

THE GLOBAL POLITICS
OF PHARMACEUTICAL MONOPOLY POWER

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Drug patents, access, innovation and the application of
the WTO Doha Declaration on TRIPS and Public Health

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List of abbreviations and acronyms

| | |
|------------------|--|
| 3TC | lamivudine |
| ABC | abacavir |
| ACP | African, Caribbean and Pacific countries |
| AIDS | Acquired Immune Deficiency Syndrome |
| API | active pharmaceutical ingredient |
| ARV | antiretroviral |
| ASAQ | artesunate/amodiaquine |
| AZT | zidovudine |
| AZT/3TC | zidovudine/lamivudine |
| BI | Boehringer Ingelheim |
| BMS | Bristol Myers Squibb |
| CAD | Canadian Dollars |
| CAFTA | Central American Free Trade Agreement |
| CIPIH | WHO Commission on Intellectual Property Rights, Innovation and Public Health |
| CIPR | United Kingdom Commission on Intellectual Property Rights |
| CL | compulsory license |
| CPTech | Consumer Project on Technology |
| d4T | stavudine |
| DDC | Drug Development Corporation |
| ddI | didanosine |
| DG Trade | Directorate General for Trade of the European Commission |
| DNDi | Drugs for Neglected Diseases initiative |
| Doha Declaration | WTO Declaration on TRIPS and Public Health |
| DSB | WTO Dispute Settlement Body |
| EC | European Commission |
| EMRs | exclusive marketing rights |
| EPAs | Economic Partnership Agreements |
| FDC | fixed-dose combination |
| FTA | free trade agreement |
| G8 | Group of Eight |
| GAO | United States Government Accountability Office |
| GATT | General Agreement on Tariffs and Trade |
| GDP | gross domestic product |
| Global Fund | The Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GPO | Government Pharmaceutical Organisation (Thailand) |
| GSK | GlaxoSmithKline |
| GSP | Generalized System of Preferences |
| GU | government use |
| HAART | highly active antiretroviral treatment |

| | |
|--------|---|
| HAI | Health Action International |
| HIV | human immunodeficiency virus |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| IDA | International Dispensary Association |
| IFPMA | International Federation of Pharmaceutical Manufacturers & Associations |
| IGWG | Intergovernmental Working Group on Public Health, Innovation and Intellectual Property |
| INP+ | Indian Network for People Living with HIV/AIDS |
| IP | Intellectual Property |
| IPC | Intellectual Property Committee |
| KEI | Knowledge Ecology International (formerly CPTech) |
| LDC | Least-Developed Country |
| MAP | World Bank Multi-country HIV/AIDS Program |
| MEDS | Mission for Essential Drugs and Supplies (Kenya) |
| MEPs | Members of the European Parliament |
| MMSA | US Military Medical Supply Agency |
| MSD | Merck Sharp & Dohme |
| MSF | Médecins Sans Frontières |
| NAFTA | North American Free Trade Agreement |
| NDA | new drug application |
| NGO | non-governmental organisation |
| NHS | United Kingdom National Health Service |
| NME | new molecular entity |
| PEPFAR | United States President's Emergency Plan for AIDS Relief |
| R&D | research and development |
| TB | Tuberculosis |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNDP | United Nations Development Programme |
| UNICEF | United Nations Children's Fund |
| US | United States |
| US FDA | United States Food and Drug Administration |
| USAID | United States Agency for International Development |
| USD | United States Dollars |
| USTR | United States Trade Representative |
| WHA | World Health Assembly |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |
| UK | United Kingdom |

Timeline of events Related to access to medicines and intellectual property

- 1957 – 1962 The United States Senate Sub-committee on Anti-trust and Monopoly, under the chairmanship of Senator Estes Kefauver, examines the prescription drug industry and recommends legislation to curtail the monopoly powers of the pharmaceutical industry. In the late 1950s-early '60s, the US invoked government use powers on a routine basis to order generic medicines from abroad, regardless of the patent status of the products.
- 1965 Pfizer Corporation unsuccessfully challenges the United Kingdom's routine use of compulsory licenses ("Crown Use") for the provision of generic medicines to the National Health Service.
- 1969-1992 Canada issues 613 compulsory licenses for importation and/or local production of medicines as part of its cost containment measures.
- 1986 Launch of the Uruguay Round of the GATT (the predecessor of the WTO).
- Early 1990s Highly Active Antiretroviral Therapy (HAART) becomes available in Europe and North America, changing AIDS from a lethal disease to a chronic illness.
- 1995 Establishment of the World Trade Organization (WTO) and the adoption of the TRIPS Agreement.
- 1995 UNAIDS created.
- 1996 Brazil starts offering universal free ARV treatment to people living with AIDS.
- 1996 (May) World Health Assembly (WHA) adopts the Revised Drug Strategy and strengthens WHO's mandate in the area of intellectual property; the WHA requests the WHO 'to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate.'
- 1997 Brazil starts granting pharmaceutical product patents.

- 1998 The South African Pharmaceutical Manufacturers Association and 39 mostly multinational pharmaceutical companies bring suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 violated TRIPS and the South African constitution.
- 1999 Médecins Sans Frontières (MSF) launches its international Campaign for Access to Essential Medicines.
- 1999 (March) MSF, Health Action International (HAI) and Consumer Project on Technology (CPTech) organise the first meeting on compulsory licensing of AIDS medicines, held at the UN in Geneva
- 1999 MSF, HAI and CPTech organise an international conference on access to medicines in the run-up to the Seattle WTO Ministerial conference.
- 1999 Seattle WTO Ministerial meeting collapses. For the first time, delegates officially discuss the consequences of the WTO TRIPS Agreement for access to medicines.
- 2000 (May) US President Clinton issues Executive Order 13155 supporting sub-Saharan African countries in using measures such as compulsory licensing to allow production and import of generic AIDS drugs, without fear of trade retaliation.
- 2000 (May) Multinational drug companies announce price reductions for AIDS drugs.
- 2000 (July) The 13th International AIDS conference takes place in Durban, South Africa. This was the first time that this prestigious conference was held in a developing country.
- 2000 (December) A 3-day G8 summit on infectious diseases takes place in Okinawa, Japan, drawing attention to the need for global action and new financing for health.
- 2001 (February) The Indian generic medicines manufacturer Cipla announces triple-ARV AIDS treatment for 350 USD per patient/year.
- 2001 (April) Following a global public outcry against the 39 drug companies' actions in South Africa, the companies are compelled to drop their lawsuit.
- 2001 (November) The Fourth WTO Ministerial Conference adopts the Doha Declaration on TRIPS and Public Health.
- 2001 WHO launches the Prequalification Programme to ensure the quality of medicines for HIV/AIDS, TB and malaria.
- 2002 WHO includes ARV medicines in its Essential Medicines List (EML) for the first time.

- 2002 The Global Fund to Fight AIDS, Tuberculosis and Malaria is established.
- 2003 The WHO starts the '3 by 5' initiative to expand access to HIV treatment to 3 million people by 2005.
- 2003 Thailand offers universal access to ARVs to people living with AIDS.
- 2003 WTO adopts the "August 30th" decision to allow drugs to be produced under a compulsory license predominantly for export.
- 2003 In South Africa, the Treatment Action Campaign (TAC) wins its case against GlaxoSmithKline and Boehringer Ingelheim before the Competition Commission, which found the companies guilty of anti-competitive practices.
- 2003 US President's Emergency Plan for AIDS relief (PEPFAR) is launched.
- 2003 The Drugs for Neglected Diseases Initiative (DNDi), a not-for-profit drug development organisation, is founded.
- 2003 The UK Commission on Intellectual Property Rights publishes its report, concluding that the new global architecture for intellectual property has serious drawbacks for developing countries, in particular for access to medicines.
- 2005 (March) India amends its 1970 Patents Act to introduce pharmaceutical product patents, as required by the TRIPS Agreement.
- 2006 (January) Indian Patent Office rejects the patent application by Novartis for imatinib mesylate (Glivec).
- 2006 (March) The Indian Network of People Living with HIV/AIDS and the Manipur Network of Positive People file at the Kolkata patent office in India a pre-grant opposition to GSK's patent application for AZT/3TC (Combivir).
- 2006 (May) Novartis sues the Indian government over its amended Patents Act, attempting to overturn the provision (Section 3d) that establishes higher patentability criteria. The criteria were aimed at only granting patents to highly innovative products, thereby preventing frivolous patenting and "evergreening" of patents.
- 2006 Establishment of UNITAID, a new mechanism for the purchase of medicines, financed by a tax on airline tickets.
- 2006 WHO Commission on Intellectual Property Rights, Innovation and Public Health publishes its report, leading

- the World Health Assembly to establish the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG).
- 2006 (August) GSK announces the withdrawal of its patents and patent applications for a specific formulation of AZT/3TC which were subjects of civil society actions in India and Thailand.
- 2006 Thailand issues a compulsory license for the AIDS drug efavirenz.
- 2006 – 2008 IGWG negotiations take place in Geneva.
- 2007 (January) Thailand issues CL for the AIDS drug lopinavir/ritonavir and the heart disease drug clopidogrel
- 2007 (May) Brazil issues a compulsory license for efavirenz.
- 2007 (July) Rwanda notifies the WTO that it intends to use the “August 30” system to import medicines produced under a compulsory license.
- 2007 (October) In the first use of the “August 30th” system, Canada issues a compulsory license for the production of a triple fixed-dose combination ARV for export to Rwanda.
- 2008 (January) Thailand issues compulsory licenses for four anti-cancer drugs: docetaxel, letrozole, erlotinib, imatinib.
- 2008 World Health Assembly adopts the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property drawn up by the IGWG.
- 2008 UNITAID Board decides, in principle, to set up a patent pool for AIDS medicines.

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Ellen 't Hoen
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Executive Summary

The Global Politics of Pharmaceutical Monopoly Power

Introduction to access to medicines & the Doha Declaration

The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines they need to treat disease or alleviate suffering. The high cost of AIDS medicines has focused attention on the relationship between patent¹ protection and high drug prices. The difficulties developing countries experience in paying for new essential medicines has raised concerns about the effects of the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which mandates global minimum standards for the protection of intellectual property (IP).

Most significantly, the TRIPS Agreement harmonized patent terms for a minimum of 20 years and mandated the granting of patents in all fields of technology; this requirement made it no longer possible to exclude medicines and food from patenting. The full implications of the TRIPS Agreement for health are just beginning to emerge, but will only become fully apparent in the years to come. All new health products, including drugs, vaccines and diagnostics, are likely to be affected by the new TRIPS-based patent regime.

The Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar, responded to these concerns by adopting the Declaration on TRIPS and Public Health. The Doha Declaration, as it is widely known, affirmed the sovereign right of governments to take measures to protect public health,

¹ 'A patent is the right granted to an inventor by a State, or by a regional office acting for several States, which allows the inventor to exclude anyone else from commercially exploiting his invention for a limited period, generally 20 years' (WIPO).

including the use of compulsory licensing² and parallel importation.³ It also allowed least developed countries (LDCs) not to grant or enforce pharmaceutical product patents until at least 2016. These measures have become known as the ‘TRIPS flexibilities.’

A key issue that remained unresolved in Doha was how to ensure that products manufactured under a compulsory license could be exported to countries without domestic production capacity. It took two years of difficult negotiations at the WTO to arrive at the ‘August 30th’ decision, which established a cumbersome process to allow such export (See Section 4.5); to date, it has been used by only one country. The Doha Declaration also did not address the as-yet-unfulfilled promises of increased R&D in exchange for higher levels of IP protection, an expectation that was part of the bargain when countries were negotiating the TRIPS Agreement.

Nevertheless, the Doha Declaration is one of the most significant developments of the last decade in trade and health. It signalled a sea change in thinking about patents and medicines, and is at the root of a cascade of activities aimed at reformulating IP protection as a social policy tool for the benefit of society as a whole, rather than a mechanism to protect only limited commercial interests.

Implementation of the Doha Declaration

The Doha Declaration has had an important impact on national and international policies. Between 2001 and end 2007, 52 developing and least-developed countries have issued post-Doha compulsory licenses for production or import of generic versions of patented medicines, given effect to government use provisions, and/or implemented the non-enforcement of patents. Many countries have also used the flexibilities as leverage in price negotiations with patent-holding pharmaceutical companies.

The use of TRIPS flexibilities has been applied primarily to AIDS-related drugs, particularly antiretrovirals (ARVs). However, Thailand has recently issued government use orders for treatments for cardiovascular disease and cancers. The Thai example is important because chronic (non-communicable or Type I) diseases account for half of the disease burden in the developing world, and is rapidly increasing. The World Bank estimates that

2 Compulsory licensing enables a competent government authority to license the use of a patented invention to a third-party or government agency without the consent of the patent-holder against a payment of ‘adequate remuneration’.

3 Parallel imports are cross-border trade in a patented product, without the permission of the manufacturer or publisher. Parallel imports take place when there are significant price differences for the same good in different markets.

by 2015, chronic diseases will be the leading cause of death in the developing world (Adeyi et al. 2007). These diseases may not mobilize advocates and campaigns for access to medicines in the same way as HIV/AIDS. Medicines to treat chronic diseases exist but many are far beyond the means of developing country governments and populations.

In many cases, countries were able to use the TRIPS flexibilities to access lower-priced generic drugs because these drugs could still be produced in countries such as India where product patent protection was not introduced until 2005. However, as pharmaceutical product patents start to be granted in producing countries, this situation will change. The patent law in India, which has long served as the ‘pharmacy of the developing world’, is particularly influential. The Doha Declaration and the general awareness of the need for more health-sensitive patent policies has enabled India to implement a patent law containing a number of very significant safeguards, including: strict patentability criteria to limit the number of patented products, automatic compulsory licensing for generic drugs brought to market between 1995 and 2005, and the possibility for anyone to oppose the granting of a patent. While this law was challenged – most significantly by Novartis after it was denied a patent on its cancer drug imatinib mesylate – thus far, it has been upheld and has set an important example for other countries wishing to build more flexibilities into their national patent laws.

Nevertheless, the future supply of generics from India will not be easy. In principle, India could make use of the August 30th mechanism to allow its industry to continue to produce and export generic versions of medicines that do become patented. However, since this authorization can only be done drug order by drug order, and only upon request by another country, it is highly unlikely that this system will provide sufficient economic incentive to keep the generic medicines sector in business. Rather, it is to be expected that the Indian generic medicines sector will shift its business orientation away from supplying new medicines to the developing world, and towards the export of off-patent generics to more affluent markets. Trends in that direction are already visible (Sampath 2005).

Reactions to Implementation of the Doha Flexibilities

There is no denying that the pharmaceutical industry has responded harshly to the Doha Declaration and to some uses of compulsory licensing. Developing countries that make use of the flexibilities tend to receive much

stricter scrutiny than past compulsory licensing practices by Western European countries, Canada and the US.

The reaction has been particularly harsh when TRIPS flexibilities are used in countries with emerging economies. The growth opportunities for the industry lie in these emerging markets, since sales in Western markets are stagnating, partly due to saturation and stagnating innovation (PricewaterhouseCoopers 2007). In addition, TRIPS-plus provisions in free trade agreements, trade retaliation and political pressures all have seriously impeded the full use of the Doha Declaration.

However, in contrast to the past, these trade and political pressures no longer remain unseen or unheard. The change in international thinking about IP, coupled with legal opportunities in developing countries, enabled civil society groups and individuals to challenge weak patents and to successfully campaign for policy changes to blunt the sharpest edges of the new global IP regime.

However, the developments over the last 7 years do not take away from the fact that the TRIPS Agreement, which forced countries to give up the diversity and flexibility in IP law that had existed before, is highly detrimental to access to medicines. While the Doha Declaration can offer relief in dealing with access problems and high drug prices, full implementation is still far from a reality. Over time, the effectiveness of compulsory licensing will wear off unless a more satisfactory solution is found to encourage competition, and in particular, to ease countries' ability to export medicines produced under a compulsory license (MSF 2006).

Towards Access and Innovation

While the Doha Declaration was important for drawing attention to and offering policy options for the access problems related to IP, until recently there has been little attention to the question of innovation. Many of the pro-access measures described in this book resulted from an ad hoc case-by-case approach that was often highly dependent on an active civil society. A sustainable policy that tackles the fundamental problem of a monopoly-based innovation and access system is still far away.

The current pharmaceutical innovation system largely depends on patent protection for financing and priority-setting. Patent protection in the pharmaceutical field has increased over the last 20 years, but the rate of innovation has fallen while the number of 'me-too drugs' of little or no therapeutic gain has increased. This global trend in R&D has had a

disproportionately heavy impact on the needs of people in developing countries.

The voices calling for a reassessment of the current R&D incentive system are growing stronger. Recent studies have demonstrated the drawbacks of relying on patents as the main financing mechanism for innovation. Most notable is the 2006 report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH). As a result, international talks have commenced to examine alternative models for innovation and financing of essential health R&D under the auspices of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG).

In May 2008, the IGWG concluded its work with the World Health Assembly's (WHA) adoption of the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (WHA Resolution 61.21).

Conclusions & Recommendations

A policy agenda for access and innovation is sorely needed and should address both immediate steps to be taken, as well as tackle the fundamental question of how to create incentives for R&D that do not create access barriers.

Ensuring lower prices for medicines and other health care products requires the full implementation and use of the provisions of the Doha Declaration. Furthermore, the WTO should extend the 2016 deadline for LDCs to comply with obligations in the TRIPS Agreement to provide pharmaceutical product patents and protect undisclosed test data; it should also review the August 30th decision on production for export under a compulsory license. Finally, the international community, including patent-holding and generic pharmaceutical companies, should consider supporting patent pools as a tool for improving the management of IP for access and innovation.

In the longer term, medical research should be targeted in the direction of greatest need. Some alternatives currently being tested and/or debated include: a not-for-profit drug development model, prize funds that reward innovation based on health impact; and an R&D treaty that focuses on equitable contributions to the cost of R&D through multiple means – not exclusively through the granting of patent monopoly rights.

Since globalisation accounts for a major part of the problem of high drug prices in the developing world, perhaps the solution will also be found at the global level, in a new agreement on sharing the costs and benefits of medical R&D for the sake of humankind.

1. Introduction

Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health

The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed – in every country – of the economic and social consequences of the TRIPS Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents.

1999 Human Development Report, UNDP

The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines they need to treat disease or alleviate suffering. The high cost of AIDS medicines has focused attention on the relationship between patent protection and high drug prices.¹ The difficulties developing countries experience in paying for new essential medicines has raised concerns about the effects of the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which mandates global minimum standards for the protection of intellectual property (IP).

Most significantly, the TRIPS Agreement harmonised patent terms for a minimum of 20 years and mandated the granting of patents in all fields of technology; this requirement made it no longer possible to exclude medicines and food from patenting. The full implications of the TRIPS

¹ 'A patent is the right granted to an inventor by a State, or by a regional office acting for several States, which allows the inventor to exclude anyone else from commercially exploiting his invention for a limited period, generally 20 years' (WIPO).

Agreement for health are just beginning to emerge, but will only become fully apparent in the years to come.

Access to medicines is by no means a recent problem for the developing world. For decades countries have suffered from dependency on Western companies for the supply of medicines (Chetley 1990:94-106). The TRIPS Agreement's extended requirements for pharmaceutical patents are likely to further increase developing countries' dependency on multinational pharmaceutical companies. The AIDS crisis provides an alarming preview of the consequences of such dependence, which is by no means confined to AIDS medicines. All new health products, including drugs, vaccines and diagnostics, are likely to be affected by the new TRIPS-based patent regime.

The Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar, responded to these concerns by adopting the Declaration on TRIPS and Public Health. The Doha Declaration, as it is widely known, affirmed the sovereign right of governments to take measures to protect public health, including the use of compulsory licensing² and parallel importation.³ It also allowed least developed countries (LDCs) to exclude pharmaceutical products from patenting. These measures have become known as 'flexibilities in patent law' or the 'TRIPS flexibilities'.

The Doha Declaration was a landmark decision because it was the first time developing countries had succeeded in pushing back on IP requirements, after decades of bilateral and multilateral pressures to ratchet them up. It offers clear guidance to WTO Members regarding their rights under TRIPS to take measures to ensure the availability of more affordable medicines. A key issue that remained unresolved in Doha was how to ensure that products manufactured under a compulsory license could be exported to countries without domestic production capacity. The Doha Declaration also did not address the as-yet-unfulfilled promises of increased R&D in exchange for higher levels of IP protection, an expectation that was part of the bargain when countries were negotiating the TRIPS Agreement.

The Doha Declaration has impacted national and international policies. Since 2001 an increasing number of countries have used the flexibilities in patent law to allow for production of generic versions of

2 Compulsory licensing enables a competent government authority to license the use of a patented invention to a third-party or government agency without the consent of the patent-holder against a payment of 'adequate remuneration'.

3 Parallel imports are cross-border trade in a patented product, without the permission of the manufacturer or publisher. Parallel imports take place when there are significant price differences for the same good in different markets.

patented essential medicines, to import generic medicines from countries where pharmaceutical product patents do not exist, or as leverage in price negotiations with multinational pharmaceutical companies.

Countries' use of the Doha Declaration has not been without controversy. In particular, multinational pharmaceutical companies and their home governments fiercely opposed the practical implementation of TRIPS flexibilities, as was demonstrated in Thailand and Brazil in 2007-2008. (See Sections 5.3.1 and 5.3.2.)

These trade conflicts have also drawn attention to the larger question of the legitimacy of the patent system. The current pharmaceutical innovation system largely depends on patent protection for financing and priority-setting. Recent studies have demonstrated the drawbacks of relying on patents as the main financing mechanism for innovation. Most notable is the 2006 report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH). As a result, international talks have commenced to examine alternative models for innovation and financing of essential health R&D under the auspices of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). In May 2008, the IGWG concluded its work with the World Health Assembly's (WHA) adoption of the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (WHA Resolution 61.21).

Other factors besides price and patents affect access to medicines; for example, irrational use, inadequate health financing, unreliable medicines supply, the quality of medicines, and lack of R&D for new medicines all play a role. This book does not cover all these aspects, but rather, focuses on the impact of recently expanded IP protection on access to medicines and pharmaceutical R&D. The book describes historical developments needed to understand the globalisation of IP norms with respect to pharmaceuticals, and the practical implementation of the Doha Declaration on TRIPS and Public Health. It also lays out the current debates on pharmaceutical innovation and access. Finally, the book makes recommendations for a policy agenda aimed at ensuring both health-needs driven innovation and access to the fruits of innovation.

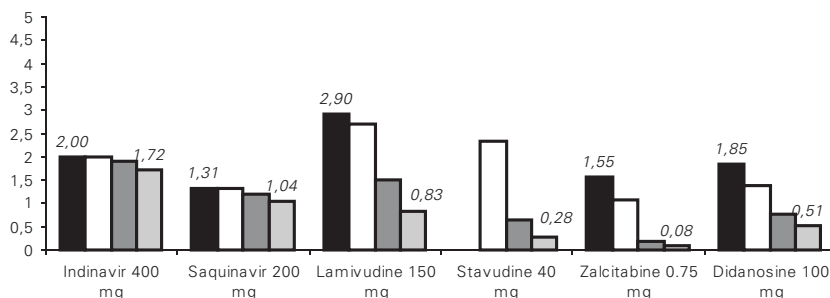
2. Key IP-related issues in access to new essential medicines

An estimated 30% of the world population does not have access to the medicines they need (WHO 2004). The reasons for this situation are manifold, but price is a major issue. A Médecins Sans Frontières (MSF) survey of 122 people on AIDS treatment in Nigeria found that 72% had experienced treatment interruption, with financial difficulties as the leading cause (MSF 2005).¹

Patents have a major impact on product prices because they prevent competition. The price of a drug is related to the degree of competition among producers. In the case of antiretroviral drugs (ARVs) for AIDS, it was only after competing generic products arrived on the market that originator drug companies agreed to a dramatic reduction in their prices (MSF 2008). If generic competition increases, in general, prices come down (See Figure 1).

Before TRIPS, many developing countries did not grant pharmaceutical product patents and/or they limited patent terms, which allowed a generic industry and competition to flourish. Generic companies made relatively

Figure 1. Cost per capsule or tablet in USD 1996 - 2000



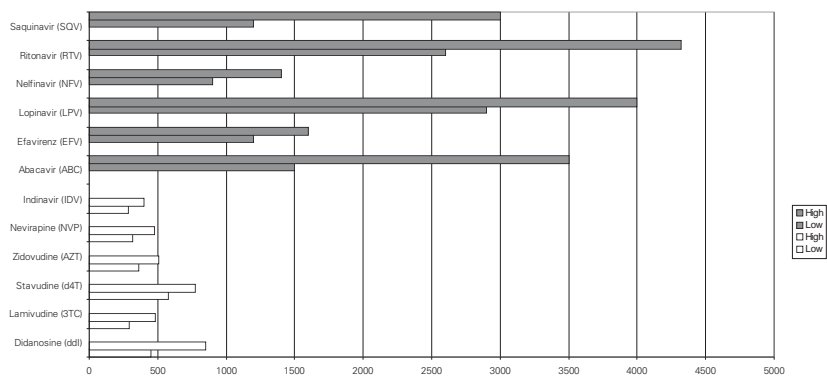
Source: UNAIDS, B. Samb, 2000, quoted in WHO-Health Technology and Pharmaceuticals, Revised Drug Strategy, April 2000

1 Financial reasons were cited by 61% of respondents, 'other reasons' by 19%, government stock out by 14%, and side effects by 6% (MSF 2005).

new products available in developing countries; these products would have been costly or unavailable had they been patent-protected. India's 1970 Patents Act, for example, provided for process patents but not product patents; this law encouraged the development of a generics industry that reverse-engineered its own versions of new medicines that were often patented elsewhere. Developing countries have for many years relied on countries such as India, Egypt, Israel, Jordan, Brazil, and Argentina for their supply of affordable medicines. Developing countries that did not grant pharmaceutical product patents at the date of application of the TRIPS Agreement (1st January 2000) were allowed under the transitional rules to delay the implementation of product patents until 2005.² Countries that made use of this transition period were, however, obliged to have "mailbox" provisions to receive patent applications during the transition (For further discussion of mailboxes, see Section 5.3.6).³ India was one of the few countries to make full use of the TRIPS Agreement's transition provisions.

Following the full implementation of TRIPS on January 1st 2005 in India and several other developing countries that did not previously grant pharmaceutical patents, reverse engineering is no longer possible. As a result, access to affordable new drugs is expected to become more difficult.

Figure 2. Prices of active pharmaceutical ingredients in 2004, USD/kilo



<http://www.who.int/entity/3by5/amds/en/API.pdf>

2 TRIPS Agreement Article 65.4

3 TRIPS Agreement Article 70.8 and 70.9.

Successful AIDS programmes such as those of Brazil and Thailand were possible, in part, because key pharmaceuticals were not patent-protected and could be produced locally at much lower costs. These are primarily '1st line' drugs, which are used when patients first begin AIDS treatment. The production of ARVs in Brazil created a larger market for ARV active pharmaceutical ingredients (API), making it possible for Indian companies to start production of ARVs in large volumes; the resulting economies of scale allowed for dramatically reduced prices. In Figure 2 the white bars represent products that could be produced in Brazil because they were not patent protected there. Brazil's purchasing power reduced the price of the API on the global market.

Most of the ARVs currently available at affordable prices come from India. In 2008, an estimated 3 million people in low and middle income countries received ARV therapy for HIV/AIDS. It is estimated that approximately 60% of the ARVs come from India, including up to 80% of first-line treatments (Nguimfack, personal communication, 2008). Furthermore, in 87 developing countries, 70% of the treatment for patients purchased by the United Nations Children's Fund (UNICEF), International Dispensary Association (IDA), the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and the Clinton Foundation, comes from Indian suppliers. MSF purchases 80% of its ARVs in India for projects in over 30 countries. The purchase by the US President's Emergency Plan for AIDS Relief (PEPFAR) of Indian ARVs resulted in cost-savings of up to 90%, and 91% of the generic ARVs approved by the US Food and Drug Administration (US FDA) for PEPFAR are from India (MSF 2007).

However these medicines were brought on to the market in the pre-TRIPS era. Today, all products may be subject to at least 20 years of patent protection in all but the LDCs and a few non-WTO Members. Because TRIPS implementation will affect both producers in key manufacturing countries and countries that depend on these manufacturers for raw materials, prices will remain high and access to new medicines will become more problematic for populations in the developing world. Generic producers will also be blocked from developing fixed-dose combinations or paediatric formulations until the relevant patents on the individual components of the combinations expire. Second-line ARVs, used to treat patients for whom 1st line drugs are no longer effective, were more recently developed and therefore are widely patented; they tend to be far more expensive than 1st line treatments.

Table 1. Price comparison of selected medicines in the US and India

| <i>product</i> | <i>US price per pill (USD)</i> | <i>Indian price per pill (USD)</i> | <i>Indian price as % of US price</i> |
|----------------------------------|------------------------------------|--|--|
| Lipitor (atorvastatin calcium) | 3.1 | 0.35 | 11.3 |
| Zocor (simvastatine) | 3.8 | 0.35 | 9.3 |
| Norvasc (amlodipine besylate) | 1.3 | 0.11 | 8.5 |
| Celebrex (celecoxib) | 2.4 | 0.11 | 4.6 |
| Zyprexa (olanzapine) | 8.3 | 0.18 | 2.1 |
| Paxil (paroxetine hydrochloride) | 2.44 | 0.24 | 9.9 |
| Vioxx (rofecoxib) | 2.47 | 0.11 | 4.4 |
| Zoloft (sertraline Hcl) | 2.21 | 0.26 | 11.9 |
| Pravachol (pravastatin sodium) | 2.5 | 0.33 | 13.2 |
| Fosamax (alendronate sodium) | 15.3 | 0.70 | 4.6 |

Source: adapted from 'Taking advantage of the transitional period to implement the TRIPS Agreement: features of access to medicines in Brazil and India' (Barbara Rosenberg 2006).

Therefore, comparing the prices of 1st and 2nd line ARVs provides a useful illustration of the effect of the lack of generic competition on price. In general, the best price of a 2nd line ARV regimen is 4.4 times the price of the 1st line regimen (MSF 2007c). In Brazil these price differentials mean that three patented AIDS medicines (out of a total of 17) accounted for 65% of the total national expenditure on ARV procurement (Brazil Ministry of Health 2005).

The effect of generic competition is not confined to ARVs. Table 1 demonstrates the large differences between US and Indian prices for the same medicine.

2.1 Debates on access to medicines and the TRIPS Agreement

The debate on patents and access to medicines should not be seen in isolation from the debate on IP in general and the TRIPS Agreement in particular. The debate on the effects of the IP system on access to medicines is much older than the recent attention to access to AIDS drugs may suggest. The recent focus on compulsory licensing as a remedy to the socially undesirable effects of patent monopolies may also give the false impression that these are new mechanisms. Yet this impression is far from the truth. Compulsory licensing is as old as patent law itself. History reveals a variety of uses of compulsory licensing, including in the field of health.

2.1.1 *Brief history of TRIPS*

In 1958 the economist Fritz Machlup wrote, 'If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.'

And yet 37 years later, the WTO TRIPS Agreement came into being, globalising intellectual property requirements that were only recently adopted by rich nations. TRIPS was part of a set of international treaties agreed upon at the conclusion of the Uruguay Round of negotiations within the General Agreement on Tariffs and Trade (GATT); this round concluded with the creation of the WTO and was intended to encourage trade among Members of the new organization. What was an agreement that created monopolies – which inherently restrict free trade and competition – doing in an institution whose main purpose was to encourage free trade and global competition? What were the forces behind the adoption of the TRIPS Agreement?

The TRIPS Agreement signalled a fundamental change, in that for the first time, global minimum requirements for the creation and protection of IP were enforceable through the WTO. Before TRIPS, pharmaceutical patent law, policies and practices differed immensely among countries, in particular between developed and developing countries. The patenting of essential goods such as medicines and foods was for a long time considered an act against the public interest. At the time the Uruguay Round launched in 1986, 49 of the 98 members of the Paris Convention⁴ excluded pharmaceutical products from patent protection, 10 excluded pharmaceutical processes and 22 excluded chemical processes (WIPO 1988). Countries varied in the periods of protection granted and/or set out other conditions that restricted patent holders' rights. Such exceptions were also common in Western countries. For example the following European countries excluded pharmaceutical products from patentability: France (until 1960), Switzerland (until 1977), Italy (until 1978), Sweden (until 1978) and Spain (until 1992) (Dutfield 2003).

4 The Paris Convention for the Protection of Industrial Property, signed in Paris, France, on March 20, 1883, was one of the first multilateral intellectual property agreements. It is administered by the World Intellectual Property Organisation (WIPO) and has today 173 contracting parties. As a result of the Paris Convention, intellectual property systems, including patents, of any contracting state are accessible to the nationals of other states party to the Convention.

The Netherlands abolished its patent system in the name of free trade

In 1869, the Netherlands abolished its patent system and suspended the Dutch patent law. The grounds for this action lay in the liberal economic thinking of the time, which considered this form of government intervention in trade undesirable. The granting of patents was also seen as a barrier to trade, a hindrance to industrial development and an undesirable mechanism that created artificially high prices of goods. A new patent law was not adopted until 1912 and only after extensive lobbying by interest groups and pressure from foreign countries. The Netherlands was at that time a member of the Paris Convention, which meant that Dutch nationals could apply for patents in other member countries. The lack of reciprocity came under fierce criticism from other nations, in particular the US, which urged the Netherlands to reinstate a patent system. The 1912 patent law, however, did not grant product patents. The general understanding at the time was that product patents discouraged innovation by taking away incentives to seek more efficient production methods, particularly in the chemical industry (Gerzon 1986).

The TRIPS Agreement was not accepted without opposition. In the Uruguay Round developing countries initially objected to a substantial agreement on IP protection as part of the package of trade agreements. The Group of Ten developing countries (India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia) argued that talks should be limited to a counterfeit code for fashion goods and trademark infringement. Their concerns were that a more substantial intellectual property agreement would have a negative effect on their ability to obtain technology, and on the cost of pharmaceuticals and agrochemicals. They argued that the United Nations agency, the World Intellectual Property Organization (WIPO), would be a better forum for negotiating international agreements on intellectual property (Matthews 2002). In contrast, American commercial interests took the view that much more could be achieved in expanding IP protection at the WTO than at WIPO, and lobbied hard for the inclusion of IP in the GATT.

India was a leading force in the Group of Ten. On 10 July 1989 India made a detailed submission to the Negotiating Group on Trade-related aspects of Intellectual Property Rights, in which it outlined its position (Government of India 1989). The document presented the concerns of developing countries about the consequences of patent monopolies for their socio-economic development. Of particular concern were the 'serious adverse effects' a patent system could have in sectors of critical importance to developing countries such as food production, poverty alleviation, nutrition, health care and disease prevention (Government of India 1989:4). India took the view that only 'restrictive and anti-competitive practices of

the owners of IP can be considered trade-related' and argued that it 'would not be appropriate to establish within the framework of the GATT any new rules and disciplines pertaining to standards and principles concerning the availability, scope and use of intellectual property rights' (Government of India 1989: 20).

Developing countries wished to design rules for a New International Economic Order to facilitate access to technologies protected by intellectual property rights (IPRs) in the West, while limiting the scope of IP protection in the developing world to encourage economic development (UNCTAD and ICTSD 2005:3). This objective was diametrically opposed to the interests of the US, which saw its supremacy in manufacturing declining as a result of competition from Japan and newly industrialised countries that had initially imitated many of the technologies developed in the US (Correa 2000).

Western industries with diverse IP interests (trademark, copyright, patent and semiconductor) came together and formed an international lobby group in 1986: the Intellectual Property Committee (IPC). The IPC became a powerful influence. This lobby successfully framed US-style IP protection as a trade-related issue that belonged in the GATT, and thereby sold the notion that creating monopolies was part and parcel of fair competition. This was a most bizarre result of the GATT, which was a forum designed to deregulate trade, but seemed to be doing the opposite with the adoption of TRIPS (Dutfield 2003).

The resolution of the diametrically opposed positions in the GATT negotiations was not the result of multilateral discussions but of harsh unilateral measures by the US. In 1984, the US Congress amended Section 301 of the Trade Act of 1974 to allow the United States Trade Representative (USTR) to take action against nations for the failure to protect intellectual property. This unilateral retaliation mechanism became a strong weapon in the hands of the US to push its IP agenda at the multilateral negotiating table. In 1991 the US put India, China and Thailand on the Special 301 Watch List, which served as a precursor to trade sanctions. In 1992 the US carried out its threats by suspending Generalized System of Preferences (GSP) tariff exceptions for Indian pharmaceutical products, which caused a 60 million USD loss in Indian pharmaceutical exports and a subsequent softening of the Indian position at the GATT negotiations (Matthews 2002:31).

An important factor for developing countries in agreeing to the TRIPS Agreement was the anticipation of being free from unilateral pressures on IP (Dutfield 2003:197). However, this side of the bargain was not kept. In 1994, the US Special 301 law was amended to clarify that a country could be found lacking in adequate and effective intellectual property protection even if it was in compliance with its obligations under the TRIPS Agreement. Today, new Members of the WTO are pressured in their accession agreements to adopt ‘TRIPS-plus’ provisions – that is, IP protection that is even more stringent than required by TRIPS. For example during its WTO accession negotiations, Jordan was urged not to seek recourse to transition periods, among a number of other TRIPS-plus provisions (WTO 1999). The Jordan-US Free Trade Agreement, signed on 24 October 2000, also included a range of TRIPS-plus provisions and became the model for subsequent agreements with other countries (Drahos & Braithwaite 2002:16) (For further discussion of Jordan, see Section 6.1).

2.1.2 Scope, objective and principles of the TRIPS Agreement

Once the opposition to a substantive WTO agreement on intellectual property was broken, developing countries fought hard to blunt what they saw as the harshest edges of the new global IP regime. This is reflected, for example, in the principles, objective and scope of the TRIPS Agreement. Interest groups representing IP rights-holders sometimes give the impression that TRIPS is primarily concerned with protecting commercial interests. Careful reading of the treaty demonstrates that this is not the case. The TRIPS Agreement includes references to overall public interest and development objectives. This section discusses those provisions of TRIPS that are most relevant for health.

The Preamble

The preamble to TRIPS draws attention to the fact that the purpose of the Agreement was not to protect the private interests of a small group of IP rights-holders, but rather, was to serve the wider goals of trade and economic development. It warns in the first paragraph that IP itself could become a barrier to trade. It defines IP as a means to an end, not as an end in itself. This idea is reflected in the fifth clause of the preamble to TRIPS, which reads: ‘Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.’

Nature and scope of obligations: Article 1

TRIPS Article 1.1 indicates that it sets out the ‘required’ minimum standards. Where it reads that countries ‘shall not be obliged’ to implement more extensive protection, Article 1 also reflects the fact that these standards are the maximum countries were prepared to agree on. Article 1.1 reads:

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

According to legal scholar Carlos Correa, Article 1.1 of TRIPS provides protection against demands for higher standards than TRIPS requires and outlaws unilateral sanctions such as Section 301 of the US Trade Act (Correa 2000:9). A country demanding TRIPS-plus provisions from a trade partner would thus be acting in bad faith with regard to its TRIPS obligations (UNCTAD and ICTSD 2005:24). A counter argument is that countries have the sovereign right to adopt higher standards if they so desire. However Article 1.1 aims to provide some protection from TRIPS-plus pressures in the absence of maximum standards in the Agreement. Developing countries also counted on the multilateral dispute settlement mechanism of the WTO to put an end to unilateral sanctions (Correa 2000:11).

Objective: Article 7

The stated objective of the TRIPS Agreement includes reference to social and economic welfare, thereby stipulating that TRIPS does not only create and protect the private rights of innovators but also serves the broader public interest. Article 7 reads:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The inclusion of this objective was the result of proposals made by developing countries that were concerned about their ability to obtain Western technologies under an IP system that ran ahead of their level of industrial development. Article 7 also made clear that IP protection should be seen as a social policy tool designed to benefit societal and economic welfare. The TRIPS objectives together with Article 1.1 give countries leeway in how the Agreement can be interpreted and implemented.

The 2001 Doha Declaration strengthens the notion even further that the TRIPS Agreement should serve a greater public good. It further expands the freedom countries have to implement TRIPS in a manner that takes into account specific needs with regard to health and access to medicines.

Developing countries' concerns were also at the root of Article 8, which allows for measures 'to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.'

Developing countries also obtained transition periods. (Flexibilities with regard to substantive provisions are discussed in Chapter 4.)

But all of these clauses do not take away from the fact that the TRIPS Agreement obliges countries to give up much of the diversity and flexibility in intellectual property law and practices that existed beforehand.

3. History of the debate on intellectual property protection and pharmaceuticals

Intellectual property in the form of patents should be thought of as a very useful tool with a relatively narrow applicability rather than as a means for owning ever larger swathes of human knowledge which is the way it is being driven at the moment (2008).

Sir John Sulston, 2002 Nobel Prize for Physiology or Medicine

3.1 US Senate investigations into pharmaceuticals and anti-trust (1950s-60s)

The debate on patents and access to medicines is not new. Interesting lessons can be learned from the investigation of the US Senate Subcommittee on Anti-trust and Monopoly under the chairmanship of Senator Estes Kefauver, which ran from 1957-1962, and examined the steel industry, the automobile industry, bread bakery and prescription drug industry ('ethical' drug industry). The findings of the Subcommittee seem alarmingly contemporary.

The Subcommittee examined the price differences between US companies and foreign companies for a number of medicines widely-used at the time, including: tranquillisers, diabetes drugs, arthritis drugs and antibiotics. It also looked into marketing and advertising practices and the safety of medicines.

The hearings revealed huge price differences between the US and Europe. For example, a hypertensive drug developed by the Swiss company CIBA was sold in Europe for 1 USD while the US subsidiaries were charging 4.50 USD. Penicillin V cost 6.50 USD in the UK and 18.00 USD in the US. Tolbutamine (sold as Orinase), a diabetes drug developed by Hoechst, sold in Germany for 1.85 USD and in the US for 4.17 USD, where it was available exclusively from the licensee Upjohn (Kefauver 1965:55).

Witnesses for the pharmaceutical industry justified high prices with the need to invest in R&D. In defence of aggressive brand name promotion,

they also asserted that generic medicines were of inferior quality and that advertising was an essential means of providing information to the medical profession. Pharmaceutical companies still use the same arguments today in response to their critics. However, in the early 1960s they did not impress the Senate Subcommittee. For example, the testimonies that high drug prices in the US were needed to pay for R&D did not convince the committee, as European originator companies had carried out R&D for many of the drugs but still sold them in their home markets for a fraction of the US price.

Instead, the Subcommittee found that patenting practices were a determining factor when comparing European and US drug prices. European countries generally took the position that drugs were too important to public health to allow private monopolies, and product patents were not available for drugs. Germany and Switzerland, both leaders in drug research, only granted process patents, which allowed others to make competing products using new processes. This greater freedom to produce resulted in greater price competition in Europe (Kefauver 1965:56-57).

Individual Americans who had to pay out-of-pocket had little choice but to shoulder the burden of high drug costs in the US. In contrast, for public procurement, the US government exercised its “government use” powers to purchase drugs at the best price on the global market, regardless of the patent status of the drug at home. Government use is a form of compulsory licensing, in which a government or its assignee makes use of a patent for public purposes (See Section 5.1 for further discussion of compulsory licensing). It should therefore be no surprise that the first draft of the 1960 Kefauver-Cellar drug bill proposed to remedy some of the findings of the Subcommittee: dramatically reducing the then-existing 17-year patent terms, the bill required compulsory licensing after 3 years of patent protection with a maximum 8% royalty based on sales (Bill S 1552). Kefauver also recommended that combinations and modifications of existing products only be patentable if they were therapeutically superior to the original products. The pharmaceutical industry vowed to fight the proposed legislation to the death.

The Kefauver-Harris Act subsequently adopted the promotion of generics and made generic labelling compulsory. It also expanded the FDA's role in evaluating the efficacy of drugs (including drugs already on the market), in addition to monitoring safety and adverse drug reactions. But the sections on patenting and licensing were deleted.

Ironically, the Kefauver-Harris legislation went down in history as the law drawn up in response to the thalidomide disaster and the need for reform at the FDA. Thalidomide was a safety issue – which, in fact, the FDA had dealt with adequately by never approving the product for human use. Despite the fact that the Subcommittee investigation focused on the monopolistic position of pharmaceutical companies and the consequences for competition, the subsequent legislation emphasized the safety and efficacy aspects of pharmaceutical regulation, but had little force in countering the effects of monopoly pricing. The compulsory licensing provision was omitted from the final version passed by Congress and no corrective action was taken. Kefauver pointed out, ‘In terms of protection of the public’s pocketbook, this constitutes a serious gap in the law’ (Kefauver 1965:98).

3.2 Early debates at the World Health Assembly

In more recent history, the public health community first raised concerns about the consequences for drug access of globalising intellectual property standards during the 1996 World Health Assembly (WHA). This annual gathering of the health ministers of WHO Member States is charged with setting the direction of WHO’s work. A resolution on the Revised Drug Strategy (RDS) set out the WHO’s medicines policy and requested the WHO ‘to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate’ (WHO 1996: Paragraph 2(10)). This resolution gave the WHO the mandate to publish the first guide for Member States recommending ways to implement TRIPS while limiting the negative effects of tighter levels of patent protection on drug availability (Velasquez & Boulet 1999). The US and a number of European countries pressured the WHO to prevent publication of the guide, but did not succeed (Benkimoun 2001).

At that time, the WHO’s involvement in trade issues was highly controversial. The emphasis on public health needs over trade interests was seen as a threat to the commercial sector of the industrialised world. For example, in 1998, in response to the draft WHA resolution on the RDS and in reference to ‘considerable concern among the pharmaceutical industry,’ the Directorate General for Trade (DG Trade) of the European Commission concluded: ‘No priority should be given to health over intellectual property considerations’ (1998).

However, subsequent WHA resolutions have strengthened the WHO's mandate in the trade arena. (For further discussion see Section 4.2.6.)

4. The Doha Declaration on TRIPS and Public Health

Debates on access to medicines spilled over from the WHO to the WTO, leading to the adoption of the 2001 Doha Declaration on TRIPS and Public Health. The Doha Declaration was a landmark legal and political declaration. It clarified unambiguously the rights of countries to take measures such as compulsory licensing to protect public health and created new rights for LDCs by allowing them to postpone pharmaceutical product patenting, enforcement of pharmaceutical product patents and the protection of undisclosed test data until at least 2016. Implicitly, it recognised the concern of developing countries about the effects of TRIPS on access to medicines. However the WTO failed to resolve effectively the burning question of production for export under a compulsory licence.

This chapter explains the key events that led to the Doha Declaration, analyses its component parts, and discusses how the WTO managed the export question noted above.

4.1 Negotiations on TRIPS and Public Health at the WTO 1999 - 2001

The debate on TRIPS and public health started at the WTO in 1999 at the ministerial meeting in Seattle. Though in 1999 public health and access to medicines did not form part of the official agenda in Seattle, the issue did receive attention for a number of reasons.

First, in Seattle, the European Commission prepared a Common Working Paper that, in its section on TRIPS, proposed that developing countries ought to be allowed to issue ‘compulsory licenses for drugs appearing on the list of essential drugs of the World Health Organization’ (European Commission 1999). Since only about 11 of the 306 products on the WHO Model List of Essential Drugs were widely-patented, this proposal would likely have limited the use of compulsory licensing, rather than making sure it became a useful tool to overcome patent-related access barriers such as prohibitive pricing.¹

1 At that time, a high price was grounds for excluding a drug from the WHO Essential Drug List.

Second, then-US President Clinton chose Seattle as the venue to declare a change in US policy with regard to intellectual property rights and access to medicines. The US government had come under fierce attack from AIDS activists because of its policies in South Africa. In particular Vice-President Al Gore was criticised for being the envoy of the US pharmaceutical industry in its attempts to challenge the South African Medicines Act (Babcock & Connolly 1999). Under the new policy, the USTR and the US Department of Health and Human Services would together establish a process to analyse health issues that would arise in the application of US trade-related intellectual property law and policy. In his speech, President Clinton referred specifically to the situation in South Africa and the HIV/AIDS crisis, declaring: 'The United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won't have to go without medicine they so desperately need' (Clinton 1999).

In May 2000, President Clinton confirmed the change in US policy by issuing an Executive Order on Access to HIV/AIDS Pharmaceuticals and Medical Technologies, supporting the use of compulsory licenses to increase access to HIV/AIDS medication in sub-Saharan Africa (Clinton 2000). Although this policy change contributed to breaking the taboo on the use of compulsory licensing in the health field, attention to TRIPS and medicines at the WTO was diverted by the collapse of the WTO ministerial conference in Seattle, leaving all matters on the table unresolved. At the time, an editorial in the *Pharmaceutical Executive* commented: 'Unlikely as it seems, the pharmaceutical industry may have reason to thank the demonstrators who brought Seattle and the ministerial meeting of the World Trade Organization (WTO) to a standstill. Had the demonstrators not disrupted the gathering, the forecast for global pharma might be much cloudier' (Gopal 2000).

However, outside the WTO, the debate on access to medicines, TRIPS, and compulsory licensing grew more intense.

4.2 From Seattle to Doha

The period between the failed Seattle WTO Ministerial conference in 1999 and the 2001 WTO meeting in Doha saw a number of developments that had a profound effect on the debate on access to medicines and intellectual property. First, trade disputes arose between Western and developing countries that tried to bring the price of medicines down. Second, there

was increased attention to the devastating effects of the AIDS crisis in the developing world. And third, national treatment programmes that relied on locally-produced generic ARVs began to experience the consequences of aggressively enforced pharmaceutical patents on AIDS drugs.

4.2.1 Trade dispute in South Africa: Big Pharma vs. Nelson Mandela

Perhaps the most significant trade dispute in the running up to the Doha WTO Ministerial Conference was the legal challenge mounted by 39 drug companies against the South African medicines legislation. In February 1998, the South African Pharmaceutical Manufacturers Association and 40 (later 39, as a result of a merger) mostly multinational pharmaceutical manufacturers brought suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 ('Medicines Act') violated TRIPS and the South African constitution (Pharmaceutical Manufacturers' Association of South Africa 1998).

The 1997 Medicines Act had introduced a legal framework to increase the availability of affordable medicines in South Africa. Provisions included generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines.

At the start of the litigation, the drug companies could rely on the support of their home governments. For its part, the US had put pressure on South Africa by withholding trade benefits and threatening further trade sanctions, aiming to force the South African government to repeal the Act (Barber 1998; Omnibus Consolidated and Emergency Supplemental Appropriations Act 1999). In 1998, the European Commission joined the US in pressuring South Africa to repeal the legislation (Brittan 1998). AIDS activists effectively highlighted these policies, profoundly embarrassing then-presidential candidate Al Gore, who found himself confronted at election campaign rallies with his personal involvement in the dispute (Barber 1999). As a result of increasing public pressure, the US changed its policies.

Demonstrators in major cities asked the companies to drop the case; several governments and parliaments around the world, including the European Parliament, demanded that the companies withdraw from the case. The legal action turned into a public relations disaster for the drug companies (Cooper et al. 2001). By the time the case finally reached the

courtroom in May 2000, the drug companies could no longer count on the support of their home governments.

During the course of the trial it became clear that the most contentious section of the Medicines Act was based on a draft legal text produced by the WIPO Committee of Experts (Sidley 2001), a fact that made it difficult for the drug companies to maintain their position that the Act violated South Africa's obligations under international law. Eventually, the international public outrage over the companies' legal challenge of a developing country's medicines law and the companies' weak legal position caused them to withdraw unconditionally from the case in April 2001.

4.2.2 Trade dispute in Brazil: The Brazilian AIDS Programme

In February 2001, the US took action against Brazil at the WTO Dispute Settlement Body (DSB) over Article 68 of the Brazilian intellectual property law, which allowed for compulsory licensing (Law 9,279, 1996). Under that provision, Brazil required holders of Brazilian patents to manufacture the product in question within Brazil – a so-called 'local working' requirement. If the patent-holder did not fulfil this requirement, the patent would be subject to compulsory licensing after three years, unless the patent-holder could show that it was not economically feasible to produce in Brazil or that the requirement to produce locally was not reasonable. If the company was allowed to work its patent by importation instead of manufacturing in Brazil, parallel import by others would be permitted.

The US argued that the Brazilian law discriminated against US owners of Brazilian patents and that it curtailed patent holders' rights. The US claimed that the Brazilian law violated Article 27.1 and Article 28.1 of TRIPS (WTO 2001a). Brazil argued that its Article 68 was in line with the letter and spirit of TRIPS, including Article 5.4 of the Paris Convention, which allows for compulsory licensing if there is a failure to work a patent. (Article 2.1 of TRIPS incorporates relevant articles of the Paris Convention).

The US action came under fierce pressure from the international NGO community, which feared it would have a detrimental effect on Brazil's successful AIDS programme (MSF 2001). Since the mid-1990s, Brazil had offered comprehensive AIDS care, including universal access to ARV treatment since 1996. Brazil had been vocal internationally in the debates on access to medicines. On several occasions, including the Group of Eight (G8), the Roundtable of the European Commission, and WHO meetings, Brazil had offered to transfer technology and know-how to help developing

countries increase their drug manufacturing capacity. NGOs feared that the US action could have a negative effect on other countries' ability to accept Brazil's offer of assistance. On June 25, 2001, in a joint statement with Brazil, the US announced that it would withdraw the WTO complaint against Brazil (Cooper 2001).

US Trade Representative Robert Zoellick explained the move in the media by calling it another step forward in the Bush administration's 'flexible approach' to health and intellectual property issues (Cooper 2001). However this 'flexible approach' was certainly a result of growing criticism of US policies in support of the pharmaceutical industry. Zoellick recognised that maintaining an inflexible attitude towards IP in the face of the global health crisis could, as he said, 'put at risk the whole intellectual property rights system' (as quoted in Blustein 2001).

4.2.3 Trade dispute in Thailand

Thailand's national AIDS programme today offers universal access to treatment, care and prevention. It is celebrated globally as a huge success. It started to provide ARV mono-therapy in 1992, dual-therapy in 1995 and triple-therapy in 2000. Initially the costs of the triple-therapy were high and could only be provided to 1500 people. Scale-up of ARV triple-therapy did not occur until 2003 (Ford et al. 2007:22).

The local production of low-cost generic AIDS medicines has been central to the success of the Thai programme. The Thai Government Pharmaceutical Organisation (GPO), a state company producing low-cost generic drugs, has been producing generic zidovudine (AZT) since 1992, which reduced the price of the drug 82% between 1992 and 1996 (Von Schoen-Angerer et al. 2001). In 1998, as a result of a Thai NGO campaign, generic companies were authorised to produce generic fluconazole. Fluconazole (marketed by Pfizer) is an essential medicine for the treatment of cryptococcal meningitis, an opportunistic infection affecting one out of ten people living with HIV/AIDS. Without treatment, patients with this infection have a life expectancy of one month. The treatment for cryptococcal meningitis is life-long and requires one pill a day. The product was not patented in Thailand but fell under the so-called Safety Monitoring Program, and as a result was granted a period of market

exclusivity, which kept the price at monopoly levels.² In 1998, three Thai companies began to produce generic versions of fluconazole and within nine months the price dropped 97% from 200 Baht (6 USD) to 6.5 Baht (0.19 USD) per pill, dramatically expanding access to the medicine. In 1999, Thai activists, motivated by the fluconazole experience, asked the government to issue a compulsory license for the AIDS drug didanosine (ddI) to enable local production of ddI tablets. In 1998, the launch of a generic version of ddI had been blocked by Bristol-Myers Squibb (BMS), which held a formulation patent related to the tablet form of the drug.

In January 2000, the US warned Thailand against the use of compulsory licensing (USTR 2000), provoking global NGO mobilisation to pressure the USTR to reverse its position. On 7 February 2000, USTR wrote to the Thai government, 'If the Royal Thai Government determines that issuing a compulsory license is required to address its health care crisis, the United States will raise no objection, provided the compulsory license is consistent with the provisions of the WTO Agreement TRIPS' (Barshefsky 2000). However, the Thai government, wary of trade sanctions, decided to authorise GPO to produce only the powdered form of ddI, which would not infringe the BMS patent.³ The powdered form, however, was less well-tolerated by patients than the tablet form protected by BMS.

Table 2. Wholesale prices of 200 mg fluconazole capsules

| <i>manufacturer</i> | <i>country</i> | <i>price per USD</i> |
|---------------------|----------------|------------------------|
| Biolab (Thailand) | Thailand | 0.29 |
| Cipla (India) | India | 0.64 |
| Bussie (Colombia) | Guatemala | 3.00 (negotiated) |
| Pfizer | Thailand | 6.20 |
| Vita (Spain) | Spain | 6.29 |
| Pfizer | South Africa | 8.25 |
| Pfizer | Kenya | 10.50 |
| Pfizer | Spain | 10.57 |
| Pfizer | Guatemala | 11.84 (negotiated) |
| Pfizer | USA | 12.20 |
| Pfizer | Guatemala | 27.60 (not negotiated) |

(Perez-Casas et al. 2000)

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- 2 The Safety Monitoring Program (SMP) was put in place in August 1989 following a demand of the USTR that Thailand offer pipeline protection for pharmaceuticals that were not patented. The SMP provided five years of market exclusivity and de facto functioned as a surrogate for patent protection and had little value for improving drug safety.
 - 3 Thai AIDS groups argued that the BMS patent for the ddI tablet form was not valid and in May 2001 challenged the patent in court, leading to the withdrawal of the patent by BMS in February 2004. For details see Wisartsakul 2004 and Cawthorne et al. 2007.

By then both the fluconazole case and the ddI case had been widely publicised and received a lot of attention worldwide. These cases helped to illustrate the enormous price differences between patented and non-patented medicines, the weakness of negotiating prices when generic competition was lacking (see Table 2) and the difficulties countries experienced when attempting to issue a compulsory license.

4.2.4 Cipla's announcement of 1 USD a day ARV treatment.

On 6 February 2001, the Indian generic medicines producer Cipla offered triple-therapy AIDS treatment for 350 USD per patient/year to MSF and for 600 USD for governments of developing countries (McNeil 2001). At that time the price of the same drug cocktail from multinationals was between 10,000-15,000 USD per patient/year. A number of African countries were engaged in negotiations with the multinational pharmaceutical companies, whose best offer at the time for the same product was about 1000 USD (Zimmerman et al. 2001). Cipla was able to reduce the price to this level because Brazil's local production had brought down the cost of the raw materials (active pharmaceutical ingredient, or API) for ARVs by creating a larger international market. Cipla's dramatic price reduction, which received widespread media attention, hammered the message home that the multinational drug companies were abusing their monopolistic position in the face of a catastrophic human disaster. It also focused attention on the effects of generic competition in bringing drug prices down.

On 1 December 2003, the WHO prequalification project approved the Cipla product.⁴ Almost three year later, on 17 November 2006, the FDA also granted it tentative approval under 'expedited procedures for the President's Emergency Plan for AIDS Relief (PEPFAR) program.' This triple-therapy is currently available without any geographical restrictions for less than 90 USD per patient/year.

⁴ The Prequalification Project, set up in 2001, is a service provided by the WHO to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. It offers assessments of drugs following an application by the company. These assessments can be used by procurement agencies and national authorities to accelerate access to medicines from manufacturers that meet the international quality standards (WHO 2004).

4.2.5 Protest on university campuses in the US

Researchers and students began to realize that, while their universities made significant contributions to the development of AIDS drugs, they were paralysed when it came to making these products available in the developing world as a result of university technology transfer and IP policies.

A controversy over the cost of the drug stavudine (also known as d4T) came to a head on the Yale University campus in March 2001. Stavudine was an important drug used to treat HIV/AIDS. It was developed by researchers at Yale University, which held the patent on the drug. Yale licensed the patent to BMS, and it had been a great commercial success for both BMS and Yale. In 2000, Yale earned over 40 million USD in royalties from the stavudine license (Yale University Office of Cooperative Research 2000). In March 2001, researchers and students campaigned on the Yale campus, demanding that Yale not enforce its stavudine patent in South Africa so that generic versions of the drug could be used. At that time, the price of the generic version of stavudine in South Africa was thirty-four times less than the price of the BMS brand-name product. Yale Professor William Prusoff, who, together with the late Dr. Tai-Shun Lin, demonstrated the value of stavudine in treating AIDS, stated publicly, 'People shouldn't die for economic reasons, because they can't afford the drug' (as quoted in Demenet 2002). Under pressure from researchers, students, and access advocates, Yale renegotiated its license with BMS to ensure the availability of generic versions of stavudine in developing countries (t Hoen 2003).

4.2.6 World Health Assembly (WHA)

In 1999, the WHA had strengthened WHO's role in intellectual property 'to ensure that public health interests are paramount in pharmaceutical and health policies' (WHO 1999). This put health advocates at the table of trade negotiations, as the subsequent developments at the WTO TRIPS Council and the Doha WTO ministerial conference would show. The resolution also urged countries to look into the options they had under current trade rules to safeguard access to essential medicines, a clear reference to TRIPS flexibilities such as compulsory licensing. Most importantly, the Assembly requested the WHO to assess the health implications of trade agreements, which was understood to mean TRIPS, with a view to assist countries in mitigating the negative effects of these agreements.

This resolution had come in response to country requests to WHO for technical assistance in implementing the TRIPS flexibilities. In 2000 and 2001 the debates on access to medicines and intellectual property at the WHA further intensified. In 2000 a resolution was adopted that instructed the WHO to advise countries on how to overcome legal and regulatory barriers to purchasing low-priced medicines in the global marketplace, including advice on how to overcome obstacles relating to intellectual property protection. During the debate on the WHO Revised Drug Strategy, developing countries stressed the need for the WHO to provide independent and pro-active advice on intellectual property issues relating to health. The 2000 WHA was marked by an unprecedented level of participation from trade and intellectual property experts representing the industrialized Member States and international organisations such as the WTO and WIPO. In response to their presence, some developing country delegates commented: 'We are at the World Health Assembly, not the World Intellectual Property Assembly.'

At the following year's WHA, a conflict about WHO's role in monitoring medicines prices flared up, following a Brazilian proposal for the creation of a WHO database of drug pricing information and an expanded role for the WHO in trade and health matters. The proposal was met with fierce opposition from the US and the EU despite the fact that the 1999 Revised Drug Strategy had charged the WHO with the task of monitoring and analysing the public health impact of TRIPS and other trade agreements on an ongoing basis. In May 2001, the WHA adopted two resolutions that had a particular bearing on the debate over TRIPS (WHA 54.10 2001; WHA 54.11 2001). The resolutions addressed 1) the need to strengthen policies to increase the availability of generic drugs, and 2) the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs. As a result, the WHO's work programme on pharmaceuticals now includes the provision of policy guidance and information on intellectual property to countries for monitoring and analysing the effects of TRIPS on access to medicines (WHO 2001). But despite this progress, WHO has problems operating effectively (New 2006). The programme is not adequately staffed and WHO is reluctant to publish practical guidance for countries on the use of the TRIPS flexibilities. This has left a void in policy and technical guidance from the world's most important norm setting agency in health.

4.2.7 Attention to the AIDS medicines crisis

In 2000 the G8 paid unprecedented attention to health and the need for action to increase access to medicines. In December of that year, a 3-day G8 summit on infectious diseases took place in Okinawa, Japan. For AIDS in particular it set the following priorities: (1) preventing the spread of HIV/AIDS, (2) providing care and support to those infected and affected by HIV/AIDS, and (3) enhancing research and development for international public goods. The summit put an important emphasis on new approaches to R&D and called for a new partnership for the improvement of the availability of international public goods through R&D and access to knowledge (Ministry of Foreign Affairs, Japan 2000). This summit was also the birthplace of the Global Fund to Fight AIDS, Tuberculosis and Malaria (henceforth, 'the Global Fund').

Since Okinawa, infectious diseases and access to medicines has been a recurring subject at the G8 meetings. Unfortunately, the G8 has lost much of its decisiveness since Okinawa. While the 2000 Okinawa Summit promised new approaches to managing IP and emphasized the need for access to medicines and innovation to address health needs in the developing world, subsequent G8 meetings have significantly watered these down.⁵

Another important event that year was the 13th International AIDS conference that took place in Durban, South Africa. It was the first time that this prestigious meeting was held on the continent most severely affected by the disease. This conference signalled a paradigm shift, with participants focusing on the fact that most of the 30 million people with HIV/AIDS lived in developing countries and had no hope of receiving the life-saving treatment that had become the norm in the West.

Other organizations, such as the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Bank, the Group of 77, and regional organizations such as the Organization of African Unity, added their voice to the debate on intellectual property and access to medicines. The UN Sub-Commission for the Protection and Promotion of Human Rights passed a resolution pointing out the negative consequences for the human right to food, health, and self-determination if TRIPS were implemented in its current form. Referring specifically to pharmaceutical patents, the

5 The 2007 Heiligendam G8 was a particular low point, when the heads of state could not even agree on making a reference to the Doha Declaration (G8 Summit Declaration 2007). Instead, they uncritically promoted IP as the backbone of innovation.

resolution stressed the need for intellectual property rights to promote social welfare (United Nations Economic and Social Council Commission on Human Rights 2000). In 1999, the United Nations Development Programme's (UNDP) Human Development Report made a plea for re-writing the rules of globalisation to make them work 'for people – not just profits.'

4.2.8 Changing landscape

In summary, between the Seattle WTO ministerial meeting in 1999 and the Doha WTO ministerial meeting in 2001 the landscape had changed. Numerous events had focused the attention of many players on pharmaceutical IP protection and access to medicines. Within a year, discussions about pharmaceutical IP protection had moved from the exclusive realm of industry lobbyists, IP lawyers and trade negotiators in Geneva to a public debate that held the attention of the media. Knowledge and information about pharmaceutical pricing and access issues became more readily available, while the Internet helped to disseminate information rapidly and mobilize a growing movement for access to medicines.

Unable to turn a deaf ear to the rising chorus of critics of TRIPS and its effects on access to medicines, the WTO changed course. In April 2001, the chair of the TRIPS Council, Zimbabwe, proposed a special TRIPS Council session on access to medicines, arguing that the WTO could no longer ignore this issue that was being actively debated outside the WTO but not within it (WTO 2001b). But the battle was not won yet.

4.3 Why the Doha Declaration came to pass

How was it possible to achieve a declaration on such a contentious issue in 2001 at Doha, considering that public health hardly appeared in trade talks just two years earlier? Michael Moore, then the WTO Director-General, made it clear on the opening day of the conference that the issue of TRIPS and public health might be the deal-breaker for a new trade round, putting the success of the entire Doha trade talks in the hands of those negotiating on TRIPS and access to medicines. Observers point to a number of factors that contributed to the success of the negotiations (Banta 2001): First, the developing country Members were extremely well-prepared and operated as one block. Second, the uncompromising positions of Western countries such as the US and Canada were hard to maintain in light of the anthrax

crisis and the threat of a shortage of the only known treatment, ciprofloxacin. After anthrax was sent through the US postal system in October 2001, both the US and Canada rapidly expressed their willingness to set aside the patent held by the German company Bayer if other solutions to the shortage and the high price of ciprofloxacin could not be found (Harmon & Pear 2001). The anthrax scare forced all WTO Members to ask themselves how much of a prisoner they wanted to be of their own patent systems. Third, a growing and active international access to medicines movement ensured the issue would be high profile, and that NGOs would monitor different countries' positions.

NGOs have played a key role in advocating for the use of TRIPS provisions, such as compulsory licensing, to increase access to medicines. The first international meeting specifically on the use of compulsory licensing to increase access to AIDS medicines was organized in March 1999 by Consumer Project on Technology (CPTech), Health Action International (HAI), and MSF at the Palais des Nations in Geneva. Later that year, the same group of NGOs organized the Amsterdam Conference on Increasing Access to Essential Drugs in a Globalised Economy, which brought together 350 participants from 50 countries on the eve of the Seattle WTO ministerial conference. The Amsterdam Statement that emerged from this conference focused on three objectives: establishing a working group in the WTO on TRIPS and access to medicines, considering the impact of trade policies on people in developing and least-developed countries, and providing a public health framework for the interpretation of key features of WTO agreements.

The working group was to address questions related to the use of compulsory licensing to increase access to medicines, mechanisms to allow production of medicines for export to a country with no or insufficient production capacity, patent barriers to research, and overly restrictive and anti-competitive interpretations of TRIPS rules regarding protection of pharmaceutical test data.⁶ In addition, the working group was to examine

6 There is only one article in the TRIPS Agreement that talks about test data: Article 39.3 of TRIPS states that: 'Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.' TRIPS requires that WTO Members protect 'undisclosed test or other data' against 'unfair commercial use' and 'disclosure'. TRIPS does not require that Members provide *exclusive rights* to the originator of the data for a *given period* (WHO 2006).

‘burden sharing’ approaches for R&D that would permit countries to consider a wider range of policy instruments to promote R&D and to consider the practical burdens on poor countries of administering patent systems. The Amsterdam Statement also urged national governments to develop new and innovative mechanisms to ensure funding for R&D for neglected diseases.

The Amsterdam Statement has served as a guide for the work of NGOs and other advocates on TRIPS and public health.⁷ The working group was not established, but the issues related to pro-access mechanisms such as compulsory licensing were taken up in the TRIPS Council and ultimately led to the Doha Declaration. The Statement was also ahead of its time. In 1999 it called for different approaches towards health-needs driven R&D. In 2008 this issue was at the core of international talks at the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.

Some have warned against overemphasising the role of NGOs in influencing global IP rules. Peter Drahos commented in his report to the UK Commission on Intellectual Property:

NGOs, after states and business, have become a third force in the global politics of intellectual property rights. NGOs function as an analytical resource for developing states and as possible partners in a global coalition of minority factions on international intellectual property standard-setting issues. But these kinds of coalitions are difficult to put together, are issue specific and predominantly rely on a crisis of some kind to be truly effective. They do not threaten the standard-setting dominance of the US and EU, especially when these two states are united on the direction in which global regulation should travel (Drahos 2002).

Nevertheless in a more recent paper, Drahos called the Doha Declaration ‘a case of a weak coalition making a gain that an observer would not have predicted given the power resources of the US-led coalition’ (Drahos 2007). He specifically described the NGO/developing country networking and coalitions as pivotal in the adoption of the Doha Declaration.

⁷ Many international and national NGOs, such as the Oxfam ‘Cut the Cost’ campaign, MSF, CPTEch, the South African Treatment Action Campaign, Act Up Paris, Third World Network, and the Health Gap Coalition in the US are today involved in campaigning for access to medicines.

4.4 Provisions of the Doha Declaration: Paragraphs 1-5 and 7

The Doha Declaration contains seven paragraphs (see Annex 1 for full text). The first four paragraphs set out the scope, background and basic principles of the Declaration. Paragraph One reads:

We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Notably, the Declaration covers ‘health problems’ without restrictions. Paragraph One highlights the examples of ‘HIV/AIDS, tuberculosis, malaria and other epidemics’, but this text is meant to illustrate some of the problems, not to limit the use of the Doha Declaration to these three diseases or epidemics only.⁸

Paragraph Two was included to signal that WTO Members recognised that IP was not the only factor that affected access to medicines. It reads:

We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

Some Members, in particular the US, strongly pushed the notion that factors other than IP were the cause of access problems. In one submission, in order to illustrate why patents were not relevant, the US argued that some people were so poor they could never afford to buy medicines, even at the most competitive prices (USTR 2002).

Paragraph Three reads:

We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

8 Throughout the negotiations over the Declaration, developed countries attempted to limit the scope to a fixed set of diseases but such attempts were unsuccessful. Nevertheless, this is a much misunderstood and misinterpreted paragraph. In the media one can regularly find statements that the Doha Declaration can only be invoked in cases of emergency or epidemics. For example, Jon Pender of GlaxoSmithKline said in relation to government use licenses in Thailand: ‘Although compulsory licensing is legal, TRIPS rules allow it only under limited circumstances, such as national health emergencies, and only after lengthy efforts to negotiate prices with firms’ (*The Economist* 2007). For further details, see ‘t Hoen 2002; ‘t Hoen 2003; and Correa 2002.

The significance of this text is that it recognises the link between patents and high medicines prices and the difficulties this creates for developing countries. Carlos Correa commented: ‘The consensus achieved on patent protection’s impact on drug prices may be considered one of the major political achievements of the developing countries in the Doha Ministerial Declaration’ (Correa 2002:7).

Paragraph Four is often referred to as the core of the Declaration, and reads:

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

Paragraph Four is critical because it gives primacy to public health considerations and clarifies that this principle is not restricted to certain selected provisions of TRIPS, but rather stretches out over the entire TRIPS Agreement. ‘Measures to protect public health’ is not limited to medicines only but also refers to vaccines, diagnostics and other health tools needed to facilitate the use of these products.

Paragraphs Five, Six and Seven are the substantive sections of the Declaration. Paragraph Five lays out the key measures and flexibilities within TRIPS, such as compulsory licensing that can be used to overcome intellectual property barriers to access to medicines. It reads:

Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

- c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

The use of the term ‘include’ in the first sentence of this paragraph makes it clear that the flexibilities in implementing TRIPS are not limited to those listed in the Doha Declaration. Paragraphs Four and 5 (b) identify compulsory licensing as a key measure for developing countries to limit the exclusive rights of patent-holders and to identify alternate sources of medicines, whether through local production or importation. It strengthens countries’ rights to use compulsory licensing and is unambiguously clear on the fact that there are no limitations as to the grounds for issuing compulsory licenses. Paragraph 5(c) reiterates countries’ freedom to determine what is a national emergency or circumstance of extreme urgency. This clause is important because TRIPS waives certain procedural requirements, such as prior negotiation with the patent-holder, if a compulsory license is issued in a situation of emergency or urgency. It does not mean that a compulsory license can only be applied in cases of emergency or urgency. This is a common misunderstanding regarding TRIPS.

Paragraph 5(d) resolves once and for all the question of whether TRIPS authorizes parallel trade by noting that TRIPS leaves ‘each Member free to establish its own regime for such exhaustion without challenge’.

Paragraph Six, which dealt with production for export under a compulsory license, requires lengthier discussion and is therefore covered separately in Section 4.5.

Paragraph Seven extends the transition period from 2006 to at least 2016 for the implementation of pharmaceutical product patents and the protection of undisclosed test data for LDC Members. Since many LDCs had already granted those rights, it also allows them not to enforce such rights until at least 2016. The paragraph reads:

We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

While paragraph Five provides an interpretation of existing rights under TRIPS, paragraph Seven creates new rights for LDCs.

4.5 Paragraph 6 of the Doha Declaration: production for export under a compulsory license

The TRIPS Agreement stipulates that production under a compulsory license must be ‘predominantly for the supply of the domestic market’ (Article 31f) except when the compulsory license is granted to remedy an anticompetitive practice (Article 31k). This restriction limits the quantity of products that can be produced for export. This limitation was a key issue because it could render local production of a drug uneconomical for a WTO Member, even if – in principle – production was legally permissible under the compulsory license. It is precisely economies of scale and access to export markets that has made low-cost high-volume production economically attractive, as is illustrated by the case of India.

The Doha Ministerial decided to postpone a resolution of this problem to a later date, but called for an ‘expeditious solution’ in Paragraph 6 of the Doha Declaration, which reads:

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

However, the cooperative spirit of Doha quickly evaporated once negotiators were back in Geneva. It took the TRIPS Council nearly two years to reach an agreement to allow the export of medicines produced under a compulsory license. (For a detailed account of the negotiating history, see Annex 5.)

During this period, the fundamental disagreement was over whether the solution would be simple and economically feasible or complex and economically risky. On the one hand, developing countries, the WHO, and NGOs supported a solution that would have automatically allowed export once the importing country had expressed the need and/or issued a compulsory license.⁹ On the other hand, industrialized countries pushed to restrict the use of compulsory licensing as much as possible, attempting to restrict the solution to a fixed set of diseases, to a limited number of eligible countries, or to national emergencies or other situations of extreme urgency.

Finally, on 30 August 2003, a decision was adopted, which later became an amendment to TRIPS Article 31.¹⁰ The mechanism put in place was meant to waive the requirement that compulsory licensing be predominantly for the supply of the domestic market. However, the mechanism was not automatic, but rather, needed to be invoked on a drug-by-drug, case-by-case, country-by-country basis. It ignored the economic reality of generic medicines production, which needs economies of scale and thus access to export markets in order to achieve low costs. In addition, the mechanism was needlessly cumbersome. The requirement that the importing and exporting countries notify the TRIPS Council in advance of their intention to use the mechanism unnecessarily exposed

9 This solution would have relied upon TRIPS Article 30, and considered export under compulsory license to be a 'limited exception' to a patent right. The European Commission initially signaled its openness towards this approach, but later moved toward the more restricted position of the US. Article 30 reads: Exceptions to Rights Conferred: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

10 The August 30 Decision provides for a temporary waiver in order to allow export. In December 2005, the waiver was followed by an amendment to the TRIPS Agreement, which will come into force once two-thirds of the WTO membership has ratified it. As of December 2008, only seven out of the 150 Member countries have done so. United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Rep. of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007). The waiver will stay in place until the amendment (Article 31bis) comes into force.

developing countries to political pressure from industrialized countries, creating a further disincentive to use the mechanism (MSF 2006).

To date, a limited number of countries including Canada, Norway, China, India and the European Union, have adopted legislation to implement the August 30th Decision.¹¹ In some countries, such implementation has introduced additional limitations. For example China and Canada limited the scope of diseases and products for which the mechanism may be used, and Canada introduced extra procedural requirements (MSF 2006). In July 2007, Rwanda became the first country to notify the TRIPS Council that it intended to use the mechanism to import generic medicines from Canada (WTO 2007a).

The lack of use of the mechanism can partly be explained by the fact that many of the 1st line AIDS drugs needed today are 'pre-TRIPS' – that is, they are not patented in India and are still available as generics. A single compulsory license, government use order¹² or non-enforcement statement¹³ suffices to allow for the import of these products when a valid patent exists in the importing country. However, as pharmaceutical product patents start to be granted in producing countries such as India, this situation will change. In principle, India could make use of the August 30 mechanism to allow its industry to continue to produce and export generic versions of patented medicines. However, since this authorization can only be done drug order by drug order, and only upon request by another country, it is highly unlikely that this system will provide sufficient economic incentive to keep the generic medicines sector in business. Rather, it is to be expected that the Indian generic medicines sector will shift its business orientation away from supplying new medicines to the developing world, and towards the export of off-patent generics to more affluent markets. Trends in that direction are already visible (Sampath 2005).

Many have noted that the system has serious flaws. The WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) recommended that the effectiveness of the August 30th Decision 'needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary' (WHO 2006). The European Parliament, citing the ineffectiveness of the solution, initially postponed

11 The Netherlands published policy guidelines that allow the production for export under a compulsory license (*De Staatscourant* 2004). See also Bannenbergh 2005.

12 According to Paragraph 5 of the Doha Declaration.

13 According to Paragraph 7 of the Doha Declaration.

ratification of the TRIPS amendment and indicated that it wished to re-open the TRIPS and access to medicines debate more broadly. The Parliament also asked the European Commission and the EU Member States to do more to ensure that developing countries could make use of the TRIPS flexibilities to expand access to medicines and to increase R&D for neglected diseases. Parliamentarians also asked for a restriction of the mandate of the Commission 'in order not to negotiate pharmaceutical-related TRIPS-plus' measures in trade agreements, which would negatively affect public health and access to medicines (European Parliament 2007). In October 2007, the European Parliament finally gave its assent to the ratification of the TRIPS amendment by the Commission. The Parliament only agreed to vote in favour after it had obtained assurances from the Council of Ministers that its above-mentioned demands would be met (Montesquieu Institute 2007).

The August 30 Decision is a textbook example of a WTO compromise with little practical use. At the end of the day, the objective was to reach an agreement – any agreement – without regard to the effectiveness of the compromise.

5. Practical implementation of the Doha Declaration on TRIPS and Public Health

The most significant flexibility available under TRIPS and the Doha Declaration is compulsory licensing. Compulsory licensing allows other parties to make use of a patented invention without the consent of the patent holder. A state authority grants compulsory licenses upon request, or, for example, as a result of a court decision. A government can also make use of a patent without the consent of the patent holder. This legal tool is called ‘government use’ or, in some countries, ‘Crown Use’. Today developing countries and least developed countries use compulsory licensing mostly for the purchase of antiretroviral drugs for their AIDS programmes. Compulsory licensing in the pharmaceutical field is not new, as the next section explains.

5.1 History of compulsory licensing

Patent monopolies were originally created to advance the public good, and with the patent grant came obligations; if these obligations were not fulfilled, the state has always had the authority to limit severely or revoke a monopoly grant. A 1623 listing of such obligations drawn up by a British patent authority included: ‘the continuous production of the patented article in sufficient quantity, the maintenance of a sufficient stock on hand, the keeping of its quality up to the prescribed standards; and the selling of it at easy and reasonable prices with reference to a standard price’ (Penrose 1951:163). Failure to fulfil these conditions could lead to cancellation of the patent.

Compulsory licensing made its first appearance in an amendment proposed by the Senate to the first United States patent law of 1790. The House refused the amendment, but the proposal was significant as the first reference to compulsory licensing in legal history. It took another century for it to appear in law (Penrose 1951:166).

The Vienna Patent Congress of 1873 offered important support for compulsory licensing (Penrose 1951). At the time, compulsory licensing was seen as a way to resolve the controversy between the pro-patent lobby

and the free-trade group, which considered patents a threat to the free flow of international commerce. Subsequently, the German law of 1877 obliged the patentee to grant a license if the public interest required it. Initially, the 1880 Paris Convention left the matter of compulsory licensing up to the individual member countries. In 1925 the principle of compulsory licensing was included in the International Convention (Paris Convention) after which most member countries revised their laws to include compulsory licensing provisions (Penrose 1951:168).¹ Compulsory licensing was seen as a milder measure than forfeiture or revocation of the patent, which was until then the remedy for patent abuse (including failure to work). Revocation of a patent thereby became a last resort measure, only to be invoked in case compulsory licensing was proven ineffective.

The issue of compulsory licensing was not without controversy. In reference to a German law that allowed compulsory licenses to be granted to those found infringing a patent, one American official called CL a 'cloud on the entire patent system' while a French official took the view that it was a 'form under which the community expresses its rights over the invention' (Penrose 1951:197).

In the early 20th century the significance of compulsory licensing in the pharmaceutical sector was limited, because many countries excluded pharmaceuticals from patentability. In fact, strong supporters of compulsory licensing could be found in the pharmaceutical sector. For example, the chairman of Boots Pure Drug Company said in a speech to shareholders about compulsory licenses: 'The license to manufacture should be granted to any firm that can provide satisfactory assurances of its competence to do so. If international agreements on those lines could be adopted, there would be a freer exchange of ideas and a wider availability of products, instead of an unnecessary and often uneconomical dependence upon others' (as quoted in Penrose 1951:185).

1 Members of the Union for the protection of industrial property (Paris Convention) at that time were: Australia (territory of Papua & New Guinea, Norfolk Islands, Nauru), Austria, Belgium, Brazil, Bulgaria, Canada, Cuba, Czechoslovakia, Denmark and Faeroe Islands, Dominican Republic, Finland, France (Algeria and colonies), Germany, Great Britain and Northern Ireland (Ceylon, Tanganyika, Trinidad and Tobago, Singapore), Greece, Hungary, Ireland, Italy, Japan, Lebanon, Luxembourg, Mexico, Morocco, Netherlands (Antilles, Surinam and Curacao), New Zealand, Norway, Poland, Portugal with Azores and Madeira, Rumania, Spain, Sweden, Switzerland, Syria, Tunis, Turkey, United States, Yugoslavia.

5.2 Examples of compulsory licensing on medicines in industrialized countries

There are a number of examples of compulsory licensing in the pharmaceutical sector in industrialised countries that deserve mention.

5.2.1 *Canada's pharmaceutical compulsory licensing regime*

From 1923 until the North American Free Trade Agreement (NAFTA) in 1993, Canada had a special compulsory licensing provision for pharmaceuticals and food. Compulsory licensing was used to promote price competition for medicines for almost 70 years.² However, from 1923 to 1969 only 49 applications for compulsory licenses were received, of which 22 were granted. At the time, the recipient of a compulsory license was required to manufacture locally the product in question; however, in many cases, the Canadian market was considered too small for local production to be economically viable. In 1969, in response to high drug prices, the law was amended to allow import of generics under a compulsory license (Lexchin 1997:70).

Under the new system, between 1969 and 1992, Canada issued 613 compulsory licenses for importation and local production. As a result, Canada had some of the lowest medicines prices in the industrialised world (Reichman & Hasenzahl 2003). By 1983, savings on drug costs were estimated at 211 million USD per year in a market worth 1.6 billion USD (Lexchin 1993:150). The compulsory license legislation allowed the development of a local generic pharmaceutical industry and a drug benefits programme for welfare recipients and the elderly. It is important to note that the compulsory licensing policy did not gravely harm the multinational pharmaceutical companies, which only lost 3.1% of the market to generic competition. The 1983 Eastman report found that 'growth [of the pharmaceutical industry] has been more buoyant in Canada than it has been in the United States since 1967' (Canada 1985). Nevertheless, the multinational industry mounted numerous campaigns against the law.

2 Beginning in the early 20th century Canada actively encouraged industrial development by stimulating local production through its patent law. It required patentees to work the patent locally, which meant that production within Canadian borders or licensing on reasonable grounds was a prerequisite to maintaining a patent. In 1935, compulsory licensing replaced revocation of the patent as a remedy for the failure to work locally. Canada took these measures because it considered its level of development insufficient to merit more stringent patent policies.

In 1987, Canada adopted legislation that made compulsory licensing permissible only after seven to ten years of patent life (Bill C-22), and in 1993 Canada effectively abolished all forms of compulsory licensing in the medicines field (Bill C-91) (Pharmaceutical Policy in Canada 1997). Since then Canada has seen a rapid increase in drug prices. For example between 1987 and 1993 the average price per prescription essentially doubled from 12.48 USD to 24.09 USD (Lexchin 1997:74). Between 1996 and 2004, total expenditure for prescription drugs in Canada also doubled from 7.6 billion CAD to 18 billion CAD (Morgan 2005). In exchange for the restrictions on compulsory licensing, the pharmaceutical industry promised to increase its R&D activities and create jobs in the R&D sector. These promises were not fulfilled (Lexchin 1997).

An important lesson from the Canadian experience is the effectiveness of CL in increasing competition to reduce prices. The role of importation has been key in making CL efficient in Canada. Today many developing countries are at a far lesser level of industrial development than Canada was at the time of its CL policy. The fact that the Canadian market was not considered large enough to merit a purely local pharmaceutical production strategy should sound a cautionary note to advocates of local production solutions for high drug prices, and to those who support restrictions on importation, such as those contained in the WTO August 30th Decision. The Canadian case demonstrates clearly that economies of scale are key to driving prices down.

5.2.2 UK Crown Use

Most countries have CL and government use provisions (often called Crown Use in Commonwealth countries) in their patent laws. The UK has a history of Crown Use in the provision of generic medicines to the National Health Service (NHS). The NHS would purchase medicines that were patented in the UK from producers in countries where pharmaceutical patents were not granted, mostly from Italy. The Ministry of Health ordered medicines to be bought through tendering according to standard government contracts that authorized and required the supplier to disregard patent rights. The patentee had the right to compensation from the government but could not halt the importation and use of the generic. The Pfizer Corporation challenged this practice in 1965 after the Minister of Health had authorised the purchase of a generic version of the antibiotic tetracycline from Italy for use in NHS hospitals (Pfizer vs. Ministry of

Health 1965). Pfizer's main argument was that using drugs to treat hospital patients was not use 'for' the Crown. The case went all the way up to the House of Lords, which dismissed Pfizer's arguments and ruled in favour of the Ministry of Health. Lord Reid observed at the time of the ruling:

... It appears to me that the natural meaning of use 'for the services of the Crown' is utilization by members of such services in the course of their duties. Sometimes, as in the case of the armed services, that use will or is intended to benefit the whole community; sometimes it will benefit a particular section of the community and sometimes it will benefit particular individuals... Therefore the use of patented drugs for National Health Service patients is use 'for services of the Crown (as quoted in Lyngwa 2008).

In 1975, renowned IP scholar Stephen Ladas commented: 'Although this power of the Ministry of Health to purchase drugs and medicines from sources independent of the patentee has been much criticised by the pharmaceutical industry, it is not likely to be affected by such criticism. Such power will be exercised if the patentee is alleged to maintain unduly high prices for these products' (1975). Unfortunately, recent cases of government use in developing countries have proven him wrong (See for example Section 5.3.2 on Thailand).

The Crown Use provision is still part of UK patent law today.

5.2.3 US Government use of pharmaceutical patents

In the late 1950s and early 60s the US used on a routine basis government use powers to procure generic medicines from abroad. Because much of Europe did not grant product patents on pharmaceuticals, medicines from the continent were often much cheaper than in the US. In 1959, the US Military Medical Supply Agency (MMSA) placed an order for generic tetracycline in Italy for 0.08 USD per capsule. At the time, Pfizer was charging 0.17 USD per capsule. When another tender was issued in 1961, Pfizer responded by reducing the price to 0.06 USD, but the Italian supplier beat this offer by bidding 0.05 USD per pill. By 1963, international price competition made possible by the compulsory licensing powers of the US government had driven down the price of tetracycline to 0.0015 USD per capsule, less than one-tenth of Pfizer's 1959 price.

5.2.4 Other recent compulsory licenses

Compulsory licensing in industrialised countries is not a historical artefact, as illustrated by the willingness of Canada and the US to invoke this measure when faced with a shortage of ciprofloxacin during the 2001 anthrax scare (See Section 4.3 for details). Furthermore, Italy recently issued a number of compulsory licenses related to antitrust cases, including: on 21 June 2005 for imipenem/cilastatin, a broad spectrum antibiotic marketed by Merck Sharp & Dohme (MSD); on 26 February 2006 for sumatriptan succinate, a GSK product to treat migraine headaches; and on 26 March 2007 for the active ingredient finasteride, an MSD product to treat benign prostate enlargement and male baldness. The licenses are royalty free. The Italian antitrust authority cited refusal to license as the grounds for the CL and mentioned anticipated price reductions, promotion of more widespread use of generics and benefits for consumers when it announced its decision (Autorita Garanta della Concorrenza E Del Mercato 2006, 2007).

5.3 Use of TRIPS flexibilities by middle-income developing countries (medicines producing and exporting countries)

This section discusses the use of compulsory licensing and government use by developing countries, which is more widespread than some commentators suggest (Scherer 2006). However, developing countries that make use of the flexibilities tend to receive much stricter scrutiny than past CL practices by Western European countries, Canada and the US.

Between 2001 and end 2007, 52 developing and least-developed countries have issued post-Doha compulsory licenses, given effect to government use provisions or implemented the non-enforcement of patents. This section covers some of the more significant cases.

5.3.1 Brazil

An estimated 600,000 people are infected with HIV in Brazil (Okie 2006). Since 1996, Brazil has offered universal free ARV treatment. In 2005, 170,000 people with HIV/AIDS received ARV treatment. The Brazilian AIDS programme has reduced AIDS-related mortality by more than 50 percent between 1996 and 2002 (Okie 2006). Between 1997 and 2004, Brazil averted 791,069 AIDS-related hospitalisations, which represents a savings



Brazil, a tiger without teeth? National gathering of NGOs working on HIV/AIDS in Curitiba, Parana, Brazil calling the Brazilian government a 'Tiger without Teeth' for threatening to issue compulsory licences for AIDS drugs, but not actually issuing one. (5 September 2005)
Photographer: Michel Lotrowska

of 2.2 billion USD in hospital and treatment costs for AIDS-related infections (Ministry of Health, Brazil 2005).

At the core of the success of Brazil's AIDS programme is the ability to produce medicines locally. Currently 17 different ARVs are distributed through the public health system, including new drugs such as atazanavir, tenofovir and enfurvitide. Of these 17, eight are produced as generics in Brazil.³ The locally-produced products have never been patented in Brazil, because they were developed before Brazil introduced pharmaceutical product patents in May 1997. Brazil's ARV production has lowered the international prices of APIs, and as a result, has led to lower prices elsewhere in the developing world (WHO 2004, Pinheiro et al. 2006). Brazil has also negotiated lower prices for patented drugs by using the threat of production under a compulsory license (Ministry of Health Brazil 2001, Rich 2001). Since 1997, the average annual cost of ARVs has declined from 6240 USD per patient/year to 1336 USD in 2004 (Okie 2006).

3 These are: zidovudine, stavudine, didanosine, lamivudine, nevirapine, ritonavir, saquinavir and indinavir (Brazil Ministry of Health presentation at the International AIDS Society meeting (IAS) 2005).

Table 3. Best price of key antiretroviral drugs in Brazil and internationally (in USD)

| | <u>2003</u> | | | <u>2006</u> | | |
|---------------------|------------------|--------------------------|-------------------|------------------|--------------------------|-------------------|
| | govern. price | best intern. price | <i>difference</i> | govern. price | best intern. price | <i>difference</i> |
| Efavirenz | 580 | 438 | x 1.3 | 580 | 220 | x 2.6 |
| Lopinavir/ritonavir | 3241 | 500 | x 6.5 | 1380 | 338 | x 4.1 |
| Nelfinavir | 1718 | 880 | x 2.0 | 1537 | 683 | x 2.3 |
| Tenofovir | 2905 | 500 | x 5.8 | 1382 | 500 | x 2.8 |

Ford et al., 2007

However, the need for newer medicines, either to respond to growing drug resistance or to improve treatment to meet current guidelines, is leading to an increase in the cost of AIDS drugs. Newer AIDS medicines are patented in Brazil and are purchased through importation. As a result, in 2005 the average cost of ARVs rose to 2500 USD per patient/year.

Out of the total 2005 budget for ARVs of 395 million USD, the eight locally produced medicines cost 85 million USD (21.4%) while the branded products consumed the majority of the budget at 310 million USD (78.6%). It is alarming to note that over 60% of this budget was spent on the purchase of only three ARVs: efavirenz (Stocrin, Merck), tenofovir (Viread, Gilead) and lopinavir/ritonavir (Kaletra, Abbott). In 2005, these were single-source products for which no local production took place.

On 4 May 2007, Brazil issued a compulsory license that would allow for the import and production of generic versions of efavirenz (Ministry of Health Brazil 2007). Despite numerous threats in the past, Brazil had never before actually issued a CL for an AIDS drug.⁴ Before the CL, Brazil had been paying Merck 580 USD per patient/year for efavirenz, which comprised about 18% of the ARV budget that year. As a result of the CL, the price will come down to 165 USD per patient/year (Cohen 2007), a considerably lower price than Brazil had been able to obtain through negotiations.

5.3.2 Thailand

Since 2001, Thailand has offered universal access to essential medicines through its national public health insurance scheme (National Health

4 Many media reports and casual observers have been under the false impression that Brazil had used compulsory licensing multiple times before 2007, perhaps because its negotiations with pharmaceutical companies were often highly-publicized in the international media.

Security Act 2002) and since October 2003, has offered universal access to ARVs. Only 2 % of the population purchases private health insurance (Ministry of Public Health and National Health Security Office, Thailand 2007), with the remainder of the population relying on the public health system. Thailand has an essential medicines list,⁵ which contains about 900 items. In 2004, 572,000 people were living with HIV/AIDS in Thailand, and about 60,000 people received ARVs through the National Access to Antiretroviral Programme for People Living with HIV/AIDS (NAPHA) or through the Social Security Scheme. Widespread access to ARV treatment in Thailand is recent, but the Thai government was able to roll out treatment quickly once the Government Pharmaceutical Organisation (GPO) started the production of a fixed-dose triple combination (GPO-vir) of stavudine, lamivudine and nevirapine at a cost of 1200 Baht (30 USD) per month. Between 2002 and 2005, the number of people receiving ARVs rose from 3000 to 52,593 (Bank 2005:4). Local production of these first-line ARVs was possible because none of the products was patented in Thailand.

However, like Brazil, Thailand is facing rising drug costs because of the need to access second-line ARVs that are patent-protected in Thailand. In 2004, the World Bank calculated the average cost of first-line regimens at 360 USD and of second-line regimens at 6,737 USD - a nearly 20-fold difference.⁶ In 2005, the World Bank recommended that Thailand issue compulsory licenses to allow for the local production of patented second-line ARVs (World Bank 2005:22). As of early 2007, 8000 people needed lopinavir/ritonavir (Kaletra), but because of the high price charged by Abbott, the Thai government could only provide the drug for 600 people (Cawthorne et al. 2007). An additional complication was that lopinavir/ritonavir was not heat-stable and thus difficult to use in tropical climates. Abbott had developed a heat-stable version of the product, but this new version was not made available in developing countries where it was most needed (MSF 2006).

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- 5 'Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility' (WHO 2008).
- 6 Calculations were based on the lowest prices available for both generic and branded products in September 2004.

Citing the high drug prices and its obligation to provide access to essential medicines, Thailand issued government use (GU) orders (a type of compulsory license) for three drugs on the national essential medicines list: efavirenz (November 2006), lopinavir/ritonavir (January 2007), and clopidogrel, a heart disease drug marketed as Plavix by BMS (January 2007). The patent holders were entitled to a royalty of 0.5% of the total sales of the generic product. The GU authorised GPO to import or produce generic versions of these products for non-commercial use in the public health sector. Initially the GU was used for importation.

It was particularly urgent to resolve the availability of efavirenz; in addition to the high cost, Thailand experienced regular stock-outs, which made reliable provision and use of the product difficult (Ford et al. 2007). Generic efavirenz arrived in the country in February 2007. The immediate effect of the GU was to increase by 20,000 the number of people with access to efavirenz. Prior to the GU, only those suffering from the most severe side effects received efavirenz. After the GU was issued, Thai health authorities purchased generic efavirenz from Indian generics firm Ranbaxy for 216 USD per patient/year, a 50% decrease from Merck's price of 468 USD (MSF 2007).

Up until 2006, Abbott had sold lopinavir/ritonavir to the Thai government for 2967 USD per patient/year (Ford et al. 2007). Following continued international pressure, Abbott further reduced the price to 2200 USD per patient/year for middle-income countries, including Thailand. Yet the production cost of the drug in 2006 was estimated to be less than 400 USD (Pinheiro et al. 2006).

The TRIPS Agreement does not require prior negotiation with the patent holder for government use licenses. Nevertheless, between 2004 and 2006 Thailand tried to negotiate better prices for these drugs with the patent-holders without significant results. Only after the appreciation of the Thai currency in early 2006 were some price reductions obtained, but they were less than the currency appreciation (Ministry of Public Health and National Health Security Office, Thailand 2007:5).

The case of the Thai government use orders is of particular interest because of the fierce responses it provoked from the media, politicians, pharmaceutical companies and their lobby groups. This outcry was all the more surprising considering that the issuing of the government use orders was done in a legal manner, fulfilling all national and international procedural requirements. The USTR Susan C. Schwab had to acknowledge this after pressure on the home front: twenty-two members of the US

Congress had urged her to respect the right of Thailand and other nations to implement the Doha safeguards, and expressed concern about a possible US government intervention (Allen et al. 2007). In her response, Schwab clearly stated: ‘We have not suggested that Thailand has failed to comply with particular national or international law’ (Schwab 2007).

On 10 July 2007 the EU Trade Commissioner Peter Mandelson wrote to the Thai Minister of Commerce to complain about Thailand’s government use orders (Mandelson 2007). Mandelson wrote: ‘Neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licenses wherever medicines exceed certain prices’ (Mandelson 2007). The legal basis, if any, of Mandelson’s assertion is unclear; his defence of the European drug industry is not. He also urged the Thai minister to engage in negotiations with the drug companies (Mandelson 2008), which Thailand was not required to do in cases of non-commercial use. Mandelson acted against the instructions of the European Parliament to refrain from the pursuit of TRIPS-plus measures.⁷

Abbott responded to the GU on its drug lopinavir/ritonavir by withdrawing all new drug applications from the Thai Food and Drug Administration, including the much needed heat-stable version of lopinavir/ritonavir. This unprecedented action led to international condemnation from the public health community, NGOs and AIDS activists (Dyer et al. 2001).

WHO’s Director-General Margaret Chan was initially critical of Thailand’s government use order, and urged the Thai government to negotiate further with the pharmaceutical companies, a position also being pushed by the US (Treerutkuarkul 2007). She had to reverse this position after heavy criticism from developing countries, AIDS groups and NGOs (Chan 2007, Piyaporn 2007, Cawthorne et al. 2007).

An international media campaign portrayed the Thai government as a pirating military junta that showed no regard for property rights. In a series of editorials, the *Wall Street Journal* characterized Thailand’s actions as a ‘seizure of foreign drug patents’ and a ‘frontal attack on property rights’, and called those who supported Thailand ‘anti-patent hooligans’ (2007). A conservative lobby group, USA for Innovation, in full-page ads in US

7 The chair of the Committee of International Trade of the European Parliament wrote to Mandelson on 21 May 2008: our letter to the Thai Government could be seen as inconsistent with the resolution adopted by the European Parliament and by the position supported by the European Commission and the Council on the Protocol amending the TRIPS Agreement during the plenary debate last October as well as the Commitment made by Council and Commission in plenary last year (Markov 2008). See also Section 4.5.

newspapers called on the White House and Congress to ‘take retaliatory action in the form of trade or economic sanctions or the removal of military aid’ (as quoted in Samabuddhi 2007). Ed Silverman, a long-time observer of the pharmaceutical industry, wondered how far the pro-pharma lobby would go in an article ironically entitled ‘Should the US invade Thailand?’ (2007).

The medical journal the *Lancet* took a counter-position to the attacks in the financial press, writing that the failure to support Thailand would have serious consequences for the rights of developing countries to protect public health and further harm the reputation of the World Trade Organisation (2007).

Initially, UNAIDS Director Peter Piot had been alone when on 26 December 2006 he commended the Thai Minister of Health for allowing the import of generic efavirenz. It required extensive international NGO mobilisation to further bolster political support for Thailand. NGOs played a key role in generating support from Members of the European Parliament, the French Ministry of Foreign Affairs, Members of the US Congress, and the Clinton Foundation.

5.3.3 *Malaysia*

In 2001 Malaysia offered free ARV triple-therapy to limited groups of people, while most people requiring ARV treatment had to purchase two of the three medicines out of pocket.⁸ In late 2002, Malaysia changed its AIDS policy to provide free triple-therapy to all people living with AIDS who met certain medical criteria.⁹ The Malaysian government entered into negotiations with pharmaceutical companies to seek price reductions without satisfactory results. On 29 October 2003, the Malaysian

Table 4. Monthly cost per patient (in USD)

| regimen | 2001 price for patented product | 2004 price for patented product | 2004 price for generic equivalent |
|------------------------|---------------------------------------|---------------------------------------|---|
| D4T + ddl + nevirapine | 261.44 | 197.10 | 45.32 (FDC) |
| AZT/3TC +EFV | 32.63 | 136.34 | 115.14 |

Ling, 2006

8 HIV-infected mothers after delivery, children with HIV/AIDS, health care workers infected in the line of duty and people infected through contaminated products.

9 Treatment was offered to people living with HIV/AIDS with a CD4 count of less than 400.

government issued a government use authorisation for didanosine (BMS), zidovudine (GSK) and lamivudine/zidovudine (GSK).

The authorisation was valid for two years from 1 November 2003, and allowed for the importation of generic versions of these medicines from the Indian producer Cipla. The products were for use in public sector hospitals only. The initial GU order provided for royalty payments to the patent holder, the level of which was to be set at a later date. The Ministry of Health proposed a royalty rate of 4% of the generic sale price to the patent holder, however, the patent holders have not yet claimed this payment (Oh 2006).

With the arrival of generic ARVs after the issuing of the government use order, pharmaceutical companies began to demonstrate a greater willingness to decrease prices. For example, GSK reduced its price of lamivudine/zidovudine from 3432 USD per patient/year in 2001 to 696 USD in 2004, a reduction of 80%. BMS reduced the price of didanosine from 763 USD per patient/year in 2001 to 392 USD in 2004, a reduction of 50%.

While the patent-holders in 2004 offered significant price reductions compared to 2001, generic producers still offered far lower prices, as shown in Table 4.

As a result of the GU, the average treatment cost per patient fell from about 3800 USD to 700 USD. The number of people that could be treated nearly tripled from 1500 to 4000 (Ling 2006).

5.3.4 South Africa

In December 2003, GSK and Boeringer Ingelheim (BI) granted voluntary licenses as part of a settlement after the South African Competition Commission had found the companies guilty of anti-competitive practices in the case *Hazel Tau vs. GSK and BI*. Technically, these were voluntary licenses; however, it is doubtful that the companies would have agreed to voluntary licenses without the Commission's ruling and the prospect of considerable fines and compulsory licenses. It is therefore more appropriate to discuss this case in this section on non-voluntary measures.

Two years prior to the *Hazel Tau* settlement, GSK and BI had reached voluntary license agreements with one South African generic company, Aspen Pharmacare. These licenses were limited to the supply of the South African public sector and the requested royalties were 30% of the generic sales price for GSK and 15% for BI. These licences were highly problematic

because by only licensing one company they severely restricted competition, and by limiting the market to the South African public sector, they prevented economies of scale in manufacturing. In 2001, a public sector market in South Africa for ARVs hardly existed. Export to other nations was not permitted under the licenses. The royalties were high and set an undesirable precedent. These licenses seemed to be aimed at carving up the monopoly rather than introducing real competition in the market.

In September 2002, a group of eleven individuals living with AIDS, health care workers, AIDS treatment organizations and a trade union (Treatment Action Campaign 2003) launched a complaint against GSK and BI at the South African Competition Commission (Tau 2002). The complainants alleged that the companies engaged in excessive pricing of ARVs to the detriment of consumers, as prohibited by Section 8(a) of the Competition Act, 89 of 1998. They argued that the excessive pricing of ARVs was directly responsible for the premature, predictable and avoidable deaths of children and adults living with HIV/AIDS. The ARVs concerned were: zidovudine, lamivudine, the fixed-dose combination of lamivudine/zidovudine and nevirapine.

The complainants had a well-prepared case, and offered the Competition Commission detailed information on the epidemiology of the AIDS epidemic, medical and scientific information about ARV treatment, detailed information on ARV prices in South Africa compared to prices available elsewhere, and data on the costs of pharmaceutical R&D (see Table 5). National and international interested parties, including Action for

Table 5. Adult formulations per tablet/capsule in 2002

| product | price sold to private sector | | intern. best price offer branded product | WHO pre-qualified generic | intern. best price offer generic |
|------------------------------|------------------------------|----------------------|--|---------------------------|----------------------------------|
| AZT (300mg) | ZAR 9.70 USD 0.92 | ZAR 6.30 USD 0.60 | ZAR 2.59 USD 0.25 | ZAR 2.01 USD 0.19 | |
| Lamivudine (150mg) | ZAR 10.67 USD 1.02 | ZAR 6.30 USD 0.60 | ZAR 1.46 USD 0.14 | ZAR 0.95 USD 0.09 | |
| AZT/lamivudine (300mg/150mg) | ZAR 13.33 USD 1.27 | ZAR 8.93 USD 0.85 | ZAR 3.81 USD 0.36 | ZAR 2.93 USD 0.28 | |
| Nevirapine (200mg) | ZAR 6.00 USD 0.57 | ZAR 6.30 USD 0.60 | ZAR 2.39 USD 0.23 | ZAR 1.61 USD 0.15 | |

taken from Tau 2002

South Africa, Oxfam International, MSF, the Canadian HIV/AIDS Legal Network, Consumer Project on Technology and the Council of Medical Schemes, provided affidavits to the Competition Commission on a series of specific issues (Competition Commission Complaint 2003).

On 16 October 2003, the Competition Commission found that GSK and BI had contravened the Competition Act of 1998 (South Africa Competition Commission 2003). The firms were found to have abused their dominant positions in their respective ARV markets.

In particular, the Commission found that the firms were guilty of the following restrictive practices: denied a competitor access to an essential facility, excessive pricing and engaged in an exclusionary act. The Commission decided to refer the matter to the Competition Tribunal for determination and requested the Tribunal to impose the following sanctions:

- Compulsory licenses of the patented medicines to allow any person to exploit the patents to market generic versions of GSK's and BI's patented medicines or fixed-dose combinations that require these patents, in return for the payment of a reasonable royalty.
- A penalty of 10% of the annual turnover of GSK's and BI's ARVs in South Africa for each year that they are found to have violated the Act.

This decision and the hefty sanctions that were requested from the Tribunal brought the companies to the negotiating table, and on 10 December 2003 an agreement between the parties was reached (Treatment Action Campaign 2003b). The South African Treatment Action Campaign (TAC) played a key role in both the preparation of the case and the negotiations with the companies. The settlement included the following provisions:

- Licenses for four generic companies to produce, import, sell and distribute zidovudine and lamivudine, and licenses to three generic companies to produce, import, sell and distribute nevirapine (both adult and paediatric formulations).
- Royalties were set not to exceed 5%.
- Licenses were for both public and private sector markets.
- Licenses allowed for export but limited the export to sub-Saharan African countries.

In principle this meant that the South African government could benefit from the best prices on the global market. TAC pointed out that as a result of the licenses, South Africa too could now benefit from a price agreement that the Clinton Foundation had made in October 2003 with four Indian companies to supply triple-combination fixed-dose ARVs for 140 USD per patient/year (TAC 2003c). In practice, however, the Indian companies could not be part of the South African government's tender because the licence with GSK and BI had not been finalised at the time of the tender (with the exception of a partial award to Cipla for d4t) (Berger, personal communication 2007). This was a significant drawback of the voluntary nature of the license: if the South African government had made government use or issued a compulsory license, this delay in accessing the lowest-priced medicines could have been avoided and competition could have been more effective. Five years later, the original tender was still in place. Apart from Cipla's contract, Aspen was the only generic company supplying the South African public sector in 2008 (Berger, personal communication 2008).

Nevertheless, the use of competition law by groups campaigning for access to medicines reduced the price of first-line ARVs dramatically in South Africa. In 2007, a co-blister package of stavudine+lamivudine+nevirapine was available in the public sector for 180 USD per patient/year.¹⁰ Problems with monopoly pricing remain in areas where competition does not exist or companies restrict licensing to just one grantee (Avafia et al. 2006).

5.3.5 Kenya

Kenya, as a developing country WTO Member, has used parallel import provisions in its Industrial Property Bill to allow the import of generic drugs patented in Kenya, as long as the product is put on the market legitimately in the exporting country. Industrial Property Bill Section 58 (2) states: '... the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.' This provision was included in the Kenyan Industrial Property Act in July 2001. The Kenya Coalition for Access to Essential Medicines had been campaigning for a public health

10 Providing these drugs in a fixed-dose combination (three medicines in one pill) is medically preferable to a co-blister (three medicines in separate pills but packaged together), because it simplifies treatment for patients and helps prevent partial dosing. However, patent barriers can block the use of fixed-dose combinations.



friendly law. In May 2002, MSF, Mission for Essential Drugs and Supplies (MEDS), Nyumbani Orphanage and Action Aid used the provision for the first time to import generic ARVs from India. There have been attempts in 2002, 2005, 2006, and 2007 to amend Section 58(2) to read: ‘... the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya **by the owner of the patent or with his express consent**’ (emphasis added). Such an amendment would effectively end the current practice of importing generics from India because such importation would be subject to approval from the patent-holder, an unlikely event. In 2002 such an amendment passed but was reversed by President Moi following complaints by civil society. A curious aspect of the attempts to amend Section 58(2) of the Act is that until today no one has been able to trace the origin of the amendments (Leusenkamp 2007a). As of mid-2008, an official investigation was underway to determine the origin of the recurring proposed amendments to the Industrial Property Act (Garwood 2007).

The Kenyan generic company Cosmos produces a generic version of zidovudine/lamivudine under a voluntary license from GSK. Cosmos is not WHO pre-qualified and as a result, its market in Kenya is quite small because most donor supported procurement in Kenya requires drugs whose quality is approved by WHO or the US FDA. As a result, Cosmos supplies primarily private health facilities (Leusenkamp 2007b). Kenya came close to issuing compulsory licenses for ARVs in 2004 after Cosmos won a tender to provide ARVs that were patented in Kenya; however, the companies concerned, GSK (Leusenkamp 2007c) and BI, subsequently granted voluntary licenses (Avafia et al. 2006, New 2007).

5.3.6 India

The idea of a better ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death.

Indira Gandhi, 1982 World Health Assembly

The case of India is of particular importance because of its longstanding role as supplier of low-cost medicines to the developing world. The way in which India implements its patent law is likely to affect access to medicines far beyond its borders. It is for this reason that many anticipated with dread India's deadline to comply with the TRIPS Agreement on 1 January 2005. As of this writing, India has not issued compulsory licenses or government use orders to allow the generic production of medicines. Pharmaceutical product patents are very recent in India, and only a handful has been granted. However India did make use of the flexibilities provided in TRIPS and the Doha Declaration when it amended its 1970 Patents Act to become TRIPS compliant. For that reason the case of India is discussed in this section.

In March 2005, the Indian Parliament adopted amendments to the 1970 Patents Act to comply with TRIPS obligations. The 1970 Indian Patents Act did not allow the patenting of pharmaceutical products. It only provided for process patents. The law was modelled after the German patent law. As a result India developed a pharmaceutical industry that, through reverse engineering, could develop generic versions of new medicines patented elsewhere without infringing any patents in India. India could supply these products to any country in the world where the products were not patented or where compulsory licenses had been issued.

However, from 2005 onwards, all new drugs were subject to at least 20 years of product patent protection in India. India had a preview of what extended levels of pharmaceutical patent protection could bring when an exclusive marketing right (EMR) for imatinib mesylate (Glivec) was granted to Novartis. The grant of the EMR put at risk the availability of generic versions of the drug from Indian generic manufacturers, costing approximately 200 USD per patient/month as opposed to the Novartis price of 2600 USD per patient/month (MSF 2006). (The Glivec case is discussed in more detail in Section 6.2.2.)

The possible consequences of a changing patent environment in India had not gone unnoticed by those who depended on countries such as India for their supply of affordable newer medicines. A number of developing countries expressed their concern to the WHO about the effects of TRIPS

implementation in India on their own ability to scale up AIDS treatment (Kim 2004).

Politicians, UN officials, and international NGOs also called on Indian policymakers to take into account India's responsibility as a supplier of affordable medicines (ACT-UP Cleveland et al. 2004, Gillies & Laouabdia-Sellami 2005, Hobbs 2005, Loos 2004, Sadik & Lewis 2005, Dangor 2005).

A New York Times editorial called upon the Indian Parliament to ensure that India could continue to play its role as leading supplier of low-cost medicines and to ensure that the amended patent law protected India's ability to make AIDS medicines available (*The New York Times* Editorial Board 2005). This editorial received serious attention in India and was read out in Parliament during the debate on the Patents Act in March 2005.

When the Indian Patents Act was amended, it included the following key safeguard provisions:

a. High criteria for patentability:

By restricting patents on known inventions, the patentability criteria were formulated to award significant innovation and discourage both the 'evergreening' of patents and frivolous claims. Section 3(d) of the Indian Patents (Amendment) Act 2005 excluded from patentability the following:

'(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation – For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.'

These requirements will likely restrict the number of patents granted.

b. Pre-grant opposition:

The Act allows any person to oppose the granting of a patent by the patent controller and bring to the attention of the patent controller any knowledge that should lead to the refusal of granting of the patent.

c. Protection of generic production of 'mail-box' patented drugs:

TRIPS allowed developing countries that did not grant pharmaceutical product patents to delay doing so until January 2005. However, developing countries were obliged to have provisions for receiving patent application from the date of general application of the TRIPS Agreement (1 January 2000). This transitional provision is often referred to as the 'mailbox'. Section 11 A(7) of the Indian law ensured that generic production of medicines for which mail-box patent applications were made between 1995 and 2005 could continue. The patent holder is entitled to a reasonable royalty but cannot take action to halt the production. This is a type of automatic non-voluntary license that does not require case-by-case decision making. At the time of the patent law amendment, there were over 6000 pharmaceutical-related patent applications in the mailbox waiting for examination. For example, GSK had applied for a patent for its combination product zidovudine/lamivudine. This product is one of the most widely-used combination ARV drugs supplied by Indian manufacturers. A patent on the product would have given GSK the authority to demand the Indian manufacturers to halt production, which likely would have increased the price and possibly created supply problems. Section 11 A(7) averts this risk. It reads:

Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises.

d. Compulsory licensing for export:

Section 92 A(1) of the amended patent law provides that compulsory licenses

'... shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by

notification or otherwise, allowed importation of the patented pharmaceutical products from India.’

The term ‘shall’ here is important because it indicates that the CL will be granted automatically without separate scrutiny or procedural requirements in India. This amendment also corrected an earlier provision that required a CL to be issued in the importing country.¹¹

In addition, Section 90 of the Patents Act as amended in 2005 allows the export of products that are produced under a compulsory license for domestic supply in India, to countries where an export market exists that is not being supplied or developed.

e. Data protection

As of this writing, India was still studying how best to implement Article 39.3 of TRIPS, which requires the protection of undisclosed test data against unfair commercial use. An inter-ministerial committee has made a proposal that has the following features:

- The term of data exclusivity starts running from the first filing date worldwide, and a company must file for marketing approval within one year of this date to get the benefits of data exclusivity.
- Exclusivity is limited to ‘new chemical entities’ defined strictly, and is not available for new indications, dosage forms, isomers, etc.
- Data exclusivity could be waived to safeguard public health protection.

A decision on data protection was expected in 2007 but is still pending.

The amendments to the Indian Patents Act, which established the first pharmaceutical product patent regime since 1970, took into account India’s role as a prime supplier of essential medicines to the developing world as well as concerns about the effects of pharmaceutical patents on prices for Indian consumers (Government of India 2007).

5.4 Medicines importing countries

The use of flexibilities in patent law is widespread in LDCs and developing countries, both WTO and non-WTO members. Most developing countries

¹¹ This earlier provision in the Patents (Amendment) Ordinance (Ord. No 7 of 2004) would have excluded LDCs that did not grant or enforce patents or countries where the relevant patent did not exist or was not valid.

depend heavily on medicines produced abroad, and therefore use the flexibilities primarily for generic import rather than for production.

This study obtained information about the use of TRIPS flexibilities by searching the Internet, particularly the listserv IP-health, which is dedicated to sharing information about intellectual property and health related matters. The study also obtained statements by 65 countries authorising the procurement, import and use of generic medicines for the treatment of AIDS between 2004 and 2008. These so-called procurement letters are mostly issued by ministries of health and addressed to medicines suppliers such as UNICEF or IDA. They are almost exclusively confined to medicines related to AIDS and in some cases to ARVs only. Some of the letters contain statements about the patent status of the particular products concerned. Often, however, there is no reference to specific products.¹²

The letters and the references to the Doha Declaration therein are aimed at providing the necessary confidence to medicines suppliers that the import and procurement of these medicines, regardless of patent status, is done with the authorisation of the appropriate government authorities.

In general LDCs allow the import and use of generic medicines with reference to paragraph 7 of the Doha Declaration. This paragraph allows LDC members of the WTO to postpone the protection and enforcement of pharmaceutical product patents until at least 2016.

Other developing countries allow the import and use of generic medicines with a reference to a national emergency caused by the AIDS epidemic. This allows governments or the competent authorities to provide compulsory licenses without approaching the patent holder to obtain a voluntary license. The rationale behind this provision is that approaching the patent holder would take up precious time for negotiations, which is not available in case of an emergency or other situation of urgency. The obligation to first approach the patent holder before issuing a compulsory license is also waived in case the government makes use of a patent – the government use provisions discussed earlier. The procurement letters used by developing countries often contain references to both: government use and national emergency.

12 Contact author for examples on file.

Table 6. Countries that used TRIPS flexibilities

| <i>countries</i> | <i>CL/GU</i> | <i>non - enforcement</i> | <i>no patent</i> |
|------------------|--------------|------------------------------|----------------------|
| DCS | 16 | – | 4 |
| LDCS | 2 | 24 | – |
| non-WTO | 7 | 3 | 4 |

DC = developing country members of the WTO, LDC = least -developed members of the WTO,
CL = compulsory license, GU = government use license

5.4.1 Results

Based on the 65 documents obtained, each letter was categorized based on which type of TRIPS/Doha flexibility was used. The overall results are presented in Table 6.

Analysis of the cases demonstrates the following: Sixteen non-LDC developing country Members have issued compulsory licenses or government use authorizations for the production or import of generic medicines for AIDS treatment.¹³ With the exceptions of Thailand (discussed above) and Taiwan (which issued a compulsory license for oseltamivir in July 2004 (Hille 2005)), the licenses were for medicines related to AIDS treatment. Eight countries, stated they did not have patents on the AIDS medicines they intended to import.¹⁴

Since 2001, 26 of 32 total LDC WTO members have, with reference to the Doha/TRIPS flexibilities, allowed import of generic health products.¹⁵ Of them 24 called upon paragraph 7 of the Doha Declaration to allow the import of generic products regardless of the patent status. Two countries allowed import of generic products with a reference to government use only.¹⁶

13 Brazil, Cuba, Gabon, Georgia, Ghana, Guatemala, Guyana, Honduras, Indonesia, Ivory Coast, Malaysia, Philippines, Swaziland, Taiwan, Thailand, Zimbabwe. (2/3 of the 150 members of the WTO are developing countries).

14 Bolivia, Namibia, Nigeria, Uzbekistan, East Timor, Guinea Equatorial, Moldova, Somalia (Puntland).

15 Angola, Benin, Burkina Faso, Burundi, Central African Republic, Cambodia, Chad, Democratic Republic of Congo, Djibouti, Gambia, Guinea, Guinea-Bissau, Haiti, Lesotho, Malawi, Mali, Mozambique, Myanmar, Niger, Senegal, Rwanda, Tanzania, Togo, Uganda, Zambia.

16 Mauritania and Tanzania.

It is interesting to note that even though neither TRIPS nor the Doha Declaration applies to non-WTO countries, Doha nevertheless seems to have encouraged a significant number of such countries to make use of patent law flexibilities to allow the use of generic medicines regardless of the patent status of the product. Eleven non-WTO members have allowed the import of generic AIDS medicines regardless of the patent status of the medicines in the country.¹⁷ Three suspended enforcement of patent protection, making reference to Doha paragraph 7. Six have issued government use licenses to allow generic entry, often with a reference to national emergencies. Four non-WTO countries declared that they did not have patents on the ARVs to be imported.¹⁸ While it is encouraging to see that an increasing number of countries allow the import of generic medicines with reference to the Doha Declaration, there is also reason for concern. Some of the procurement letters reflect an alarming lack of understanding by the authorities regarding their own situation with regard to the WTO or the patent status of the products in question. For example, two countries stated that they were WTO Members when they were not.¹⁹ Another stated that patents existed on its territory for ABC and 3TC, but not for abacavir and lamivudine; since ABC is an abbreviation for abacavir, and 3TC for lamivudine, it would be impossible for both statements to be true. Another potential weakness of the procurement letters is that it is not confirmed that they indeed provide sufficient legal protection in case of an infringement suit by the patent holder. It is also unclear whether in all cases the letters or declarations are issued in compliance with national law.

5.5 International and multilateral donors: Procurement policies, IP, and access to medicines

In recent years, international funding for health has increased dramatically. New funding mechanisms, such as the Global Fund, PEPFAR and UNITAID, have been created and are involved in the procurement of medicines, vaccines and other essential health tools. Other donors, such as the World Bank and the European Commission, have opened or expanded possibilities to finance the procurement of health commodities, including

17 Belarus, Cape Verde Islands, Comoros, Eritrea, Ethiopia, Liberia, Sao Tome & Principe, Sudan, Somalia, Tajikistan, Ukraine. Note that except for Eritrea and Somalia all these countries are WTO observers, which means that within five years of obtaining observer status they are obliged to start accession negotiations.

18 East-Timor, Uzbekistan, Guinea Equatorial, Somalia.

19 Eritrea and Liberia.

ARVs. In general, all of these funding mechanisms have rules for medicines procurement that address the question of intellectual property. This section examines how far these funding mechanisms encourage the use of the Doha Declaration through their procurement policies.

5.5.1 The Global Fund to fight AIDS, TB and malaria

The Global Fund requires that their 'recipients must procure their products in accordance with national and international laws. The Global Fund encourages recipients to apply the flexibilities provided within national laws and in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (as interpreted in the Declaration on the TRIPS Agreement and Public Health [the Doha Declaration]) in a manner that achieves the lowest possible price for products of assured quality.'

In the event that a recipient does not have the requisite capacity to assess the national and international intellectual property rights issues that apply to the desired products in their country, it may, using funds budgeted in the Global Fund grant, contract the necessary expertise. Few countries have applied for financial support under this provision. In practice, many countries procure through UNICEF and IDA and, in particular in Sub-Saharan Africa, countries make use of Doha paragraph 7, government use provisions or compulsory licensing through declaration to their suppliers.

5.5.2 The World Bank

The World Bank has expressed concern about the consequences of an increasingly global IP regime and predicted that developing countries will be the net losers, since IP is largely owned by entities in developed countries. In 1999, the Bank estimated a deficit for developing countries of 7.5 billion USD in royalties and licensing fees across all fields of technology (Commission on Intellectual Property Rights 2002:21).

In light of this finding, it is perhaps less surprising that the World Bank addresses head-on the question of whether a recipient under the Multi-country HIV/AIDS Program (MAP) can use the received funds to purchase generic ARVs from India. In its procurement guide, 'Battling HIV/AIDS', the Bank provides clear and detailed policy advice (Tayler 2004).

The World Bank policy is that MAP recipient countries may use those funds to procure ARVs in any circumstances that are legal. The guide gives

detailed information to countries about what action to take should a patent form a barrier to the procurement of lower-cost generic medicines. It recommends that developing countries use parallel importation, compulsory licensing or government use provisions, and that LDCs not enforce patents on pharmaceutical products nor any obligation under data protection rules (Tayler 2004:17). The guide provides decision-making charts and checklists for use by local authorities. It also encourages allowing decisions related to patents and procurement to be made by the procurement authority on behalf of the government (rather than, for example, by the Minister of Trade or the President, as is the case in some countries).

5.5.3 UNITAID

UNITAID is a relatively new financing mechanism set up in 2006 as a way of securing sustainable financing through a tax on airline tickets. UNITAID focuses on financing of medicines for AIDS, TB and malaria with a special focus on second-line ARV drugs and drugs to treat multi-drug resistant diseases. UNITAID also plans to play a role in the development of new medicines, for example, paediatric formulations for AIDS drugs or fixed-dose combinations where they do not exist. In July 2008, the UNITAID board decided in principle to establish an international patent pool to deal with both access and innovation issues related to the patents of new WHO-recommended first-line ARV drugs, including the development of products for paediatric use (UNITAID 2008). In general, UNITAID has pledged to pursue innovative ways to obtain its objectives and is one of the few donors that has taken a clear position on the implementation of the Doha Declaration in its constitution.

In relation to intellectual property, the UNITAID constitution states:

To fulfill its mission, UNITAID will use sustainable, predictable and additional funding to help generate a steady demand for drugs and diagnostics, thereby significantly impacting market dynamics to reduce prices and increase availability and supply. UNITAID will base its price reduction strategy on market competition. Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha declaration on the Trade-Related Aspects on Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable.

5.5.4 *The US President's Emergency Plan for AIDS Relief (PEPFAR)*

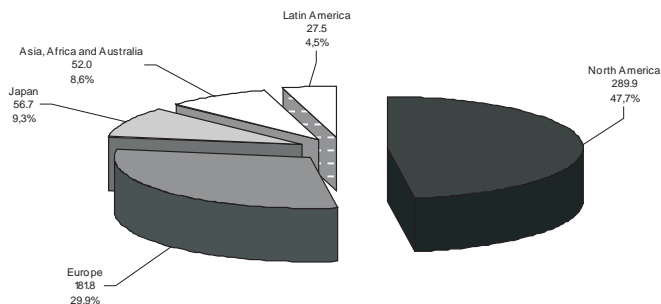
PEPFAR was established by law in 2003 (Public Law 108-25, May 27 2003). When PEPFAR became operational in 2004 it required its recipients to purchase according to the standards of the United States Agency for International Development (USAID), which meant that USAID-financed medicines had to be produced in and shipped from the United States. PEPFAR also instructed its field officers not to allow the purchase of generic ARVs, stressed the need for medicines to meet the standards of the US FDA and stated that WHO Prequalification did not constitute approval by a stringent regulatory authority for procurement. The US General Accounting Office (GAO) identified this policy as a constraint on PEPFAR's ability to support country treatment programmes, such as those that had purchased generic FDCs to boost adherence (2004).

In 2004, the US implemented its own drug assessment procedures at the FDA for medicines for use in PEPFAR programmes. As a result, medicines that are not registered in the US because of patent protection could receive FDA approval and subsequently be made available in the 14 PEPFAR recipient countries. As of end 2007, 57 generic ARV formulations have been approved by the US FDA. Today PEPFAR recipients may purchase generic ARVs. However PEPFAR does not give support for the implementation of the Doha Declaration. In the US, however, the FDA approvals have had the side benefit of expediting the availability of 7 generic ARVs in the US market when they came off patent (PEPFAR 2008).

5.6 Summary

Experience with the implementation and use of the Doha Declaration to increase access to medicines paints a mixed picture. On the one hand, there are the LDCs in sub-Saharan Africa that refer to the Doha Declaration to justify the non-enforcement of patents. This practice has led to the widespread availability of generic ARV drugs, particularly first-line fixed-dose combinations. Rich countries hardly ever challenge the practice in LDCs, even if the mechanisms used to disregard patents may raise issues of proper procedure. So far the use of Doha flexibilities in Africa has not gone beyond medication used in AIDS treatment. At this point in time it is hard to predict whether procurement authorities will use the mechanism for the purchase of other medicines.

The situation for middle-income countries is quite different. Middle-income developing countries that have made use of the Doha Declaration

Figure 3. Global pharmaceutical sales by region, 2006 (607.9 USDBN)

and flexibilities in national patent law have come under tremendous pressure regardless of whether the correct procedures were followed or not.

The contrast in responses by wealthy countries reflects the following pattern: the LDCs in Africa are left alone when they take measures to set patents aside, while the middle-income developing countries in Asia and Latin America face huge trade disputes if they take the same measures.

The explanation of this policy incoherence most likely lies in the difference in share of the pharmaceutical market these regions represent.

In 2006 global pharmaceutical sales were valued at 643 billion USD, almost double 1999 levels (IMS 2007a). Of the global market, 86.9% is in North America, Europe and Japan. While Asia and Latin America comprise a much smaller share, they are currently significant growth markets for a pharmaceutical industry that is seeing its sales stagnate in high-income countries. The fastest growing markets are in Latin America where sales were up 12 %, while Africa, Asia and Australia had a combined growth rate of 9.8% (driven largely by Asia) compared to 8% growth in North America, 4.8% in Europe and a decrease in sales in Japan of 0.7% (IMS 2007b). These trends help explain why the pharmaceutical industry has responded so strongly to recent actions by Thailand and Brazil to bring drug prices down.

While these emerging economies today represent only around 5% of the global pharmaceutical market, it is predicted that opportunities to increase sales in these markets will grow exponentially. The GDP of the so-called E7 emerging economies (China, India, Russia, Brazil, Mexico, Indonesia, Turkey) is expected to triple by 2020, compared to only a 40% increase in the G7 countries (PriceWaterhouseCoopers 2007). It is expected

that diseases formerly associated with industrialized countries will increase in these emerging economies. For example, in 2004, 639 million people with hypertension lived in the developing world, and by 2025 this number is expected to grow to 1 billion (Kearney et al. 2005).

Another reason that may explain the different responses is that in Asia compulsory licenses are issued outside the scope of AIDS treatment. Thailand, for example, has issued CLs for a heart disease medication (clopidogrel) and cancer treatments, products that account for large sales. For example, clopidogrel, a blood thinner used in the treatment and prevention of heart disease, is the fourth-best selling drug in the world, accounting for 5.8 billion USD in global sales in 2006 (IMS 2007c).

However, middle-income developing countries are important not only for the size of their markets but also because they have the production capacity to supply generic medicines in the developing world. It is imperative for global access to medicines that these countries take measures to protect the viability of their industries. If the sources of generic production cease to exist, the African continent will find itself soon without a supplier to whom to issue procurement letters. In other words, the effectiveness of the Doha Declaration in sub-Saharan Africa largely depends on the success of the application of that same declaration in middle-income countries. The *de facto* position of rich countries that the use of the Doha Declaration should only be condoned in the poorest countries, where manufacturing capacity is extremely limited, may over time have disastrous consequences for access to medicines.

6. Attempts to limit the scope and use of the Doha Declaration.

Though still on a limited scale, developing countries have begun to use the Doha Declaration to access affordable medicines and to develop more public health-friendly patent laws. It is therefore of serious concern that Western industrialized countries continue to attempt to limit the scope and use of the Doha Declaration in the pursuit of stricter IP requirements.

The pursuit of stricter levels of pharmaceutical IP protection than required by the TRIPS Agreement or the Doha Declaration comes in different shapes and forms. It is carried out in trade agreements, in particular with the US, and in accession agreements to the WTO. It is pursued through legal action by pharmaceutical companies challenging the implementation of flexibilities in national patent legislation, such as Novartis's legal challenge of the Indian Patents Act section 3(d) in 2007, and through political pressure on countries that want to make use of the TRIPS flexibilities, as was the case recently in Thailand.

The attempts to limit the scope of diseases covered by the Doha Declaration and the grounds on which the TRIPS flexibilities could be invoked have existed since the negotiations on TRIPS and public health started at the WTO in 1999. Despite the clarity of the 2001 Doha Declaration on this issue, debates on the scope of the declaration continue to flare up (MSF 2003). This situation is helped along by a constant stream of misinformation in the media about the grounds and conditions for compulsory licensing and other TRIPS flexibilities by the proponents of strong IP protection and ill-informed editors. (See for example Cass 2007, *The Economist* 2007.)

Today bilateral trade agreements, in particular with the US, form the most serious threat to the scope and effectiveness of the Doha Declaration, as discussed in the following section.



Demonstrations against TRIPS-plus during the US-Thai FTA negotiations Jan 9-13 2006.
 Photographer: FTA Watch

6.1 US objectives for IP in bilateral and regional trade agreements

After having been forced to compromise in multilateral negotiations, the US has stepped up its efforts to tighten IP standards through bilateral and regional trade agreements. These agreements have, until fairly recently, attracted little attention. They are highly technical and negotiated in secret, without draft texts being available for public scrutiny (Rangel et al. 2007). Another huge problem is that the trade ministers, but not the health ministers, are at the negotiating table. Often health authorities find out only after the fact that a trade agreement has consequences for health and pharmaceutical policies.

The United States is seeking to secure, or has secured, the inclusion of several intellectual property provisions in its regional and bilateral trade agreements that are particularly detrimental to the objective of achieving access to medicines for all. Some of the TRIPS-plus provisions found in FTAs are also included in the accession agreements of new members of the WTO.

The following TRIPS-plus features of trade agreements with the US can delay the introduction of generic medicines:

- Patent linkage: Prohibits granting of marketing approval by drug regulatory authorities during the patent term without the consent of the patent holder. These provisions effectively create a new function for health authorities in the enforcement of patents on medicines;
- Data exclusivity: Prohibits for a certain period of time the use of pharmaceutical test data for drug regulatory purposes, which will delay the registration and thereby the marketing of generic medicines regardless of the patent status of the product;
- Extension of the patent term for pharmaceuticals beyond the 20 years required by the TRIPS Agreement, which will further delay generic competition;
- Extension of the scope of patent protection to allow known substances to be patented for each 'new use';
- Restrictions on the grounds for compulsory licensing
- Prohibitions of parallel importation (in some cases)

Some or all of these provisions appear in concluded agreements such as the Central American Free Trade Agreement (CAFTA),¹ the US-Singapore Free Trade Agreement, the US-Chile Free Trade Agreement, the US-Morocco Free Trade Agreement, US-Peru Trade Promotion Agreement and other agreements that have already been signed.² The TRIPS-plus provisions reappear or are likely to reappear in trade agreements being negotiated with Thailand, Panama, the Andean countries (Bolivia, Colombia, Ecuador) and the countries of the Southern African Customs Union (SACU), and have also appeared in accession agreements with new WTO Members, for example, China and Cambodia (WTO 2008).³

The proliferation of TRIPS-plus rules through FTAs poses a very serious threat to the effective use of the patent law safeguards. It also launches the process of globalising new IP norms and standards, which the US would not be able to obtain in multilateral negotiations. (See also Bannenberg 2005).

1 CAFTA originally included Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua, but the Dominican Republic agreed in March 2004 to sign on to CAFTA as well.

2 NAFTA (US, Canada, Mexico) as well as several bilateral investment agreements with the US.

3 ACU includes Botswana, Lesotho, Namibia, South Africa and Swaziland.

Jordan provides some insight into the effects of TRIPS-plus provisions on access to medicines, since it acceded to the WTO in 2000 and the US-Jordan FTA has been in place since December 2001.

Jordan became a member of the WTO on 11 April 2000 (WTO 2000). Jordan did not grant pharmaceutical product patents before it became a WTO member. The accession agreement with the WTO contains a number of TRIPS-plus provisions not dissimilar to those seen in US FTAs. These provisions include, for example, five years of data exclusivity, patent linkage, limits to parallel importation and the introduction of pharmaceutical product patents before the expiration of the transition period allowed in TRIPS. The US-Jordan FTA's TRIPS-plus provisions include:

- Patent linkage. The drug regulatory agency is required to notify the patent holder when a generic producer applies for marketing authorisation, which may hamper the drug regulatory authority to assess an application during the time of the patent term.
- An additional three years of data exclusivity (beyond five years) for new uses of already known chemical entities.
- Compulsory licensing permitted only to remedy an anti-competitive practice, in case of public non-commercial use, or in the case of national emergency or other situations of extreme urgency.
- Patent extension for unreasonable curtailment of patent term as a result of a delay in the marketing approval process.
- Best efforts to accede to or ratify the Patent Cooperation Treaty.

In 2007, Oxfam published an analysis of the effects of the TRIPS-plus rules that had been in place in Jordan since 2001. Oxfam analysed the effects of data exclusivity on 108 new drugs multinational companies had put on the market in Jordan since 2001. Out of the 108 products, 81 (79%) had no generic equivalent because of data exclusivity. The availability of generic equivalents would have made it possible to reduce expenditures on medicines by an estimated 6.3-22.05 million USD.

6.1.1. Push back in the US

Recently there has been some push back from the US Congress to the Bush Administration's TRIPS-plus agenda. In May 2007, Congress and the White House reached an agreement on loosening some of the TRIPS-plus

provisions in FTAs. The agreement contains the following requirements, which are conditions for Congressional approval of FTAs (USTR 2007):

Clarification that the period of protection for test data for pharmaceuticals in developing country FTA partners will, in some circumstances, not extend beyond the period that such protection is available for the same product in the United States, coupled with a provision that will encourage our partners to process marketing approval applications for innovative drugs in a timely manner.

A more flexible approach, for developing country partners, to restoring patent terms to compensate for processing delays. This flexibility is accompanied by new provisions, stipulating that trading partners will make best efforts to process patent and marketing approval applications expeditiously.

More flexibility in terms of the types of procedures and remedies that developing country partners may implement to prevent the marketing of patent-infringing pharmaceutical products.

Clarification that FTA partners may implement exceptions to the rules for protecting test data if necessary to protect public health.

Integration within the intellectual property chapter of a recognition that nothing in the chapter affects the ability of US FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

This agreement took the sharpest edges off of the US FTAs and was cautiously welcomed by groups that had campaigned against TRIPS-plus provisions. However, the changes did not go far enough. Knowledge Ecology International commented, 'In general, the changes are welcome, as a partial but still incomplete step toward honouring the 2001 Doha Declaration (2007).'

Nevertheless, it is good news that in the US a non-domestic access to medicines issue received strong enough attention from members of Congress to force the White House to change course.

6.2. Other TRIPS-plus developments

6.2.1 *European Commission*

While the focus with regard to TRIPS-plus provisions has been on the US free trade agreements, the current policies of the European Trade Commissioner also merit attention. The European Union has a long tradition of TRIPS-plus requirements in accession agreements with new EU Member States. Following complaints by the European Federation of Pharmaceutical Manufacturers (EFPIA), the European Commission has had regular contact with Turkey to pressure it to adopt and implement EU-style data exclusivity.

The EU-Turkey Customs Union Agreement requires the prior marketing of the original/reference product in Turkey before a generic application can be lawfully filed. The European Commission reported in July 2007 on Cases under the Trade Barrier Regulation (2007):

The issue of the respect of the regulatory conditions and requirements applicable to the processing and approval of generics applications, and the recent approval by the Turkish Ministry of Health of a generic product in violation of Turkey's commitments under the EC acquis, were raised on multiple occasions by the Commission services. The Commission continues to monitor developments and has urged Turkey to fully comply with the relevant EC acquis on the matter.

The Commission has shared the pharmaceutical industry's concern about 'the long-standing issue of unlawfully filed generics applications' with the Turkish health authorities. Though the regulation of drug safety and efficacy is a matter of health law, not trade law, the Commission is interfering with Turkey's domestic health regulation when it demands the implementation of EU-style data exclusivity under the aegis of TRIPS (Article 39.3). This is a clear example of a TRIPS-plus policy.

In South Korea, the Commission is monitoring the government's pharmaceutical regulatory practices and pricing and reimbursement policies, despite the fact that the Commission could not identify any violation of WTO rules (European Commission 2007:35). In 2002, the Commission had pressured Korea into abandoning its drug pricing policy, which had been based on the lowest price found on the market (European Commission 2007:36). The Commission had also pushed for a range of

TRIPS-plus measures that would undermine the government's efforts to control pharmaceutical costs.

Again, the South Korean example demonstrates that the European Commission's bilateral trade policies are driven by concerns for the European brand-name pharmaceutical industry's market access rather than by concerns for access to medicines for all. Under the guise of dealing with trade barriers, policies that support generic use and cost containment have come under pressure from the Commission.

The European Union has formally adopted a policy in support of the Doha Declaration and has committed not to pursue pharmaceutical-related TRIPS-plus provisions in 'poor developing countries', though it has not clarified which countries it means by this term (Antunes 2007). But in reality, the European Commission has not refrained from TRIPS-plus demands that affect the pharmaceutical field in its bilateral and regional trade negotiations.

In the European Partnership Agreements (EPAs) with the African, Caribbean and Pacific (ACP) countries, the EU seeks to impose new obligations on developing countries in the area of intellectual property rights. In their report to the European Parliament, IP experts Abbott and Reichman list the following TRIPS-plus demands that may have a negative effect on access to medicines (2007):

- Adherence to or acceptance of the obligations of the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT), which will lead to more extensive pharmaceutical patenting in ACP countries;
- Duty to implement the terms of its Intellectual Property Enforcement Directive, the provisions of which may have a strong chilling effect on generic medicines suppliers, who may be threatened with seizure of products and costly legal procedures even before infringement is established.

The authors warn that:

A developing country that enters into an FTA with the United States and an EPA with the EU along the lines of those presently proposed will be constrained to provide a very strong market dominant position for pharmaceutical originator companies, and thus to create substantial obstacles to the introduction of generic products.

They recommend that the EU should refrain from imposing any new intellectual property obligations on APC countries that could affect their

public health programs and that the European Parliament should encourage the EU expressly to endorse full implementation in APC countries of the flexibilities in the TRIPS Agreement, as recognized in the Doha Declaration, in order 'to promote access to medicines for all' (Abbott & Reichman 2007:38).

The European Union's stated support for the Doha Declaration creates a responsibility for the EU and its institutions to ensure that full implementation of the Declaration is indeed possible. Being silent about the relentless US pursuit of TRIPS-plus measures makes the Commission complicit. There is no denying that the European drug industry benefits from the TRIPS-plus provisions in US bilateral FTAs; once implemented, these provisions will benefit pharmaceutical companies without regard for nationality.

If the EU indeed wants to support the implementation of the Doha Declaration it should be compelled to intervene proactively in the US pursuit of TRIPS-plus, refrain from TRIPS-plus demands in relations with other countries, and adopt measures that encourage the use of the Doha/TRIPS safeguards. Such support could include, for example, technical and legal assistance and explicit political support. Such political support was missing in the case of Thailand when the head of IP at DG Trade characterized the Thai CL as violating the spirit of the Doha Declaration (see Section 5.3.2).

6.2.2 A legal challenge of TRIPS flexibilities: Novartis and the Indian Patents Act.

In February 2006, the Indian patent controller granted the first pharmaceutical product patent under the new legislation to Roche India Pvt Ltd, the Indian arm of Swiss drug maker F Hoffmann La Roche, for its biotech drug Peginterferon alpha-2a (Pegasys) (*The Financial Express* 2006). In January 2006, it had rejected the patent application by Novartis for imatinib mesylate (Glivec) on the basis that it was a new form of a known substance and therefore was not patentable under Section 3(d) of the Indian patent law. The Novartis patent application had been opposed by Natco Pharma Ltd., an Indian drug firm that produced a generic version of the product, and by the Cancer Patients Aid Association (CPAA).

Imatinib mesylate is a drug used in the treatment of chronic myeloid leukaemia (CML), a specific type of cancer of the blood. Novartis had applied for an earlier patent on imatinib in 1993 in countries where this was possible. However, because India did not have a product patent system



People living with AIDS in India calling on Novartis to drop the case against section 3(d) of the Indian Patents Act. (29 January 2007)

Photographer: Sheila Shettle

at that time, Novartis could not apply for this patent in India. Nor was it possible to make a mailbox application because the mailbox system was not established until 1995, according to WTO requirements.

In 1998, Novartis did submit a mailbox patent application for the new form of imatinib mesylate and received an exclusive marketing right (EMR) for the product in 2003. As a result of the EMR, generic production of imatinib mesylate had to stop. At that time Novartis's international price for one year of treatment with imatinib mesylate was 27,000 USD. The Indian generic companies were selling the product for 2,700 USD per patient/year (Datta 2004). In January 2005, the Chennai High Court ordered Novartis to make the drug available to all patients suffering from CML with an income below 336,000 rupees (7700 USD) per month; the decision came after Novartis had stopped its donation programme in India, which had been conditional on the absence of generic production (Newindpress.com 2003; The Hindu Businessline 2005).

The decision to reject the imatinib mesylate application demonstrated the new Indian Patents Act at work: the rejection was based on the patentability criteria laid down in Section 3(d) of the Act, and third parties had the opportunity to make a pre-grant opposition through which they could bring evidence for rejection to the attention of the patent controller.

Following the amended 2005 Patents Act, generic companies and patient groups had filed many pre-grant oppositions. The key grounds for rejection of many of these oppositions were based on non-compliance with the patentability criteria of Section 3(d). For example, in March 2006 the Indian Network for People Living with HIV/AIDS (INP+) filed an opposition to GSK's patent application for a fixed-dose combination of zidovudine and lamivudine. INP+ based its opposition on Section 3(d) of the patent law, arguing that the patent claim in question was not for a new invention but rather for the combination of two existing drugs. Soon after its application was opposed in India, GSK announced the withdrawal of all its patents and patent applications for the fixed-dose combination of zidovudine and lamivudine (Tanglerpaibul 2006).

Following the 2006 rejection, Novartis legally challenged both the decision to deny a patent for imatinib mesylate and the legality of Section 3(d) of the Indian Patents Act. Novartis argued that Section 3(d) violated India's Constitution and the TRIPS Agreement. Novartis' action aroused very strong international criticism, reminiscent of the 2001 South African court case. NGOs organised global petitions calling upon Novartis to drop the case. Numerous politicians and personalities joined this call (MSF 2007a). The Novartis challenge was seen as a direct assault on the TRIPS flexibilities, an attack that was deeply troubling in a country that had become known as the pharmacy of the developing world.

On 6 August 2007, the Madras High Court ruled against Novartis and rejected all its claims. On the question of TRIPS compatibility, the court declared itself not competent and deferred to the Dispute Settlement Body set up for WTO Members to resolve trade disputes. Whether a country will indeed challenge the Indian Patents Act at the WTO is not known at this point, but no complaint has come to light as of this writing. Furthermore, Novartis announced that it would not appeal the Madras High Court's decision and declared the case a matter for the WTO (Jack 2007).

In practice, this means that Section 3(d) of the Indian Patents Act remains in force and that the patent offices will continue to use the standards contained therein to assess patent applications and rule on pre-grant opposition cases.

Nevertheless, this case demonstrates that the space countries have to implement pro-health patent law is not easily ceded by IP-holding industries. Furthermore, the pursuit of extended levels of IP protection takes place not only through multilateral and bilateral governmental negotiations, but also through direct challenges in domestic courts.

7. Rationale for the pharmaceutical patent system

We have no model which would meet the need for new drugs in a sustainable way ... You can't expect for-profit organisations to do this in a large scale. If you want to establish a system where companies systematically invest in this kind of area you need a different system.

Daniel Vasella, CEO Novartis in *The Financial Times* 2006

The rationale for the patent system is based on the assumption that granting temporary monopolies to the inventor encourages innovation by allowing the inventor to recoup R&D costs. The downside is that it comes at a cost to society. A patent gives the patentee the right 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product' (TRIPS Article 28). This has a number of consequences. First, prices of single source (monopoly) products are, in general, higher than they would be if there was free competition. Second, patent monopolies limit what others can do with the subject matter and may hamper follow-on innovation, such as the development of fixed-dose combinations or other dosage forms of medicines.

The pharmaceutical industry argues that without patents there would be no innovation at all. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) claims: 'Without patent protection, the world would have been deprived of the innovative medicines which have saved countless lives (2008).' History does not support such broad sweeping claims. One of the most important innovations of the last century was the polio vaccine. When Jonas Salk was asked who would own the patent, he replied: 'Who owns my polio vaccine? The people! Could you patent the sun?' (as quoted in Smith 1990). He considered his invention a public good.

More recently established not-for-profit drug development initiatives take a very similar view. For example, the Drugs for Neglected Diseases Initiative (DNDi) patent policy states: 'DNDi regards drug research as a

public good that should primarily lead to the advancement of health.’ Its first product brought to the market, in collaboration with pharmaceutical company Sanofi-Aventis, is a fixed-dose combination anti-malaria medicine. The drug, artesunate/amodiaquine (ASAQ), was not patented, but rather, was marketed as a generic product from the first day. This accomplishment garnered numerous positive responses from politicians.^{1,2}

Pharmaceutical innovation also depends on heavy investment by the public sector. In 2005 public funding for health R&D by high-income countries was 64 billion USD. In 2005, the US government alone spent 35 billion USD on health R&D (Burke & Matlin 2008). In the US the public sector was involved in the development of 70% of the medicines with therapeutic gain (UNDP 1999). Especially since the adoption of the Bayh-Dole Act in 1980 in the US, the pharmaceutical industry has greatly benefited from these investments and subsequent inventions developed in academia or the public sector (Angell 2004).

7.1 Patents and innovation – where is the evidence?

There have always been fierce debates between the proponents of the patent system and its critics. However if one looks beyond the rhetoric, the broader question remains: how strong is the evidence that patent protection in the pharmaceutical field leads to innovation that creates health benefits? This question is particularly pertinent now that patent standards have been globalised and the societal costs of the system are felt everywhere, with especially harsh consequences for the developing world.

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- 1 The vice president of the European Parliament wrote: ‘therefore would like to offer my deepest congratulations to DNDi and Sanofi/Aventis, as you finally give us the tangible evidence that patents can be skipped in the interest of public health, especially for poor people with no purchasing power. As you know, this is a concern that all human rights organizations and the civil society worldwide have voiced for years, claiming the fundamental people right of access to essential health tools. This battle is still on, and we are still working on it. I also consider the innovative partnership between DNDi and Sanofi/Aventis a concrete answer to the Novartis case in India, in which I’m personally engaged in favour of the lawfulness of the generic version of ‘Gleevec’ distribution. Thanks to ASAQ solution, it will be more difficult now for the big pharmaceutical companies to defend the thesis according to which it is not possible to make progress in pharmaceutical innovation, without the patent profit mechanism’ (Morgantini 2007).
 - 2 The German minister of development cooperation Heidemarie Wiecek-Zeul wrote: ‘I am particularly pleased of course that the new drug will be available without any patents for all suppliers and patients i.e. as a public good. By taking this route, all those involved are making an important statement about affordable medical care for the people in the developing countries and I would like to thank you most sincerely for that!’ (2007).

A 2006 report by the US Government Accountability Office (GAO) analysed pharmaceutical drug development and the recent decline in the number of new drug applications (NDA) submitted to the US FDA. While pharmaceutical R&D expenses had increased by 147% since 1993 from 16 to 39 billion USD, NDAs had increased by only 38%. Applications for approval of ‘new molecular entity’ (NME) drugs, or drugs that differed significantly from others already on the market, had risen only 7%. Overall the number of applications had declined since 1999. According to the report, the majority of newly developed medicines were so-called ‘me-too’ drugs, which are substantially similar to existing drugs, are less risky than NME drugs to develop, and ‘offer little in the way of therapeutic breakthroughs’ (GAO 2006).

The report concluded that ‘current patent law discouraged drug companies from developing new drugs by allowing them to make excessive profits through minor changes to existing pharmaceuticals’.³

Studies carried out in other parts of the world found similar results. A review of new medicines published in April 2005 by *La Revue Prescrire*, concluded that 68% of the 3,096 new products approved in France between 1981 and 2004 offered ‘nothing new’ over previously available medicines (*Prescrire International* 2005). *The British Medical Journal* published a study rating barely 5% of all newly-patented drugs in Canada as ‘breakthroughs’ (Barer 2005). And a breakdown of over one thousand new drugs approved by the US FDA between 1989 and 2000 revealed that over three quarters had no therapeutic benefit over existing products (National Institute for Healthcare Management Foundation 2002). Drugs classified as ‘me-too drugs’, or as having no added therapeutic benefit, were the most important driver of increased retail spending on prescription drugs and accounted for 67% of the increase associated with new drugs, and 44% of the total increase in spending on new drugs between 1995 and 2000. These studies provide a telling illustration of a system that rewards innovation, regardless of whether it also represents a therapeutic advance.

The GAO convened a panel of experts to look into the reasons for the decline in innovation. The panel identified the following reasons:

3 US Senator Richard Durbin commented: ‘The findings in this new GAO report raise serious questions about the pharmaceutical industry claims that there is a connection between new drug development and the soaring price of drugs already on the market. Most troubling is the notion that pharmaceutical industry profits are coming at the expense of consumers in the form of higher prices and fewer new drugs’ (as quoted in Lee 2006).

- Difficulties in translating basic research discoveries into new medicines.
- A business environment that favoured the development of costly blockbuster drugs – at the expense of the development of innovative but less profitable products – and “me-too” products, which are less risky to develop but offer little additional health benefits.
- The abandonment of drug development efforts because of mergers in the sector.
- Regulatory uncertainty over what the FDA would accept as safe and effective.
- Patent law that allowed manufacturers to obtain patents for minor changes to products or new indications, reducing the incentive to develop new medicines.

The GAO lists suggestions to remedy the last problem, such as additional financial incentives and a change in patent law that would allow variable patent terms depending on the usefulness of the innovation. For example, one could shorten the patent terms for ‘me-too’ products to ten years.

In addition, the investment sector has voiced concerns about the pharmaceutical industry’s declining ability to innovate despite dramatically increased spending on R&D. Data from the US Security and Exchange Commission showed that research expenditure by the pharmaceutical industry on average is 13 % (20% -6%) of revenue, while expenditure for marketing and administration accounts for 32% (46% - 16%) of revenue. Graham Dukes points out that accurate estimates of research spending are difficult to ascertain, as it is common practice in the industry to count marketing research and distribution of samples as R&D expenditure (2006). A recent report by PricewaterhouseCoopers recommends fundamental changes in the way the industry functions (2007). In 2006 in North America, the pharmaceutical industry spent 55.2 billion USD on R&D (3/4 global spending) while the FDA only approved 22 NMEs. The report identified a number of barriers to innovation including the fact that priority setting is dictated by the need to answer to the shareholders. This leads to risk-averse behaviour and conservatism in R&D. Companies prefer to invest in line extensions and me-too products, rather than riskier but more innovative pharmaceutical research. The current international patent system exacerbates this development because the rewards are the same for a

me-too drug as for a real therapeutic breakthrough. The report suggests altering the patent system to have more varied awards that allow for the recognition of the therapeutic and/or preventive value of the products.

7.2 Patents and drug development for ‘neglected’ and ‘most neglected’ (WHO Type II and III) diseases

The crisis in pharmaceutical R&D disproportionately affects developing countries. In the last three decades there has been no progress in innovation for the so-called ‘neglected diseases’.⁴ Between 1975 and 2004, of the 1,556 new chemical entities marketed globally, only 20 new drugs - a mere 1.3% - were for tropical diseases and tuberculosis. Yet these diseases account for 12% of the total disease burden. This one percent ratio has been steady over the last three decades, despite the expansion of pharmaceutical patent protection in the developing world. Thus, the notion that the lack of patent protection has caused the lack of innovation in tropical medicines is a very weak argument that is not supported by the evidence.

In 1999, Pécoul et al. questioned whether R&D for tropical diseases would indeed become a reality as a result of the implementation of TRIPS in developing countries, as drug companies were arguing at the time. Since 1999, a number of studies have looked into this question. In 2001, MSF published the results of a survey of the top pharmaceutical companies in Europe, Japan and the US regarding their R&D activities in the field of infectious and parasitic diseases (MSF and Drugs for Neglected Diseases Working Group 2001). Eleven companies responded to the survey, each representing an R&D budget of 500 million to over 1 billion USD per year. Out of the eleven respondents, eight had spent nothing at all over the previous fiscal year on the most neglected diseases (sleeping sickness, leishmaniasis, Chagas disease), one company did not give information.

4 The CIPIH used the following classification of diseases: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Many medicines and vaccines are developed for these diseases, but are often not available to people in developing countries because of cost. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries. As a result, the market may not be attractive enough to attract R&D investment for the development of new products. Type II diseases are often called ‘neglected diseases’. *Type III diseases* are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially based R&D in the rich countries. Type III diseases are often called the ‘most neglected diseases’.

Two companies reported spending on malaria and 5 companies reported spending on TB. Seven companies reported spending less than 1% on any of the five diseases or failed to respond. Overall this provided a very alarming picture of the pharmaceutical industry's involvement in infectious and parasitic disease R&D, despite increasingly stringent IP protection in the developing world. The report proposed 'a R&D treaty which would provide a new framework to correct the imbalance that exists between private sector rights and obligations under present international treaties and agreements (e.g. TRIPS) and provide new legal options to make drugs for neglected diseases global public goods.'

Concerns about the imbalance between the obligations of developing countries under the new IP rules and the lack of R&D were confirmed in April 2006 when the WHO Commission on Intellectual Property Innovation and Public Health (CIPIH) published its report. The CIPIH concluded that: 'There is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II and particularly Type III diseases. Insufficient market incentives are the decisive factor.'

8. Conclusions and recommendations

A policy agenda for IP, access and innovation

The problems of public policy in the realm of private monopoly are acute.

US Senator Estes Kefauver in 1965

The WTO Declaration on TRIPS and Public Health is one of the most significant developments of the last decade in trade and health. The Doha Declaration signalled a sea change in thinking about patents and medicines, and is at the root of a cascade of activities aimed at reformulating IP protection as a social policy tool for the benefit of society as a whole, rather than a mechanism to protect only limited commercial interests. The Doha Declaration provided an authoritative interpretation of the TRIPS flexibilities, gave political backing to countries that wanted to use these provisions, and created new rights for LDCs not to grant or enforce pharmaceutical product patents until at least 2016. In the history of the WTO, the Doha Declaration has no precedent (Banta 2001).¹

The use of TRIPS/Doha flexibilities is extensive and has been essential for increasing access to first-line ARVs for AIDS treatment. These drugs could still be produced as generics in countries such as India, where product patent protection was not introduced until 2005. The non-enforcement of patents by LDCs is also widespread; it is actively encouraged by UNICEF and IDA, often as part of drug procurement with Global Fund financing. Developing countries also increasingly make use of compulsory licensing or government use.² Compulsory licensing is being applied by Thailand and Brazil to increase access to second-line ARVs, and

1 Peter Drahos asserts that the only real win for developing countries in the history of the WTO negotiations has been the Doha Declaration on TRIPS and Public Health. He points out that the role of NGOs has been pivotal in this. See Drahos 2007.

2 The practical execution of these measures can be improved. For example several developing countries that have issued CLs do not offer royalties to the patent holder. Over the long run, this practice will be politically unsustainable, though it can be easily remedied by offering reasonable royalties.

in the case of Thailand, for treatments for cardiovascular disease and cancers.

The Thai example is important because chronic (non-communicable or Type I) diseases account for half of the disease burden in the developing world, and is rapidly increasing. The World Bank estimates that by 2015, chronic diseases will be the leading cause of death in the developing world (Adeyi et al. 2007). These diseases may not mobilize advocates and campaigns for access to medicines in the same way as HIV/AIDS; the lack of outcry regarding the overpricing and non-availability in developing countries of the HPV vaccine to prevent cervical cancer suggests as much. Medicines to treat chronic diseases exist but many are far beyond the means of developing country governments and populations.

The Doha Declaration and the general awareness of the need for more health-sensitive patent policies has enabled India to implement a patent law containing a number of very significant safeguards, including: strict patentability criteria to limit the number of patented products, automatic compulsory licensing for generic drugs brought to market between 1995 and 2005 (during the mailbox period) and the possibility for anyone to oppose the granting of a patent. India also has a simple provision for production of generics under compulsory license for export to countries without manufacturing capacity.

There is no denying that the pharmaceutical industry has responded harshly to the Doha Declaration and to some uses of compulsory licensing – in particular, when they are granted by countries with emerging economies. The growth opportunities for the industry lie in these emerging markets, since sales in Western markets are stagnating, partly due to saturation and stagnating innovation (PricewaterhouseCoopers 2007). In addition, TRIPS-plus provisions in FTAs, trade retaliation and political pressures all have seriously impeded the full use of the Doha Declaration.

However, in contrast to the past, these trade and political pressures no longer remain unseen or unheard. In May 2007, Congress and the White House reached an important agreement on loosening some of the TRIPS-plus provisions in the FTAs (USTR 2007).

The change in international thinking about IP, coupled with legal opportunities in developing countries, enabled civil society groups and individuals to challenge patents. Examples include the *ddI* case in Thailand, in which an NGO coalition successfully challenged the BMS patent on the drug; pre- or post-grant oppositions in Thailand (zidovudine+lamivudine), China (tenofovir), Brazil (tenofovir) and India

(multiple); the competition case against GSK and BI in South Africa; and US students' challenge of BMS's abuse of the Yale patent on d4t, which led to the re-negotiation of the license to BMS to allow the use of generics in developing countries.

This somewhat optimistic analysis by no means indicates that the problems are solved. None of the developments over the last 7 years take away from the fact that the TRIPS Agreement is highly detrimental to access to medicines.³ The full implications of the TRIPS Agreement for access to medicines are beginning to emerge, but will only become apparent in the years to come.

While the Doha Declaration can offer relief in dealing with access problems and high drug prices, full implementation is still far from a reality. Over time, the effectiveness of compulsory licensing will wear off unless a more satisfactory solution is found to encourage competition, and in particular, to ease countries' ability to export medicines produced under a compulsory license (MSF 2006).

Many of the pro-access measures described in this book resulted from an ad hoc case-by-case approach that was often highly dependent on an active civil society. A sustainable policy that tackles the fundamental problem of a monopoly-based innovation and access system is still far away.

While the Doha Declaration was important for drawing attention to and offering policy options for the access problems related to IP, until recently there has been little attention to the question of innovation. The discussions at the WTO and the Doha Declaration have failed so far to address an important issue that underlies the WTO TRIPS Agreement, namely, that increased levels of patent protection should lead to increased pharmaceutical R&D and innovation.

Patent protection in the pharmaceutical field has increased over the last 20 years, but the rate of innovation has fallen while the number of "me-too drugs" of little or no therapeutic gain has increased. This global trend in R&D has had a disproportionately heavy impact on the needs of people in developing countries. There is abundant evidence that implementing TRIPS has not increased R&D dedicated to the needs of the poor (UK CIPR 2002; WHO 2006).

3 TRIPS forced countries to give up the diversity and flexibility in intellectual property law and practices that existed pre-TRIPS. For example, by introducing a minimum 20 year patent term and obliging patenting in all fields of technologies, it was no longer possible to exclude medicines and food from patenting. It also introduced requirements for test data protection that, in practice, have created additional forms of monopoly by creating exclusive rights to the data needed to obtain marketing approval (data exclusivity).

In the meantime, however, the lobby to further expand patent protection for pharmaceuticals is pursuing its mission with vigour. But the voices that call for a reassessment of the current R&D incentive system are also growing stronger; they were responsible for the call by the 60th World Health Assembly in 2007 to encourage the WHO Director-General to develop proposals for mechanisms that would de-link the incentives for R&D from the incentives for production (WHA 2007). In other words, R&D costs would no longer be recovered through the price of medicines.

A policy agenda for access and innovation is sorely needed and should address both immediate steps to be taken, as well as tackling the fundamental question of how to create incentives for R&D that do not create access barriers. The following section will outline some key elements of such a policy.

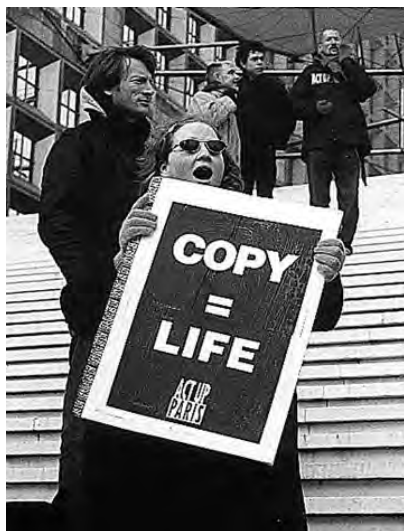
8.1 Access: towards pro-access management of IP

To resolve today's problems of high drug prices as a result of patent monopolies, and in particular, the high prices of medicines needed to treat HIV/AIDS, countries should make full use of the provisions in the Doha Declaration. Currently, rewards based on 20 year monopoly rights are the accepted business model; however, one could also imagine a system in which patents are granted to innovators but their award comes in the form of royalties from multiple users of the patent. This would allow for a competitive market in production and sales, while the innovator receives his or her awards. The legal framework to do so now exists. Organisations such as the WHO, World Bank and the Global Fund should proactively encourage the use of CL and government use measures in day-to-day procurement practices. This should include guidance on how to issue compulsory licenses, how to determine reasonable royalty rates to be paid to the patent owner, and other legal and technical matters.

Following are a few suggestions to develop more systematic mechanisms for licensing.

8.1.1 Routine compulsory licensing and government use in procurement

In the past, countries such as Canada, the UK and the US have liberally used CLs and made government use of patents to procure health products for the public sector or the military. The success of these practices in bringing prices down in Western countries should serve as a model for developing countries today. After all, the level of industrialization in most developing



Demonstration against pharmaceutical companies' legal action in South Africa (March 5 2001)

Photographer: Act Up-Paris

countries today is still far behind that of Western countries when they excluded drugs from patenting or routinely used compulsory licensing.

8.1.2 Licences of right

Licences of right are a particular form of licensing that could be of use in developing countries. If a patent is marked with a licence of right it means that the patent-holder is required to grant such a licence should a qualifying applicant request it. A patent can be marked with a licence of right by a competent authority or the patent-holder. The advantage of a licence of right is that the third party's entitlement to a licence is automatic and does not require justification by the licensee. Licences of right were the basis of the Canadian pharmaceutical compulsory licensing policy that was in place from 1923 to 1993. (See section 5.2.1)

8.1.3 Extend the 2016 deadline for LDCs

The WTO should extend the 2016 deadline for LDCs to comply with obligations in the TRIPS Agreement to provide pharmaceutical product patents and protect undisclosed test data.

8.1.4 Patent pools

Dealing with existing patents can be done on a case-by-case basis through voluntary or non-voluntary licensing. But it is also possible to manage IP collectively through patent pooling. A patent pool is created when a number of patent rights, held by different owners (companies, universities, government institutions), are brought together (pooled) and made available on a non-exclusive basis to manufacturers and distributors of medicines against the payment of royalties. Third parties (e.g. generic manufactures of drugs) can make use of the patents against the payment of a royalty. It serves as 'one stop shop' for all involved.

Potential benefits of pooling include: a) reduced licensing transaction costs through 'one stop' licensing rather than multiple agreements; b) elimination of blocking patents; c) management of multiple owners and stacking of royalties; d) the potential to encompass non-patent technology and know-how; e) the potential to facilitate downstream innovation and development; and f) the potential to facilitate technology transfer and a sustainable scaling-up of capacity and access in the developing world (Clark et al. 2000).

Patent pools are not new and have been established in several fields of technology. The WHO Severe Acute Respiratory Syndrome (SARS) Consultation Group and the SARS IP Working Group (key owners of SARS-related intellectual property) are developing a patent pool for a SARS vaccine (Simon 2004). This group has found that innovation would be delayed and constricted by the multiplicity and restriction of patents.

An area where the establishment of a patent pool would have immediate and obvious advantages is in the development of fixed-dose combinations (FDC) of the newly WHO-recommended first-line ARV treatment. This treatment consists of tenofovir, lamivudine and either nevirapine or efavirenz. An FDC of three of these drugs currently does not exist. The patents on every compound in this triple-therapy are held by a different company. A generic company seeking voluntary licenses for the development and production of these FDCs would have to obtain licences from four different patent holders. However, if these patents could be combined in a patent pool, the generic company wishing to develop, produce and market the FDC would only have to deal with the pool, which would also be responsible for the collection and payment of royalties. A patent pool may be an attractive way for patent-holding companies to avoid the proliferation of compulsory licences and the associated public

relations problems that arise from IP conflicts, to get access to new markets (through the licensee), and to improve the overall public image of the company.

Currently UNITAID is exploring the establishment of a patent pool for the development and production of second-generation ARV FDCs for adults and children. Other countries should support this initiative. It could serve as a pilot project to provide a model to be expanded for other products.

8.2 Access and innovation

8.2.1 Change the incentive system for health R&D

While the recommendations above are aimed at solving immediate access problems, they do not address the more fundamental question of how an R&D incentive system can be improved so that it no longer creates access barriers. At the core of the issue is the fact that the financing of innovation depends on the ability to charge high prices. The stronger the monopoly, the greater is the ability to charge high prices. But the societal cost of patent monopolies is high, and for developing countries it is too high. Policy-makers have started to focus their attention on examining how effective the IP system is at encouraging the development of needed products.

In the last few years, a number of important studies on IP, access and innovation have been published that have demonstrated the weakness of the current market-based R&D system (CIPR 2002; CIPIH 2006). The 2006 report of the WHO Commission on Intellectual Property, Innovation and Public Health is perhaps the most significant, calling attention to the need for changes in the way health R&D is prioritised and financed.

The CIPIH report lists 60 recommendations to increase access and move towards a more health-needs driven innovation system. It introduced a re-conceptualised definition of innovation as encompassing discovery, development and delivery, thereby including access as an integral part of innovation. Following the CIPIH report, the WHA established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) to negotiate new frameworks and a plan of action for priority setting and financing of essential health R&D (WHA 2006). These multilateral negotiations on IP, health, access and innovation started in 2006 at the WHO and are scheduled to conclude with a Plan of Action in 2009.

The 60th WHA in 2007 asked the WHO Director-General to:

encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage of the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries (WHA 2007)

This resolution was echoed in the Organisation for Economic Cooperation and Development (OECD) Noordwijk Medicines Agenda, which also called for an exploration of 'alternative policy mechanisms to reward innovation' (OECD 2007). The Noordwijk Agenda also recognised that 'innovation includes both the development of new healthcare products and the delivery and diffusion of those products, and any efforts to improve the availability of medicines, vaccines, and diagnostics must be accompanied by efforts to improve access to health care and to strengthen health systems.'

The CIPIH has shown that when market prospects guide the R&D agenda, important health needs are neglected. But as long as health R&D depends on patent monopolies for its financing, prices are likely to remain an access barrier. Access problems and the lack of R&D are two sides of the same coin. Their solution lies in altering the way R&D is financed, by separating the incentives for medicines R&D from the incentives for medicines production.

Moving away from patent monopolies as the main mode of financing R&D is not a farfetched idea. There are already interesting experiments taking place and proposals being discussed. The IGWG's Global Strategy adopted by the World Health Assembly in May 2008 is a forceful call for change. The strategy includes proposals for patent pools for upstream and downstream technologies to increase access and innovation, promotes the use of compulsory licensing to encourage competition in the pharmaceutical generics market, rejects TRIPS-plus measures in trade agreements, and encourages the development of new incentive mechanisms, such as prizes and government involvement in R&D priority-setting.

More ambitiously, the Global Strategy opens the door for fundamental change in two key areas:

First, building on WHA Resolution 60.30, it calls for the development of proposals for health-needs driven R&D, including 'addressing the

de-linkage of the costs of research and development and the price of health products.’ De-linking paying for the cost of R&D from the price of the product would break the vicious cycle of financing R&D through high drug prices. As long as R&D depends on the ability to charge high prices, steering the current market-driven R&D system towards more health-needs driven research will remain wishful thinking; and reducing drug prices sustainably will be impossible, other than through painstaking drug-by-drug, country-by-country battles. Prizes are one way to achieve the de-linking of R&D costs from price (Stiglitz 2007).

The second more fundamental change that the Strategy may usher in is the possibility of intergovernmental talks about an essential health and biomedical R&D treaty to change the rules of medical R&D. The Strategy includes the following proposal:

‘encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty.’

Today’s predominant global R&D treaty, the TRIPS Agreement, is based on granting monopolies as the predominant incentive for innovation. And its provisions for technology transfer are limited. If one asks whether the TRIPS Agreement would come into being today, knowing what we know now about access and innovation – even its fiercest proponents would likely say no. International talks that have health needs driven R&D as its focus will likely come to a different result than talks that aim at increasing IP protection per se.

The IGWG and its Global Strategy is, after the 2001 Doha WTO Declaration on TRIPS and Public Health, the second most important multilateral attempt to alter IP policies so they respond better to real health needs. This time, the health authorities are leading the negotiations - the process is taking place at WHO, and not at WTO.^{4, 5} Its success will thus depend on WHO’s forcefulness and resolve.

4 ‘WHO is the only intergovernmental organization with a formal international mandate to protect and advance health internationally’ (Pecoul et al. 1999).

5 Another forum where the issue of access to medicines and the need for IP reform is debated is the World Intellectual Property Organisation (WIPO) – a specialised UN agency on intellectual property (See in particular the WIPO Development Agenda debates).

8.2.2 Not-for profit drug development

An example of a new business model experiment for R&D for neglected diseases is the DNDi, which finances R&D up front and offers the outcome of its research on a non-exclusive basis to generic producers. The two products that DNDi has developed are not patent-protected. Such a business model could be adopted on a much larger scale. Even if drug developers patent the products they have developed, this does not have to lead to monopolies. Drug developers and, in particular, not-for-profit drug development initiatives can adopt non-exclusive open licensing policies that would allow for technology transfer and competition among multiple producers.

A similar change in the licensing practices of government-funded research and university research should be encouraged. Aside from helping to combat monopoly pricing, such policies could also help overcome patent barriers to research (Universities Allied for Essential Medicines 2006, 2008). Non-exclusive licensing practices would be particularly opportune in situations where the inventor is not dependent on sales of the invention to finance his or her work, such as in the case of government, university or otherwise up-front funded research.

8.2.3 Novartis R&D fund proposal

Novartis has proposed to create a global fund for R&D for neglected diseases to support not-for-profit innovation. The proposal includes centralised portfolio management and IP management. Beneficiaries of the fund would be required to license their IP exclusively to the funding body for the neglected disease, but would be allowed to exploit their IP in more affluent markets provided that royalties were paid to the fund. In case the new molecule had advantages in the treatment of a disease with greater commercial value, the inventor/company would be allowed to develop and or market such a product on condition that compensation would be paid to the fund for data developed with financing intended for neglected diseases (Herrling 2007). The proposal focuses on neglected diseases only and is limited in the sense that it does not suggest fundamental changes to the global R&D system.

8.2.4 Prize model

Barbados and Bolivia have made proposals to the WHO IGWG for prizes for innovation. The idea to award innovators with a prize is not new. One of

the early prizes in the medical field was for the best essay on ‘the means of Diagnosticating Latent Tuberculosis before its appearance or after its Cure.’ This prize was established in 1892 by the Congress for the Study of Tuberculosis and awarded in 1898 to Dr Koch among others, whose mode of diagnosing TB – sputum smear microscopy - is still the most widely available means of diagnosing TB in developing countries. An improved method is desperately needed, as it detects less than half of patients with pulmonary TB (Guillerm et al. 2006).

The idea of awarding and incentivising innovation with prizes rather than with monopolies is again gaining ground (Stiglitz 2007). A more recent example is the prize offered by InnoCentive, an online platform for matching problems and rewards with inventors. InnoCentive offered a prize for a ‘Safe and Economical Synthetic Route for PA-824, a candidate drug for tuberculosis.’ In December 2008, InnoCentive awarded 20,000 USD each to two researchers in India and China who submitted an improved method of synthesizing this potential new medicine; the prize was funded by the Rockefeller Foundation in support of the Global Alliance for TB Drug Development, a non-profit drug development entity (InnoCentive 2008).

The Barbados and Bolivia proposals made to the WHO IGWG suggested starting to explore multiple prizes: for the development of a low cost rapid diagnostic test for tuberculosis, for new treatments for Chagas disease, for new cancer treatments in developing countries, a priority medicines and vaccines prize fund and a licensed products prize fund for donors (Barbados and Bolivia 2008). These proposals aim to create incentives that are not price-based for research into diseases that are neglected by market-driven R&D. It is expected that these proposals will be examined in the context of the IGWG plan of action that is currently being finalised (IGWG 2008).

8.2.5 The Medical Innovation Prize Act 2005

The Medical Innovation Prize Act was first introduced by US Representative (now Senator) Bernie Sanders in 2005 and was revised in 2007 for reintroduction (Sanders 2007). The bill is also based on de-linking the cost of R&D from the price of the drug by creating an annual prize fund of 80 billion USD that would remunerate drug developers. The Sanders bill set aside 6.4 billion USD for neglected diseases, global infectious diseases such as HIV/AIDS, and medicines needed to respond to bio-terrorism. The

Sanders bill was not based on price controls to reduce prices, but rather on the elimination of exclusive marketing monopolies. Patents would be used to establish entitlement to a payment from the prize fund, but could no longer be used to establish market exclusivity. The Sanders bill would create a competitive generics market for new pharmaceutical products while providing abundant financing for innovators.

8.2.6 A proposal to solve the drug price crisis in the US: Finkelstein & Temin

The need to look at incentives schemes for innovation is not only inspired by the lack of attention to diseases that affect the developing countries, but also by those concerned about high drug prices and the lack of pharmaceutical innovation in more affluent markets. In their 2008 book *Reasonable Rx: solving the drug price crisis*, Stan Finkelstein and Peter Temin of the Massachusetts Institute of Technology make the case for a radical change in the US drug industry. They join those who propose to solve the drug price crisis by changing the way R&D is financed. At the core of their proposal is the elimination of the linkage between drug prices and drug discovery. With reference to the 'de-integration' of the telecommunications and electric power industry, they propose to divide the drug industry in two parts: an R&D sector and a production and marketing sector. The government would set up an independent drug development corporation (DDC), which would serve as an interface between the development sector (profit or not-for-profit) and the distribution sector. Drug marketing firms would obtain patent licenses that would allow them to sell new drugs after FDA approval through auctions of innovations held by the DDC. These licenses would contain price controls. The revenues of the auctions would remunerate the innovator. The DDC would be financed with public funds and the revenues of the auctions. Finkelstein and Temin also envisage contributions by foreign countries.

In this de-linked scenario of drug R&D, the risk of drug development would be spread among many firms that are engaged in drug development and society. Drug discoverers would be paid sooner than if they had to wait for remuneration throughout the patent term. The priorities for pharmaceutical R&D would be set by the DDC based on needs, and the savings on drug prices realised through the new system would pay for the functioning of the DDC.

The Finkelstein-Temin proposal does not detail how the system could be applied globally and how it could make a contribution to the

development of drugs for neglected diseases. But one can see similarities with others that have proposed a global approach with a similar underpinning, such as the Sanders Medical Innovation Prize Fund.

8.2.7 R&D treaty: Hubbard & Love

At the time TRIPS was negotiated there was no international public debate on IP and health, the scale of the AIDS epidemic in developing countries was not known, and understanding of the technical and legal details of IP issues among health groups was virtually non-existent. In contrast, commercial interests were strongly represented and played a crucial role in drafting the text and lobbying for its support. For these reasons, TRIPS was negotiated as a treaty to protect intellectual property rather than a treaty for R&D.

However, if one were to design an international agreement on essential health R&D today, the incentives would likely be much more diverse than IP alone. This concept is at the root of the proposals by Hubbard and Love for a new trade framework (2004). They propose a trade framework for R&D that focuses on equitable contribution to the cost of R&D through multiple means – not exclusively through the granting of patent monopoly rights. As a result, new products would be more widely accessible rather than being tied up in 20-year patents. In their model, there would be a market for R&D and, a separate competitive market for production and sales in which all products would be generics. An international norm for contributions to R&D would be established by the treaty, and would ensure that the financial resources for R&D would be available but would no longer depend on high prices and the subsequent rationing of access to the products.

If the framing of the debate shifts from IP to R&D, this is likely to strengthen the leverage of developing countries to change the dynamics of IP negotiations in trade agreements. When the talks are no longer about how strict IP standards should be but, rather, how each country could contribute to essential health innovation, the power dynamic is likely to change to the point that TRIPS-plus demands will be hard to maintain.

The Global Strategy of the IGWG contains the following actions:

‘encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty.’

Furthermore, the new Global Strategy offers the opportunity to explore fundamental changes when it says:

Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.

While these more fundamental changes in global R&D policy will take time, politicians and academia are beginning to explore alternatives to monopolies as the single most important incentive for health R&D.

8.3 Conclusion

Ironically, change may be fuelled by the increasing concern about high medicines prices in wealthy countries and the inability of their citizens and health insurance schemes to pay for them. Even in Europe, where most consumers have been immune to the effects of rising drug prices because these costs are covered by health insurance, the situation has begun to change because expensive treatments are increasingly being excluded from reimbursement (*The Guardian* 2008).

Since globalisation accounts for a major part of the problem of high drug prices in the developing world, perhaps the solution will also be found at the global level, in a new agreement on sharing the costs and benefits of medical R&D for the sake of humankind.

However, these ambitions should not shroud the fact that measures can and need to be taken today to ensure lower prices for medicines and other health care products that exist, and to steer medical research in the direction of greatest need.

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Annex 1: Declaration on the TRIPS Agreement and Public Health ('Doha Declaration')

DOHA WTO MINISTERIAL 2001: TRIPS

WT/MIN(01)/DEC/2

20 November 2001

Declaration on the TRIPS agreement and public health

Adopted on 14 November 2001

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

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

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

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Annex 2: Selected Articles from TRIPS

Agreement on trade-related aspects of intellectual property rights (TRIPS)

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 30

Exceptions to rights conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other use without authorization of the right holder

Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or

other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.

In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

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

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ('the second patent') which cannot be exploited without infringing

another patent ('the first patent'), the following additional conditions shall apply:

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 66

Least-developed country members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Annex 3: 2005 Indian Patents (Amendment) Act, Section 3(d)

Section 3(d):

'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'

Explanation. — For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Annex 4: 2003 WTO 'August 30th' Decision (including Chairperson's Statement)

TRIPS: COUNCIL FOR TRIPS
Decision of 30 August 2003
IP/C/W/405

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ('the WTO Agreement');

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the 'Declaration') and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of

Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

(a) 'pharmaceutical product' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (1)

(b) 'eligible importing Member' means any least-developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members (3) have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) 'exporting Member' means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

- (i) specifies the names and expected quantities of the product(s) needed (5);
- (ii) confirms that the eligible importing Member in question, other

than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website (7) the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence

is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in

question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Notes:

1. This subparagraph is without prejudice to subparagraph 1(b).
2. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
3. Australia, Austria, Belgium, Canada, Denmark, Finland, France,

Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

5. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

6. This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

7. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

8. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

9. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

30 August 2003

INTELLECTUAL PROPERTY

The General Council Chairperson's statement

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without

prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. 'Best practices' guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.

- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

Attachment 'Best practices' guidelines

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa.

- Novartis has used different trademark names, one (Riamet® for an anti-malarial drug provided to developed countries, the other (Coartem® for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.

Annex 5: Negotiating history of the 'August 30th Decision'

The TRIPS Agreement stipulates that production under a compulsory license must be 'predominantly for the supply of the domestic market' (Article 31f) except when the compulsory license is granted to remedy an anticompetitive practice (Article 31k). This restriction limits the quantity of products that can be produced for export. This limitation was a key issue because it could render local production of a drug uneconomical for a WTO Member, even if – in principle – production was legally permissible under the compulsory license. This would have important consequences for countries without their own production capacity that rely on import to give effect to a compulsory licensing.

The Doha Ministerial decided to postpone a resolution of this problem to a later date, but called for an 'expeditious solution' in Paragraph 6 of the Doha Declaration, which reads:

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

However, the cooperative spirit of Doha quickly evaporated once negotiators were back in Geneva. It took the TRIPS Council nearly two years to reach an agreement to allow the export of medicines produced under a compulsory license.

During this period, the fundamental disagreement was over whether the solution would be simple and economically feasible or complex and economically risky. On the one hand, developing countries, the WHO, and NGOs supported a solution that would have automatically allowed export once the importing country had expressed the need and/or issued a compulsory license. This solution would have relied upon TRIPS Article 30,

and considered export under compulsory license to be a 'limited exception' to a patent right.

In support of a solution based on Article 30, the WHO said in the TRIPS council on 17 September 2002:

'...WHO has published a paper, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, WHO/EDM/PAR/2002.3. This paper describes the features of a solution to the so-called 'paragraph 6 problem' which are desirable from a public health perspective. These include: a stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country; facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines.

Thus, the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.

Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs.

In its submission to the TRIPS Council on 4 March 2002 (IP/C/W/339) initially the European Commission signalled openness to proposals based on an interpretation of Article 30. The EC said:

To this end, WTO Members could adopt a declaration stating that a WTO Member may, in accordance with Article 30 of the TRIPS Agreement, provide that the manufacture, on its territory, of a patented product, without the authorization of the right holder, is lawful when it

is meant to supply another country which has granted a compulsory licence for the import and sale of the product concerned in its territory in order to deal with a serious public health problem.

While negotiations went on in the TRIPS Council, the European Parliament on October 23, 2002 adopted Amendment 196 to the EU Directive 2001/83/EC relating to medicinal products for human use. This amendment reads as follows:

Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that country.

The Parliament's amendment had no impact on the EU's position in the TRIPS Council, which by then had abandoned its initial openness towards a solution based on an interpretation of Article 30 and was advocating a solution solely based on Article 31(f).

NGOs also supported a solution based on Article 30. In June 2002, MSF published a briefing note entitled: 'Why Article 30 will work. Why Article 31 will not' (MSF 2002). The note drew attention to the fact that a solution based on Article 31 would require, in many cases, two compulsory licenses with all the procedural requirements that come with it, while an exception would be automatic:

Put yourself in the position of someone suffering from a lethal disease and in need of medicines that are unaffordable under patent. Your government has acted and issued a compulsory licence for import to your country. Would you prefer that the medicines you need could be produced and supplied to your country (a) automatically; or (b) after somebody in a different country has eventually come to a decision that, in this case, it would be allowed?

The decisions in answer (b) could have life and death consequences for millions of people. Answer (b) is the preferred option of those who favour an Art 31 solution even though it is the less swift and sure option. The best option, answer (a), is instead the Article 30 solution.

Unfortunately the WTO negotiations took an entirely different direction. Months of discussions in the TRIPS Council showed a deep divide between the developing countries that were seeking a workable solution and the

industrialised world that tried to limit the scope of any solution as much as possible. In an attempt to meet the 2002 deadline most delegations were prepared to accept a far from ideal compromise text that became known as 'the December 16 Motta text' named after the chair of the TRIPS Council. The Motta text was ambiguous on the scope of diseases through its reference to Paragraph 1 of the Doha Declaration which mentions AIDS, TB and malaria. A more appropriate basis for the scope of disease would have been Paragraph 4 of the Doha Declaration, which refers to public health problems in general. On the issue of country eligibility, the Motta text seemed to be at odds with the Doha Declaration, which called for TRIPS to be implemented in a manner to 'promote access to medicines for all.' The Motta text also created cumbersome procedures to determine the eligibility of countries to use the system, and measures to prevent diversion of medicines to rich country markets.

Although the Motta text was seen as far from ideal, all countries were ready to agree to it. NGOs called upon the negotiators to reject the text (Consumer Project on Technology et al. 2002). In the end it was the US that vetoed the proposal. The drug companies had been lobbying fiercely to restrict the scope of diseases and eligible countries. The US considered the scope of diseases in the Motta text to be too broadly defined, and rejected the proposal and announced a unilateral moratorium on disputes. In an attempt to break the deadlock, the European Commission followed up on an earlier US proposal and listed diseases for which the solution could apply, and introduced an advisory role for WHO in case a Member requested this.¹

This proposal was rejected by the developing countries as backtracking on the Doha Declaration and was met with a wave of objections from all over the world. In numerous letters, professional medical organizations, individual medical doctors, NGOs, consumer groups and human rights groups rejected any further narrowing of the scope of the Doha Declaration. Apart from HIV/AIDS, the list included only diseases for which

1 The EC proposal read: 'This covers at least HIV/AIDS, malaria, tuberculosis, yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus measles, shigellosis, hemorrhagic fevers, and arboviruses. When requested by a Member, the World Health Organization shall give its advice as to the occurrence on an importing Member, or the likelihood thereof, of any other public health problem.' This was a particularly cynical proposal since this list contained diseases for which a) there were no treatments available, or b) for which the treatment is off patent and c) for which little R&D was being carried out offering no prospect of any new medications soon. The list did not contain any diseases such as cancer or diabetes that would require access to patented treatments that actually existed.

there was either no treatment or where virtually all the recommended treatments were so old as to be off-patent. The negotiations in the WTO became quite bizarre, with trade negotiators trying to determine public health priorities for countries.

The latest attempt to make the Motta text palatable for the US came from the Chair of the TRIPS Council, who proposed in January 2003 to adopt a statement that there was an understanding that the solution 'under paragraph 6 of that Declaration as being essentially designed to address national emergencies or other circumstances of extreme urgency.' Again this proposal was rejected by the developing countries. NGOs reacted fiercely in an open letter to the WTO members and called upon the Members to reject the proposal. The use of compulsory licensing was never meant to only address emergency situations. It would certainly have been unacceptable to limit the use of compulsory licensing for countries without production capacity even further, when the entire purpose of the Paragraph 6 discussions was to lift the barriers to using compulsory licensing for these very countries (MSF 2008b).

At this point it had become clear that there was little left of the spirit that had led to the Doha Declaration. In particular, the US seemed to want to turn back the clock to the pre-Doha era.

Finally, on August 30, 2003 a decision was adopted. The August 30 decision contained a waiver of the obligations of Article 31(f) and was followed by an amendment to the TRIPS Agreement (Article 31 bis) on 6 December 2005. The amendment will come into force once two-thirds of the WTO membership has ratified it. As of this writing, seven out of the 150 Members have done so.²

The waiver will stay in place until Article 31bis comes into force. Both the August 30 Decision and the adoption of the amendment in December 2005 were accompanied by a Chairman's statement representing several 'key shared understandings' related to the non-commercial nature of the Decision, the need to take measures against trade diversion, the need to resolve issues expeditiously and amicably and the need to bring all information gathered on the Decision's implementation to the attention of the TRIPS Council (See Annex 4 for the text). It also included an annex of 'best practice guidelines' listing methods to prevent diversion of drugs from the multinational drug companies' discount and donation programmes.

2 United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Rep. of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007).

The note also listed the countries that had notified the WTO that they had opted out of using the solution or had restricted it to use in emergency situations only.³

Many have noted that the system has serious flaws. The WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) recommended that the effectiveness of the August 30th Decision 'needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary' (WHO 2006).

For a discussion of the national implementation of the August 30th decision and broader implications for access to medicines, see Section 4.5.

3 Fifteen Members have agreed to only use the mechanism as an importer in case of national emergency or extreme urgency. Nine countries and the European Union opted out of the use of the August 30 decision to allow import of generic medicines under any circumstances, even in cases of extreme urgency or national emergency. Recent cases such as shortages of ciprofloxacin in the US and Canada and price disputes between Pfizer and France (in which Pfizer threatened to withdraw products from the French market) show that wealthy countries may also face situations that may require importing drugs from sources other than the patent-holder. It is unclear how the decision to opt out of the August 30 decision can be in the interests of the citizens of these countries. It seems therefore that this decision was driven by political motives, namely, signalling that it was not acceptable to use the mechanism.

