

Human Rights and the WTO: The Case of Patents and Access to Medicines

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Background of the Debate

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Abstract and Keywords

This chapter discusses the facts that called attention to the conflict between the TRIPS Agreement and access to medicine. The public discussion was initially triggered by the pricing decision of the patent holder of the first AIDS medicine AZT. It took on global proportions when the pharmaceutical industry sued the South African government that wanted to impose compulsory licences for patents on pharmaceuticals to provide its population with cheap AIDS medication. The chapter also recounts the events surrounding the anthrax attacks in the United States, when the Canadian and US governments threatened to break Bayer's patent on Cipro.

Keywords: TRIPS Agreement, access to medicine, international patents, AZT, South Africa, AIDS, Anthrax, Cipro

The conflict between the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) and access to medicine—the subject of this study—sounds exceedingly dry: patents are commonly deemed to be an abstract topic accessible only to those skilled in sciences—even by lawyers. What is worse, the TRIPS Agreement belongs to the World Trade Organization (WTO) Agreements and thus additionally suffers from the stigma of technicality attached to that particular area of international law. And yet, the conflict between international patent law and access to medicine has garnered an astonishing amount of public attention in recent years. Before examining the legal questions raised in detail, it is worthwhile

presenting some of the events that have caused the issue to stand at the forefront of the international debate surrounding globalization. These events are not only essential to understand the legal arguments made, they also explain the rancour with which activists and the pharmaceutical industry exchange arguments and accusations. But the historic account comes with a caveat: most of the events presented focus on the HIV/AIDS pandemic and even though no presentation of the conflict between the TRIPS Agreement and access to medicine would be complete without them, the solutions appropriate for the pandemic might differ from what is appropriate for other cases.

The first part of this chapter treats the appearance of the HIV/AIDS pandemic and the invention of the first medication targeting HIV itself, a scientific success that can largely be credited to publicly funded research institutions (I). Nevertheless, a private company obtained a patent on the use of the drug against AIDS in several countries and priced the drug in such a way that many people could not afford it, causing an outcry by AIDS activists (II). Part III will bring us up to date on the AIDS pandemic, its extent, currently available treatment, and the accessibility of that treatment. Part IV will then recount the South African pharmaceutical trial that brought the issue of patents and access to drugs to the attention of a wider public. Contrary to a common perception, the issue of the TRIPS Agreement and access to medicine is not limited to HIV/AIDS drugs. To illustrate this point, part V will tell the story of *Cipro*, a patented antibiotic that gained sudden prominence as the only approved treatment for anthrax and the patent on which Canada and the United States threatened to break to drive down the price.

(p. 2) I Finding a Cure for a New Disease

The beginnings in the developed world ¹ of what proved to be the most severe pandemic of our times went almost unnoticed: in 1981 in New York several young gay men were identified with an unusually aggressive case of a rare skin disease called *Karposi's sarcoma*, ² while at roughly the same time the US Centers for Disease Control (CDC) observed a significant increase in cases of another rare disease by the name *Pneumocystis carinii pneumonia* (PCP). ³ The *New York Times* reported a 'rare cancer seen in homosexuals', ⁴ but over time members of other groups, too, were acknowledged as falling victim to the disease: drug addicts, recipients of blood transfers and, later, heterosexuals in general. The early connection of the Acquired Immunodeficiency Syndrome (AIDS) ⁵ with marginalized groups and sex attached a powerful stigma to the disease and those affected that

endures to this day, hampering the public health response to the pandemic.
⁶ Maybe it was partly for this reason that the realization that AIDS was a worldwide pandemic did not emerge until 1984 with the publication of a CDC-sponsored study in Zaire finding the disease already rampant there. ⁷

Before researchers could consider finding a cure for the new disease they had to track down the agent responsible for it. Two publicly funded institutions staked a claim to scientific victory, illustrating the importance of public sector research for medical science. A group of researchers headed by Montagnier at the *Institut Pasteur* isolated the new virus—later to be called ‘Human Immunodeficiency Virus’ (HIV) ⁸—in May 1983 and subsequently developed a test for the new disease. ⁹ Researchers under Gallo, head of the Tumour Cell Biology lab at the National (p. 3) Cancer Institute (NCI), part of the US National Institutes of Health (NIH), isolated a virus, too, mass-produced it and developed a test for antibodies. ¹⁰ Besides the scientific honours what was at stake in the race were patents on an antibody test kit. The first US patent was awarded to the United States naming Gallo as inventor, ¹¹ prompting the *Institut Pasteur* to initiate an interference proceeding at the US Patent and Trademark Office and a lawsuit against the United States before the US Claims Court. ¹² It took an agreement between President Reagan and Prime Minister Chirac to settle the issue, declaring Gallo and Montagnier joint inventors of the test kit and splitting the royalties based on sales in each country. ¹³ The Agreement was revised in 1994 in favour of France, when US health officials conceded that Gallo had actually identified a virus provided under a cooperation contract by the *Institut Pasteur* and not, as he had claimed and as had been assumed during the patenting of the test kit, a different virus. ¹⁴

With the virus identified, progress towards an AIDS medication could be made. Again, public institutions were very much at the forefront of the research. Indeed, one public institution had already achieved a breakthrough before HIV was even discovered: funded by the NCI Horwitz, a researcher at the Detroit Institute for Cancer Research, synthesized a chemical entity called *azidothymidine* (AZT) to stop malignant cells in 1964. ¹⁵ The compound proved a failure and had no appreciable anti-tumour activity. ¹⁶ Horwitz never patented AZT, which thus fell into the public domain. Ten years later Ostertag of the *Max Planck Institut für Experimentelle Medizin*, a publicly funded German research institute, experimented with AZT, finding that ‘[i]n some instances azidothymidine might favourably replace [Bromodeoxyuridine] BrdUrd for medical treatment of diseases caused by (p. 4) DNA viruses’, ¹⁷ in other words: AZT showed promise in the treatment

of retroviruses. Not until a decade later, with the advent of AIDS, would the combined findings of Horwitz and Ostertag prove their significance. In its quest for a cure for AIDS, the NCI created a special task force, a member of which developed a method to screen compounds for effectiveness against HIV. Lacking adequate facilities, the NCI attempted to make the private sector run the tests in their labs, but the corporations recoiled. The potential market for an AIDS drug appeared to be too small and the prospect of a dangerous virus escaping from a company's lab was a liability nightmare. Finally, the NCI ran the tests in its own lab, with the drug companies providing the compounds. The samples sent by the companies were coded to protect the identity of the compounds.¹⁸ In 1985 the Institute's researchers found what they had been looking for: one of the compounds showed activity against HIV. The compound turned out to be AZT, sent in by the British pharmaceutical company Burroughs Wellcome (BW), which had chosen AZT for testing at the NCI lab after screening compounds using two mouse retroviruses. BW had already drafted a patent application for the United Kingdom before sending the compound to NCI. After the NCI tests were successful, BW filed the patent application and, soon after, filed for a patent in the United States (granted in 1988), claiming amongst others '[a] method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of' AZT.¹⁹ It also initiated the course towards approval of AZT by the US Food and Drug Administration (FDA).²⁰ With the clinical studies successful²¹ the FDA approved AZT in 1987 and BW, which before had given away free AZT priced at \$10m to some 4,500 patients,²² began to market the drug under the trademark *retrovir*.²³ BW also obtained special beneficial treatment in the United States available for 'orphan drugs', drugs for diseases affecting only a few patients, because the patient population eligible for AZT under the original indication of the drug was small.²⁴ For many years AZT was to remain the only drug available in HIV treatment.

(p. 5) II BW's Decision on AZT Pricing Causes Outrage

The patent on the use of AZT to treat AIDS put BW in the favourable position of being able to set the price for a drug that promised to be the only available life-saving therapy for a desperate patient population. The decision the company took became one of the causes around which activists were to rally and illustrates the claim that pharmaceutical patents result in higher prices thus reducing the accessibility of drugs: BW set the retail price for a year's supply of AZT for one patient at \$10,000. The tab was staggering for HIV/AIDS patients, who also had to grapple with the reluctant government

response to the disease. They began to set up highly effective activist groups. The AIDS Coalition to Unleash Power (ACT UP) was particularly rambunctious. In later years, some of their activists went so far as to barricade themselves in BW's offices. ²⁵ Many other groups have taken up the cause, as well, such as Médecins sans Frontières, the Consumer Project on Technology, OXFAM, or the Treatment Action Campaign. The outcry of those affected by the disease led to Congressional hearings scrutinizing the pricing decision. BW argued that the high price was justified by the cost of research, development, synthesizing, and marketing of the drug as well as the need to generate revenues, particularly in light of the fact that better therapies could be introduced soon. ²⁶ The argument did not convince Congressional critics. BW's research and development costs were far below the average drug development costs given the extent of government involvement in the research. ²⁷ At the same time sales of AZT were booming due to a large trial conducted under Volberding of the San Francisco General Hospital and funded by the National Institute of Allergy and Infectious Diseases (NAID) ²⁸ showing that AZT could slow the progression of AIDS if administered to HIV-positive patients without symptoms and not just to patients with fully developed AIDS. ²⁹ By the end of 1991, cumulative sales exceeded \$1b. ³⁰ The pressure that Congressman Waxman put on BW attained a 20 per cent cut in the AZT price in 1987, ³¹ but the cut was not sufficiently steep to silence activists. BW continued to refer to its own research efforts to justify the price level of AZT. This justification, however, began to enrage US government researchers, who responded with a letter published in the *New York Times* pointing out the government's significant contribution to the development of AZT and lambasting BW's reluctance to work with live HIV. ³² The NIH began to insert a reasonable pricing clause in the cooperative research and development agreements it signed with the industry for federally funded research. However, the clause was (p. 6) later eliminated for fear that it would discourage the industry from collaborating with the public sector. ³³

The fact that BW could obtain a patent on the use of AZT in AIDS treatment seems surprising considering that the compound was synthesized by Horwitz with US public funding, tested for antiretroviral activity by Ostertag with German public funding and tested for activity against HIV by the NCI, again with US public funding. Two companies, Barr Laboratories and Novopharm, questioned the validity of the patent and filed Abbreviated New Drug Applications ³⁴ for generic versions of AZT, ie copies of the drug using the same active ingredient. In the ensuing suit for patent infringement filed by BW they stated that NCI scientists should have been named as coinventors

of AZT. Novopharm argued that the failure to do so with deceptive intent rendered the patent unenforceable for inequitable conduct. Barr Laboratories relied on a licence to manufacture and sell AZT it had obtained from the US government, the owner of the alleged interests of the NCI scientists. In a 1994 decision, the Federal Circuit sided with BW. It reasoned that conception, the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice', is the touchstone of inventorship.³⁵ As evidenced by the draft UK patent application, BW inventors had such a definite and permanent idea before they sent AZT to the NCI and thus the NCI scientists were not joint inventors.³⁶ Nevertheless, litigation over the validity of the AZT patent continued throughout the patent's life span. The non-profit organization 'AIDS Healthcare Foundation' raised both antitrust and patent invalidity claims before the US District Court for the Central District of California in a suit that was refiled in 2003.³⁷ The US AZT patent expired in 2005.³⁸

III The HIV/AIDS Pandemic Today

Since the early days of the HIV/AIDS pandemic our knowledge about the pandemic has grown enormously. AIDS is characterized by a range of symptoms that (p. 7) differ from case to case. The disease is caused by HIV—a retrovirus, ie a virus having a core consisting of RNA and replicating as DNA inside the host cells by means of the enzyme reverse transcriptase. HIV attaches itself to the body's T4 lymphocyte cells and reprograms them to produce new viruses which are later released to infect new cells. The T4 lymphocytes are part of the body's immune defence, so the infection with HIV leaves the body defenceless against a number of opportunistic infections, which can cause the death of the patient. Two strains of the virus are widespread: HIV1, which was the first discovered virus, and HIV2, a virus that has been detected in West Africa. HIV is transmitted by blood, sexual intercourse or from mother to child.³⁹

The scope of the pandemic facing the world defies the imagination. The Joint United Nations Programme on HIV/AIDS (UNAIDS), which brings together ten United Nations agencies in a common effort to fight the pandemic, estimates that as of 2005 there were 38.6 million people living with HIV. The brunt of the disease's burden is carried by the developing world: 24.5 million of the affected people live in Sub-Saharan Africa, compared to 720,000 in Western Europe and 1,300,000 in North America.⁴⁰ 25 million people have already died of the disease.⁴¹ In some countries HIV/AIDS has reached an

extent that threatens the very foundations of society: in Swaziland more than 30 per cent of all adults are infected, three other Sub-Saharan African countries have infection rates of more than 20 per cent, South Africa is struck severely with an infection rate of 18.8 per cent. ⁴² In many countries life expectancy has dropped due to AIDS, eg in Cambodia it is estimated to be four years lower than it would have been without the disease. ⁴³ The devastating effects are felt in every sector of society: staggering numbers of AIDS orphans have to be supported, teachers to pupil ratios are reduced due to high infection rates among teaching staff, household income declines significantly where AIDS affects a working family member, economic growth suffers, health systems are overstretched, and so on. ⁴⁴ Tragically, many of the countries affected already belonged to the poorest countries in the world before the advent of the pandemic. But even though Africa is hardest hit, other regions should not be lost from sight: the pandemic is spreading in Asia and Eastern Europe, too. ⁴⁵ The threat that AIDS poses to the world can hardly be overestimated. In 2004 the UN Secretary-General's High-level Panel on Threats, Challenges and Change listed AIDS as a threat to international peace and security and gave the world a failing (**p. 8**) grade for its response: 'International response to HIV/AIDS was shockingly slow and remains shamefully ill-resourced.'⁴⁶

Treatment is an essential element of any strategy to fight AIDS. ⁴⁷ For years AZT was the only available medication attacking HIV itself. As a so-called nucleoside reverse transcriptase inhibitor AZT inhibits the reverse transcriptase HIV needs to reproduce. ⁴⁸ But the one-drug treatment was defective, not just because of the toxicity of the drug, but mainly because HIV reproduces quickly and mutates around the drug. Today, three other classes of antiretroviral drugs are available: protease inhibitors, non-nucleoside reverse transcriptase inhibitors, and fusion inhibitors. As of October 2003, 20 antiretroviral agents belonging to these four classes have been approved in the United States. ⁴⁹ The World Health Organization (WHO) currently recommends a therapy with two nucleoside reverse transcriptase inhibitors and one non-nucleoside reverse transcriptase inhibitor or a protease inhibitor. ⁵⁰ These modern therapies have changed the prospect for HIV-positive patients drastically. If several drugs aiming at different targets are administered simultaneously, the chances of the virus mutating around the drugs is basically zero. ⁵¹ Experts hope that a patient receiving proper treatment can live through a normal life span. ⁵² Initially, the combination drug regime was difficult to follow. Patients had to take several drugs at different times of the day, some with food, some on a fasting stomach, some of the medication even requiring refrigeration. ⁵³ This gave some

justification to the claim that treatment in the third world is not feasible and should only be administered carefully as it might lead to an increase in resistances. However, in the area of AIDS there is no more justification to this claim: the WHO-recommended three-drug combination is available as a generic fixed-dose combination with the three components in one pill that has to be taken once or twice a day. It can therefore be administered in countries with extremely poor infrastructure with an adequate adherence to the therapy—anywhere in the third world. ⁵⁴ The Indian drug manufacturer Cipla, the best-known developing country generic manufacturer, offers such a combination under the name of *triomune*, consisting of *nevirapine* (patents for which are owned by Boehringer Ingelheim), *stavudine* (patents for which are owned by Bristol-Myers Squibb), and *lamivudine* (patents for which are owned by GlaxoSmithKline), requiring one pill to be taken twice a day. ⁵⁵ Cipla was granted a patent on the combination in (p. 9) South Africa. ⁵⁶ Since May 2002 the same combination has also been produced by Thailand's state-owned Government Pharmaceutical Organization under the name of *GPO-Vir*. ⁵⁷ Fixed-dose combinations are not just convenient for the patient, they also improve adherence to drug regimes and thus reduce the risk of drug resistance. ⁵⁸ However, the combination is only available where its components are not under patent or where the patent owners have granted licenses. For antitrust reasons brand-name companies, ie the companies holding patents on the components, have not yet offered such a combination themselves, as that would require the collaboration of all the companies holding patents on the components of the combination. ⁵⁹ However, the first such treatment is expected to be available in the developed world soon. ⁶⁰

Sadly, the availability of treatment does not imply its accessibility. Numerous campaigns by the WHO, ⁶¹ the Global Fund to Fight AIDS, Tuberculosis and Malaria, ⁶² UNAIDS, ⁶³ governments, ⁶⁴ NGOs, ⁶⁵ and pharmaceutical companies ⁶⁶ have been mounted to increase access of HIV infected people to treatment. Particularly in the last few years, great progress has been made, but despite the efforts UNAIDS states that as of December 2005 at least 80 per cent of those in clinical need of antiretroviral drugs were not receiving them. ⁶⁷

(p. 10) But the advances made should not be slighted: the price of a WHO-recommended combination antiretroviral regime for one patient and one year was at \$10,000– \$12,000 in 2000. ⁶⁸ Generic drugs, produced where the drugs are not on patent, have brought down the prices significantly. By 2002 Cipla offered the regime at \$350 a year, treatment costs in 2004 with *GPO-Vir* in Thailand have been reported at \$348. ⁶⁹ A deal between

the Clinton Foundation and Indian generic drug manufacturers planned to bring this figure down to approximately \$140.⁷⁰ The ambitious goal was achieved. In 2006 the most common three-drug combination pill reportedly cost \$136 a year.⁷¹ But the supply of cheap generics depends on a mere handful of countries in which the medicine is not patented and which have the technological capacity to manufacture the medicine. Both manufacturers of the *triomune* combination that in 2004 were prequalified by the WHO for procurement by UN Agencies are situated in India.⁷² The Indian generic pharmaceutical industry, which has thrived under a national legal regime allowing it to reverse-engineer drugs on patent elsewhere and shielding it against foreign competition by regulatory controls, high tariffs, foreign equity restrictions, and price controls, is certainly the most important developing country generic industry, competing successfully with Western firms.⁷³ Besides India, the capacity to manufacture generic AIDS drugs exists only in a few developing countries, among them Argentina, Brazil, China, Cuba, Egypt, South Africa, and Thailand. However, many of them import the active pharmaceutical ingredients from India.⁷⁴

Despite the difficulties, some countries have achieved remarkable success. Thus, Brazil provides free AIDS drugs to anyone who tests HIV positive and registers with the public health system. Of the 600,000 HIV-positive patients in July 2003, 250,000 received care and 130,000 antiretrovirals. The rate of new infections has plateaued since 1996.⁷⁵ The system relies on Brazil manufacturing generic medicine itself, ie medicine not protected by patents. Such production was made possible by weak patent protection and, in 1997, certain loopholes in the Brazilian (p. 11) Patent Act,⁷⁶ staunchly attacked by the United States,⁷⁷ but defended by Brazil with equal force.⁷⁸ Brazil produces 15 AIDS drugs itself and buys 13 further antiretrovirals from private corporations. Brazil's AIDS programme has reaped praise even from the US government: in 2003 Brazil and the US agreed to cooperate in advancing AIDS treatment programmes in Mozambique and Angola, with Brazil providing expertise in technology transfer for manufacturing generic antiretrovirals and overseeing their use in countries without adequate health care systems.⁷⁹

IV The TRIPS Agreement and Access to Medicine: The South African Medicines Act

Cheap generics can only be manufactured where the medication is not protected by patents. In the past, many developing countries and some developed countries did not allow patents on pharmaceutical products. But

pressure by the United States and the European Communities to provide pharmaceutical patents grew. Brazil was not the only country that felt the heat. Thailand, for example, changed its patent laws under the threat of trade sanctions.⁸⁰ In 1994 the TRIPS Agreement was signed as part of the WTO deal. It obliges all Members of the WTO to adopt a minimum standard of patent protection after a transitional period.

Even though the discussion on patents and access to medicine was already well under way in the early 1990s, it had not obtained much public interest. The topic of patents simply did not seem to lend itself to debate outside of technically interested circles. This changed with the South African Medicines and Related Substances Control Amendment Act, 1997, signed into law by President Mandela on 12 December 1997.⁸¹ Faced with an epidemic of unprecedented proportions and the ensuing burden on its overstretched health budget, South Africa had decided **(p. 12)** to take action to keep medication affordable, a decision that was all the more hastened by the fact that drug prices in South Africa were at times higher than in some developed countries.⁸² Among the measures envisioned by the Medicines and Related Substances Control Amendment Act was a provision that gave the Minister of Health the authority to limit patent rights. The highly contested newly introduced section 15C of the Medicines and Related Substances Control Act read:

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

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;

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

The provision allows the Minister of Health to make use of two measures that have become a staple in the discussion of access to medicine and patent law: parallel imports and compulsory licences. Parallel imports of a drug, authorized by paragraphs (a) and (b) of the section,⁸³ are imports of a patented drug without authorization by the patentee from a country where the patentee itself placed the drug on the market at a lower price. Compulsory licences for drugs go beyond that in that the government authorizes third parties, in return for adequate remuneration for the patentee, to manufacture and sell the patented drug without the consent of the patentee, or to import the drug from a country where it has been put on the market by a third party manufacturer. The Minister of Health is authorized to grant such licences under the *chapeau* of section 15C, as paragraphs (a) and (b) only serve as examples of the Minister's authorization.⁸⁴

(p. 13) The international pharmaceutical industry, the US government and EU officials had already criticized the Act in the harshest terms before it was signed into law.⁸⁵ A swift reaction to the signature therefore had to be expected. On 18 February 1998 42 applicants, among them several big multinational pharmaceutical companies, filed suit against the South African government.⁸⁶ The industry argued that many provisions of the Act were in violation of the South African Constitution. With respect to section 15C the powers granted to the Minister of Health to prescribe conditions for the supply of more affordable medicines were regarded as too vague, particularly as the power includes the authorization to restrict patent rights.⁸⁷ The industry also argued that the provision violated its constitutionally protected property rights.⁸⁸ Finally, the provision was alleged to be inconsistent with Art 27 of the TRIPS Agreement as it purportedly discriminates against patent rights in the pharmaceutical field.⁸⁹ The US government followed the lead of the industry and put South Africa on its 'Special 301' Watch List, a list of countries that deny adequate and effective intellectual property protection,⁹⁰ reasoning that the Act granted the Minister of Health an ill-defined authority to authorize parallel imports, issue compulsory licences, and potentially otherwise abrogate patent rights.⁹¹ In addition, the United States withheld preferential tariff treatment under the Generalized System of Preferences on four items.⁹² The South African

government, on the other hand, pointed out that under the South African Constitution it had an obligation to protect its citizens' right to health. ⁹³

(p. 14) The lawsuit of the pharmaceutical industry put the issue of access to medicine and the TRIPS Agreement on the international agenda—and the growing awareness of the extent of the AIDS pandemic ensured that it remained there. From a public relations point of view, the lawsuit turned into an unmitigated disaster for the pharmaceutical industry. Treatment Action Campaign, a South African NGO representing people affected by AIDS, joined the case as *amicus curiae*. ⁹⁴ 300,000 individuals and 140 groups across 130 nations signed a petition demanding that the pharmaceutical industry withdraw its suit. ⁹⁵ In the United States activists disrupted Vice-President Gore's campaign to draw attention to the problem. The Congressional Black Caucus started to take note and ask questions on patents and AIDS medication. ⁹⁶ Articles in major newspapers such as the *New York Times* and the *Chicago Tribune* gave the cause an ever-growing audience. Soon the issue of patents and access to medicine seemed to be everywhere. Among the fora discussing the topic were the World Intellectual Property Organization (WIPO), which held a panel discussion on intellectual property and human rights in November 1998, ⁹⁷ the WHO, which became the scene of heated debates on the topic during the discussion of its Revised Drug Strategy, that ultimately urged Member States to ensure that public health interests are paramount for pharmaceutical policies, ⁹⁸ and the Sub-Commission on the Promotion and Protection of Human Rights, that passed a resolution on intellectual property rights and human rights. ⁹⁹ Many of the numerous discussions on the AIDS pandemic and on the best way forward in the fight against the disease covered the patent question as a side issue.

Finally the pressure became too much to bear. With the Secretary-General of the United Nations mediating, the pharmaceutical industry decided to withdraw their lawsuit. In a joint statement with the South African government released on 19 April 2001 the industry declared its commitment to work together with the Republic of South Africa to further the health of the South African population. The government affirmed its commitment to the TRIPS Agreement and pledged to consult with the industry and the public about the regulations it would pass to implement Section 15C. ¹⁰⁰ The United States, too, caved in. In September 1999 it announced that an agreement had been reached with South Africa. In the agreement the governments affirm their commitment to the TRIPS Agreement and their appreciation of the South African Government's efforts to provide affordable health care to its people. South Africa explicitly states that its implementation of **(p.**

15) the Medicines Act would be TRIPS compliant. ¹⁰¹ An executive order by President Clinton forbidding the United States to seek the revision of intellectual property laws of Sub-Saharan African countries that promote access to HIV/AIDS pharmaceuticals and are TRIPS compliant paved the way to halting the 'Special 301' action against South Africa. ¹⁰²

V Beyond AIDS Drugs: Anthrax and Cipro

The heated fight about HIV/AIDS drugs has gained so much coverage that it seems as though the debate about the TRIPS Agreement and access to pharmaceuticals is intrinsically limited to the question of access to AIDS drugs. Given the scale of the HIV/AIDS pandemic, there can be no doubt that the disease is currently the single most important example of the conflict between patents and access to medicine. However, it is not the only one—to name just a few examples: Novartis' cancer drug *Glivec* has caused fierce debates, ¹⁰³ Myriad Genetic's patent on breast-cancer related genes has nearly quintupled prices for genetic tests for breast cancer in Canada and spawned a renewed discussion on patents in health care in Canada. ¹⁰⁴ Another example is *oseltamivir*, better known under its trade name *Tamiflu*, the patents on which are owned by Gilead and still in force. ¹⁰⁵ The medication marketed by Roche is WHO's recommended treatment for avian influenza or 'bird flu'. ¹⁰⁶ Cases of the disease in humans, transmitted from infected animals, have been rare, but have raised the spectre of an influenza epidemic if the **(p. 16)** virus should mutate to enable human-to-human transmission. ¹⁰⁷ With countries scrambling to stockpile *Tamiflu*, Roche's drug turned into a blockbuster and concerns surfaced that Roche would be unable to satisfy the growing demand. In several countries there were discussions about imposing compulsory licenses, forcing Roche to issue sub-licences for the drug. As the *Tamiflu* patent had not yet been granted in India, Cipla decided to start producing the drug. ¹⁰⁸

Of particular interest for this study is yet another example due to its political implications: Bayer's *Cipro*. In October 2001, shortly after the tragedy of the 11 September 2001 terror attacks on the United States, mysterious letters containing anthrax were sent to a number of important personalities, including Democratic Senator Daschle, New York Governor Pataki, as well as the offices of NBC and ABC television. ¹⁰⁹ Bayer, a large German corporation, produced the only medication approved for treating anthrax in the United States: the antibiotic *Cipro*. Whereas in Europe the patent on *Cipro* had already expired, the product was still under patent in the United States and Canada. ¹¹⁰

Demand for the drug skyrocketed as individuals prepared for large-scale biological terror attacks within the United States. The US government announced that the White House wanted to purchase a sufficient quantity of antibiotics to cover 12 million people for 60 days. Despite immediate increases in Bayer's production capacity the demand significantly outpaced the growing supply. The Indian drug maker Cipla, that had been producing a generic version of the drug for more than a decade and sold it for a fraction of the cost of the brand-name drug, ¹¹¹ offered to supply *Cipro* to the United States. The situation was fraught with irony: Cipla, one of the major suppliers of generic AIDS drugs and as such on the other side of the trenches in the fight about access to AIDS drugs, offered *Cipro* to the United States, even though it was still protected by Bayer's patent. ¹¹² At first, however, it seemed that the US administration would hold on to its pro-patent position. Bayer announced it would triple *Cipro* production to 200 million tablets over three months and the US Secretary of Health and Human Services, Thompson, stated publicly that his agency would not disregard patents. ¹¹³

But the situation changed when Canada announced that it would purchase 900,000 tablets of a generic version of *Cipro* for what was reported to be roughly (p. 17) half the price that Bayer would have charged. After Bayer threatened litigation the two sides agreed that Canada would not break Bayer's patent and Bayer would deliver medication within 48 hours' notice at \$1.30 per pill—much lower than its usual government price of \$1.83. Secretary of Health and Human Services Thompson radically changed his position: he threatened that the United States would buy *Cipro* from generic manufacturers if Bayer would not make significant price concessions. ¹¹⁴ The threat was backed by an Executive Order issued by President Bush extending national defence contracting authority to the Department of Health and Human Services, an implicit threat that the Department would contract with a competitor to obtain *Cipro*. ¹¹⁵ Bayer felt its options were exhausted and agreed to supply 100 million tablets of *Cipro* for \$0.95 per tablet. In addition, the United States obtained an option for an additional 200 million tablets. ¹¹⁶ The about-face in the US government's position compared to the one adopted during the South African trial was widely noted. ¹¹⁷ To this day the debate about access to medicine and patent law continues and the United States has remained the most ardent defender of stringent patent protection.

Notes:

- (1) Much later studies showed that HIV/AIDS had already been prevalent in Africa before these events.
- (2) KB Hymes *et al*, 'Kaposi's sarcoma in homosexual men: A report of eight cases' (1981) 2 *Lancet* 598.
- (3) PS Arno and KL Feiden, *Against the Odds. The Story of AIDS Drug Development, Politics and Profits*, (1992) 86; MD Grmek, *History of AIDS. Emergence and Origin of a Modern Pandemic*, 6 (RC Maulitz and J Duffin trans 1990).
- (4) L Altman, 'Rare Cancer Seen in 41 Homosexuals', *NY Times* (3 July 1981).
- (5) CDC, 'Update on acquired immune deficiency syndrome (AIDS)' (1982) 31 *Morbidity and Mortality Weekly Rep* 507.
- (6) Behrman describes how the Reagan administration engaged in denial of the imminent pandemic. It was Congress that pushed through funding: By the end of Reagan's second term AIDS research funding had jumped to \$500m a year. G Behrman, *The Invisible People. How the US Has Slept through the Global AIDS Pandemic, the Greatest Humanitarian Catastrophe of Our Time* (2004) 1 ff; M Goozner, *The \$800 Million Pill. The Truth Behind the Cost of New Drugs* (2004) 95, 102.
- (7) The study went unpublished for almost a year before it was accepted by the *Lancet*. In 1983 the World Health Organization saw no necessity to get involved as 'AIDS is being well taken care of by some of the richest countries in the world (...) where most of the patients are to be found' (memo cited by Behrman). Behrman (n 6 above) 10, 14.
- (8) JL Marx, 'Aids Virus Has New Name—Perhaps' (1986) 232 *Science* 699.
- (9) F Barre-Sinoussi *et al*, 'Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)' (1983) 220 *Science* 868.
- (10) Arno and Feiden (n 3 above) 12.
- (11) US Patent No 4,520,113, Serological detection of antibodies to HTLV-III in sera of patients with AIDS and pre-AIDS conditions. A similar application by the *Institut Pasteur* had been made in Europe in September 1983 and in

the United States in December 1983. The US patent was granted one year after Gallo's test was on the market. C Norman, 'Patent Dispute Divides AIDS Researchers. The War on AIDS, Pt 2' (1985) 230 Science 640; C Norman, 'FDA Approves Pasteur's AIDS Test Kit' (1986) 213 Science 1063.

(12) *Institut Pasteur v United States*, 10 Cl Ct 304 (Cl Ct, 1986). The lawsuit was an action for breach of contract, alleging that the virus used by Gallo had been provided by the *Institut Pasteur* solely for study purposes—a claim that Gallo denied, arguing he had extracted a different virus. The suit was dismissed on jurisdictional grounds, but the decision was reversed on appeal. *Institut Pasteur v United States*, 814 F2d 624 (Fed Cir, 1987). DM Barnes, 'AIDS Case Dismissed on Legal Technicality' (1986) 233 Science 414.

(13) Arno and Feiden (n 3 above) 13; DM Barnes 'AIDS patent dispute settled' (1987) 236 Science 17. On the whole issue RI Gordon, 'Facilitating the Transnational Exchange of Scientific Information: Institut Pasteur v United States' (1988) 6 BU Int'l LJ 179.

(14) L Garrett, 'French First to Isolate HIV', *Newsday* (12 July 1994); E Chen, 'US Admits French Role in HIV Test Kit', *Los Angeles Times* (12 July 1994); J Cohen and E Marshall, 'NIH-Pasteur: A Final Rapprochement?' (1994) 265 Science 313; J Cohen, 'Pasteur Wants More HIV Blood Test Royalties' (1992) 255 Science 792; J Cohen, 'HHS: Gallo Guilty of Misconduct' (1993) 259 Science 168; J Cohen, 'US-French Patent Dispute Heads for a Showdown' (1994) 265 Science 23.

(15) JP Horwitz, J Chua, and M Noel, 'The Monomesylates of 1-(2'-Deoxy-b-D-lyxofuranosyl) thymine' (1964) 29 J Org Chem 2076.

(16) Arno and Feiden (n 3 above) 40 ff.

(17) W Ostertag *et al*, 'Induction of Endogenous Virus and of Thymidine Kinase by Bromodeoxyuridine in Cell Cultures Transformed by Friend Virus' (1974) 71 Proc Nat Acad Sci USA 4980, 4984.

(18) Arno and Feiden (n 3 above) 39 ff.

(19) US Patent No 4,724,232, Treatment of human viral infections (note that several patents with similar claims were granted, which will be treated as one for the purposes of this study). BW could not claim the compound itself, as that had been invented much earlier by Horwitz. *Burroughs Wellcome Co v Barr Laboratories, Inc et al*, 828 FSupp 1208, 1211 (E D North Carolina,

1993); *Burroughs Wellcome Co v Barr Laboratories, Inc et al*, 40 F3d 1223, 1225 f (Fed Cir, 1994); Arno and Feiden (n 3 above) 41 ff.

(20) Arno and Feiden (n 3 above) 42.

(21) Phase I: R Yarchoan *et al*, 'Administration of 3'-Azido-3'Deoxythymidine, an Inhibitor of HTLV-III/LAV Replication, to Patients with AIDS or AIDS-Related Complex' (1986) 1 *Lancet* 575; phase II: MA Fischl *et al*, 'The Efficacy of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex' (1987) 317 *New Eng J Med* 185.

(22) Arno and Feiden (n 3 above) 43.

(23) *Burroughs Wellcome Co v Barr Laboratories, Inc et al*, 40 F3d 1223, 1226 (Fed Cir, 1994).

(24) Arno and Feiden (n 3 above) 56.

(25) ACT UP, *ACT UP Capsule History 1989*, at <<http://www.actupny.org/documents/cron-89.html>>.

(26) Arno and Feiden (n 3 above) 55 ff.

(27) Arno and Feiden (n 3 above) 58.

(28) Phone interview with Volberding.

(29) Arno and Feiden (n 3 above) 113, 130 ff.

(30) Arno and Feiden (n 3 above) 59.

(31) M Chase, 'Wellcome Unit Cuts Price of AIDS Drug 20%', *Wall Street Journal* (15 December 1987).

(32) Arno and Feiden (n 3 above) 136 ff.

(33) Goozner (n 6 above) 127, 148; PS Arno and MH Davis, 'Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research' (2001) 75 *Tul L Rev* 631.

(34) See chapter 2 for a description of the drug approval process.

(35) *Burroughs Wellcome Co v Barr Laboratories, Inc et al*, 40 F3d 1223, 1228 (Fed Cir, 1994).

(36) *Burroughs Wellcome Co v Barr Laboratories, Inc et al*, 40 F3d 1223, 1227 ff (Fed Cir, 1994). Writ of *certiorari* denied: *Novopharm, Inc v Burroughs Wellcome Co*, 516 US 1071 (1996). Similar litigation took place in other countries, cf Supreme Court of Canada, *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 (2002); Cour d'Appel de Paris, *Wellcome Foundation Limited v Apotex France and Apotex Inc* (2003) 34 IIC 297.

(37) The Attorney General of the State of California submitted an amicus brief in support of the NGO: *AIDS Healthcare Foundation v GlaxoSmithKline PLC* (US District Court Central District of CA), CV 03-2792 *Brief of Amicus Curiae State of California in Support of AIDS Healthcare Foundation's Opposition to GlaxoSmithKline's Motion for Partial Summary Judgment* (2004).

(38) Aids Healthcare Foundation, 'Glaxo Loses Patent on First AIDS Drug, AZT; AHF Blasts Glaxo's & Drug Industry's Greed' Press Release, 17 September 2005.

(39) J Hubley, *The AIDS Handbook. A Guide to the Prevention of AIDS and HIV* (3rd edn, 2002) 13 ff; Goozner (n 6 above) 95.

(40) UNAIDS, *2006 Report on the Global AIDS Epidemic* (2006) 6, 505 ff.

(41) UNAIDS (n 40 above) 17.

(42) UNAIDS (n 40 above) 506.

(43) UNAIDS (n 40 above) 83.

(44) KR Hope, 'Africa's HIV/AIDS Crisis in a Development Context' (2001) 15 *International Relations* 15, 21 ff; M Rabbow, 'From Awareness to Behavioural Change—Challenges in HIV/AIDS Control in Southern Africa/Namibia' (2001) 36 *afrika spectrum* 17.

(45) UNAIDS (n 40 above) 8 ff; R Guyonnet, 'Alerte en Asie', *Jeune Afrique/L'Intelligent* (25 December 2001).

(46) High-level Panel on Threats, Challenges and Change, *A More Secure World: Our Shared Responsibility* (2004) 24.

- (47) UNAIDS, *Report on the Global HIV/AIDS Epidemic 2002* (2002) 16.
- (48) Arno and Feiden (n 3 above) 40 ff.
- (49) Panel on Clinical Practices for Treatment of HIV Infection, *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (2004) 8.
- (50) WHO, *Scaling up Antiretroviral Therapy in Resource-limited Settings: Treatment Guidelines for a Public Health Approach. 2003 Revision* (2003) 12 ff.
- (51) Goozner (n 6 above) 142.
- (52) Phone interview with Volberding.
- (53) Phone interview with Volberding.
- (54) The same is not necessarily true for all diseases. Where it is not the case, an appropriate solution for the access problem can only be found on a case-by-case basis.
- (55) 'Generic AIDS Pill Gets Patent in Africa', *Reuters* (13 July 2004).
- (56) According to Smith from Cipla/Medpro in South Africa Cipla has filed for patents for *triomune* in South Africa, DRC, Namibia, and all ARIPO countries. J Love, 'CIPLA 3 in 1 ARV patent', *IP-Health* (5 July 2004); 'Generic AIDS Pill Gets Patent in Africa', *Reuters* (13 July 2004).
- (57) 'Thailand Eyes Generic Versions of Two AIDS Drugs', *Reuters*, 10 July 2004; A Kazmin, 'Thailand's Cheap Aids Drugs Revive Patients' Hope' *Financial Times* (9 July 2004).
- (58) D Sontag, 'Early Tests for US in Its Global Fight on AIDS', *NY Times* (14 July 2004).
- (59) DG McNeil Jr, 'Study Finds Generic AIDS Drug Effective', *NY Times* (2 July 2004). GlaxoSmithKline offers a combination pill which combines three drugs from the same class instead of a mix of classes.
- (60) A Pollack, 'New Medicine for AIDS Is One Pill, Once a Day', *NY Times* (9 July 2006).

(61) At the WHO Mann set up the United Nations' Special Programme on AIDS, later renamed as the Global Programme on AIDS, in 1986. ME Wojcik, 'On the Sudden Loss of a Human Rights Activist: A Tribute to Dr Jonathan Mann's Use of International Human Rights Law in the Global Battle against AIDS' (1998) 32 J Marshall L Rev 129. Numerous programmes were to follow, most recently the '3 by 5' initiative aiming to treat three million people by 2005. UNAIDS (n 40 above) 150 ff.

(62) *The Framework Document of the Global Fund to Fight AIDS, Tuberculosis and Malaria*, available at <http://www.theglobalfund.org/en/files/publicdoc/Framework_uk.pdf> (2002).

(63) UNAIDS, *Uniting the World Against AIDS*, at <<http://www.unaids.org/en/AboutUNAIDS/default.asp>>.

(64) Intense coverage was given to President Bush's 'Emergency Plan for AIDS Relief', committed to provide \$15b over five years in the global fight against AIDS. Besides doubts whether the funding will really be made available in light of the Iraq war, criticism focuses on the question to what extent generic drugs will be provided under the programme and a peculiar nexus of the programme urging state recipients of HIV/AIDS help to not reject US food assistance with genetically modified food. United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Pub L 108-25, 117 Stat 711 (2003) (particularly § 104A(g)(1)(C), (2) of the Act); Office of the United States Global AIDS Coordinator (ed), *The President's Emergency Plan for AIDS Relief, US Five-Year Global HIV/ AIDS Strategy* (2004).

(65) Some examples are Médecins Sans Frontières' Access to Essential Medicines Campaign, Oxfam International's Cut the Cost Campaign and the Consumer Project on Technology's Health Care and Intellectual Property Campaign.

(66) International Federation of Pharmaceutical Manufacturers Associations, *Building Healthier Societies Through Partnership* (2004) 6 ff.

(67) UNAIDS (n 40 above) 155.

(68) UNAIDS, *2004 Report on the Global AIDS Epidemic* (2004) 103.

(69) A Attaran and L Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?' (2001) 286 JAMA 1886, 1891; 'Thailand Eyes Generic Versions of Two AIDS Drugs', *Reuters* (10 July 2004).

(70) S Vedantam, 'AIDS Plan Would Cut Drug Costs for Poor. WHO Would Provide 3-in-1 Pill to Nations', *Washington Post* (25 October 2003); S Boseley, 'Clinton's Aids Deal Snubs Bush Plan', *The Guardian* (7 April 2004).

(71) DG McNeil Jr, 'Clinton in Deal to Cut AIDS Treatment Costs', *NY Times* (12 January 2006).

(72) WHO, *Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality. Suppliers Whose HIV-Related Products Have Been Found Acceptable, in Principle, for Procurement by UN Agencies* (15th edn, 2004). In 2004, two drugs produced by Cipla were withdrawn from the list because of problems in a laboratory testing bioequivalence. LK Altman and DG McNeil Jr, 'UN Agency Drops 2 Drugs for AIDS Care Worldwide', *NY Times* (16 June 2004).

(73) S Banerji, *The Indian Intellectual Property Rights Regime and the TRIPs Agreement*, in C Long (ed), *Intellectual Property Rights in Emerging Markets* (2000) 47, 80 ff.

(74) A-C D'Adesky, *Moving Mountains. The Race to Treat Global AIDS* (2004) 64 ff, 383.

(75) A-C D'Adesky (n 74 above) 28 ff.

(76) The Brazilian Patent Act established a local working requirement, permitting compulsory licensing for failure to work the subject-matter of the patent in Brazil, and partly allowed parallel imports: Art 68(1), (2), (4) Lei da Propriedade Industrial N 9.279 de 14 de Maio de 1996, effective 15 May 1997. In 2005 Brazil threatened that it would issue a compulsory license for Abbott's AIDS drug Kaletra. T Benson, 'Brazil to Copy AIDS Drug Made by Abbott', *NY Times* (25 June 2005). The deal Brazil apparently negotiated with Abbott included an almost 50% price cut. P Prada, 'Brazil Near Deal with Abbott for Price Cut on AIDS Drug', *NY Times* (5 October 2005).

(77) At first the United States resorted to unilateral trade sanctions, see chapter 2. In 2000, the United States requested the establishment of a WTO panel. *Brazil—Measures Affecting Patent Protection. Request for the*

Establishment of a Panel by the United States, WT/DS199/3 (2001). The dispute was resolved by a mutually agreed solution.

(78) Brazil requested WTO consultations on certain provisions in Chapter 18 of the US Patent Act that concern inventions made with federal assistance and favour substantial manufacture in the United States. *United States—US Patent Code. Request for Consultations by Brazil*, WT/DS224/1 (2001).

(79) D'Adesky (n 74 above) 31.

(80) RS Park, 'The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients' (2002) 11 *Minn J Global Trade* 125, 135.

(81) Medicines and Related Substances Control Amendment Act 1997, Republic of South Africa Government Gazette No 18505, Act No 90, 1997 (12 December 1997).

(82) RL Ostergard, Jr, 'The Political Economy of the South Africa—United States Patent Dispute' (1999) 2 *J World Intell Prop* 875 ff; Statement by South Africa in Council for Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines*, IP/C/M/31 (10 July 2001).

(83) P Marc, 'Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?' (2001) 21 *NYL Sch J Int'l & Comp L* 109 (albeit using a broader definition of parallel imports); J Fedtke, 'Das Recht auf Leben und Gesundheit, Patentschutz und das Verfahren des High Court of South Africa zur Verfassungsmäßigkeit des südafrikanischen Medicines and Related Substances Control Amendment Act' (2001) 34 *VRÜ* 489, 499–500.

(84) WP Nagan, 'International Intellectual Property, Access to Health Care, and Human Rights: South Africa v United States' (2002) 14 *Fla J Int'l L* 155, 168; KM Bombach, 'Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement' (2001) 19 *BU Int'l L J* 273, 276–277.

(85) For a comprehensive overview of the history of the conflict cf Cptech (ed), *Appendix B. Time-line of Disputes over Compulsory Licensing and Parallel Importation in South Africa*, at <<http://www.cptech.org/ip/health/sa/sa-timeline.txt>>; an excellent account of the conflict is P Acconci, 'L'Accesso ai Farmaci Essenziali. Dall'Accordo TRIPS alla Dichiarazione della Quarta

Conferenza Ministeriale OMC di Doha' (2001) 4 La Comunità Internazionale, 637, 646 ff.

(86) High Court of South Africa (Transvaal Provincial Division), *Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa*, Case No 4183/98, Notice of Motion (1998).

(87) Paragraphs 2.1 ff of the Notice of Motion (n 86 above). Cf §§43, 44 of the South African Constitution; T Kongolo, 'Public Interest *versus* the Pharmaceutical Industry's Monopoly in South Africa' (2001) 4 J World Intell Prop 605, 616 ff.

(88) Paragraph 2.3 of the Notice of Motion (n 86 above). Cf §25 of the South African Constitution.

(89) Paragraph 2.4 of the Notice of Motion (n 86 above). Cf §44 (4), 231 (2), 231 (3) of the South African Constitution.

(90) Marc (n 83 above) 121. For details on the Special 301 Watch List see chapter 2 .

(91) Ostergard (n 82 above) 880.

(92) Park (n 80 above) 137. Cf p 156 (Development Assistance) of the 'Act Making Omnibus Consolidated and Emergency Appropriations for the Fiscal Year Ending September 30, 1999 and for Other Purposes', Pub L 105-277 (199) (21 October 1998) ('*Provided further*, that none of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997').

(93) Fedtke (n 83 above) 502.

(94) Fedtke (n 83 above) 503.

(95) Park (n 80 above) 148.

(96) Ostergard (n 82 above) 881 ff.

(97) World Intellectual Property Organization (ed), *Intellectual Property and Human Rights. A Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights. Geneva, November 9, 1998* (1999).

(98) *Revised Drug Strategy*, WHA Res 52.19 (24 May 1999).

(99) *Intellectual Property and Human Rights*, Sub-Commission on Human Rights Res 2000/7 (17 August 2000).

(100) *Text of Agreement in PMA et al v Republic of South Africa et al (High Court of South Africa—Transvaal Provincial Division, Case No. 4182/98)*.

(101) Department of Trade and Industry, *Joint Understanding between the Governments of South Africa and the United States of America*, at <<http://www.polity.org.za/html/govdocs/pr/1999/pr0917b.html?rebookmark=1>> (17 September 1999).

(102) Section 1(a) Executive Order No 13155, *Access to HIV/AIDS Pharmaceuticals and Medical Technologies* (10 May 2000). The Bush administration explicitly continued this policy. NA Bass, 'Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century' (2002) 34 *The Geo Wash Int'l L Rev* 191, 212.

(103) The Indian company Natco Pharma launched a generic version of *Glivec* under the name *VEENAT* on 26 January 2003 for 10% of the price of *Glivec*. Later the same year Novartis obtained exclusive marketing rights for the drug in India, a decision that Natco challenged in court. Meanwhile, Novartis has obtained a stay blocking six Indian companies from manufacturing generic versions of the drug. In South Korea activists unsuccessfully sought a compulsory license after a 30% price hike for *Glivec*. C Cookson and G Dyer, 'A Drugs Deal for the World's Poorest: Now the Fight over Patents and Cheap Medicine is in Middle-Income Countries', *Financial Times* (2 September 2003); 'Novartis Receives EMR for Glivec', *Express Pharma Pulse* (12 November 2003); 'Natco to Challenge Grant of Exclusive Rights to Novartis Cancer Drug', *The Hindu Business Line* (13 November 2003); J Datta, 'Exclusive Marketing Rights—Novartis Gets Stay against 6 Firms', *The Hindu Business Line* (25 January 2004); 'Government raised the Glivec Price', *IP-Health* (21 January 2003); Korea: Rejection of Glivec Compulsory License, *IP-Health* (10 March 2003).

(104) ER Gold and DK Lam, 'Balancing Trade in Patents—Public Non-Commercial Use and Compulsory Licensing' (2003) 6 J World Intell Prop 5, 7–8.

(105) Roche, *Factsheet Tamiflu* (2006).

(106) WHO, *WHO Rapid Advice Guidelines on Pharmacological Management of Humans Infected with Avian Influenza A (H5N1) Virus*, ii (2006).

(107) WHO, *Avian influenza ("bird flu")—Fact sheet*, at <http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html> (2006).

(108) 'Avian Influenza. In a Flap', *The Economist* (20 October 2005); 'Tamiflu Maker Roche Agrees on Generics', *Reuters* (8 December 2005); M Binyon, 'Indian Hero's New Mission: To Bring Cheap Drug for Bird Flu to Millions', *The Times* (6 March 2006).

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(110) 'Angst vor Milzbrand bringt Schub für Bayer-Produkt', *Handelsblatt* (17 October 2001).

(111) V Sridhar, 'Perilous Patent', *Frontline* (24 November 2001).

(112) M Peterson and R Pear, 'Anthrax Fears Send Demand for a Drug Far Beyond Output', *NY Times* (16 October 2001).

(113) M Fleischer-Black, 'The Cipro Dilemma—In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good Move?', *The American Lawyer* (January 2002); S Vedantam/T Chea, 'Drug Firm Plays Defense in Anthrax Scare', *Washington Post* (20 October 2001).

(114) S Vedantam and DL Brown, 'US Seeks Price Cut from Cipro Maker', *Washington Post* (24 October 2001); K Bradsher and EL Andrews, 'US Says Bayer Will Cut Cost of its Anthrax Drug', *NY Times* (24 October 2001).

(115) Executive Order No 13232, *Further Amendment to Executive Order 10789, as Amended, To Authorize the Department of Health and Human Services To Exercise Certain Contracting Authority in Connection with National Defense Functions* (20 October 2001).

(116) Bayer, *Bayer to Supply Government by Year-End with 100 Million Tablets for \$95 Million* (24 October 2001) at <<http://lists.essential.org/pipermail/ip-health/2001-October/002261.html>>; Department of Health and Human Services, *HHS, Bayer Agree to Cipro Purchase* (24 October 2001), at <<http://www.cptech.org/ip/health/cl/cipro/dhhs10242001.html>>.

(117) C Lenz and T Kieser, 'Schutz vor Milzbrandangriffen durch Angriffe auf den Patentschutz?' (2002) NJW 401; E Clark, 'America's Anthrax Patent Dilemma' (BBC, 23 October 2001), at <<http://news.bbc.co.uk/1/hi/business/1613410.stm>>.

