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Framing International Legal Responses to Global Health

> I've been out there on the ground talking to sufferers. I've seen the situation in parts of Africa where I've visited AIDS patients in villages, where you see a grandmother and lots of grandchildren but no mother, no father. For me it's not statistics. I've seen the human suffering and the pain. What is even more difficult is when you see somebody lying there dying who knows that there's medication and medicine somewhere else in the world that can save her, but she can't have it because she's poor and lives in a poor country. Where is our common humanity? How do you explain to her that in certain parts of the world AIDS is a disease that can be treated, that one can live with and function, but in her particular situation it's a death sentence?[1]
>
> Kofi Annan

1.1 The Current State of Global Health

This should be the golden era of global health. We now have the science to screen and test for diseases and so identify them much earlier, which can help to negate their deadly impact. We have vaccines to prevent the killer diseases of childhood and antibiotics to deal with the most dangerous pathogens. Increasingly, we have better medicines, which can treat the most common and deadliest diseases. As a result, many people in the world are experiencing better health than ever before, but this is not universal. If you are born in Europe, you can expect to live well into your 80s, but in sub-Saharan Africa life expectancy is only 57 years. For many of the world's poorest people, global health remains in constant crisis as infections spread across borders. Diseases like cholera, yellow fever, Acquired Immune Deficiency Syndrome (AIDS), swine flu, Severe Acute Respiratory Syndrome (SARS) and tuberculosis continue to take advantage of increasingly porous borders in a highly networked world

[1] Kofi Annan, Secretary General, United Nations; Interview with the BBC (28 November 2003). http://news.bbc.co.uk/1/hi/world/africa/3244564.stm last accessed 20 May 2005.

that relies on vast movements of people and goods across the globe to facilitate global trade. Less infectious diseases, such as malaria, are also continuing to devastate parts of the developing world.

Despite the existence of medicines that can treat most of these diseases, access in many parts of the developing world remains a lottery. It is estimated that one-third of the global population, almost two billion people, lack regular access to essential medicines.[2] In many parts of Asia and Africa this figure rises to almost half of the population.[3] One of the principal reasons for this inequity is the existence of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which grants pharmaceutical manufacturers the right to patent medicines, allowing them to exclude other manufacturers from making the same medicines within a set period of time. In the absence of competition, the pharmaceutical companies can set higher prices, ostensibly in order to recoup their research and development costs. Millions of people, especially those from the developing world, simply cannot afford to pay these prices. This massive inequity has meant that people from developing countries are dying of treatable diseases.

This book examines the international legal response to this problem by asking how law in the international realm has either contributed to or prevented greater access to Anti-Retroviral Medicines (ARVs). It explores this by considering legal initiatives as elements of two general categories: 'hard' or 'soft' law. Hard law can be defined as 'legally binding obligations that are precise (or can be made precise through adjudication or the issuance of detailed regulations that delegate authority for interpreting and implementing the law)'.[4] Soft law, by contrast, may be described as 'normative agreements that are not legally binding'.[5] Although the definition of these terms is justified and set out in detail in Chapter 2, this is the

[2] The WHO defines essential medicines as 'the minimum medicine needs for a basic healthcare system, listing the most efficacious, safe and cost–effective medicines for priority conditions.' Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf last accessed 5 November 2015.

[3] World Health Organization, *WHO Medicines Strategy: Countries at the Core 2004–2007* (WHO, Geneva, 2004) 3.

[4] Kenneth W Abbott, 'Hard and "soft law" in international governance', *Int'l Org*, 54 (2000), 421 [DOI: 10.1162/002081800551280].

[5] Francis Synder, '"Soft law" and international practice in the European community' in Stephen Martin (ed), *The Construction of Europe: Essays in Honour of Emile Noel* (Kluwer Academic Publishers, Dordrecht, 1994) 197, 198.

fundamental distinction adopted in this book. The underlying argument then advanced is that soft law mechanisms provide a better option for achieving greater access to ARVs for those living in the developing world.

Starting with the AIDS crisis, the book argues that a hard law response was unsuited to creating greater access to ARVs (the essential medicines needed for treating HIV/AIDS), as relying on hard law meant prioritizing patent rights, which invariably led to cost implications for the consumer. This is because the predominant hard law initiatives arose within the context of existing international legal structures that are constructed around the protection of private property or individual rights, furthering the dominant northern hegemony at the expense of the majority of people in the developing world.

By contrast, the book argues that a soft law approach has been more effective. The non-binding nature of soft law, unlike its hard law counterpart, makes it quicker and easier for States to reach agreement. This makes it preferable when dealing with public health pandemics, such as HIV/AIDS, where speed is of the essence. Soft law is also more flexible and easier to supplement, amend or replace when circumstances change.

In pursuing this argument, the book looks at the World Trade Organization (WTO) regime and the United Nations (UN) regime from which the majority of conceptual responses to the issue of access have originated. This book suggests that soft law initiatives have developed a humanitarian norm of access to ARVs so as to enhance the prospect of universal access programmes that give free ARVs to those who would have been unable to afford them otherwise.

This book will argue that the success of a soft approach in response to the HIV/AIDS pandemic ought not to be examined in isolation. A softer approach can also be invaluable when looking more generally at the broader problems of global health. Thus, the book will look at how a soft law approach has been used in creating successful global health responses to malaria and tuberculosis in the developing world. However, before clarifying the argument, this chapter provides an overview of the subject at issue. In Section 1.2, the links between AIDS, malaria and tuberculosis are sketched out. Section 1.3 analyzes why AIDS is exceptional in global health matters and attempts to explain why, despite the existence of malaria and tuberculosis, international responses have largely focused on it. Section 1.4 introduces the legal context of this response. Section 1.5 moves on to describe the nature of ARVs, and explains their importance for the pandemic and how their accessibility has been affected by law. Section 1.6 returns to the central

arguments that will be explored through this book, while Section 1.7 of the chapter deals with the parameters of the research.

1.2 AIDS, Tuberculosis and Malaria: Complex Interlinkages; Human Suffering

HIV/AIDS, tuberculosis and malaria are three major global, public health threats, which cause immense suffering and the deaths of close to five million people every year. These diseases disproportionately impact the developing world, with sub-Saharan Africa bearing the brunt of these three interrelated pandemics.

AIDS is a disease caused by the Human Immunodeficiency Virus, which leads to a wide variety of clinical conditions. HIV belongs to a class of viruses called retroviruses, which attach themselves to a host cell without immediately destroying it, using it to multiply rapidly through other cells, before eventually destroying the entire immune system.[6] AIDS is transmitted from an infected person by sexual contact, sharing needles or syringes (primarily for drug injection) or, less commonly, through transfusions of infected blood or blood clotting factors. Babies born to HIV-infected women may become infected before or during birth, or through breastfeeding. The nature of its transmission puts several groups of people particularly at risk: women, children and homosexual men.[7]

The process of infection begins much like a common cold. However, the virus rapidly multiplies, causing flu-like symptoms – muscle ache, diarrhoea, mild fever and sore throat. The virus then becomes dormant, while mutating very quickly. Eventually, it starts killing healthy immune cells, paving the way for opportunistic infections, because at that point the body's natural defences are ineffectual. In the advanced stages, the body's immune system is so weakened that sufferers are vulnerable to all sorts of conditions, such as tuberculosis, pneumonia, malaria, toxoplasmosis, esophagitis, tumours and cancers.[8]

[6] See John Iliffe, *A History of the African AIDS Epidemic* (Ohio University Press, Ohio, 2006) 3–10 for a useful account of the earliest convincing evidence of HIV.

[7] R M Anderson et al., 'The spread of HIV-1 in Africa: Sexual contact patterns and the predicted demographic impact of AIDS', *Nature*, 352 (1991), 581–9 [DOI: 10.1038/352581a0] [PubMed: 1865922].

[8] M A Jacobson and M French, 'Altered natural history of AIDS-related opportunistic infections in the era of potent combination antiretroviral therapy', *AIDS Journal*, 12 (1998), 157–63.

Of the three diseases, AIDS is the most infectious, with Africa as its epicentre.[9] It has killed thirty-nine million people so far, leaving serious implications not only for those with the disease, but for their loved ones who care for them, often watching helplessly as the sick die of the lingering disease with its multiple secondary infections, their bodies wasting away and in constant pain due to acute shortages of palliative treatment.

Tuberculosis is the second most infectious disease worldwide. It is caused by *Mycobacterium tuberculosis* and is an airborne disease, making it very contagious. There are 9.2 million new infections every year.[10] Tuberculosis also presents the most common opportunistic infection affecting HIV-positive people, leading to 700,000 new infections and 200,000 deaths every year amongst people who are HIV positive. Like AIDS, the burden of tuberculosis is disproportionate, with sub-Saharan Africa and Asia reporting the most cases. Fifty per cent of people with HIV/AIDS will develop tuberculosis, and having HIV/AIDS makes it more likely that a primary infection will develop into a case of active tuberculosis. The spread of tuberculosis has been compounded by the increase in drug-resistant tuberculosis, which once again raises issues about access to essential medicines. Although the incidence of disease is concentrated in the developing world, there is evidence to suggest a new resurgence in industrialized countries, with some cities such as London showing an increase of 80 per cent in tuberculosis cases.

Malaria is an endemic disease that affects over 189 million people annually, many of whom come from the developing world. Malaria is caused by the *Plasmodium* parasite, which is spread by female *Anopheles* mosquitoes that have bitten an infected person. Malaria causes 881,000 associated deaths each year, 91 per cent of which are in sub-Saharan Africa. There are well-documented links between HIV/AIDS and malaria, with studies showing that being HIV positive makes individuals more susceptible to the parasites that cause malaria.[11] Additionally, the weak immune systems of people living with HIV/AIDS makes it harder

[9] Iliffe, *A History of the African AIDS Epidemic*.

[10] WHO, '2008 tuberculosis facts', www.who.int/tb/publications/2008/factsheet_april08.pdf last accessed 9 January 2016.

[11] Neil French, Jessica Nakiyingi, Eric Lugada et al., 'Increasing rates of malarial fever with deteriorating immune status in HIV-1 infected Ugandan adults', *AIDS*, 15 (2001), 899–906.

for them to fight malaria, and research has shown that when treating both AIDS and malaria, some of the medications interact with each other and may lead to toxicity. This creates public health dilemmas in sub-Saharan Africa, where both these diseases are prevalent.[12]

Both tuberculosis and malaria are common secondary infections for people suffering from HIV/AIDS, and cause untold suffering. Many AIDS patients struggle with recurrent episodes of tuberculosis that spreads not only to the lungs, but throughout the body to the brain, lymph nodes, spinal cord and bone marrow, leading to extreme fatigue that renders many patients bedridden and socially and economically unproductive. Some patients suffer with severe chest pain that leaves many struggling simply to breathe and coughing up blood. For many HIV/AIDS sufferers, tuberculosis becomes a life sentence, and many of them die within 5–6 weeks of infection. What makes tuberculosis as a secondary infection particularly harmful is its unresponsiveness to treatment, and even when treated many AIDS sufferers are more likely to relapse. There have been harrowing stories of patients who have struggled through multiple six-month courses of treatment to no avail. Their constant suffering is made worse by the fact that active tuberculosis is very visible due to the fatigue and loss of weight which sufferers face, creating considerable stigmatization within communities.

The symptoms of malaria mimic those of HIV/AIDS, with many patients suffering from flu-like symptoms, headaches, vomiting, jaundice, blood in the urine, convulsions and extreme fatigue. Malaria can cause serious complications, including respiratory distress, which occurs in 25 per cent of reported cases in adults and 40 per cent in children with severe *Plasmodium falciparum* malaria. AIDS sufferers are particularly prone to cerebral malaria.

AIDS patients who are co-infected with malaria or tuberculosis also struggle with the number of drugs that are necessary to combat them successfully, as well as with drug interactions. AIDS, tuberculosis and malaria are all diseases of poverty, as they affect young, able-bodied individuals, who can no longer contribute to workforces and local economies. Women are disproportionately affected by all three diseases. They are more vulnerable to contracting HIV/AIDS, and by 2004, 53 per cent

[12] Paula E Brentlinger, Christopher B Behrens, James G Kublin, 'Challenges in the prevention, diagnosis, and treatment of malaria in human immunodeficiency virus infected adults in sub-Saharan Africa', *Arch Intern Med*, 167:17 (2007), 1827–36.

of people who were infected were women.[13] The disproportionate impact of HIV/AIDS infection in women is rooted in their lack of economic power, which shapes the life choices they make through marriage, formal or informal employment, commercial sex work, etc. In all these situations, women are disadvantaged due to low bargaining power for safe sex.[14] Moreover, in many developing countries motherhood is integral to women's identity, and so the idea of safe sex is a moot point. Thus, many women are increasingly falling victim to the AIDS pandemic within marriage.[15] Tuberculosis is among the top killers of women of reproductive age. Some 510,000 women died from tuberculosis in 2013. Women with tuberculosis are 300 times more likely to die with their unborn children during labour. They are also more likely to have babies who are premature and underweight.[16] Pregnancy also reduces a woman's immunity to malaria, making her more susceptible to infection and increasing the risk and severity of illness, which can lead to severe anaemia and death. Maternal malaria increases the risk of stillbirth, premature delivery and low birth weight, which is a leading predictor of child mortality.[17]

The impact on women of all three diseases is further heightened by the fact that many of these infected women not only struggle with the impact of the disease on themselves, but are also expected to provide care to others who are sick. Nelson Mandela talked about women who 'bear the burden of HIV infection, but also bear the burden of HIV care, with grandmothers looking after their children, women caring for their dying husbands, and children looking after dying parents and siblings'.[18] In the absence of social security mechanisms in the developing world, this care becomes an all-encompassing process provided in the home.[19] It often

[13] Alan Whiteside, 'The economic, social and political drivers of the AIDS epidemic in Swaziland: A case study' in Amy S Patterson (ed), *The African State and the AIDS Crisis* (Ashgate, Aldershot, UK, 2006) 97–126.

[14] Patricia Siplon, 'Aids and patriarchy: Ideological obstacles to effective policy making' in Patterson (ed), *The African State and the AIDS Crisis*, 17–36.

[15] Carolyn Baylies, 'HIV/AIDS and older women in Zambia: Concern for self worry over daughters towers of strength', *Third World Q*, 23:2 (2002), 351–75.

[16] WHO, 'Tuberculosis in women', www.who.int/tb/publications/tb_women_factsheet_251013.pdf last accessed 5 November 2015.

[17] WHO, 'Lives at risk pregnancy in malaria', www.who.int/features/2003/04b/en/ last accessed 5 November 2015.

[18] Nelson Mandela, From 46664 HIV/AIDS awareness concert, March 2005, as quoted in VSO (2006), 'Reducing the burden of HIV & AIDS care on women and girls'.

[19] Aashar Kapura Mehta and Seroshi Gupta, 'The impact of HIV/AIDS and women care givers in situations of poverty', (2004) www.chronicpoverty.org/uploads/publication_files/CPRC-IIPA_31.pdf last accessed 9 January 2016.

involves bathing, toilet assistance, turning patients to avoid bed sores, as well as the carer still being required to provide food for not only the patient, but also the rest of the household. Many of these families live in places with inadequate sanitation facilities, which makes the job much harder.[20] Furthermore, in many cases, the lack of basic health infrastructure makes these women helpless, as they often have neither the resources nor the knowledge to help the AIDS sufferers deal with the painful effects of the disease. Caring, therefore, becomes a constant sap on the carer's energy, underlined by the certain knowledge that they too will shortly face the same fate. Moreover, the traditional nature of this caregiving means that women's roles as caregivers are so ingrained within communities that they are mostly unsupported, unrecognized and, above all, unremunerated.[21]

Tuberculosis and malaria are not new diseases and their medicines are not as expensive as ARVs, but there are still problems for the poorest people in the world gaining access to them. According to the World Health Organization (WHO),

> Essential medicines are one of the most cost-effective elements in modern health care and their potential health impact is remarkable. This year [2015] alone, there will be over 40 million deaths in developing countries, one-third among children under age five. Ten million will be due to acute respiratory infections, diarrhoeal diseases, tuberculosis, and malaria – all conditions for which safe, inexpensive, essential drugs can be life-saving.[22]

This situation is exacerbated by the fact that a failure to access full dosages of these essential medicines is leading to resistant strains of malaria and tuberculosis, which have even more unaffordable medicines.

As we will see in Chapter 8, there were international programmes that preceded the current programmes for AIDS, tuberculosis and malaria. This book will argue that the reliance on hard law mechanisms within these programmes means that these medicines still remain unaffordable.

Several scholars have rightly queried whether HIV/AIDS is diverting the attention of the international community to the detriment of dealing with other diseases that kill even more people in the developing world.

[20] Id at 15. [21] Id at 16.

[22] WHO, 'Essential medicines and health products', available at www.who.int/medicines/services/essmedicines_def/en/ last accessed 5 November 2015.

In some cases it has, but this book argues that rightly or wrongly this focus on the AIDS pandemic gave the international community the impetus to address wider access issues. In order to fully understand access to medicines, it is therefore necessary to look at the AIDS crisis, which brought the issue of access to the consciousness of the international community.

1.3 Background to the AIDS Crisis: Making a Case for an Exceptional Response

There is a consensus among global health experts that there are interconnected aspects of the HIV/AIDS pandemic that make it exceptional. First, the modality of its transmission puts certain already vulnerable groups at particular risk, i.e., women, children, commercial sex workers, gay people, etc. Second, HIV/AIDS has profound and lasting social and cultural effects on the societies that it affects, which include the impact on development prospects, human and national security and the balance of political power, and the link with international economic and financial relations and global governance. Together these dimensions demonstrate why it is that AIDS has attracted greater concern from the international community than other diseases.[23] The fact that AIDS has no cure has compounded these effects, and with few signs of the pandemic abating, communities remain in a continuous state of crisis.

The United Nations Program on AIDS (UNAIDS), the specialized UN body that deals with HIV/AIDS, has estimated that over 60 million people have been infected with HIV so far, and 30 million of these have prematurely lost their lives due to HIV/AIDS-related illnesses. Mortality was so high that in a single year between 1999 and 2000, more people died of AIDS in Africa than all the wars that ravaged the continent at the time.[24] By 2005, many developing countries experienced extremely low

[23] The divide is stark between the developed and developing world. Although sub-Saharan Africa contained only 10 per cent of the world's population, by 2001 it accounted for over two-thirds of the 40 million people living with HIV/AIDS. Sixty-eight per cent of new infections originated in this region; 77 per cent of all deaths and over 90 per cent of AIDS orphans could be found in this part of the world. While HIV prevalence amongst pregnant women was very rare outside this region, sentinel surveillance has shown it to be greater than 40 per cent in various parts of Botswana, Zimbabwe and Swaziland. See UNAIDS, *Report on the Global HIV/AIDS Epidemic*, Geneva, June 2000. Also see A Buve, K Bishakwabo-Nsarhaza and A Mutugadur, 'The spread of HIV-1 infection in sub Saharan Africa', *The Lancet*, 359 (2002), 2011–17.

[24] Victoria Brittain, '"More die of AIDS than war in Africa," says Kofi Annan', *The Guardian* (14 March 2000).

life expectancy rates. Five sub-Saharan African countries (Botswana, Central African Republic, Lesotho, Zambia and Zimbabwe) all faced life expectancies of below 40 years.[25] Three African countries (Lesotho, Swaziland and Botswana) experienced negative population growth rates for the first time, due in large part to the AIDS pandemic.[26] The rate of mortality put increased pressure on communities; for instance, in Durban, the city council authorities ran out of space to bury the dead, leading to widespread anxiety in a community that believed in the sacrosanct nature of the funeral as a journey into the next life.[27] In Uganda at the height of the epidemic in the 1990s, there were not enough grave diggers in Rakai District, leading to fears that people would go unburied.[28]

Morbidity was particularly severe in children below five years of age. Because AIDS passes from mother to unborn child, many children were born only to die before they could reach adulthood. Between 1990 and 1995, the infant mortality rate in Zimbabwe was 50 per cent; in the first five years of the next decade, the rate had risen to 62 per cent. In Kenya, infant mortality for the same period rose from 63 per cent to 68 per cent, which was at odds with a forecasted decline to 60 per cent that had not taken into account the AIDS pandemic.[29]

The high mortality rate is only one of the consequences of the AIDS pandemic. John Iliffe states that 'HIV/AIDS was not one pandemic but four: first the virus, then disease, next death and finally societal decomposition, each superimposed upon its predecessors'.[30]

Amidst this crisis, ARVs initially offered hope. Although they were never represented as a cure, ARVs relieved the symptoms of the disease and prolonged the lives of sufferers. But the initial euphoria that accompanied their invention turned out to be premature. Their high prices meant that many people in developing countries could not afford them. The pharmaceutical companies argued that such prices were essential in

[25] United Nations Population Division, 'The impact of AIDS', *ST/ESA/SER/A/229* (United Nations Publications, New York, 2004).

[26] Id.

[27] Marine Veith, 'What about the ancestors?', *South African Times* (10 October 2010). www.iol.co.za/news/south-africa/kwazulu-natal/what-about-the-ancestors-1.684934 last accessed 20 August 2011.

[28] This led to the development of groups like Bataka Twezike, which can be literally translated as 'let us bury ourselves'. See Paul Mugyenyi, *Genocide by Denial* (Fountain Publishers, Kampala, 1999) 69–71.

[29] UNPD, 'The impact of AIDS'.

[30] Iliffe, *A History of the African AIDS Epidemic*, 112.

order to recoup research and development costs. They also argued that the right to set prices had been sanctioned by treaty law, and therefore developing countries were obliged to pay. Kofi Annan recognized and articulated the underlying moral dilemma that resulted: drugs exist that can alleviate the suffering from AIDS, but a huge number of people suffering from the disease cannot access them because they are unaffordable.

1.4 Framing an International Legal Response to HIV/AIDS

Section 1.3 highlighted the exceptional nature of the AIDS pandemic. AIDS can be framed in different ways: as an emergency, as a health issue, as a human rights issue, as a reflection of gender inequalities, as a security issue, as a short-term humanitarian problem or as a long-term development issue. These perspectives are not mutually exclusive, but each can lead to a legal response of some sort. Equally, the global nature of the AIDS pandemic challenged the international community to create legal responses. Therefore, although the legal approach to the AIDS pandemic has been merely one of the responses, it presents an important one, as it manages to encapsulate so many of the others. As Peter Söderholm stated:

> AIDS connects people irrespective of state borders, and the absence of 'AIDS markers' makes detection and subsequent interception at the borders practically useless; AIDS involves political sensitivities that governments have historically had problems dealing with; and unless AIDS is stopped globally, it will continue to spread.[31]

It was, therefore, necessary to have a legal response at the international level to stop this pandemic. However, the initial efforts by the international community were underwhelming. They were often slow and, more often than not, steeped in denial. Both domestically and internationally, actors failed to grasp the severity of the disease. Regrettably, when the world woke up to the urgency of the AIDS situation, there was a severe disparity in approach between the developed nations, who had spearheaded the international response based on the epidemiology in their own countries, and the developing world, which lacked the capacity and resources to deal with the AIDS threat adequately.[32]

[31] Peter Söderholm, *Global Governance of AIDS: Partnerships with Civil Society* (Lund University Press, Sweden, 1998) 23.
[32] Iliffe, *A History of the African AIDS Epidemic*, 65.

The UN led the way in articulating an international legal response through the WHO. The WHO is the lead 'specialized agency' of the UN charged with dealing with the right to health.[33] It derives its mandate from the UN Charter, its constitution and the International Covenant on Economic Social and Cultural Rights (ICESCR).[34] As a specialized agency with the mandate to act as the 'directing and coordinating authority on international health work',[35] the organization's principal role is to implement the aims of the Charter as far as health is concerned.

In order to create the optimal conditions for member countries to realize the highest standards of health, the WHO Constitution was endowed with broad legislative powers. It provided the organization with the power to make binding legislation.[36] Article 19 of the WHO constitution states that the World Health Assembly (WHA) 'shall have the authority to adopt conventions and agreements with respect to any matter within the competence of the Organization'.[37] David Fiddler argues that this Article, when read within the broad terms of the right to health as being the highest standard of physical and mental well-being, in effect gave the WHO unlimited potential to make binding legislation.[38] The WHO has, however, been wary of using its Article 19 powers, and has focused on using non-binding legislation to respond to the challenges of global health.[39] The WHO's response to HIV/AIDS largely took the form of non-binding legislation. This was to have a huge impact on the UN's approach to dealing with the AIDS pandemic, as we shall see in this book.

Although the WHO was the ideal body to coordinate the AIDS response, and despite its expertise on global disease, it did not get off

[33] Article 57 of the UN Charter also sees corresponding duty in the Constitution of the WHO. www.who.int/governance/eb/who_constitution_en.pdf last accessed January 2009.

[34] Paul F Basch, *Textbook of International Health* (Oxford University Press, Oxford, 1990) 342.

[35] Article 2 of the WHO Constitution.

[36] Article 21 of the WHO Constitution.

[37] The World Health Assembly is the organization's supreme decision-making body. It is the legislative organ of the WHO that is charged with determining the policies of the WHO, appointing the WHO's Director General, reviewing and approving the budget, considering health-related recommendations made by the United Nations General Assembly or other divisions of the United Nations and promoting and conducting health research.

[38] David Fiddler, 'The future of the World Health Organization: What role for international law?', *Vanderbilt J Trans Natl Law*, 31:5 (1998), 4.

[39] Kelley Lee, *The World Health Organization WHO: Global Institutions Series* (Routledge, London, 2006) 18. The influence of the WHO in choosing soft law will be dealt with in Chapter 6.

to a good start. Many of its earlier initiatives lacked the urgency needed to check a pandemic on the scale of HIV/AIDS. Despite the WHO having been officially notified of AIDS cases since 1981, by 1986 they still had only one person within the entire organization dealing with the disease, and who was also charged with dealing with other sexually transmitted diseases.[40] The WHO initially assumed mainly a monitoring role. Its response in the early 1980s comprised two meetings in 1983, one in Denmark to assess the European situation and the other in Geneva to consider the global AIDS problem.[41]

The initial lacklustre response of the WHO was due to a lack of understanding of the magnitude of the disease it was dealing with. At the onset of the massive wave of the AIDS pandemic in sub-Saharan Africa, the WHO seemed indifferent. Indeed, Halfdan Mahler, the director general of the WHO at the time, claimed that there was no need for the organization to react to HIV/AIDS, because it was being addressed adequately by rich western countries. Mahler's denial of the scope of this pandemic was to continue until the mid-1980s. In 1985, he dismissed the concentration of resources on HIV/AIDS as being diversionary.[42] To him, the WHO needed to concentrate more on its primary healthcare programme, launched in 1978. *The Times of Zambia* reported in 1985:

> Dr Halfdan Mahler said in Lusaka yesterday that if African countries continued to make AIDS a 'front page' issue the objectives of health for all programmes by the year 2000 would be lost . . . AIDS is not spreading like bush fire in Africa. It is malaria and other diseases that are killing millions of children everyday.[43]

In taking this stance, the WHO failed to deal with the AIDS pandemic in a timely manner. Dr Mahler was to admit later, 'Many people at first refused to believe that a crisis was upon us. I know that because I was one of them.'[44] This profound admission encapsulates the gradual change in views within the WHO leadership at the time.

[40] A K Soni, 'From GPA to UNAIDS examining the evolution of the UN response to AIDS', essay presented to the Committee on Degrees in Social Studies for a BA Honors Degree, Harvard, November 1998. UNAIDS, *The First Ten Years* (UNAIDS Publications, Geneva, 2008).

[41] Id.

[42] WHO Memorandum 1983, in Jonathan Mann, D J M Tarantola and T W Netter (eds), *AIDS in the World* (Cambridge, MA, 1992) 567.

[43] *Times of Zambia* (11 September 1985).

[44] Speech to the final plenary session of the Fourth International Conference on AIDS, Stockholm, July 1988 in UNAIDS, *The First Ten Years*.

By the mid-1990s, many people like Mahler were waking up to the severity of the pandemic. An increasing number of organizations became involved in trying to create international legal responses. The WHO led the way with its Global Program on HIV/AIDS (GPA) using a human rights approach. This programme consistently tried to create links between HIV/AIDS, the right to health and the right against discrimination.[45] There was a feeling that the strong human rights framework was necessary to win the war against this pandemic. The right to health was being used to create prohibition against discrimination in reproductive health, gender, children, etc. Stigmatization was therefore perceived as a central problem.

The World Bank, United Nations Development Program (UNDP), United Nations Children's Fund (UNICEF) and United Nations Population Fund (UNFPA) also introduced individual programmes on HIV/AIDS. The World Bank began with AIDS financing prevention programmes primarily in Africa and Latin America in 1986, while the UNDP recognized the social economic impact of HIV/AIDS in low-income countries in 1988.[46] The UNDP formed an independent programme in 1992[47] and UNICEF concentrated on the impact of HIV/AIDS on women and children and formed a Working Group on AIDS, focused on reducing the rate of transmission among young people and improving reproductive healthcare within the existing frameworks. The UNFPA jumped into the fray and looked at the demographic effect of AIDS, especially in low-income countries, working together with the GPA to establish guidelines on the incorporation of AIDS-related work into maternal and child health.[48]

Although these programmes lacked coordination, which reduced their efficacy, they were important because of their reliance on the normative content of the right to health.[49] However, the routine reliance on a right to health was to change rapidly with the discovery of ARVs. In trying to create access for ARVs, the state for the first time was being asked to provide medicines as part of the fulfilment of the right to health.

[45] Jonathan Mann et al., *Health and Human Rights*, 1st edn (Routledge Publishers, Abindgon, 1999).

[46] UNAIDS, *The First Ten Years*.

[47] This programme dealt primarily with social economic factors that led to the increased spread of the disease. Elizabeth Reid was also a huge advocate of gender and equality as being intrinsic in the fight against AIDS, which was an approach that was totally at odds with the WHO. See Lee, *The WHO: Global Institutions Series*, 60.

[48] Id at 61. [49] Id.

Treatment was now as important as prevention. This caused the WHO and the UN to ponder exactly what the normative content of this right entailed, whether developing countries were supposed to comply with this right despite their resource constraints and whether access to treatment could be said to be an essential part of the realization of this right.

The next section will examine the particular problems that access to ARVs created. It will begin by explaining what ARVs are and why they proved so critical in the fight against HIV/AIDS.

1.5 The Impact of Anti-Retroviral Medicines

1.5.1 What Are ARVs?

ARVs discourage the progress of retroviruses such as HIV within the body. There are five major categories of ARVs: nucleoside/nucleotide reverse transcriptase inhibitors,[50] protease inhibitors,[51] non-nucleoside/nucleotide reverse transcriptase inhibitors,[52] fusion or entry inhibitors[53] and integrase inhibitors.[54] At the beginning of treatment, the combination of medicines that a person is given is called first-line therapy. If HIV becomes resistant to this combination, or if side effects are particularly bad, then a change to second-line therapy is usually recommended. This will ideally include a minimum of three new medicines, with at least one from a new class, in order to increase the likelihood of treatment success.[55]

ARV therapy reduces mortality by up to 90 per cent and the risk of major opportunistic infections by 55–58 per cent, at least in 80 per cent of those in the first year of treatment.[56] Although ARVs do not constitute

[50] First approved for use in 1987, NRTIs interfere with the action of an enzyme called reverse transcriptase, which the virus needs to make new copies of itself.

[51] First approved for use in 1995, PTIs inhibit protease, which is another enzyme involved in the HIV replication process.

[52] First approved for use in 1997, NNRTIs also stop HIV from replicating within cells by inhibiting the reverse transcriptase enzyme.

[53] First approved for use in 2003, fusion or entry inhibitors prevent HIV from binding to or entering immune cells.

[54] First approved for use in 2007, integrase inhibitors interfere with the integrase enzyme, which HIV needs to insert its genetic material into cells. These are still not widely available in developing countries.

[55] M Dybul, A S Fauci et al., 'Guidelines using antiretroviral agents among HIV-infected adults and adolescents', *Ann Intern Med*, 137: 5 pt 2 (2002), 381–433.

[56] M Dorcucci et al., 'Temporal changes in the rate of progression to death among Italians with known date of HIV seroconversion: Estimates of the population effect of treatment', *J Acq Immune Def Syndr*, 22:1 (1999), 65–70.

a cure, in containing secondary infections they are invaluable to people who are suffering from the disease, as while taking them they can lead relatively normal lives. The role of ARVs in preventing mother-to-child transmission has saved a generation of children from growing up infected with HIV/AIDS.[57]

From a societal perspective, ARVs also decrease the substantial care burden, which has a positive bearing on the relatives of the HIV-positive individual.[58] They enable people who are affected to continue to support young and elderly dependants. Fiscal benefits to the Gross Domestic Product (GDP) result from men and women who might have succumbed to the disease but now lead constructive lives. For all these reasons, ARVs constitute a fundamental part of the response to AIDS.

ARVs gave some hope to the millions of people who, on discovering that they were afflicted, no longer merely had to wait to die. In doing so, they galvanized the response to the AIDS pandemic, just as penicillin had done for syphilis, dapsone for leprosy and the yellow fever vaccine for yellow fever.[59] However, there was a major difference between ARVs and these other medicines: ARVs were not only expensive, but would also be needed by AIDS patients for the rest of their lives. As a result, conceptualizing a response challenged the international community's traditional ways of dealing with pandemics, because long-term use of ARVs remained unaffordable for many developing countries. This created a major dispute between developing countries and the pharmaceutical companies, which were supported by the developed countries in which they primarily originated.[60]

1.5.2 The History of ARVs

Although the battle over ARVs has morphed into a struggle between pharmaceutical companies and developing countries, it is interesting to note that the story of the first ARV (azidothymidine, AZT) did not

[57] Id.

[58] Commission on HIV/AIDS and Governance in Africa (CHGA), Scaling up AIDS treatment in Africa, *Issues and Challenges: Addis Ababa* (2004). https://docs.google.com/viewer?url=http://www.uneca.org/chga/doc/scaling%2520up_bg_nw_2.pdf&embedded=true&chrome=true last accessed 2 April 2016.

[59] Iliffe, *A History of the African AIDS Epidemic*.

[60] Most ARVs were produced in the United States, United Kingdom, France and Switzerland, which made those countries very interested in the interests of pharmaceutical producers.

begin in a pharmaceutical company, but in a government laboratory in the United States. This is of particular importance, because the underlying rationale for patent rights usually stems from the pharmaceutical company's claims of huge research and development costs. AZT, however, was initially developed by Jerome Horwitz as a cancer drug at the Michigan Cancer Institute laboratory. It was shelved because it was too toxic, and when its patent expired it was acquired by Burroughs Wellcome (now GlaxoSmithKline). In 1984, the National Cancer Institute invited companies to submit compounds for testing as AIDS drugs, and one of the compounds that Burroughs Wellcome sent in was AZT.

The National Cancer Institute had a breakthrough when it discovered that AZT could suppress HIV in human cells, and developed technology for determining the optimal concentration.[61] Burroughs Wellcome Laboratories UK then carried out subsequent clinical trials, which confirmed that AZT could control opportunistic infections by raising the CD4 counts in the sufferer's body.[62] However, Burroughs Wellcome was later to claim that it independently discovered and developed AZT with no substantial help from government scientists, a claim that was strenuously denied by the National Cancer Institute, which later presented evidence that initially one of the key obstacles to the development of AZT was that Burroughs Wellcome refused to work with live HIV, nor did it want to receive samples from AIDS patients.[63] Furthermore, the US government actively enabled the development of AZT by granting it a licence under the Orphan Drug Act.[64] This gave Burroughs Wellcome an exclusive licence for seven years from July 1985. The company filed for a patent in September 1985, which covered AZT's AIDS applications, and the patent was granted in 1988.[65]

[61] H Mitsuya, K J Weinhold, P A Furman et al., '3′-azido-3′deoxythymidine (BWA509U): An antiviral agent that inhabits the infectivity and cytopathy-associated virus *in vitro*', *Proc Natl Acad Sci USA*, 82 (1985), 7096–100.

[62] Linda J Wastila and Louis Lasagna, 'The history of zidovudine (AZT)', *J Clin Res Pharmacoepidemiol*, 4 (1990), 25–37.

[63] See T E Haigler, Jr, 'Reduced dosage cuts cost of AIDS drug', *New York Times* (16 September 1989) late edition. Also see rebuttal by Hiroaki Mitsuya et al., 'Credit government scientists with developing anti-aids drug', *New York Times* (29 September 1989).

[64] Orphan Drug Act of 1983 Pub.L. No 97–414 96 Stat 2049 (codified as amended) at 21 UCSC S 301 note 360 aa-cc, 42 USCC SS 236,287 (i), 295 g-1 (Law Co-op) 1984 and supp 1990.

[65] US Patent No 4,724,232, issued 9 Feb 1988 entitled 'Treatment of human viral infections.' J Rideout, D Barry, S Lehrman, M St Cliar and P Furman named as inventors.

Burroughs Wellcome claims to have spent about US$80 million a year over 'normal' development costs. In addition, the company claimed that its fixed costs for the medicine are unusually high due to the very rare and costly product of herring sperm used in the primary raw material, thymidine, and the six separate chemical reactions that were needed for the manufacture.[66] However, a study done by the medical charity Médecins Sans Frontières (MSF) illustrated that in many jurisdictions that used generic manufacturing this medicine could be produced at a much cheaper price.[67] Generics are copies of medicines that are not subject to patents. They are credited with increasing competition, which helps in lowering prices. In their absence, AIDS was big business for pharmaceutical companies. Many pharmaceutical companies were constantly marketing already existing medicines under different brand names, and making minor changes in compounds for existing medicines and applying for different patents for those.[68]

However, the toxicity of the first reverse transcriptase inhibitors meant that there was a real need for the development of improved medicines.[69] At the Vancouver AIDS Conference in 1996, the discovery of protease inhibitors was announced to the world.[70] These were incorporated into Highly Active Anti-Retroviral Therapy (HAART) and helped to prevent the virus from replicating. HAART is typically a combination of three or four ARVs.[71] Thus, HAART is often referred to as a drug 'cocktail', or

[66] Testimony of T E Haigler, former president of Burroughs Wellcome, on the company's research of AZT, 'Congressional hearings on AIDS issues: Hearings before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, One Hundredth Congress, First Session' (1987). www.archive.org/stream/aidsissueshearin00unit/aidsissueshearin00unit_djvu.txt last accessed 19 April 2011. 'AIDS issues (Part I): Cost and availability of AZT', Subcommittee on Health and the Environment, House Committee on Energy and Commerce, 100th Congress. 10 March 1987.

[67] C Schulte-Hillen, 'Study concerning the availability and price of AZT', MSF Report (1999). www.haiweb.org/campaign/novseminar/schulte_text.html last accessed 20 March 2011.

[68] As was seen earlier, AZT had received orphan drug status in 1985 and was marketed by Burroughs Wellcome; however, it was also marketed as Retrovir by GlaxoSmithline. Zalcitabine ddC marketed as Hivid by Hoffman-La Roche received orphan drug designation in June 1998.

[69] D Richman et al., 'The toxicity of azidothymidine (AZT) in the treatment of patients with AIDS and AIDS related complex', *N Engl J Med*, 317 (1987), 192–7.

[70] H Seckinelgin, *International Politics of HIV/AIDS Global Disease-Local Pain* (Routledge, 2008) 26; John Iliffe, *A History of the African AIDS Epidemic* (Ohio University Press, Ohio, 2006) 3–10.

[71] Dybul, Fauci et al., 'Guidelines for using antiretroviral agents among HIV-infected adults and adolescents', 381–433.

triple-therapy.[72] Together with the old reverse transcriptase inhibitors such as AZT[73] and nevirapine,[74] these constituted a combination, which unlike the old mono-therapy, led to less resistance and substantially fewer side effects.

The major advantage of HAART is that it not only renews the CD4 count, but also suppresses the viral replication in the blood while attempting to prevent the virus from rapidly developing resistance to the individual ARVs. Suppressing viral replication with HAART allows the body time to rebuild its immune system and replenish the destroyed CD4 cells. As a result, HAART has been clearly shown to delay progression to AIDS and prolong life.[75]

HAART treatment had a Lazarus effect of turning people who looked terminally ill into people who could yet again enjoy a high quality of life. The use of HAART also enabled ARVs to be used for the purposes of preventing the spread of HIV/AIDS. Tests conducted in sub-Saharan Africa illustrated that a course of ARVs given to infected expectant mothers during pregnancy, and to babies immediately after birth, led to reduced transmission from mothers to their unborn children.[76] The use of ARVs in the developed world is now so routine that the transmission of HIV/AIDS from mother to unborn child has almost been eradicated.[77]

There is also substantial medical evidence to show that ARV treatment leads to reduced rates of transmission by infected persons, as viral rates decline with continued treatment. Further studies have also shown that the general population in highly infected regions make dramatically greater use of prevention services in places where HIV-positive people have access to ARVs.[78]

[72] This is typically through two nucleoside or NRTIs plus an NNRTI or a PI or another NRTI called abacavir (Ziagen).

[73] AZT was the first antiretroviral medicine discovered. It slowed down the process of replication of HIV. At an initial cost of US$3,000 per person, it was considered too expensive for most people who were afflicted with the disease.

[74] Nevirapine is a reverse transcriptase inhibitor that also slowed down the replication of HIV. See M A Fischl et al., 'The efficacy of azidothymine (AZT) in the treatment of patients with AIDS and AIDS related complex. A double blind placebo controlled trial', *NEJM*, 317 (1987), 185, 191.

[75] Id.

[76] Laura A Guay et al., 'Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial', *The Lancet*, 354:9181 (1999), 795–802.

[77] John Sullivan and Katherine Luzuriaga, 'Prevention of mother to child transmission of HIV infection', *Clin Infect Dis*, 40 (2005), 466, 467.

[78] Mariah J Wawer et al., 'Rates of HIV-1 transmission per coital act by stage of HIV-1 infection in Rakai Uganda', *J of Infectious Diseases*, 191 (2005), 1403–09; Viviane D Lima

However, HAART did not come cheaply. The initial price was US $20,000 per person per year, which was out of the reach of many in the developing world.[79] Furthermore, even the minority that could afford these medicines could not sustain the treatment, and so ended up using them intermittently, which greatly increased the dangers of resistance.[80] The exorbitant cost created a bifurcated pandemic, as access to ARVs became a geographical lottery, depending on whether one lived in the developed or the developing world. Peter Piot expressed deep unease with this state of affairs at the AIDS Conference in Vancouver in 1996 when he stated that, 'It remains unacceptable that people living with AIDS especially – but not only – in the developing world, should have to live without the essential drugs they need for their HIV-related illness . . .'[81]

1.5.3 The Role of TRIPS and the Lack of Access to ARVs in Developing Countries

The price inequity, which denied people from developing countries access to ARVs, was blatantly unfair, and made it essential to seek international solutions to the high prices of these medicines. One of the underlying causes of the high prices of ARVs was the harmonization of intellectual property rights through the TRIPS Agreement, which in effect limited the amount of competition that pharmaceutical companies were subject to, thereby keeping prices artificially high. At the Durban AIDS Conference in 2000, Edwin Cameron, a South African High Court judge, derided the international legal order that created this situation.[82] He felt strongly that the situation had been created by manufacturers

et al., 'Expanded access to highly antiretroviral therapy: A potentially powerful strategy to curb the growth of the HIV/AIDS epidemic', *J Infect Dis*, 198 (2008), 59 [DOI: 10.1086/588673] [PubMed: 18498241]; Julio S Montaner et al., 'The case of expanding access to highly active antiretroviral therapy to curb the growth of the HIV epidemic', *The Lancet*, 368 (2006), 531 [DOI: 10.1016/S0140–6736(06)69162–9] [PubMed: 16890841].

[79] Bernhard Schwartlander et al., 'The 10 year struggle to provide antiretroviral treatment to people with HIV in the developing world', *The Lancet*, 368 (2006), 541–56 [DOI: 10.1016/S0140–6736(06)69164–2] [PubMed: 16890843].

[80] In 2000, a study in Harare described private anti-retroviral use as 'therapeutic anarchy' due to intermittent usage: N Nyazema, S Khoza et al., 'Anti retroviral (ARV) utilisation in Harare', *Cent Afr J Med*, 46 (2000), 89 [PubMed: 11210341].

[81] UNAIDS, at 60.

[82] Edwin Cameron, First Jonathan Mann Memorial Lecture: The Deafening Silence of AIDS, X111 International AIDS Conference, Durban, South Africa, 9–14 July 2000. www.hhrjournal.org/archives-pdf/4065220.pdf.bannered.pdf last accessed 20 August 2015.

making medicines 'unaffordably expensive', thus creating grave injustices in Africa, where 290 million people lived on less than US$1 per day, and therefore could not afford these ARVs. Cameron argued that the international patent regime prevented the production and marketing of affordable medicines.[83]

The international patent regime was consolidated within the TRIPS Agreement in 1995.[84] This was agreed because of immense pressure by the United States and the European Union (EU), where the bulk of the pharmaceutical and related intellectual property interests were located. The negotiation of these rights into a hard law agreement that was binding on the parties, despite not necessarily being in the interests of most developing countries, reflected the developed countries' comparative advantage in high technology goods, such as pharmaceuticals and computer software.[85]

The resultant TRIPS Agreement harmonized patent rights throughout the world and compelled countries signing up to the WTO to recognize existing patent rights. These allowed the patent owner the right to exclude other producers, thus allowing the owner 'exclusive use' of the patent. Thus, 'the granting of a patent creates a monopoly', since only the patent holder is legally allowed to market the new invention.[86] As a result, the patent owner can use this advantage to keep the price high. The difference between a monopolistic and a competitive market can have profound effects on the prices of medicines, as is evident by the drastic drop in prices at the end of a patent period.[87] Furthermore, there is a huge discrepancy between the cost of the production of medicines and the cost to the consumer. The subsequent ARVs that were developed were immensely expensive, putting them out of the reach of many developing countries.

There was also evidence that market competition mechanisms led to the price of ARVs being lower in many developed countries than in the developing countries where they were needed the most.[88] At the inter-governmental conference held in Kenya in 1999, delegates were

[83] Id.
[84] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1995).
[85] Debora Halbert and Christopher May, 'AIDS pharmaceutical patents and the African state' in Patterson (ed), *The African State and AIDS Crisis*, 195–218.
[86] Robert Cooter and Thomas Ulen, *Law and Economics*, 5th edn (Bepress e-book 2007) 128 http://works.bepress.com/robert_cooter/56 last accessed 20 April 2011.
[87] Id.
[88] Meeting on Access to Essential Drugs in Kenya (Nairobi, Kenya, 31 August 1999).

told that the powerful antibiotic ciprofloxacin, which was essential for one of the major secondary infections of bronchial pneumonia, was twice as expensive in Uganda as it was in Norway.[89] This was at a time when Uganda still had one of the highest prevalence rates of HIV/AIDS in the world. This study also found that 10 out of 13 of the essential AIDS medicines were much cheaper in Canada than they were in Tanzania.[90]

It is important to note that the international legal regime had several exceptions to enable countries to bypass the rights of the patent holder to create access to essential medicines. However, all of these were largely ineffective and did very little to help developing countries. These measures included 'parallel importing', which allows developing countries to access the patented medicine in a resource-poor setting at a more affordable price by importing the patented medicine without authorization, acting as though the owner's patent rights had been exhausted.[91] Unlike other proprietary rights, patent rights are not exhausted at the point of sale unless a government reserves the right to do so, a process known as 'international exhaustion'. This removes the rights of the patent owner upon first sale, thus allowing parallel importing, whereby a distributor can sell different medicines at different prices in different markets, and in so doing, subsidize the price to developing countries.[92]

The other exemptions allowable under the TRIPS Agreement involve the use of cheaper generic alternatives of the patented medicines.[93] Compulsory licensing is a situation in which a government allows another party to produce the patented product or take advantage of the process without the consent of the patent owner.[94] This will be dealt with in further detail in Chapters 3 and 5.

Although there were substantial savings to be made while using the exemptions of the TRIPS Agreement, developing countries generally found it impossible to take advantage of them, because there was a lack

[89] This report was further substantiated by a joint report. UNAIDS, UNICEF, WHO and MSF, 'Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS (2004)'. http://apps.who.int/medicinedocs/pdf/s8112e/s8112e.pdf last accessed 20 April 2012, 31.

[90] Id. [91] They are also referred to as grey market imports.

[92] Keith E Maskus, 'Parallel importing in pharmaceuticals; Implications for competition and prices in developing countries', Final report to the World Intellectual Property Organisation (2001). www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf last accessed 2 January 2016.

[93] A generic medicine is one that is produced by a third party without patent protection.

[94] WTO, 'TRIPS and public health: Compulsory licensing of pharmaceutical products'. www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm last accessed 2 April 2016.

of clarity about when compulsory licensing mechanisms could be used. Furthermore, the reliance on waiting for the patent period to expire meant that they could not access new medicines at the times that they needed them most. Therefore, new medicines such as Tenofovir, a substitute for Stavudine and Ritonavir, but which unlike them does not require refrigeration, so is therefore ideal for resource-poor countries, could not be generically manufactured quickly enough, as they were still under patent.[95] As such, prices of the newest and most effective ARVs remained artificially high and out of the reach of developing countries.

Any attempts to reduce medicine prices faced opposition from pharmaceutical companies. Boehringer Ingelheim, one of the world's major pharmaceutical companies, stated that 'infringement of intellectual copyright laws to allow poor countries cheap access to AIDS drugs would be the thin end of a dangerous wedge. Pirating would run riot across the world – and global business would suffer.'[96]

This hostile approach led to calls for medicines to be placed into a special category of public health goods, which would allow developing countries easier access to exemptions to the TRIPS Agreement. Since generic versions of ARVs could be produced by reverse engineering these medicines, attention soon turned to whether the cheap cost of imitation, as opposed to the relatively high costs of research (the 'appropriability' problem),[97] could be allowable. This seemed reasonable, since medicines, unlike many other goods, benefit society as a whole and are therefore global public health goods.[98] With thousands of people dying each day,

[95] Peter Mugenyi, *Genocide by Denial: How Profiteering from AIDS Killed Millions*, 1st edn (Fountain Publishers, Kampala, 2008) 190.

[96] 'Protection of IP rights in the best interests of pharmaceutical companies', *Washington Post* (27 December 2000) 27.

[97] The 'appropriability' problem is a term coined by economists to explain why the patent system might be ineffectual. One of the major reasons is that it fails to account for beneficial externalities that result from the patent. The marginal cost of the understanding required to produce a pharmaceutical drug is often close to zero, compromising only of the cost of transmitting scientific knowledge. This is because patents create monopoly rents that distort research incentives and encourage inefficient efforts by other firms to create copycats that undercut the patent holder in the pursuit of monopoly rents. James W Henderson (ed), *Health Economics and Policy* (South Western Educational Publishing, New York, 2006).

[98] Heinz Klug, 'Access to essential medicines' in Keith E Maskus and Jerome H Reichman (eds), *The Globalization of Private Knowledge Goods, in International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, Cambridge, 2005) 482–3. Also see G H Brutaland, 'International trade agreements and public health: WHO's role', presented by video at the Conference on

the question of affordable medicines could no longer be treated exclusively as a question of intellectual property or a trade-related issue. Rather, a human rights perspective was needed to facilitate access to ARVs as global public goods. The essential criterion of public health goods is that they must be marked by non-rivalry in consumption and non-excludability. The benefits must also be quasi-universal. As such, this approach changed the focus from the right of the patent holder to the right of the community to share in the knowledge required to produce ARVs.[99]

Several scholars have argued that access to ARVs, when perceived from a public health good perspective, creates a good case for looking at the access-to-medicines issue in terms of socio-economic rights.[100] This is because social economic disparities between developed and developing countries might hinder the ability of developing countries to share in the beneficial dividends of these medicines as public goods. Therefore, it becomes imperative to try to construct the issue of access to ARVs through social economic right paradigms, such as the right to health. The right to health, like all other social economic rights, is a communal right, as opposed to an individual one. This view has been reiterated by the UN, which has been vocal in articulating the right to essential medicines as part and parcel of the right to health.[101]

Public health issues, by their very nature, touch on a diverse range of problems across different treaty bodies. The AIDS pandemic was no different, and as we saw in Section 1.2, it had implications for gender, children, sexual orientation, health and intellectual property. All of these issues were covered in a number of treaties, both within and outside the UN system.[102] The idea of looking at all of these respective human rights

Increasing Access to Essential Drugs in a Globalized Economy (Amsterdam 25–26 November 1999) 1. www.who.int/medicines/docs/WTO_Public_Health_Amsterdam_GBH.html last accessed 2 April 2016.

[99] I Kaul and R U Mendoza, 'Advancing the concept of public goods' in Inge Kaul et al. (eds), *Providing Global Public Goods: Managing Globalization* (Oxford University Press, New York, 2003) 78, 84; Inge Kaul et al. (eds), *Global Public Goods: International Cooperation in the 21st Century* (Oxford University Press, New York, 2003).

[100] H P Hestermeyer, 'Access to medication as a human right', *Max Planck Ybk UN Law*, 8 (2004), 101–80; J A Harrington, 'AIDS, public health and the law. A case of structural coupling?', *EJHL*, 6 (1999), 211–32; M Heywood, 'Drug access, patents and global health: "Chaffed and Waxed Sufficient"', *TWQ*, 23 (2002), 217.

[101] See General Comment No 14. This book will discuss the components of this Comment in greater detail in Chapter 4.

[102] This is because when treaty law develops in an *ad hoc* and fragmented manner; parallel and in some cases when overlapping and contradictory obligations can be created.

values amongst intellectual property rights juxtaposes IP rights against human rights norms, which can be hard for developing countries to achieve, as the struggle for access to ARVs will illustrate.

1.6 An Outline of the Book

Given the scale of the problem of the AIDS pandemic, access to ARVs is vital for developing countries. This book argues that a major way of improving access to ARVs may be through placing less emphasis on so-called hard law solutions, and more on solutions that are derived from so-called soft law initiatives.[103]

This argument is founded on the hypothesis that hard law initiatives are fundamentally unsuited to increasing access by reducing prices to a level of affordability for the poorest States and the poorest people in those States. Hard law initiatives invariably arise in the context of existing international legal structures that are constructed on the basis of the protection of private property or individual rights. Consequently, they are incapable of prioritizing public health interests and the interests of the community in enabling the greatest number of sufferers to receive the treatment they need. By adopting a soft law approach, there is a much better prospect of circumventing existing legal structures and focusing on the main concern: making ARVs available to those who cannot afford them.

To make this argument, Chapter 2 sets up the theoretical framework for the book by outlining an understanding of soft law and hard law and what distinguishes them. It begins with a general analysis of how states create international legal responses to global problems, and divides the major responses of States into what can be termed the hard/soft law dichotomy. In doing so, it introduces the different schools of legal thought behind the hard/soft law dichotomy.

Next, Chapter 3 explores the nature and problems of hard law initiatives in relation to the international response to access to ARVs. This examines the problem of patents and considers the notion that the hard law created within TRIPS was at worst a deterrent, and at best a hindrance in enabling developing countries to create generic versions of ARVs. Chapter 4 focuses on the alternative problems of the global public good argument that was pursued by the UN through examining

[103] Wolfrum Rüdiger and Nele Matz, *Conflicts in International Environmental Law* (Springer, London, 2003).

the limitations of the right to health within the ICESCR. It argues that the right to health suffers from a historical inequality that plagues social and economic rights in relation to their civil and political counterparts. It goes on to show that although the right to health in particular has now satisfied the criterion of hard law due to its increased justiciability, it still lacks clarity, and suffers from serious problems in terms of resource constraints.

The book then explains the preference for soft law initiatives, beginning in Chapter 5 with the development of soft law alternatives. This chapter discusses the emergence of soft law initiatives within both the WTO and the UN, beginning with a discussion of the Doha Declaration on Health and its role in clarifying the relationship between the rights of the patent holder and the right to public health within the TRIPS Agreement. Particular emphasis is placed on the impact of this Declaration on the creation of generic ARVs for developing countries, and concludes by examining the danger of soft law that is created specifically as a precursor to hard law. A discussion of the Paragraph 6 Agreement with a consideration of the Rwanda case illustrates the concept of 'regulatory capture', in which the strengthening of soft law through hard law may be used to claw back gains made in earlier variations of soft law.

Chapter 6 continues to explore the efficacy of soft law initiatives, specifically in relation to access to ARVs within the UN. It begins by examining the role of the WHO in trying to create soft law responses to the AIDS pandemic. It argues that the preference for soft law within the UN originates in the WHO, and considers the role of soft law in trying to harmonize the relationship between the two branches of international law: human rights and international trade. This chapter focuses on the reactive nature of soft law, which is capable of creating quick responses to the problems of accessing medicines. The focus is on the versatility of soft law in creating institutions that encompass different stakeholders, dealing with the financial implications of universal access to ARVs, and creating programmes that could spearhead the distribution of ARVs. A key question here is the extent to which this body of soft law has substantiated, clarified or amended hard law to create greater access to ARVs.

The book then examines what has happened in practice. Chapter 7 considers two programmes that were conceived through soft law: the 'Scaling up: WHO 3 million people on ARVs by 2005' (3 by 5) Program and the efforts of the semi-autonomous Global Fund. Relying on the theoretical discussion of soft law in Chapter 2, Chapter 7 illustrates how

these programmes have, to a large extent, revealed the advantages discussed. The chapter illustrates the positive quantifiable results of these programmes in creating increased access to ARVs in the developing world, and then gives a measured critique of their failings, pointing out, however, that these problems are not insurmountable. The chapter particularly focuses on how these mechanisms have used their soft law mandate to respond to the different needs of developing countries.

Chapter 8 extends the soft law approach from the case study of AIDS to look at two related global health programmes: the Malaria Initiative and the Tuberculosis Initiative. This chapter begins by explaning why malaria and tuberculosis are comparable to the AIDS pandemic in terms of the disease burdens that they create for developing countries. It examines the reasons for the failure of previous high-profile global responses to these two diseases within 'eradication programmes' that relied on the right to health. It then analyzes the interfaces that these diseases have had with the TRIPS Agreement due to the increasing reliance on new medicines that are similarly bound by IP rules.

Chapter 9 concludes the book by summarizing the key issues. It also raises broader questions of how far this approach could be used more generally within global health.

1.7 A Note of Caution

This book has limited aspirations: it does not attempt to provide absolute answers. Through an analysis of the limitations of hard law that could have enabled greater access to ARVs, anti-malarials and tuberculosis medications, it makes a case that soft law has been more effective than hard law. It gives a further analysis on the success of soft law programmes. However, in so doing, the book does not offer an empirical study, and while it attempts to give some idea of the success of programmes by relying on quantitative data regarding the number of people who are on these essential treatments, there is an acknowledgement that UNAIDS and WHO projection methods are constantly being refined as these pandemics continue to evolve. Instead, this book considers the soft law process and its suitability in gaining access to essential medicines as a long-term solution, and does not in any way advocate a complete rejection of hard law within either the human rights or the international trade regimes. The book recognizes that hard law serves various other functions that are not related to the access to essential medicines, as discussed in the next chapter.

The very nature of this research involves analyzing the human rights and international trade regimes in tandem. There is a view by scholars such as Roger Normand that these regimes are separate and unequal frameworks with different and often contradictory philosophy, values, law and procedural enforcement mechanisms.[104] There is validity to this claim to some extent, but inherent in both of these regimes is the question of access to medicines, which provides ample commonalities within which to examine these different regimes within the international legal framework. This is further given credence under Article 28 of the Universal Declaration of Human Rights (UDHR), which states that all organizations and individuals have shared duties to promote the realization of a 'just and social order'. It is this 'just order' that the book is aimed at promoting, if only modestly, through a suggestion regarding the preferred legal responses to providing access to essential medicines for AIDS, malaria and tuberculosis.

[104] Roger Normand, 'Separate and unequal trade and human rights regimes', Background Paper for HDR (2000) UNDP Reports hdr.undp.org/en/reports/global/hdr2000/papers/normand2000.pdf last accessed 4 January 2010.