<sup>173</sup> iii) to promote and conduct research in the field of health;<sup>174</sup> iv) to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products.<sup>175</sup>

The development of the WHO included a blueprint of health that emphasised making essential medical treatment universally accessible to people by acceptable means. In particular, the blueprint aimed at having full participation at a cost affordable to each community and country. According to one article, all of the WHO's 191 member states have agreed that health is a human right, and are therefore committed to promoting access to essential drugs.<sup>176</sup>

<sup>170</sup> Leonard S Rubenstein "Human Rights And Fair Access To Medication" (2003) 17 *Emory Int'l L Rev* 525, 533.

<sup>171</sup> Constitution of the World Health Organisation, Article 1.

<sup>172</sup> Constitution of the World Health Organisation, Article 2(j).

<sup>173</sup> Constitution of the World Health Organisation, Article 2(k).

<sup>174</sup> Constitution of the World Health Organisation, Article 2(n).

<sup>175</sup> Constitution of the World Health Organisation, Article 2(u).

<sup>176</sup> See generally Mary K Schug "Promoting Access To HIV/AIDS Pharmaceuticals In Sub-Saharan Africa Within The Framework Of International Intellectual Property Law" (2001) 19 *Law & Ineq J* 229, 244 & 245.



The WHO (together with the UN) has been instrumental in bringing the HIV/AIDS crisis to the forefront of the international agenda and in promoting access to medication. However, although the WHO has taken a lead role in promoting access to medications, their goal for universally accessible primary health care is far from being realised. While globalisation leads to increased access for some, this is not true for most of the developing world. According to the figures provided by the WHO,<sup>177</sup> as at November 2003, an estimated 4.4 million adults in the African region are in dire need of Antiretroviral (ARV) treatment. Out of this number, only 100,000 are currently on ARV treatment, bringing the percentage of coverage to a mere two percent.

Therefore, bringing down prices is necessary to provide access to essential medicines. One commentator opines, however, that any solution the WHO promotes will balance intellectual property rights with the urgency of providing essential medicines to the developing world, because the WHO recognises the TRIPS Agreement.<sup>178</sup>

It is evident that the WHO must play a leading role in adoption, interpretation and enforcement of any international agreements directly effecting international public health. The WTO alone does not have the expertise to represent and address health concerns. Thus, it is vital that the WTO embrace cooperation with the WHO. According to one commentator, although the WHO attended the WTO Seattle round of trade negotiations, it was present "not as a participant – but as an active and vocal observer".<sup>179</sup> Where the WTO trade negotiations have a direct impact on public health issues, it is important for the WHO to be present at such negotiations (as a participant and not merely as an observer) and play an active role in structuring the trade agreements resulting from such negotiations.

<sup>177</sup> See the WHO's website on 'The 3 by 5 Initiative', Coverage and need for antiretroviral treatment, available at <http://www.who.int/3by5/coverage/en/> (last accessed 1 December 2003).

<sup>178</sup> Mary K Schug "Promoting Access To HIV/AIDS Pharmaceuticals In Sub-Saharan Africa Within The Framework Of International Intellectual Property Law" (2001) 19 *Law & Ineq J* 229, 245.

<sup>179</sup> Kara M Bombach "Can South Africa Fight AIDS? Reconciling The South African Medicines And Related Substances Act With The TRIPS Agreement" (2001) 19 *B U Int'l L J* 273, 304.



The WHO should also be given a role in the WTO dispute settlement system, especially where trade agreement disputes between member nations involve matters of international public health. The WHO, as a specialised health institution, is in a very good position to give expert evidence on international public health matters. Currently, as pointed out above in Part V(A) above, the involvement of non-governmental organisations (NGOs) is limited to submitting *amicus curiae* briefs in disputes brought before the WTO dispute settlement body. However, this might change in the near future, as the entire WTO dispute settlement system is being reviewed.<sup>180</sup> The outcome of the review is expected to be revealed by May 2004.<sup>181</sup>

As pointed out above, the WHO conducted a joint study, with the WTO, of the relationship between trade rules and public health. The study highlighted areas where trade and health linkages deserve more careful analysis. It also highlighted benefits that are possible when trade and health officials work closely together.<sup>182</sup> The study seems to indicate that in the future, health and trade policy-makers will be cooperating closely with each other to ensure coherence between their different areas of responsibility.

With regards to access to HIV/AIDS drugs, the WHO has unveiled its global plan to ensure that HIV/AIDS victims in third world/developing countries gain full access to ARV treatment. The global plan is to treat 3 million people living with HIV/AIDS by the year 2005. This plan is known as the '3 by 5 initiative'. The Director General of WHO has stated that "Lack of access to antiretroviral treatment is a global health emergency ... To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act." Reaching the 3 by 5 target demands new commitment and a new way of working across the global health community. Countries are on the front lines of the struggle, but they cannot succeed alone. Intensive, collaborative mobilisation linking countries, multilateral organisations (including

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<sup>180</sup> See the WTO's website page on dispute settlement, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm#negotiations](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#negotiations) (last accessed 20 February 2004).

<sup>181</sup> See the WTO's website page on dispute settlement, above.

<sup>182</sup> WTO News: 2002 Press Releases, Press/310 (20 August 2002).



pharmaceutical corporations), bilateral agencies, communities and the non-state sector is required.<sup>183</sup>

Although the WHO's 3 by 5 initiative is welcomed by most quarters, one particular non-governmental organisation, namely Doctors Without Borders (DWB), have criticised the WHO's target price for treatment in its plan to fight HIV/AIDS. According to DWB, the WHO's HIV/AIDS drugs treatment target price of \$400 per patient per year for 2004 lacks ambition and does not reflect prices that are currently available. DWB, through their AIDS programmes, currently treats 9000 patients, at the price of \$140 per patient per year. DWB uses drugs manufactured by a generic pharmaceutical company, Cipla, in their treatment programmes. The quality of HIV/AIDS drugs manufactured by Cipla has been assured by the WHO pre-qualification process.<sup>184</sup>

Lastly, it is recommended that the WHO take a lead role in initiating research into poverty-related diseases and health service delivery. The WHO should be empowered to legislate on health issues, including the development of new life saving drugs and medical treatment. Further, the WHO should assist poor countries to procure affordable drugs through the implementation of a strong generic drug policy, bulk purchasing, negotiations with pharmaceutical companies and adequate financing.

In fact, the WHO is already taking steps in that direction. In May 2003, the World Health Assembly (the supreme decision-making body for the WHO) passed a resolution, announcing its intention to establish a time-limited body known as the Commission on Intellectual Property, Innovation and Public Health.<sup>185</sup> The body will review the interfaces and linkages between intellectual property rights, innovation and public health in the light of current evidence and examine in depth how to stimulate the creation of new medicines and other

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<sup>183</sup> See the WHO 3 by 5 Strategy at <http://www.who.int/3by5/publications/documents/en/Treating3millionby2005.pdf> (last accessed 22 December 2003).

<sup>184</sup> See Doctors Without Borders website, MSF-USA: Press Release 12/01/2003, available at <http://www.doctorswithoutborders.org/pr/2003/12-01-2003.shtml> (last accessed 25 February 2004).

<sup>185</sup> See Resolution of the World Health Assembly, WHA56.27 (28 May 2003).



products for diseases that mainly affect developing countries. Its analysis will take into account of how intellectual property rights can promote innovation relevant to public health, and how funding and other incentive mechanisms, including institutional arrangements, may contribute to this end.<sup>186</sup> The Commission was officially formed on 12 February 2004. Its members include, amongst others, doctors, economists and trade policy experts.<sup>187</sup>

## VII. CONCLUSION

It is now without doubt that access to HIV/AIDS treatment is recognised by the international community as being fundamental to the realisation of the human right to health.<sup>188</sup> Whilst intellectual property rights are important to the research and development of HIV/AIDS drugs, and deserve protection, they are not being allowed to trump human rights, in particular the human right to health. Property rights have been limited to the degree necessary to protect the public health and general welfare in democratic societies. As discussed above, mechanisms already exist that caters for the modification of intellectual property rights without abrogating the right to property or without removing incentives to innovation or without threatening the research and development of new drugs.<sup>189</sup>

Mechanisms such as compulsory licensing and parallel importing (as discussed above) have been officially sanctioned by the World Trade Organisation (WTO) in the Doha Declaration. In order to combat this wide spread disease by improving access to HIV/AIDS treatment as part of their social policies, developing countries can now make full use of the flexibilities within the TRIPS Agreement, without the fear of retaliation from foreign (mainly developed) countries or pharmaceutical companies. It is highly probable that the TRIPS Agreement may even be amended in future to accommodate public health

<sup>186</sup> See Note by the Director-General of the WHO, EB113/INF.DOC./1 (15 January 2004).

<sup>187</sup> See the WHO Media Centre Press Release, available at <http://www.who.int/mediacentre/releases/2004/pr12/en/> (last accessed 25 February 2004).

<sup>188</sup> HIV/AIDS and Human Rights International Guidelines, Revised Guideline 6, available at <http://www.unhcr.ch/hiv/g6.pdf> (last accessed 12 February 2004).

<sup>189</sup> See generally Zita Lazzarini "Making Access To Pharmaceuticals A Reality: Legal Options Under TRIPS And The Case Of Brazil" (2003) 6 Yale H R & Dev L J 103, 138.



objectives of the WTO members (with special reference to developing countries) aimed at addressing pandemics such as the HIV/AIDS epidemic.

In the event of any conflict between a States' obligations under international trade agreements (such as the TRIPS Agreement, for example) and its obligations under the international law of human rights, the latter obligation(s) shall take precedence, and such is slowly being recognised by other States and by the adjudicative mechanisms of the WTO charged with interpreting those trade agreements.

In view of the joint study recently conducted by the WTO and the World Health Organisation (WHO)<sup>190</sup> and other recent developments as discussed above, it is also highly probable that the WTO would consult the WHO before finalising any new international trade agreements (or amending current agreements) which touch and concern international public health matters. The formation of the Commission on Intellectual Property, Innovation and Public Health by the WHO would, in future, drastically improve the input the WHO currently has in the WTO negotiations, especially where they involve public health issues.

With respect to the WTO's dispute settlement process, welcomed changes would be the active participation of non-governmental organisations, such as health and/or human rights agencies and organisations, in disputes between member nations involving health and human right matters. Most importantly, the WTO panels and appellate body, before issuing their reports and decisions, should ensure that their decisions would not have an undesired and negative impact on the important social policy goals of the WTO member nations (especially the developing member nations). This can be avoided by introducing expert evidence, where necessary, from specialised health and/or human rights organisations, to guide the WTO panels and appellate body reach their ultimate decision, particularly in the context of HIV/AIDS.

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<sup>190</sup> See discussion in Part IV of this paper.



All the recent developments highlighted in this research paper, in respect of access to HIV/AIDS treatment and human rights, are very encouraging and indeed, they set a positive tone for the future. It is just unfortunate that it took the HIV/AIDS crisis to reach a catastrophic level before the international community realised and acknowledged that the human rights of HIV/AIDS patients includes the right to affordable HIV/AIDS treatment. As pointed out above, millions of lives have been lost, mainly due to the lack of access to medications and treatment. However, on the positive side, it is the compassion for the loss of all these lives that has motivated the global community to act in the way it has. As the saying goes, "better late than never". Hopefully, if and when a HIV vaccine is developed and released in the near future, intellectual property rights, patents and affordability will not be a barrier to access to that vaccination. As a result of the tremendous development in this decade, it is highly probable that the lack of access to HIV vaccination, once such a vaccination is developed, would not be an issue in the future.



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