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**THE IMPACT OF TRIPS ON ACCESS TO
MEDICINES AND THE RIGHT TO HEALTH
OF CHILDREN**

Clara van Gulik

2004

Global interactions increasingly rely on law to govern them. Today, numerous rules dominate the interactions between states and non-state parties. International courts and dispute settlement mechanisms are in place to ensure compliance with commonly agreed norms.

International Law, however, is complex and often lacks universal acceptance. Worse, its influence is disproportionately strong on the poorest countries and countries in crisis. It is in situations of poverty and conflict where international law has the most impact - for better or worse. International legal structures can provide security, stability and access to economic support, but they can just as easily prevent timely and adequate assistance. Development and humanitarian actors must increasingly be aware of their potential as well as their pitfalls.

Good Governance is easily prescribed, but must become a mindset of all involved to make the system work. Less and least developed countries are often governed by constitutions that are complex and inaccessible for their citizens. Without acceptance by their subjects, they weaken and cease to safeguard the nation state against failure. Development assistance must provide more than just models and institutions to move these countries forward.

Papers in the lawanddevelopment.org series aim to contribute to the understanding of the importance of these linkages and strive to support a better concept of how law can aid development. All papers are original works and are solely published on lawanddevelopment.org

For queries write to:

The Editor
lawanddevelopment.org

P.O.Box 1106
Nairobi 00502
Kenya

info@lawanddevelopment.org

www.lawanddevelopment.org

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Introduction

“Break the patents, treat the people.”¹ These were the words chanted by the audience at the XVth International AIDS² Conference that took place in July 2004 in Bangkok. In a global health crisis where 42 million people are estimated to be infected with human immunodeficiency virus (HIV) and only 400,000 of the 6 million who need immediate antiretroviral treatment have access³, the Conference was appropriately named ‘Access for All’. The need for more funding, better policies and sustainable programmes were discussed amongst world leaders in health, politics, civil society groups and many AIDS-activists, often patients and their doctors, on increasing access to medicines. An issue that continued to be highly debated was the impact of medical patents driving the high prices of antiretroviral medicines (ARVs) manufactured by the commercial pharmaceutical industry which is one of many, yet significant, barriers to accessing drugs. This debate has centred around two areas of international law, intellectual property law and human rights law, which have been brought together by the issue of access to medicines over many conference tables and meetings.⁴ The World Trade Organisation (WTO) requires its members to implement trade agreements into their domestic legislation, one of which is the Trade-Related Intellectual Property Rights Agreement, also known as TRIPS.⁵ This agreement provides patents of products and processes for twenty years and essentially acts as a global patent protection system that includes pharmaceutical products. The requirement of developing countries is to implement patent protection into their domestic legislation by the end of 2005, and although the least developed countries (LDCs) have had an extension to 2016,⁶ the impact that TRIPS can potentially have on the poor living in the developing world who rely on accessing cheaper generic drugs could be detrimental to the battle against HIV/AIDS.

Another important issue in the global fight against HIV/AIDS that was highlighted at the Conference is that children are in danger of being forgotten.⁷ Children are at the heart of this crisis; they are the most vulnerable and most devastated, yet are also the bearers of the future of their countries. The United Nations Children’s Fund (UNICEF) has reported that there are three million children infected with the virus. In 2002, around 800,000 children under the age of 15 years became infected, of which 90% were through vertical transmission from their mothers.⁸ Of these babies born with HIV, only 50% will reach their second birthday. The number of children infected

¹ BBC News Report, ‘*Annan urges US to fight AIDS*’, Report from XVth International AIDS Conference, Bangkok, Thailand, on Tuesday 13 July 2004 available at <http://news.bbc.co.uk/1/hi/health/3888753.stm>

² AIDS stands for Acquired Immune Deficiency Syndrome which is the disease process caused by an infection with the Human Immunodeficiency Virus (HIV).

³ *2004 Report on the Global AIDS Epidemic*, publication by UNAIDS, June 2004, UNAIDS/04.16E

⁴ P. Cullet, ‘Patents and medicines: the relationship between TRIPS and the human right to health’, *International Affairs* vol 79, 1, p.139-160, 2003

⁵ WHO Policy Perspectives on Medicines, *Globalization, TRIPS and access to pharmaceuticals*, No.3, March 2001, WHO/EDM/2001.2

⁶ See paragraph 7, The Declaration on TRIPS and Public Health, Annex I

⁷ Save the Children, *Remembering children in HIV/AIDS Treatment*, News Release 14 July 2004, available on www.savethechildren.org.uk/scuk/jsp/resources/details.jsp

⁸ UNICEF, ‘*Fighting HIV/AIDS: Strategies for Success 2002-2005*’, UNICEF publication

may be marginal in comparison to adults infected at present, but what is not a marginal problem is the number of children who are being orphaned by AIDS. UNICEF has estimated that by 2010, up to 25 million children may be orphaned as a result of pandemic.⁹

Lack of access to medicines has had a drastic impact directly and indirectly on the lives of millions of children. In the developing world, children living with HIV have been denied access to medicines and babies are denied adequate prevention from infection from their mothers. Those who are not infected but live with HIV/AIDS in their families are also being denied their basic rights. The enjoyment of the right to health, the right to life, survival and development, the right not to be separated from their parents, the right to education, non-discrimination and many more rights which are fundamental to children are being denied. The Convention on the Rights of the Child (CRC) is the most globally ratified human rights treaty and should be at the centre of the battle against HIV/AIDS, and the TRIPS Agreement should in no way hinder children from enjoying their most fundamental rights.

In Part One, there will be a general examination of issues in the debate between intellectual property rights and human rights in relation to patents and access to medicines. The first will examine whether intellectual property rights are universal human rights on par with the right to health. The second issue brings up the argument of the pharmaceutical industry that patent protection is not a significant source of the problem of access to medicines. While the third issue questions whether TRIPS can be implemented without impinging on access to medicines but improving the right to health. This section will examine the safeguards available in the TRIPS Agreement which allow measures to be taken to protect the needs of public health.

In Part Two, the impact of the HIV/AIDS crisis will be focussed on children who are living with the pandemic. The virus has affected children's lives in many ways, and thereby has denied them of many rights which will be examined in section one. The second section examines how TRIPS affects children.

Part Three briefly examines the possibility of tackling the HIV/AIDS epidemic by focussing on treating women and children's rights. The United Nations Secretary-General, Kofi Annan, has been advocating on behalf of UNAIDS, UNICEF and the World Health Organisation (WHO) that the epidemic needs to be challenged with a female face. Women and young girls, who are marginalised even more in light of the epidemic, hold the key to gaining some sustainable management of the crisis. I hope to portray that education, prevention, treatment and supportive care of women and girls will ensure a brighter future for children born into a world of HIV/AIDS.

⁹ Ibid

PART ONE

Access to Medicines, intellectual property rights and human rights

1. Why are patents a health issue in the context of HIV/AIDS?

The impact of medical patents on access to medicines, particularly in the context of HIV/AIDS, has produced many discussions amongst various international organisations and their member governments. At the centre of this debate sits the TRIPS Agreement of the World Trade Organisation and the right to health of human rights law. The HIV/AIDS pandemic has garnered so much attention, not only for the resulting human tragedy, but also for its devastating economic and social consequences.¹⁰ Although there is no cure for infection with HIV, improvements in antiretroviral medicines have nearly eliminated mortality from AIDS in developed nations. Yet despite this, 95% of people with HIV live in the developing world where less than 8% have access to treatment.¹¹ The cause of the phenomenal growth of the pandemic is multi-factorial and the cost of drugs is but one of many barriers that presents itself when trying to provide good, sustainable management of HIV/AIDS. Yet as the deadline of 2006 approaches for developing countries, the concerns of the impact of TRIPS implementation on human rights obligations has produced much debate as well as potential solutions at the WTO. Prior to examining the debates surrounding this issue, a brief outline explaining TRIPS and the right of access to medicines will follow.

A. The TRIPS Agreement

The TRIPS Agreement is the most comprehensive international instrument on intellectual property rights and resulted from negotiations at the General Agreement on Tariffs and Trade (GATT) meeting in Uruguay following strong pressure from the industrialised countries.¹² The US launched an initiative to universalise standards of intellectual property protection to counter their declining competitive position in world markets in the 1980s. As a result of a too-open technological and scientific system that allowed foreign countries to imitate and profit from US innovations and the growing manufacturing capacities of Japan, first, and then later the newly industrialising countries in Asia, US technological firms were losing their profits and failing to recoup their investment spent on research and development (R&D).¹³ Despite concerns voiced from the developing world since the initial negotiations, the TRIPS agreement was adopted to incorporate a framework of universally standardised intellectual property rights into domestic legislation of all 144 WTO member states.

One of the US industries that took aggressive action for the establishment of TRIPS is the pharmaceutical industry. For this industry, which is currently dominated by firms from the United States, Japan, Switzerland, Canada, Germany and the United Kingdom, TRIPS implementation means that they will no longer need to register their

¹⁰ A.E.Yamin, 'Not just a tragedy: access to medications as a right under international law', *Boston University International Law Journal*, Fall 2003

¹¹ From WHO '3-by-5' initiative programme, available on <http://www.who.int/3by5/coverage/en/>. Only 4% have access to treatment in Africa.

¹² C.Correa, *Intellectual Property Rights, the WTO and Developing Countries* (2000), Zed Books Ltd, New York

¹³ Ibid

patents of all their new products and processes in WTO member states as domestic legislation would provide them with patent protection.

The intellectual property system provides the necessary incentives for R&D, and is essentially a system to promote technological innovation.¹⁴ Aside from patents, intellectual property protection includes copyright, trademarks, geographical indications and protection of trade secrets. A patent is a time-bound monopoly right given by the State exclusively to the inventor for the commercial exploitation of a scientific or technological invention and preventing others from using it without the right-holder's consent.¹⁵ This system is a derogation from the principle of free trade and rewards the inventor with exclusive profits in return for money and time spent in R&D. This derogation of the free trade rule is restricted by the fact that the rights are only for a specific length of time and that the inventor must disclose the invention so as to ensure that the society in general benefits from the scientific development. Article 27 of TRIPS explains what can be patented are discoveries which 'are new, involve an inventive step and are capable of industrial application'.¹⁶

Patent protection is absolutely vital for the pharmaceutical industry, as without the extensive period of exclusive profit, the industry could not recoup the R&D costs for the new drug. On the other hand, patent protection provides the producer with a market monopoly, free from market competition that allows the patent holder to charge any price they feel the market will bear.¹⁷ So new drugs are sold at prices much higher than the marginal cost of production and distribution, and universal patent protection through TRIPS can push these prices even higher.

For the majority of people living in the developing world it already is a struggle to afford medicines. A cheaper generic version produced in developing countries where patent protection of pharmaceutical products is not enacted in domestic law has alleviated the problem of access to some extent. Yet with the incorporation of TRIPS, affordability of drugs whether by individuals or governments will be greatly affected.

Representatives of the pharmaceutical transnational corporations (TNCs) have argued that patent protection is not a significant contribution to the problem of access to medications in the developing world.¹⁸ Many of these companies insist that the problem of access to medicines is a multi-faceted issue that is mainly based on poverty and poor health infrastructures.¹⁹

¹⁴ P. Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health', *International Affairs*, 79, 1 (2003) p.140

¹⁵ Oxfam, *Fatal Side Effects: Medicine Patents under the Microscope*, (2001) publication by Oxfam GB, Oxford

¹⁶ WHO Policy Perspectives on Medicines-*Globalization, TRIPS and access to pharmaceuticals*, No.3, March 2001, WHO, Geneva

¹⁷ N. Ford, 'TRIPS Revisited', *British Journal of General Practice*, 6 November 2001 available at <http://www.accessmed-msf.org/prod/publications.asp?scntid=7112001142712&contenttype=PARA&>

¹⁸ From speeches and corporate statements on the websites of GlaxoSmithkline, Merck and Roche

¹⁹ ¹⁹ Presentation given by Chris Strutt, GSK, 'Do patents help stimulate research on medicines developing countries need? Are they a barrier to accessing medicines?', held at the Overseas Development Institute, 12 February 2003 available at http://www.odi.org.uk/speeches/IPR_2003/meeting2.html

B. Access to medicines and the Doha Declaration

Access to medicines is a fundamental aspect for the enjoyment of the right to health. The right to health is a fundamental human right²⁰ which has developed into binding international law since its initial documentation in the Universal Declaration of Human Rights (UDHR)²¹, and can now be found in numerous international and regional treaties. Its core provision in international human rights law is set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which recognises ‘the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’. It further states ‘to achieve the full realisation of this right’ it is necessary for States parties to take steps for ‘the prevention, treatment and control of epidemic, endemic, occupational and other diseases’ and ‘the creation of conditions which would assure to all medical service and medical attention in the event of sickness.’²² HIV/AIDS has drastically affected many lives and has impeded on many rights of millions of people. Accessibility to medicines is a critical component not only of the right to health, but also of the rights to life, non-discrimination, an adequate standard of living, benefits of scientific progress, and many others.²³ The right to life is considered as one of the most basic of rights, to the extent that some would say it is of *jus cogens* status. Yamin states “given that medications can be indispensable for life, it is foreseeable that state policies likely to lead directly to diminished physical accessibility and affordability of certain medication will, in effect, deprive people of life.”²⁴

In the acute context of AIDS, access to medicines is a crucial factor to ensure health and life for the millions who are now infected. The effect of patents on access to medicines has the potential to hurt these people the most, and will deprive them of their rights to health and life. There are 148 signatories to the ICESCR (right to health), 151 signatories to the International Covenant on Civil and Political Rights (ICCPR) (right to life) and there are 144 member states to the WTO. Most nations in the world have thus signed up to all three legally binding treaties and are all obliged to ensure that acting on one agreement does not impinge on another. This explains the concern of the human rights movement with the potential impedance on human rights law by the incorporation of TRIPS into national legislation.

Both intellectual property rights and human rights are important developments in international law. Differing interpretations by different governments has produced a debate that requires a solution where TRIPS can be implemented while respecting the right to health. That this debate is of major international concern is exemplified by the numerous discussions and meetings relating to it at the WTO, WHO, UNICEF and various human rights bodies of the United Nations. At the Fourth WTO Ministerial meeting in Doha, the Declaration on TRIPS and Public Health (referred to as the

²⁰ The preamble of the Constitution of the World Health Organisation states, “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”

²¹ Article 25, UDHR 1948, ‘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.’

²² P.R. Gandhi, *International Human Rights Documents*, 3rd edition (2002), Oxford University Press, New York

²³ A.E.Yamin, ‘Not just a tragedy: access to medications as a right under international law’, *Boston University International Law Journal*, Fall 2003

²⁴ *Ibid*

‘Doha Declaration’) was produced to clarify aspects of the TRIPS agreement that were believed to be in contention with human rights law and in which the primacy of the right to health in implementing intellectual property rights was affirmed:²⁵

“We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”²⁶

The Doha Declaration also reaffirmed the right of developing countries to use the safeguards available in the TRIPS agreement in order to deal with public health issues, such as the HIV/AIDS pandemic, and has extended the implementation date for the least-developed countries (LDCs) to 2016. However, soon after the US government began to pressurise developing member States into implementing patent protection of pharmaceutical products in bilateral trade agreements such as in Thailand.²⁷

The governments of the US, Japan, Canada, Australia and Switzerland have continued to press their agenda for stricter patent protection,²⁸ while governments of the developing countries, particularly India, Brazil, Thailand and South Africa which have large generic pharmaceutical industries, demonstrate increased access to medicines through resisting strict patenting of essential ARVs. Meanwhile, civil society groups and non-governmental organisations (NGO) continue to press the pharmaceutical TNCs to lower prices of drugs and increase R&D for the markets and the diseases of the developing world.

The debate between intellectual property rights and human rights will be examined based on three separate issues. The first highlights that access to medicines is a human right under international law; and then questions if intellectual property rights in the context of medicines are also a matter of rights under human rights law. The second questions whether patent protection actually affects access to medicines, as the pharmaceutical industry claims it does not. The third issue examines whether TRIPS can be implemented in a manner that respects and protects the right to health, and whether it can, as its incentive to innovate should, complement access to medicines.

²⁵ E.F.M. ‘t Hoen, ‘TRIPS, Pharmaceutical patents and Access to Essential Medicines: Seattle, Doha and Beyond’, *Chicago Journal for International Law*, 2002

²⁶ Declaration on the TRIPS agreement and public health, Fourth WTO Ministerial Meeting, Doha. See Annex I

²⁷ S. Boseley, ‘France accuses US of Aids blackmail’, *The Guardian*, 14 July 2004

²⁸ TRIPS-plus is an extension of IP protection beyond the minimum standards of TRIPS which includes extending patent life beyond 20 years, further limitations on compulsory licensing and limiting exceptions that facilitate prompt introduction of generics. See further in WHO Policy Perspectives on Medicines.

2. The international debate surrounding access to medicines: Intellectual property rights versus human rights

A. Issue One: Intellectual property and access to medicines as human rights

Alicia Ely Yamin, says of access to medicines under human rights law:

“No issue more starkly illuminates the egregious inequalities that exist in the world today between and within countries and demands that we address such inequalities as urgent matters of social justice in accordance with international human rights law. At the same time, no issue more clearly demonstrates the indivisibility of civil/political and economic/social/cultural rights and challenges national courts and international human rights bodies to evolve in their definitions and approaches toward different rights categories.”²⁹

She highlights the importance that amongst discussions on pharmaceutical policies, trade and intellectual property agreements, in the context of HIV/AIDS and other diseases, it must be remembered that access to medicines is also a matter of rights under international law.³⁰ As mentioned above, the right to health has been ratified by most countries in the world through the ICESCR, but is further incorporated into international law through many other legally binding articles,³¹ including the Convention on the Rights of the Child (CRC)³², Convention on the Elimination of Discrimination Against Women (CEDAW)³³ and the constitution of the WHO³⁴. Regional instruments such as the European Social Charter³⁵, the Additional Protocol to the American Convention on Human Rights³⁶, the African Charter on Human Rights³⁷ have also, detailed provisions for the right to health. Domestically, the right to health and access to healthcare has found its place into over sixty Constitutions, and national courts have increasingly dealt with right to health cases, particularly regarding access to medicines.³⁸ One internationally renowned case details the South African government’s decision to endorse compulsory licenses for essential medicines into national legislation, including cheaper generic AIDS medicines. A union of 39 pharmaceutical companies filed a lawsuit against South Africa to prohibit this.

²⁹ A.E.Yamin, ‘Not Just a Tragedy: Access to medications as a right under international law’, *Boston University International Law Journal*, Fall 2003, p. 328

³⁰ A.E.Yamin, ‘Not Just a Tragedy: Access to medications as a right under international law’, *Boston University International Law Journal*, Fall 2003

³¹ V. Leary, ‘The Right to Health in International Human Rights Law’, *Health and Human Rights: An International Journal*, vol. 1 (1994)

³² Article 24: State Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. State Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

³³ Article 12, CEDAW

³⁴ The Preamble of the Constitution of the WHO states: The enjoyment of the highest attainable standard of health is one of fundamental rights of every human being.

³⁵ Article 13: Right to social and medical assistance; Article 17: Right of mothers and children to social and economic protection

³⁶ Article 10: Right to health; Article 16: Rights of children

³⁷ Article 16 (1)... the right to enjoy the best attainable state of physical and mental health
(2)... States parties... take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick

³⁸ Statement by Paul Hunt, Special Rapporteur on the Right to Health, 59th Session of Commission on Human Rights, 3 April 2003, Geneva

Following intense lobbying from civil society groups and pressure from widespread public disapproval the lawsuit was dropped.³⁹

In AIDS Access Foundation, Mrs Wanida C and Mr Hurn R v Bristol-Myers Squibb company and the Department of Intellectual Property⁴⁰ in Thailand, the right to health as provided by the Thai constitution took precedent over intellectual property rights. Under intense pressure from Bristol-Myers Squibb (BMS), patent holders of the ARV in question, and from the US government in the form of trade sanctions, the Thai Intellectual Property department buckled and decided not to grant a compulsory license allowing the domestic generic pharmaceutical company to produce an affordable version of the ARV. The final verdict of the court stated, “Medicine is one of the fundamental factors necessary for human beings, as distinct from other products or other inventions that consumers may or may not choose for consumption” and that “lack of access to medicines due to high price prejudices the human rights of patients to proper medical treatment.”⁴¹

Although the issue has revolved around the concerns of TRIPS and patents acting as an impediment to human rights, the argument that human rights law takes precedent over certain trade law when public health is involved loses its grounding if one were to consider intellectual property rights as human rights. In fact, this changes the debate entirely as it becomes one to be considered within the existing human rights framework. Rosemary Coombe asks the question, “What would it mean to recognise intellectual property rights as international human rights?”⁴² She notes that even if there is a case to be made that intellectual property rights are human rights, it rarely is approached from this angle by either governments or holders of the rights. Coombe points out that intellectual property as a right holds an ambiguous place, both as the right to property in the UDHR⁴³ and in Article 15 (c) of the ICESCR ‘To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author’. Robert Ostergard evaluates intellectual property rights as a form of the right to property and explains that this dates as far back as the Chinese Zhou dynasty (1122BC).⁴⁴ He evaluates the justifications that intellectual property rights are property rights examining Nozick’s interpretation of John Locke’s labour theory of property as well as a utilitarian interpretation of property. He summarises that a libertarian interpretation of Locke’s theory fails to present justification to the existence of intellectual property rights to protect all intellectual objects as people are potentially worse off under IPR systems. The

³⁹ D. Barnard, ‘In the high court of South Africa, case no. 4138/98: the global politics of access to low-cost AIDS drugs in poor countries’, *Kennedy Institute of Ethics Journal*, vol 12, p. 150-174 (2002), available on Medline

⁴⁰ This case was heard at the Central Intellectual Property and International Trade Court, 2002(10), and is cited in N. Ford et al., ‘The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand’, *The Lancet*, vol 363, p.560-63 (2004)

⁴¹ This case was heard at the Central Intellectual Property and International Trade Court, 2002(10), and is cited in N. Ford et al., ‘The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand’, *The Lancet*, vol 363, p.560-63 (2004) p. 365

⁴² R. Coombe, ‘Intellectual Property, Human Rights and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conversation of Biodiversity’, *Indiana Journal of Global Legal Studies*, Fall 1998

⁴³ Article 17 of UDHR: Everyone has the right to own property alone as well as in association with others

⁴⁴ R. L. Ostergard, Jr., ‘Intellectual Property: A Universal Human Right?’ *Human Rights Quarterly* 21.1 (1999) p. 156-178

utilitarian view that the long-term benefits outweigh the short-term costs of IPR as they provide an incentive for innovation is considered by Ostergard to be too weak. He proposes an alternative approach claiming that not all intellectual property rights are justified. The reasoning Ostergard defends is, “because the state’s responsibility to provide for people’s physical welfare takes precedence over an individual’s right to profit”.⁴⁵ His two points of argument are that firstly, “there exists a hierarchy of intellectual objects based on a generally perceived notion of physical welfare” and secondly, “when discussing IPR, the emphasis must not be exclusively on the rights of producers; IPR must also be examined from the perspective of consumers and the national welfare.”⁴⁶

Within the network of the WTO, the industry and its governments have exuded an aura of protecting material interests rather than human interests, thereby focussing TRIPS on just protecting trade and material products rather than the rights of the author or inventor of the product. Using Article 15 (c) could potentially close off the debate between TRIPS and human rights, as intellectual property rights could not be an infringement on human rights if it is a human right itself. It is curious that despite this opportunity, the pharmaceutical industry and their governments have not observed this line of argument. This leads to further questions, such as whether multinational corporations acting on behalf of their scientist should be allowed to claim the right of individual human rights; and if the human rights regime were to accept intellectual property rights as a human right, in the current climate of universal human rights being indivisible and of no hierarchy, how would Article 15 (c) be interpreted in light of Article 6 (ICCPR) and 12 (ICESCR) with regards to access to medicines? It may be that Ostergard’s theory provides a working answer to the latter, however a further examination into this issue falls beyond the scope of this paper.

B. Issue Two: Do patents affect access to medicines for the poor?

“...Intellectual property protection is not the cause of the present lack of access to medicines in developing countries.”⁴⁷ Sir Richard Sykes, former Chairman of Glaxo Smithkline (GSK), is one of many voices from the pharmaceutical industry who maintain that patent protection is not the source of the problem but that poverty, poor health infrastructure and a lack of political will are the obstacles preventing the poor accessing medicines. It is true that accessible healthcare requires more than just cheaper drugs. Many developing countries need to develop and build up a sustainable and accessible health infrastructure, treatment needs to be administered in appropriate conditions with adequate monitoring and follow up facilities. Governments need to focus more of their budget on primary healthcare, particularly health education, personnel training and disease prevention. Yet it is also true that in most developing countries people pay for medicines out of their own pockets and hence the cost of the drug has a direct impact on their affordability.

⁴⁵ Ibid, p. 157

⁴⁶ Ibid, p. 157

⁴⁷ Presentation by Sir Richard Sykes at the Royal Institute of International Affairs, London, 14 March 2002, cited in the CIPR Report

i) Yes, patents do affect access to medicines

Nathan Ford, from the MSF Access to Medicines campaign, says that price can be a predominant factor in limiting access to medicines as in some developing countries up to 80 percent of health expenditure is on medicines.⁴⁸ He explains that,

“For the individual, inability to pay for full treatment can result in sub-optimal treatment, debt or even no treatment at all. At the country level, health budgets spent on expensive medicines means money diverted from other essential areas like training of health workers and improving health infrastructure.”⁴⁹

Many NGOs such as MSF and Oxfam have produced many reports indicating that it is the poorest and the most vulnerable for whom the cost of drugs such as ARVs are the determining factor for being unable to afford treatment. The Commission on Intellectual Property Rights (CIPR), set up by the Department for International Development in the UK, has demonstrated studies in its report ‘Integrating Intellectual Property Rights and Development’⁵⁰ presenting considerable evidence that consumption of medicines is sensitive to price. A study in Uganda estimated that a reduction of the price of ARV triple therapy from \$6000 per annum to \$600 per annum would increase the demand for treatment from 1000 to 50000 patients when associated with relatively modest investments in treatment infrastructure.⁵¹ Another study in Uganda showed that the import of generic products lowered the price of those produced by the commercial pharmaceuticals and thereby increased the number of patients being treated threefold between 2000 and 2001.⁵²

The level of healthcare and social welfare is hugely disparate between the developed and the developing world, and whereas in Western countries medicines are partially subsidised by a national health care system or health insurance system, such a system is not present for all the population in many of the developing countries. Where individuals must buy medicines with a full price tag, the cost of the drug determines whether it can be afforded or not. No pharmaceutical representative could surely disagree with that or the fact that this is the case for millions of families living in the developing world.

ii) No, patents do not affect access to medicines

GSK is certainly not the only pharmaceutical company that will maintain that patents are not the cause for a lack of access to medicines. Roche states that, “The existence of patents has often been viewed as a barrier preventing those living in resource-poor

⁴⁸ N. Ford, ‘Patents, access to medicines and the role of non-governmental organisations’, *Journal of Generic Medicines*, Vol. 1 No.2, p. 138

⁴⁹ Ibid, p. 138

⁵⁰ Commission on Intellectual Property Rights, ‘*Integrating Intellectual Property Rights and Development Policy*’, Executive Summary of the Report of the Commission on Intellectual Property Rights, (London 2002). This report will be referred to as the ‘CIPR Report’ from here on.

⁵¹ *Continent in Crisis*, Report by McKinsey and Company on increasing access to ARVs in Uganda, 2000. Source: <http://www.mckinsey.com/firm/people/feature/uganda/main/index.asp>, cited in CIPR Report (2002)

⁵² Oxfam, *Generic Competition, Price and Access to Medicines*, Oxfam Briefing Paper No. 26, Oxfam, Oxford (2002) cited in the CIPR Report

countries from accessing medicines. Patent protection is not a major barrier to care in developing countries.”⁵³ Considering it was the major pharmaceutical companies that had pressed their governments to ensure globalisation of patent protection and hence the inclusion of pharmaceutical products in the TRIPS Agreement this consistent response is not surprising. These firms do back up their reasoning behind the belief that patents are not barriers to access to medicines. Firstly, there is what one might call the ‘blame it on poverty’ approach. Poverty is a major cause of denials of numerous human rights throughout the developing world, and it plays a significant role in the problem of access to medicines. Secondly, in link to poverty, is the lack of spending on health care and the absence of a suitable health infrastructure that distributes and administers medicines adequately causing major constraints to access to medicines. The US pharmaceutical industry association states:

“Handicapped by limited financial resources, these nations’ ability to contain AIDS and address a host of other killer diseases is compromised by inadequate infrastructure, cultural barriers to care, and mismanaged health care systems. Some developing countries also are hampered by political leadership that lacks the will to confront or even acknowledge their nation’s health care needs.”⁵⁴

An interesting comment made by a participant at a conference for the report of the Commission on Intellectual Property Rights was:

“... I would like to discourage the Commission from arriving at the conclusion in this debate (that it is all) about infrastructure and resources. If that is the conclusion, I think you will have what the title says: “People are poor”. So don’t make recommendations that people are poor because we know that. We are trying to solve their problems, not to tell them that they are poor.”⁵⁵

At a conference chaired by the Department for International Development, Chris Strutt, Vice-President of External Relations at GSK, also argued that most essential drugs are not patented. He provided data that 95% of the 308 drugs on the WHO ‘Essential Medicines’ list were not patented.⁵⁶ Until recently, medicines had to be of low cost as a criteria to be on the Essential Medicines list, which can exclude several more expensive yet better essential drugs including antiretroviral medicines.

The other argument that pharmaceutical companies have pointed out is the prevalence of patenting. Although patent protection is available in most developing countries, pharmaceutical TNCs have not patented their products in all of them.⁵⁷ In a study of 53 African countries, it was found that the extent of patenting of 15 important antiretroviral drugs was 21.6% of the possible total, and that in 13 of these countries

⁵³ Roche website, available under 'Sustainability' section 2004

⁵⁴ Report from Pharmaceutical Research and Manufacturers of America (2002), ‘Health Care in the Developing World’, PhRMA available at <http://world.phrma.org/ip.access.aids.drugs.html>

⁵⁵ Presentation given by Sisule Musungu at the Session on Medicines, Commission Conference, London, 21-22 February 2002. Cited in ‘Integrating Intellectual Property Rights and Development Policy’, CIPR or www.iprcommission.org

⁵⁶ Presentation given by Chris Strutt, GSK, ‘Do patents help stimulate research on medicines developing countries need? Are they a barrier to accessing medicines?’, held at the Overseas Development Institute, 12 February 2003 available at

http://www.odi.org.uk/speeches/IPR_2003/meeting2.html

⁵⁷ CIPR Report

there were no patents at all.⁵⁸ In countries with a small market and limited technological capacity, such as manufacturing of drugs, it is not worth the expense for pharmaceutical TNCs to obtain patent protection if the risk of infringement into their market is so small. This small prevalence of patents means that they are not a significant barrier to access to treatment in Africa.

On the other hand, the worst hit areas of HIV/AIDS is limited to particular regions of Africa, such as sub-Saharan Africa, and other areas such as northern Africa has so far been spared of a major epidemic. The prevalence of patents is much higher in countries which have a higher prevalence of HIV and which also have domestic technological capacity for pharmaceutical products. For example, South Africa has the highest number of HIV positive population in Africa and 13 of the 15 antiretroviral drugs are patented.⁵⁹

The argument that the industry makes is that even if there are no patents, access to medicines are still a problem; another point they make is that intellectual property does not act as a barrier to access to medicines. An example that Strutt delivers in his speech and used by many in the industry⁶⁰ is that of India. In India the patent legislation recognises process patents but not product patents on pharmaceuticals⁶¹. The 1970 Indian Patents Act allowed the domestic generic pharmaceutical industry to grow into one of the most developed generic industries of the world.⁶² They are major suppliers of generic antiretroviral drugs to the African continent, yet the vast majority of people with HIV in India do not have access to the drugs themselves.

Firstly, on the issue of prevalence of patents, countries that have no patents will have to implement patent protection when TRIPS becomes obligatory in their domestic legislation by either 2006 or 2016, and thus patents will become an issue for them. Secondly, many of these countries rely on generic imports from countries that produce generic medicines such as South Africa and India. These countries will have their generic antiretroviral drug production further tightened by TRIPS. Compulsory licences will have to be used to manufacture generic antiretroviral drugs which are patented and worse still for the smaller countries, Article 31(f) restricts the use of drugs produced under a compulsory licence mainly to the domestic market only. Compulsory licensing and Article 31(f) will be explained in further detail in the following section.

In defence of the industry though, some of the pharmaceutical corporations have actively addressed the issue of access to medicines in developing countries. Roche for example has developed a global patent policy to maximise access to all its medicines in which no patents will be filed for any of their drugs in LDCs. They also have a specific HIV/AIDS patent policy whereby no patents will be filed on new ARVs and

⁵⁸ A. Attaran, L. Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?' *Journal of the American Medical Association*, vol 286, no.15, p. 1886-1892 (2001)

⁵⁹ UNAIDS report (2002) p. 189-201, cited in CIPR report

⁶⁰ India is used as an example by GSK and Roche by their Corporate Responsibility sectors. These can be found on their respective websites.

⁶¹ P. Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health', *International Affairs*, 79, 1 (2003), p. 143-144

⁶² Ibid, P. Cullet article, and Roche-Patents, 'Patents in Developing Countries', available at www.roche.com/home/sustainability/sus_med/sus_med_pat.htm

no action will be taken against manufacturers of generic versions in LDCs and sub-Saharan Africa.⁶³ Over the past few years, several of these multi-national pharmaceutical companies have produced ‘access to medicines’ programmes with greatly reduced prices of drugs for the developing world, including ARVs, to not-for-profit prices.⁶⁴ Charitable donations have also been negotiated between some companies and governments.⁶⁵

C. Issue three: Can TRIPS be implemented and improve public health?

i) Research and development

The perspective of the pharmaceutical industry is that TRIPS is essential to incentivise innovation and thereby promote further investment into R&D of newer and better medicines. As GSK puts it, “No patents, no cures.”⁶⁶ The industry’s standpoint is that no new medicines would be developed unless both intellectual property protection and a market is present. Patents protect the financial incentive from a drug, and the industry can only justify the amount spent on R&D and by recouping the investment spent. TRIPS allows firms to charge a higher price for the duration of the exclusive right, during which the firm is expected to absorb its cost in R&D. After this time, competition from generic versions of the drug brings the cost down but as demand for medicines remain high, the cost often remains too high for the poor. In the context of HIV/AIDS the amount of R&D that has gone into antiretroviral medicines over the past two decades is remarkable, and the consequential improvement in the quality of treatment has been a phenomenal success. In the industrialised nations where antiretroviral treatment is readily available, people with HIV will die from old age or other age-related illnesses rather than from the virus. The development of a new drug is both time-consuming and costly, yet it is not so to copy a drug. The patent system for that reason is essential for the pharmaceutical industry to continue their R&D into newer and better medicines and vaccines. Many pharmaceutical firms at present have poured funds in to the research for an HIV-vaccine, and because of the protection guaranteed of their potential patent by TRIPS, these firms continue to find better drugs that aid public health.

The problem is that the benefits of R&D are not felt equally throughout the world’s populations. Less than 5% of the money spent on R&D by pharmaceutical firms is actually for diseases that predominantly affect the developing countries.⁶⁷ It has been estimated that only 13 of 1393 new drugs produced between 1975 and 1999 were to

⁶³ Roche-Patents, ‘Patents in Developing Countries’, available at www.roche.com/home/sustainability/sus_med/sus_med_pat.htm

⁶⁴ Merck, GSK, Roche and Astra Zeneca are some of the pharmaceutical companies that have created Access to Medicines programmes, of which some are for HIV/AIDS.

⁶⁵ Boehringer-Ingelheim has a Viramune Donation Program where they have pledged the antiretroviral drug Nevirapine (Viramune) free of charge to developing countries on negotiation with the governments. Further information available on www.ifpma.org/Health/hiv/health_viramune_hiv.aspx

⁶⁶ Presentation given by Chris Strutt, GSK, ‘Do patents help stimulate research on medicines developing countries need? Are they a barrier to accessing medicines?’, held at the Overseas Development Institute, 12 February 2003 available at http://www.odi.org.uk/speeches/IPR_2003/meeting2.html

⁶⁷ CIPR Report

treat tropical diseases.⁶⁸ The developing world provides a small market in terms of effective demand, and as mentioned above, R&D is funded depending on the potential market demand and the availability of patent protection. Although HIV/AIDS drugs have received much private sector R&D as the disease is also prevalent in the developed world, there are areas of neglect when the concern pertains only to the developing world. For example, most of the R&D going into an HIV vaccine is currently for subtype B, which is the sub-type prevalent in North America, Europe and Japan. Yet the majority of people suffering from AIDS are in Africa and Asia where subtypes A and C are prevalent.⁶⁹

“So what role does IP protection play in stimulating R&D on diseases prevalent in developing countries?”⁷⁰ The Commission’s report questioned this and replied:

“All the evidence we have examined suggests that it hardly plays any role at all... we do not think that the globalization of IP protection will make a significant contribution to increasing R&D expenditure by the private sector relevant to the treatment of diseases that particularly affect developing countries.”⁷¹

If TRIPS fails to stimulate R&D in developing countries and thus fails to improve public health, should added costs covering R&D be paid for by those in the developing world? This may support moves towards differential pricing which is an option that can benefit developing countries and remain compliant with TRIPS. The following section expounds on the provisions available in the agreement to promote differential pricing.

ii) Using TRIPS in Favour of Public Health

At the WTO Ministerial Conference in Doha in November 2001, ministers stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and the creation of new medicines.⁷² The interpretation of the “flexibilities” that are written into TRIPS for the purpose of public health were not utilised prior to Doha by member governments as most were unclear as to when and how they could be used. Resulting from a concerted and united effort from the African member states that form the African Group, a clarification of these flexibilities was mostly settled in what became the Doha Declaration. The ministers agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. The Declaration confirmed that compulsory licences could be granted by member states and the grounds on which they are granted is up to that government, so long as it is compliant with the TRIPS Agreement. In order to meet the national demand for certain drugs, member states can also implement parallel importation.⁷³ Although some critics have described the Doha Declaration as a failure in amending the TRIPS

⁶⁸ P. Trouiller et al, ‘Drug Development for Neglected Diseases: a Deficient Market and a Public Health Policy Failure’, *The Lancet*, vol 359, p. 2188-94

⁶⁹ *State of the World’s Vaccines and Immunization*, Joint document by WHO, UNICEF and the World Bank, published by World Health Organization (2002), p. 38

⁷⁰ CIPR Report, p. 38

⁷¹ CIPR Report, p.39

⁷² WTO Press Release, Intellectual Property; *Decision removes final patent obstacle to cheap drug imports*, 30 August 2003 available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

⁷³ See Annex I, the Declaration on the TRIPS Agreement and Public Health

Agreement to ensure access to medicines for the poor⁷⁴, other writers have noted how much both the attitude and the language of the international community and the pharmaceutical companies have changed since.⁷⁵

One way to ensure that poorer people have better access to medicines is to differentiate the price at which the drugs are sold to different countries. A differential pricing system allows low prices in developing countries to coexist with higher prices in developed countries, and this form of market segmentation allows for the poorer people to obtain cheaper products while the multinational companies can maximise their profits by selling in both the high and low income markets. For this system to work, firstly, exports and imports of relevant products must be strictly controlled through effective domestic legislation to prevent low priced medicines from entering the higher priced markets.⁷⁶ To ensure that differential pricing works, developing countries need to develop and design national policies that provide a process by which to admit parallel imports or to provide compulsory licences in compliance with the TRIPS Agreement.

Compulsory licensing enables a government to authorise production of a patented product without the consent of the patent holder. This license thus allows a domestic pharmaceutical company to manufacture and produce a generic version of a patented drug which essentially will be much cheaper. In accordance with TRIPS, compulsory licences should be used when a government is faced with a national emergency such as epidemics, anti-competitive prices by drug companies or for public non-commercial use,⁷⁷ but the patent holder retains the intellectual property rights and “shall be paid adequate remuneration” in certain circumstances.⁷⁸ The problem is that certain procedures and conditions, which are not necessarily easy for developing countries to use, apply. The Commission on Intellectual Property Rights has pointed out four reasons why developing countries have not used the system. Firstly, the level of administrative and legal infrastructure required is not available in many developing countries and secondly, there is a fear of the threat of bilateral or multilateral sanctions by Western governments. Thirdly, compulsory licensing has to be “predominantly for the domestic market”. Fourthly, the licensee must have the resources and technology to reverse-engineer and manufacture the drug, and must also foresee a large enough market to justify the costs of investment.⁷⁹

Brazil has successfully used the threat of using compulsory licensing to negotiate cheaper prices with pharmaceutical companies in pursuit of implementing their National STD/AIDS Programme (NSAP). NSAP provided free ARVs to those who

⁷⁴ P. Cullet, ‘Patents and medicines: the relationship between TRIPS and the human right to health’, *International Affairs*, 79, 1 (2003)

⁷⁵ E. F. M. ‘t Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’, Updated account of publication in *Chicago Journal for International Law*, Vol.3 (1), Spring 2002

⁷⁶ CIPR Report

⁷⁷ WHO Policy Perspectives on Medicines-*Globalisation, TRIPS and access to pharmaceuticals*, WHO

⁷⁸ Article 31: *Other Use Without Authorization of the Right Holder*; Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.

⁷⁹ CIPR Report

need them through the national public health care system. With the assistance of NGOs working on HIV/AIDS, the national public health services network for drug distribution supplies ARVs to nearly 105,000 of Brazil's estimated 600,000 HIV/AIDS patients. This has reduced mortality among AIDS patients to half what was predicted in the 1990s and has decreased hospital admissions by 80%. In 2001, the final cost of NSAP was estimated by the Brazilian Ministry of Health to be negative with a net saving of US\$50m.⁸⁰ The prices of ARVs fell by 72.5% between 1996 and 2000 as many drugs were not patented and manufactured by the local government producer, and prices of those purchased from multi-national companies were significantly lowered through negotiations following the threat of the use of compulsory licensing.

In Thailand, production of a local generic version of fluconazole, an antifungal drug that treats fatal meningitis prevalent in AIDS patients, brought the price of the patented drug by Pfizer from US\$14 to US\$3 as the locally manufactured one was US\$1.⁸¹ Thus compulsory licences actually also bring prices of patented drugs down. Many developing nations though who provide compulsory licenses to their domestic pharmaceutical producers have encountered economic threats such as sanctions on exports or removal of favourable trade agreements by, in particular, the US government.⁸² Yet the Doha Declaration has reaffirmed in paragraph 5 (b) that 'Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'⁸³

TRIPS-Plus, which extends patent life beyond the 20-year limit of TRIPS and limits compulsory licensing even more, has been pushed by WTO members such as the US, Japan, Canada and Switzerland. Yet these are the very countries that did not implement patent protection until their own industries could withstand an open market and have used compulsory licensing in the past. In fact recently, in light of the anthrax scare in the US and Canada, the supply of ciprofloxacin, an antibiotic to treat anthrax, was noted to be insufficient. The two nations were going to issue compulsory licences to produce their own cheaper generic versions, until a deal was struck with the German company Bayer who holds the patent on the drug.

If patents prevent a product from being available to the poorer segment of the society in a developing country, because of the high prices set by the patent holder, the government can allow imports of the same products, parallel to the official imports, at a price level that is set by the free market rather than the patent holder. This promotes competition for the patented product as the same brand product marketed at lower prices in other countries can be imported in parallel. In the TRIPS Agreement, Article 6 states that practices relating to parallel importation cannot be challenged under the

⁸⁰ From UNAIDS, cited in CIPR Report

⁸¹ Cited in Oxfam, *Fatal Side Effects: Medicine Patents under the Microscope*, p. 19 referenced from *Focus Corporation*, 'The American Drug Lords' by R. Mokhiber and R. Weissman, 7 April 1999 source: www.haiweb.org/campaign/cl/corpfocus.html

⁸² The US government put pressure on Thailand to implement stronger patent protection by trade sanctions which has cost the Thais US \$165million dollars in lost export revenue. Despite the Doha Declaration, the US government is accused of still continuing to apply trade pressures to developing countries such as Thailand. See in N. Ford et al., 'The role of civil society in protecting public health over commercial interests: lessons from Thailand', *Lancet*, vol 363, p.561 and S. Bosely, 'France accuses US of AIDS blackmail', *The Guardian*, 14 July 2004

⁸³ See Annex I, The Declaration of the TRIPS Agreement and Public Health

WTO dispute settlement system (apart from when there is discrimination on the basis of the nationality of the persons involved).⁸⁴ This can be interpreted as meaning that parallel importation is a matter of national discretion.

Parallel imports can thus ensure that lower priced products can be supplied to those who need the lower prices. Yet in order to ensure this system does not allow low priced products to enter the high price markets, many developed countries have established strict legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries. Market segmentation also requires developing countries to implement a system to prevent exports of drugs that are donated or bought through the differential pricing scheme to the developed world.⁸⁵ As parallel imports can be an effective pro-competitive measure that is compliant with TRIPS, developing countries should be facilitating the use of parallel imports into their national legislation. As long as the patentee's rights have been exhausted in the foreign country, the patent holder cannot use their right in the importing country to prevent parallel importation.

iii) The Paragraph six issue

Paragraph 6 of the Doha Declaration addresses the one problem that was not fully settled at the conference in Qatar.⁸⁶ The TRIPS Council was left to find a solution for the issue of compulsory licensing for countries with an insufficient manufacturing capacity. Article 31(f)⁸⁷ was at the centre of this debate as it limited compulsory licenses to be granted for the production of medicines for the domestic market. The Council decided that in exceptional circumstances as those faced by countries which do not have their own pharmaceutical capability of using a compulsory license, a waiver of the obligations set out in paragraphs (f) and (h) of Article 31 can be justified with respect to pharmaceutical products. Thus as long as specified terms are met by the importing member, the exporting member can grant a licence to the extent necessary for the purposes of production of a pharmaceutical product and its export to the importing member. This decision removed the final patent obstacle for developing countries to import cheap drugs, and was welcomed by Director-General Supachai Panitchpakdi of the WTO as:

“The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people.”⁸⁸

The WTO governments decided that this waiver will last until the article is amended.

⁸⁴ WHO Policy Perspectives on Medicines-*Globalisation, TRIPS and access to pharmaceuticals*, WHO

⁸⁵ CIPR Report p. 49

⁸⁶ Doha WTO Ministerial Declaration on TRIPS and Public Health, Paragraph 6:

‘We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.’

⁸⁷ TRIPS Agreement Article 31: Other Use Without Authorization of the Right Holder

(f) any such use shall be authorised predominantly for the supply of the domestic market of the member authorizing such use

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization

⁸⁸ WTO Press Release, *Intellectual Property: Decision removes final patent obstacle to cheap drug imports*, 30 August 2003 available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

PART TWO

Child rights, HIV/AIDS and medical patents

The debate between intellectual property rights and human rights has been mainly centred on the global HIV/AIDS public health problem. The impact of the TRIPS Agreement on accessibility of medicines related to HIV and AIDS has been addressed as an issue that impinges, *inter alia*, on the right to health and the right to life. Whether a child or an adult, female or male, access to medicines is a vital aspect to enjoying basic human rights, but just as there is a separate Convention on Child Rights (CRC) highlighting that children need to be observed as a group of their own with specific needs and rights, there is a need to observe the relevance of access to medicines on children's rights. Amongst many negotiations and discussions within inter-governmental, UN or non-governmental organisations regarding policies and plans to tackle the HIV/AIDS pandemic, children have often been the least discussed.⁸⁹ Save the Children have warned that "in the rush to expand access to care and treatment for HIV/AIDS", children are in danger of being forgotten.⁹⁰

So, why have the needs of children been neglected? Initially children were considered as only marginally affected by HIV/AIDS, as they comprised only a small percentage of the total number of people infected. Government projects, funding, NGO focuses and international attention have been on the disease amongst the adult population. More recently, child-focussed organisations such as Save the Children and Unicef have highlighted that children are at the centre of the HIV/AIDS crisis and are the most vulnerable and the most devastated by it.⁹¹ The UN Committee for the Rights of the Child has also noted that "policies and programmes for the prevention, care and treatment of HIV/AIDS have generally been designed for adults with scarce attention to the principle of the best interests of the child as a primary consideration."⁹² The committee reminds its members of Article 3, paragraph 1, of the Convention which states 'In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration'. To deal with the growing pandemic in a sustainable manner, children's rights must be considered at the heart of designing and implementing HIV/AIDS policies and projects. The need for this approach to tackle this public health crisis is because children are and will continue to be the most affected by it. Millions of children live in a world with HIV/AIDS; 14 million children have lost one or both parents to AIDS and 3.2 million children under 15 are infected with HIV.⁹³ Concerns are that children orphaned are at high risk of becoming homeless, entered into exploitative labour and becoming victims of abuse and discrimination resulting from the stigma of being associated with AIDS.⁹⁴ The HIV pandemic has had an impact on so many children in so many ways

⁸⁹ Save the Children, *Remembering children in HIV/AIDS Treatment*, News Release 14 July 2004, available on www.savethechildren.org.uk/scuk/jsp/resources/details.jsp

⁹⁰ *Ibid*

⁹¹ Save the Children, *Beyond the Target: Ensuring children benefit from expanded access to HIV/AIDS treatment*, Report produced for XVth International AIDS Conference 2004 and UNICEF, *Fighting HIV/AIDS: Strategies for Success 2002-2005*, Unicef publication

⁹² UN Committee on the Rights of the Child, 32nd session, General Comment No. 3 (2003), paragraph 10, CRC/GC/2003/3

⁹³ UNICEF, *Fighting HIV/AIDS: UNICEF Strategies for Success 2002-2005*, p. 5, data from UNICEF/UNAIDS/WHO 2002

⁹⁴ *Ibid*

and is stopping children enjoying so many of their rights. Medicines to treat opportunistic infections and antiretroviral cocktails to control HIV can prolong the quality and quantity of life that a parent can spend with their children and can prevent the transmission of the virus to newborn babies. Increasing the access of medicines is vital to producing future generations of healthy, skilled and educated young adults to build the social and economic structure of these countries devastated by the epidemic. Expansion of medicines to those who need it, effective medical intervention to prevent transmission and sustainable care of those millions that are already affected are all essential actions to protect the rights of children.

In this Part, the first section examines the impact of HIV and AIDS on children and their rights. The second examines the effects of patent protection on children living with the pandemic and how the potential incentives outlined in TRIPS has failed to provide for children. The final section will examine why women need to be the central focus of HIV/AIDS policies and programmes to build a future for our children.

1. Impact of HIV/AIDS on children

Like many other debilitating chronic illnesses, AIDS does not just affect the victim of the illness but also all those around them. Children have been affected either by suffering from the infection itself or through seeing parents and relatives suffer painful deaths due to it. Some are orphaned too young to understand or remember the loss of a parent, and others have to become the sole breadwinner or carer. Many children, particularly girls, stop attending school to support ill parents or young siblings, or due to diversion of money to medical care can no longer afford the enrolment at school. The Committee of the CRC states that “adequate measures to address HIV/AIDS can be undertaken only if the rights of children and adolescents are fully respected.”⁹⁵ In its third General Comment, the Committee refers to nearly every right that is provided in the Convention that is affected by HIV/AIDS, ranging from the right to health (article 24) to the right to non-discrimination (article 2) to the right not to be separated from their parents (article 9).⁹⁶

The right to health enshrined in international and regional treaties extends its coverage to children, but the most specific and elaborate provision for a child’s right to health is found in Article 24 of the CRC:

‘State Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. State Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.’⁹⁷

The rest of this article provides a detailed focus to the needs for children’s healthcare, and what distinguishes it from the right to health enshrined in other global human rights treaties is its particular emphasis on primary health care. Geraldine van Bueren points out that “the African Charter on the Rights and Welfare of the Child follows

⁹⁵ UN Committee on the Rights of the Child, 32nd session, General Comment No. 3 (2003), CRC/GC/2003/3, p. 3

⁹⁶ Ibid

⁹⁷ P.R. Gandhi, *International Human Rights Documents*, 3rd edition, Oxford University Press (2002)

the lead of the CRC and also adopts a holistic approach to children's health, with the emphasis on effective primary health care."⁹⁸ Particularly in sub-Saharan Africa, it is vital that a primary health care approach is considered in HIV/AIDS programs and policies, as this will be more sustainable. In the perspective of child health and the large number of children who die every year in the developing world from preventable diseases, van Bueren focuses particularly on Article 6 of the Convention. This Article incorporates the recognition by States Parties that every child has the inherent right to life and that States Parties should ensure to the maximum extent possible the survival and development of the child.⁹⁹ The right to life, survival and development are just as crucial as the right to health when considering access to HIV medicines for the millions of children who currently are HIV positive and are unable to receive appropriate life-saving treatment. Yet in the context of HIV/AIDS and children there are many more rights to consider. The following three parts will look at the practical issues that impinge on children's rights through the impact of the HIV/AIDS pandemic.

A. Children of families with HIV: Right to non-discrimination

There are millions of children who are currently living with a parent or a sibling who is HIV positive. The stigma associated to the disease often includes the children who become victims of discrimination even when they are not infected. This kind of discrimination can be the underlying reason for denying children an access to education, information, health or social care services. The stigma attached to having a parent with HIV/AIDS has resulted in children being asked to leave school or even abandoned by the extended family. A Human Rights Watch (HRW) report has examined how many children and their families living with HIV/AIDS are being discriminated against in India.¹⁰⁰ Discrimination is not just by those whose fear of the disease is due to ignorance and misunderstanding but by the healthcare workers and the very institutions that are designed to look after the vulnerable and the sick. Children encounter stigmatisation and discrimination if their parents have been diagnosed with HIV even if they themselves test negative. They have been denied access to school and hospitals and orphanages have refused children that are ill or orphaned.¹⁰¹ Children of parents with HIV have been prohibited from playing with other school children,¹⁰² and extended families have refused to take in children whose parents have died of AIDS, particularly if they are also HIV positive.¹⁰³ According to some interviewed by Human Rights Watch in India, although some doctors in private hospitals will examine and treat children with HIV, many other doctors and healthcare workers refuse to examine or even touch them and explain there is no treatment. Often they are refused admission to hospital or are referred elsewhere. The widespread experience of discrimination and the lack of treatment for the infection perpetuates refusal to HIV-testing and reluctance to seek medical help. One

⁹⁸ G. van Bueren, *The International Law on the Rights of the Child*, p. 298, Martinus Nijhoff Publishers (1995)

⁹⁹ G. van Bueren, *The International Law on the Rights of the Child*, p. 298, Martinus Nijhoff Publishers (1995)

¹⁰⁰ Human Rights Watch, "Future Forsaken: Abuses Against Children Affected by HIV/AIDS in India", July 29, 2004 available at <http://hrw.org/reports/2004/india0704/>

¹⁰¹ Human Rights Watch, "Future Forsaken: Abuses Against Children Affected by HIV/AIDS in India", July 29, 2004 available at <http://hrw.org/reports/2004/india0704/>

¹⁰² Oxfam Report 2004 from International AIDS Conference 2004, Bangkok, Thailand

¹⁰³ Human Rights Watch report

consequence of this is the lack of women seeking tests for HIV, and thus mothers with HIV are ignorant of and not offered the option of treatment to prevent mother-to-child transmission. The child's right to the highest attainable health is denied from before it is born and many more rights are violated as they continue through life with HIV/AIDS. Another major concern is gender-based discrimination against girls. This leads to their increased vulnerability by limiting access to information and control over measures to prevent sexually transmitted infections. This doubly discriminates against the child and puts them at higher risk of becoming a victim of HIV. This issue will be elaborated on later in the paper.

B. Orphaned by AIDS: Right to family life¹⁰⁴

In the past two decades, the problem of children being orphaned by AIDS was initially thought of as a marginal concern. Governments, NGOs and the international organisations had failed to foresee that this was one of the most pressing issues and the most rapidly growing burden for those States most affected with HIV/AIDS. With child –focused organisations highlighting the real problem of the exploding number of orphans in recent years, governments are just beginning to take the issues into account. Orphaned children are particularly neglected and their rights are the most likely to be violated. Not only do they suffer from the emotional, social and physical loss, but they also lose their economic support. Educational and developmental skills are not developed if they are orphaned young and not taken in by other family. They are more vulnerable to exploitative child labour, abuse, neglect, and abandonment and have an increased risk of contracting HIV.¹⁰⁵ Incidents of children orphaned by AIDS having social security and insurance denied, and their property and inheritance stripped away has been noted as a widespread problem in both Asia and Africa.¹⁰⁶ All these issues need to be addressed urgently by the governments and international organisations as a child loses a parent every 14 seconds.¹⁰⁷

C. Living with HIV: Right to life, survival and development

According to UNICEF, in 2002 around 800,000 children who were under the age of 15 years were infected with HIV and 90% of them were infected through vertical transmission from the mother.¹⁰⁸ Recent data have shown that about 1800 children are being infected everyday, over 50% of these children die before their second birthday and a fraction of that reach the age of 5.¹⁰⁹ The incidence of HIV infection amongst adolescents and young adults has been increasing at an alarming rate. The majority of

¹⁰⁴ This right is provided in Article 10 of the ICESCR 'the widest possible protection and assistance should be accorded to the family, which is the natural and fundamental group unit of society...' and in the Preamble of the CRC 'Recognizing that the child, for the full and harmonious development of his or her personality, should grow up in a family environment, in an atmosphere of happiness, love and understanding', and in CRC Article 9 to ensure that a child shall not be separated from his/her parents against their will.

¹⁰⁵ UNICEF, 'Protection and support for orphans and families affected by HIV/AIDS', UNICEF report (2004) available at www.unicef.org/aids/index_orphans.html

¹⁰⁶ Human Rights Watch Report

¹⁰⁷ 'Children in a World of AIDS', a Save the Children publication (2004) available at <http://www.savethechildren.org/publications/504AIDS.pdf>

¹⁰⁸ UNICEF, 'Fighting HIV/AIDS: Strategies for Success 2002-2005', UNICEF official document,

¹⁰⁹ R. Spira, P. Lepage, P. Msellati, et al. 'Natural history of HIV type 1 infection in children: a five-year prospective study in Rwanda', *Pediatrics*, vol 104, D1-D9, (1999)

the newly infected are in the age group 15 – 24 years, and currently make up 12 million of the HIV population. Contributions to this increased prevalence amongst adolescents include early onset of sexual activity, the lack of knowledge of sexually transmitted infections (STIs), the increase use of drugs, and the use of rape as a weapon in conflict. Use of unsafe blood products and unsterile needles for vaccinations are also preventable contributing factors.¹¹⁰

Children who are infected with HIV have a different course of infection to adults. In many children the disease progresses rapidly to AIDS and often they develop AIDS-related illnesses before they reach the age of one, others follow a similar pattern to adults and do not develop AIDS or AIDS-related illnesses for ten years. As at birth their immune system is immature and fails to develop due to the virus, opportunistic infections are more aggressive and cause more morbidity.

2. Impact of TRIPS on children living with HIV/AIDS

A. Mother to child transmission

With high costs of antiretroviral drugs and limited resources, one of the areas that have been targeted for medical intervention is the prevention of mother-to-child-transmission (MTCT). In the UK, the public health campaign to reduce the incidence of vertical transmission of HIV from mother to child has successfully reduced the number of babies born with HIV to less than 1%.¹¹¹ However, without medical intervention there is a 25-45% chance of MTCT that can occur during pregnancy, delivery or breastfeeding.¹¹² Considering the majority of children with HIV contract it through vertical transmission, investment into the prevention of MTCT can have huge socio-economic benefits to the nation's development as well as ensuring the protection of the rights of millions of children. Yet it is a difficult and costly programme for a developing country to implement. Maternal education and antenatal screening needs to be available, and the risk of bottle-feeding over breastfeeding needs to be justified. One of the key issues is also the cost of the antiretroviral drug, its availability for pregnant mothers and the recent concerns over development of resistance. ARVs such as zidovudine and nevirapine, when used as part of an appropriate MTCT prevention program can reduce transmission by nearly half.¹¹³

¹¹⁰ Save the Children, *Beyond the Targets: Ensuring children benefit from expanded access to HIV/AIDS treatment*, Save the Children publication for XVth International AIDS Conference 2004

¹¹¹ Cumulative risk when preventive measures include perinatal HAART, elective Caesarean section, undetectable maternal viral load and no breastfeeding. Source: Personal interview with Dr. H. Lyall, Consultant in Paediatric HIV and Infectious Diseases, St. Mary's Hospital, London. See also M. Sharland, D.M Gibb, G. Tudor-Williams, 'Advances in the prevention and treatment of paediatric HIV infection in the United Kingdom', *Sexually Transmitted Infections*, vol 79, p. 53-55, (BMJ 2003)

¹¹² F. Dabis, E. Ekpini, 'HIV-1/AIDS and maternal and child health in Africa', *The Lancet*, vol 359, p. 2097-104 (France, 2002)

¹¹³ The Paediatric AIDS Clinical Trials group 076 study showed Zidovudine with no breastfeeding can reduce MTCT by 50%. In the HIVNET012 randomised trial in 1999 a single-dose intrapartum and neonatal nevirapine regime showed a reduction of MTCT of 47%. Further information is available in E. Connor et al., 'Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment', *New England Journal of Medicine*, vol 331, p. 1173-80 (1994) and J. Brooks Jackson et al., 'Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: 18-month follow-up of the HIVNET012 randomised trial', *The Lancet*, vol 362, no. 9387 (2003)

Zidovudine is very expensive and complex to administer, making it unsuitable for resource-poor settings. The more recent alternative, nevirapine, is more cost-effective and less complex, and is available free of charge for developing countries on negotiation between the patent holder and the governments.¹¹⁴ Yet despite this offer, the accessibility did not come without a battle for the people and the NGOs in South Africa. In Minister of Health and others v Treatment Action Campaign and others¹¹⁵, also known as the nevirapine case¹¹⁶, the Constitutional Court of South Africa considered the appeal of a High Court decision in Pretoria which permitted the government's decision to limit the use of nevirapine for the prevention of MTCT to two public hospitals per region. The Court interpreted the right to health and the rights of the child provided in the Constitution of South Africa and found that the government had not reasonably addressed the need to reduce the risk of MTCT and thereby violated the rights of children born to HIV positive mothers.

B. Treatment and Care

For the three million children who are living with the HIV infection, treatment is most often not an option in the developing world. Antiretroviral treatment for children is more complex than for adults and requires careful monitoring and follow up. Children require varying dosing regimes as their weight and height changes, and they are more likely to suffer from side effects and complications due to their constantly altering and developing physiology. They also require aggressive treatment of any opportunistic infections as they rapidly become very ill. In most cases still, children's ARVs are too expensive and very difficult to administer in the developing world. Overall children have been marginalised in the global campaign against HIV/AIDS.

C. Has TRIPS failed Children?

“Children are not an attractive market” explained Dr. David Wilson from MSF at this summer's International AIDS Conference, highlighting why the commercial pharmaceutical industry has not developed paediatric ARV formulations and the fact that children have been neglected in the battle to get access to medicines for all.¹¹⁷ In discussion with Nathan Ford from MSF-UK, he explained how TRIPS has failed children who are living with HIV/AIDS through this lack of innovation and high costs.¹¹⁸

Firstly, the lack of innovation of paediatric formulations of HIV medicines reflects a scarcity of R&D into child-friendly drugs. Despite vast improvements in adult formulations of antiretroviral drugs, the options for children are much less. Like many paediatric medications, many ARVs come as a liquid of which some are incredibly foul tasting, require sterile water for mixing and kept refrigerated. Older children

¹¹⁴ The patent holder Boeringer-Ingelheim, has a Viramune (brand-name of nevirapine) donation program which can be found on www.ifpma.org/Health/hiv/health_viramune_hiv.aspx

¹¹⁵ Minister of Health and others v Treatment Action Campaign and others, Constitutional Court of South Africa, August 2002 www.concourt.gov.za

¹¹⁶ G.J. Annas, ‘The Right to Health and the Nevirapine Case in South Africa’, *New England Journal of Medicine* vol 348:750-754, February 2003

¹¹⁷ M. Broughton, MSF UK, ‘Children missing out on HIV drugs’, report from *BBC News*, available at <http://news.bbc.co.uk/go/pr/fr/-/2/hi/health/3892583.stm> on 14 July 2004

¹¹⁸ Discussion through e-mail exchanges between author and Nathan Ford, Manager of Manson Unit, MSF Access to Medicines Campaign in UK conducted between 12 and 14 July 2004.

cannot take syrups, as in keeping with their size, the volumes will be too large. Adult tablets can be crushed or broken up, but often leads to inaccurate dosing. The lack of formulations for children makes determining and administering doses complex and burdensome.¹¹⁹ In developing countries there often is no standardised dosing schedule and sterile water and refrigeration are not particularly user-friendly for those in the rural areas. For developing countries, a combination of three ARV drugs into a single tablet, known as fixed dose combinations (FDCs), is a key factor to access to treatment for HIV/AIDS as they are simple to use, improve compliance and are much cheaper than brand name drugs.¹²⁰ A recent study was conducted to test the efficacy of generic FDCs, as despite its widespread use some major donor agencies did not recommend them even with the prequalification by the WHO. This study, conducted independently from the WHO and the generic company manufacturing the drug¹²¹, concluded that generic FDCs are just as effective as the equivalent commercial FDC tablets.¹²² Unfortunately, FDCs have not been developed or hardly even researched for children. It appears though that some generic companies in India and Thailand are taking an interest in developing a three-in-one tablet or syrup for children, although this appears to be still in its early stages.¹²³

The second problem is that paediatric formulations are much more costly than those for adults, with some drug treatment costing up to five times more.¹²⁴ This is as a result of the lack of innovation and production of children's ARV formulations and hence the lack of competition in the market that would normally lower the prices of the drugs. These two issues reveal that global patent protection with TRIPS has not stimulated innovation of drugs to improve access to medicines for children.

3. The Future for children living with HIV/AIDS

WHO figures released just before the AIDS Conference showed that the virus had infected a record 5 million people and caused 3 million deaths in 2003. This is a higher number than any single year since AIDS was first recognised in 1981 to which UN Secretary-General Kofi Annan remarked, "We are not doing nearly well enough".¹²⁵ He has particularly pledged for an approach focussed on women who are at the centre of the HIV/AIDS pandemic and a concerted effort to tackle gender discrimination and social inequalities that puts them most at risk. The rate of infection in recent years have been higher in women than in men, with 57% of adults with HIV in sub-Saharan Africa being women and amongst the 15-24 year age group, young

¹¹⁹ 'MSF AIDS Treatment experience: Rapid expansion, emerging challenges', publication from MSF Access to Medicines Campaign available at www.accessmed-msf.org

¹²⁰ MSF Press Release, 'An advance for HIV/AIDS treatment access in the developing countries; A fixed-dose combination of generic antiretroviral drugs is validated in a clinical trial', MSF 2 July 2004

¹²¹ The drug tested was Triomune, a FDC which is the most widespread used treatment and manufactured by Cipla, an Indian generic pharmaceutical company

¹²² C. Laurent et al, 'Effectiveness and safety of a generic fixed-dose combination of nevirapine, stavudine and lamivudine in HIV-1-infected adults in Cameroon: open-label multicentre trial', *The Lancet*, vol 364, p. 29-34 (2004)

¹²³ Personal interview with Dr. D. Gibb, Medical Research Council Clinical Trials Unit, delegate and speaker at the International AIDS Conference 2004, Bangkok, Thailand. Cipla in India and Geovar in Thailand are researching this.

¹²⁴ The first-line FDC treatment regime for adults is available for about US\$200(generic) per year, while the equivalent paediatric formulations are about US\$1300 per year. Data from UNAIDS, cited on www.access-med.msf.org

¹²⁵ CNN News Report, 'Annan on AIDS', CNN, 11 July 2004, report from Bangkok, Thailand

women are three times as likely to be infected as young men. Annan questions the reason for the increased vulnerability of women when, “they are not the ones with the most sexual partners outside marriage, nor more likely than men to be injecting drug users”.¹²⁶ He cited “poverty, abuse and violence, lack of information, coercion by older men, and men having several concurrent sexual relationships that entrap young women in a giant network of infection” and addressed the urgent need to deal with the socio-economic and cultural inequities women face.¹²⁷ Surrounded by abuse and violence, particularly during civil unrest and armed conflict, women and girls have particularly fallen victim to sexual violence and coercion, increasing their vulnerability to HIV infection manifold.¹²⁸

Along with UNICEF, UNAIDS, UNIFEM and UNFPA, the Secretary-General highlights the importance of girls to enjoy their right to education.¹²⁹ In comparison to men, girls and women know much less about how HIV/AIDS is transmitted and how to prevent infection as they are often denied access to critical information, education and knowledge about sexuality. Education and empowerment come hand in hand, and the respect for the fundamental rights of women can ensure that women and girls receive both, particularly in the context of sexual and reproductive health,¹³⁰ and control over their bodies and their lives. Educated girls can say no to unprotected or coerced sexual activity, well-informed mothers can demand for measures to prevent mother-to-child-transmission, and empowerment of women can stop the risk through sexual violence, trafficking and prostitution.

With resources still scarce in the battle to control the epidemic, HIV/AIDS treatment programs need to be focussed and prioritised to women.¹³¹ Treating young women and mothers will not only reduce transmission of the virus to future generations, bearing in mind that 90% of children infected in 2002 were from MTCT, but also contribute to reducing the number of children being orphaned through HIV/AIDS. The presence of a healthy mother enhances the development, education and health of a child, and these children have a better chance of generating another generation that is educated against the risks of devastating illnesses such as HIV/AIDS.

¹²⁶ Ibid

¹²⁷ Ibid

¹²⁸ Unicef, *State of the World's Children 2004 Official Summary and Women and HIV/AIDS: Confronting the crisis*, joint report by UNAIDS, UNIFEM, UNFPA 2004 available at www.unfpa.org/hiv/women/report/index.htm

¹²⁹ Ibid

¹³⁰ *Women and HIV/AIDS: Confronting the crisis*, joint report by UNAIDS, UNIFEM, UNFPA 2004 available at www.unfpa.org/hiv/women/report/index.htm

¹³¹ Personal interview with Dr. H. Lyall, Consultant in Paediatric HIV and Infectious Diseases at St. Mary's Hospital, London, conducted on 16 July 2004 at St. Mary's Hospital

Conclusion

In the current era of globalisation, agreements at the WTO should facilitate a more open market enhancing free trade and distribution of products worldwide. Although the TRIPS Agreement incorporates a similar agenda, overall strict patent protection could reduce the distribution of essential medicines in developing countries. The Doha Declaration and the recent amendment to paragraph six should allow developing States to make use of the flexibilities in TRIPS and encourage differential pricing. The WTO needs to aid developing member States to incorporate TRIPS together with effective administrative and legal means to facilitate the use of these flexibilities if necessary. The WTO or the TRIPS Council should ensure that differential pricing is effective and sustainable until market segmentation is no longer necessary. There has been a significant drop in price of some brand name drugs when placed in competition to generics. This needs to be encouraged until epidemics such as HIV/AIDS are controlled as in the West. To expand access to care and treatment though does not only require cheaper antiretroviral medicines. Concerted effort and persistent political will to fight this devastating epidemic is required from all governments; the Western governments need to provide the resources and aid promised without conditions or contradictory trade threats, and the Southern governments need to redistribute their resources towards health infrastructures and personnel. These are not duties of morality, but in fact obligations that most governments in this world are tied to under international law. There are 191 countries that have ratified the rights of the child in the CRC. It is a violation of their rights when children are allowed to suffer all the consequences, including death, of AIDS when the medicines to alleviate the burden of the crisis are available.

There are many good drugs available to control HIV, but they need to reach six million people who need them immediately. The WHO initiative to treat 3 million people by 2005 is already behind schedule and the burden of HIV/AIDS is growing on a daily basis. Access to treatment and care of HIV/AIDS needs to be expanded in the most efficient way and the gateway to this is to prioritise treating women and focussing on ensuring the rights of the child. Treating women with combination antiretroviral therapy will reduce the large number of children born with HIV and prolong their lives to ensure the healthy growth and development of their children. Men too are important as usually they are the sole breadwinners but the likely situation is that women and children are already marginalised and treatment often is in favour of urban men.

The quality of fixed-dose combination ARV drugs available in the West is the result of heavy investment by the pharmaceutical industry and a forceful example of the benefit of incentivising innovation. Yet TRIPS must ensure that the industry holds their side of the bargain and increases R&D of child-appropriate ARV medicines suitable for the developing world. As paragraph four of Article 24 recognizing the right of the child to the highest attainable standard of health states, “governments should undertake to promote and encourage international cooperation with a view to achieving progressively the full realization of the right”.

Humanity has faced devastating epidemics of this kind before and has come out of it victorious, albeit the many lives lost. The plague was eventually eradicated through a concerted public health effort to improve hygiene and sanitation, and the small pox through the hard work put into developing a vaccine. The scientific and technological advances that humanity has gained in public health and medicine since then means that nothing but a lack of human will and determination should be hindering the achievement of access for all.

ANNEX I

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH FOURTH SESSION MINISTERIAL CONFERENCE, WORLD TRADE ORGANISATION, NOVEMBER 2001 IN DOHA, QATAR

Adopted on 14 November 2001

WT/MIN(01)/DEC/2

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm 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. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

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SPEECH REPORT

'Do patents help stimulate research on medicines developing countries need? Are they a barrier to accessing medicines?'

Conference held at the Overseas Development Institute, London on 12 February 2003. Chaired by Charles Clift, Department for International Development, author of report
Speakers: Nathan Ford, Access to Medicines Adviser, Medecins sans Frontieres and Chris Strutt, Vice-President, External Relations, Worldwide and International, Glaxo Smithkline

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