Playing by the Rules:

Using Intellectual Property Law and Policy to Improve Access to Essential Medicines

July 2008

Access to Essential Medicines Initiative

OPEN SOCIETY INSTITUTE
Public Health Program

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1. About this publication

People living throughout the developing world are far less likely than people in developed countries to have access to medicines to treat a wide range of life-threatening illnesses, from HIV to diabetes to heart disease to high blood pressure. It is therefore not surprising that they suffer and die from such conditions more frequently. In general, they are often unable to obtain relief because neither the individuals themselves nor their local health systems can afford to purchase medicines that are usually easily available in wealthier countries.

A growing number of people and governments find the disparities in access to such "essential" medicines to be inhumane and unfair. Spurred by civil society and public health groups, they have been seeking to identify the roots of the problem and devise effective and sustainable solutions. This publication considers developments around one increasingly common approach: the use of intellectual property law and policy as a tool to reduce drug prices and, by extension, increase access to essential medicines.

Most notably, the report provides an overview of options available through provisions of a global trade agreement from the 1990s, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It considers specific TRIPS-related strategies and steps taken by governments and their allies in different contexts around the world. The goal is not to provide in-depth, exhaustive examples. Instead, the publication aims to highlight, in the simplest terms possible, the wide range of possible options that policymakers and civil society might pursue to improve the availability of essential medicines to all who need them.

The report contains an introduction and overview (Section 5) followed by case studies (Section 6) from six countries: South Africa, Thailand, Brazil, the Philippines, Rwanda, and Kenya. Section 7 is a glossary of the key terms and concepts discussed throughout this report in regards to intellectual property, access to medicines, and global trade policy.

2. Acknowledgments

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issues in the developing world), and Robert Weissman (Essential Action). The author would also like to thank Roxana Bonnell and Jane Li from the Open Society Institute.

3. Acronyms and abbreviations

AIDS = acquired immune deficiency syndrome
ART = antiretroviral treatment
ARV = antiretroviral
GSK = GlaxoSmithKline
HIV = human immunodeficiency virus
KEI = Knowledge Ecology International
LDC = least developed country
MSF = Médecins Sans Frontières
R&D = research and development
TAC = Treatment Action Campaign
TB = tuberculosis
TRIPS = Trade-Related Aspects of Intellectual Property Rights
WHO = World Health Organization
WTO = World Trade Organization

4. Notes on text

Unless specified otherwise, all figures marked by "$" are U.S. dollar amounts.

Whenever possible, the generic names of medicines are emphasized and spelled out fully. Brand names are included when relevant.

5. Introduction and overview

Over the past few decades it has been considered politically and culturally appropriate to refer to the world's wealthiest nations and their poorer counterparts as "developed" and "developing," respectively. This somewhat bland and misleading rhetoric—what does it mean to be "developed," after all, when economies and countries are not standing still?—should not be allowed to disguise the significant gaps between the relatively rich and poor.

Granted, there has always been fluidity, with the general trend toward more prosperity over time (as seen most recently in countries including Brazil and China). Yet people living in the developing world are not only poorer in general, but they have far fewer opportunities to improve their lives. One of the most glaring examples is access to health care. According to a recent global health survey, released in December 2007, "the gaps between rich and poor nations in reports of hunger and lack of health care remain enormous. In nearly half of the nations surveyed, at least 40 percent of the public reports that they did without health care for lack of money."[1]

Such results can be blamed to a large extent on relative poverty among both individuals and throughout different societies. Respondents' inability to obtain health care is also not surprising when another crucial element of adequate health care is considered: access to medicines. Although about 80 percent of the world's population lives in developing countries, only 20 percent of all pharmaceuticals are consumed in these countries.[2] The situation is even worse in parts of the world disproportionately affected by life-threatening diseases, including HIV, malaria, and tuberculosis (TB). An estimated one-third of the world's population, nearly all of whom live in those regions, have no access to potentially life-saving drugs to treat such conditions.[3]

5.1 The development of mechanisms related to intellectual property and trade policies

As bad as it is now, the situation was once far worse. Civil society advocacy—initially around HIV drugs, but more broadly in recent years—has played a key role in humanizing the impact of the wide gaps in access to medicines between developed and developing countries. Organizations used the media to draw greater attention to the suffering and deaths in poorer regions. They collaborated on designing and initiating effective strategies to push governments and multilateral agencies to act decisively. The amount of aid devoted to increasing access to essential medicines (and not just to fight HIV) has grown substantially as a result.

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[1] Kaiser/Pew Global Health Survey, released December 13, 2007. Online: www.kff.org/kaiserpolls/pomr121307nr.cfm. The survey involved telephone and face-to-face interviews with more than 45,000 people in 46 countries plus the Palestinian territories. Both developing and developed countries were included.

[2] Martin, G, et al, "Balancing intellectual monopoly privileges and the need for essential medicines," *Global Health*. Published online in June 2007: www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1904211.

[3] Ibid.

Governments and civil society groups over the past couple of decades have also sought other (and more sustainable) ways to help boost greater availability of crucial drugs. Mechanisms focusing on trade and intellectual property are simultaneously a promising and controversial entry point. A key watershed in that regard occurred in 1995, when the majority of the world's nations—developed and developing alike—acceded to the newly launched World Trade Organization (WTO). Among the new entity's sections was one that focused on defining and harmonizing global standards and policies related to intellectual property rights, including patents. The treaty therefore had a direct impact on issues related to access to medicines.

Keen supporters of rigid patent rights, including the United States, spearheaded the relevant agreement, known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). They and their business allies, including the pharmaceutical industry, secured nearly global acknowledgment of the importance of recognizing and enforcing patents. Developing countries would not likely have approved the TRIPS agreement without certain compromises, however. The most important to them and their civil society allies are provisions, known as "flexibilities," that outline steps and tactics countries may take to reduce the price of and improve access to pharmaceuticals, patented or not.

Among the specific TRIPS flexibilities are "compulsory licensing" and "parallel importing." Along with a few other important tactics not mentioned in the TRIPS agreement, such as voluntary licensing and patent pools, these flexibilities offer a range of opportunities and options for countries in need. (***Section 7*** *of this report contains a comprehensive glossary of terms and concepts related to the TRIPS agreement and patents, including compulsory licenses, parallel importing, voluntary licenses, and patent pools. It also includes background information on the WTO and the TRIPS agreement itself.*)

Through the negotiation of foreign trade agreements, the overall process of identifying and codifying trade rules with direct pertinence to essential medicines continues to this day. It should be noted too that the WTO is not the only forum in which such issues are discussed. For example, government representatives, civil society advocates, and legal experts continue to discuss potential policy changes vis-à-vis essential medicines through mechanisms such as the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), which seeks to create a new global framework for essential health research and development (R&D). Proposed by the governments of two developing nations, Brazil and Kenya, the IGWG held its first global meeting of WHO member-states in December 2006. The IGWG Secretariat and member-states developed a new framework continued during a follow-up meeting 11 months later, in November 2007. A version of the framework was agreed upon at the World Health Assembly in May 2008, and an expert committee will be selected to develop an action plan based on this framework.

5.2 Reasons for the relatively limited utilization of legal rights

It is not yet possible to determine the full extent of the TRIPS agreement's impact, given its relative newness and ongoing steps by countries to implement its provisions. Several possibilities and trends are nonetheless notable. On the one hand, severe constraints on access to essential medicines are a clear concern in light of the agreement's patent-upholding elements. That and other potentially negative impacts are not, however, being addressed as extensively as possible through currently available mechanisms. As observed by Jacqui Wise, writing in the *Bulletin of the World Health Organization* in May 2006:

> Developing countries are failing to make full use of flexibilities built into the [WTO's TRIPS agreement] to overcome patent barriers and, in turn, allow them to acquire the medicines they need for high priority diseases, in particular, HIV/AIDS. . . . [M]any of these countries are not using all the tools at their disposal to overcome these barriers.[4]

Why are more eligible countries not "using all the tools at their disposal," especially the tools that are specifically allowed under TRIPS?

A Kenyan expert quoted in the WHO analysis, Sisule Musungu, blamed the lack of action on "widespread lack of clarity about the options available, coupled with the lack of local legal and technical expertise to incorporate and implement TRIPS flexibilities in national law and policy."[5] The legal rights and issues involved are indeed highly technical; resources are available, however. Both the WHO and some civil society organizations, such as Knowledge Ecology International (KEI), currently offer technical assistance free of charge or at highly subsidized fees to trade, public health, and other government policymakers.

An equally important obstacle—and to most advocates, far more insidious—is ongoing efforts by some countries in the developed world to coerce developing countries into giving up their rights to utilize some or all of the TRIPS flexibilities. One strategy used by richer nations is to negotiate bilateral or multilateral trade agreements that contain explicit provisions (known as "TRIPS-Plus") limiting signatories' ability to issue compulsory licenses, for example.[6]

Multinational pharmaceutical companies wholeheartedly support such efforts, of course. They are not opposed per se to the widespread distribution of their products; on the contrary, greater usage is their goal. What they do oppose are efforts to restrict or remove their ability to maintain complete control over marketing, sale, and pricing of their patented products. Drug firms hold sacrosanct their intellectual property rights (most notably, the awarding and enforcing of patents) from both legal and financial standpoints.

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[4] See www.who.int/bulletin/volumes/84/5/itmb.pdf.
[5] Ibid.
[6] See the "TRIPS-Plus" entry in Section 7.8 of this report.

Most pharmaceutical companies and their supporters, including some governments in the developed world in particular, assert that restrictions on their longstanding business model are counterintuitive to opponents' stated goal of increasing availability and access to medicines. They contend that efforts to substantially limit their control over pricing and intellectual property ultimately stifle innovation by reducing the amount of funds available for and inclination to step up R&D. Such developments, they warn, can only have a negative impact on their ability to bring new drugs to the market.

There are elements of truth in those arguments. After all, most pharmaceutical companies are for-profit entities that respond to profit-making incentives. Most civil society advocates and developing country governments accept that business model, but stress at the same time that the prices some companies charge for key essential medicines seem unreasonably high and thus have no relation to consumers' relative buying power in different nations. The failure rate of R&D efforts also does not justify high drug prices since the industry itself says that total R&D (including failure rate) is less than 20 percent of industry costs.[7] Many advocates also note that drug companies often benefit from government-financed research, especially in the United States and Western Europe, to produce new medicines. Frequently they spend little or nothing on R&D for such compounds, yet reap benefits from selling finished products on the open market.

Even though public opinion is increasingly on their side, developing countries seeking to boost access to essential medicines often find these barriers difficult to overcome. It can take years to build up critical in-country capacity to fully understand, lobby for, and implement TRIPS flexibilities. Many LDCs (least developed countries), for example, have not moved aggressively even though a special TRIPS clause exempts them from needing to recognize, protect, or enforce patents until 2016.

Many developing countries also find it difficult to resist pressure from developed nations and influential commercial interests in their own countries to resist signing trade agreements containing TRIPS-Plus provisions. And finally, deep-pocketed pharmaceutical companies are not shy about threatening to unilaterally pull vital products from local markets if they feel their rights are not upheld.

5.3 Overcoming the barriers and moving forward

There is ample evidence that these obstacles are not insurmountable. A growing number of developing country governments have stepped up pressure on drug companies and exercised their legal TRIPS rights in recent years. The majority of steps have been taken in response to HIV epidemics, including in Indonesia, Malaysia, Mozambique, Zambia, and Zimbabwe. Developments in a number of other countries in recent years also offer important and useful examples for national governments and their civil society allies seeking to increase access to essential medicines. They include the following:

[7] See, for example, "Research and Development in the Pharmaceutical Industry," an October 2006 report from the U.S. Congressional Budget Office. Online in PDF format: www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

- **South Africa**: Patent-holding multinational and domestic pharmaceutical companies have signed several agreements to allow the domestic production of lower-cost, generic drugs, notably ARVs. Civil society has played the leading role in using national laws, which were amended to allow TRIPS flexibilities, to pressure makers of branded drugs to lower prices.

- **Thailand**: Since 2006, the government has utilized TRIPS flexibilities by issuing seven compulsory licenses—including two for ARVs and one for a drug to treat heart disease. The government has also considered issuing similar licenses for certain cancer drugs.

- **Brazil**: In May 2007, the government issued a compulsory license for an important ARV, efavirenz. Unlike in Thailand, where policymakers acted relatively forcefully, the Brazilian government took that step reluctantly when faced with rising costs of a much-needed drug. Health and trade officials previously had focused on negotiations with patent-holding companies for price discounts of patented products. Like Thailand, Brazil has a domestic pharmaceutical industry with the capacity to manufacture generics.

- **Philippines**: Government officials in 2006 imported generic samples of a key hypertension drug so they could prepare for generic drug registration when the medicine's patent expired a year later. However, the patent-holding company filed a lawsuit against the officials, claiming improper patent infringement because there was no specific domestic law permitting such action. With civil society backing, the government in early 2008 was poised to approve a new law that specifically permits the steps its officials took, known as "early working" of patented drugs, as part of an effort to speed up marketing authorization. The new law is also intended to facilitate the use of compulsory licensing, and it includes a price control system and other important measures to lower prices and promote access to important medicines.

- **Rwanda**: A relatively new TRIPS flexibility was first utilized in Rwanda in 2007. A WTO waiver agreed to in 2003 is intended to increase options for countries without domestic pharmaceutical manufacturing capacity to access lower priced generic drugs. Under the original TRIPS provisions, countries like Rwanda were largely unable to issue compulsory licenses on their own because the drugs in question could not be made domestically.

  In July 2007, the Rwandan government announced its intention to import a generic ARV combination from a manufacturer in Canada. The Canadian government had changed its national patent law so it—not Rwanda, the country to benefit directly—could formally issue a compulsory license permitting the generic drug maker to manufacture the combination using medicines still under patent in Canada. The Canadian government duly did so a couple of months later, and then notified the WTO (as required by TRIPS).

- **Kenya**: The government in 2002 passed a law that put it in compliance with TRIPS. The law contains provisions specifically permitting the utilization of a range of TRIPS flexibilities, including parallel importation of vital medicines from abroad. Kenyan civil society groups have been instrumental in resisting persistent efforts to weaken the law. Voluntary licenses have also been pursued in Kenya with domestic pharmaceutical firms reaching agreements with patent-holding companies to produce generic medicines for the local market. Two voluntary licenses agreed to in 2004 led to steep reductions in the domestic price of important ARVs.

These examples are similar in that they are all based on intellectual property rights, rules, and procedures. They differ, though, in scale and approach, with some emphasizing the retention of patent rights and others overriding them decisively. Altogether, they illustrate the variety of different approaches and strategies that might be used, depending on a nation's economic status, health care needs, and expertise. Each example is discussed more extensively in this publication's case studies (Section 6).

Finally, it is important to reiterate that both the WHO and the WTO, the world's preeminent health and trade bodies, respectively, are on record as supporting utilization of TRIPS flexibilities to the fullest extent possible. In April 2006, the WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) released a massive report titled "Public Health, Innovation, and Intellectual Property Rights." The report aimed to establish parameters and guidelines not only for governments, but for all other stakeholders involved in health-related intellectual property issues. Among its 50-odd recommendations were the following:[8]

- All companies should adopt transparent and consistent pricing policies, and should work toward reducing prices on a more consistent basis for low and lower middle income developing countries.
- Access to drugs cannot depend on the decisions of private companies alone and governments should take an active responsibility in making medicines accessible.
- Developing countries should retain the possibilities to benefit from differential pricing, and the ability to engage in parallel importation of lower priced medicine.
- Countries should enact legislation to encourage generic entry on patent expiry, such as the "early working" exception.

[8] See www.who.int/intellectualproperty/report/en/.

6. Case studies

The case studies in this section focus on recent developments and achievements in six developing countries. (Only one—Rwanda—is technically considered an LDC.) Policymakers in all six nations have sought to increase access to essential medicines by exercising legal rights enshrined in the WTO's TRIPS agreement. Broadly speaking, the three larger economies are listed first, followed by the three smaller ones.

6.1 South Africa

Key legal and regulatory issues:

Parliament has passed three laws that specifically address and permit TRIPS flexibilities, including the Patents Act (1978, amended thereafter, most notably in 2002); the Medicines and Related Substances Act (1965, amended thereafter, most notably in 2002); and the Competition Act (1998, amended thereafter).

Mechanism(s) used to lower drug prices and increase access to essential medicines:

- Legal challenges and threats of lawsuits, instigated largely by civil society

Important factors:

South Africa is a developing country with a strong civil society sector. Local NGOs such as the Treatment Action Campaign (TAC) and the AIDS Law Project (ALP) have extensive experience using various means available to increase access to essential medicines, especially those to treat HIV. In particular, they have used legal means to pressure the government and various pharmaceutical companies. TAC and its allies frequently cite the South African constitution, which guarantees the right of access to health care services, and amendments to specific laws passed in recent years to allow the use of TRIPS flexibilities.

Local civil society mobilization in South Africa benefited greatly from the support of international organizations and advocates, especially in the early years of the century when TAC and other key local groups were being formed. For example, international expertise and engagement were vital in one high-profile case from six years ago: the successful effort to convince South African courts to reject pharmaceutical companies' challenges to provisions in the Medicines and Related Substances Act.

Recent developments and achievements:

Example 1: Threat of lawsuit prompts multinational company to unilaterally lower prices.[9] The drug amphotericin B is an antifungal agent used to treat cryptococcal meningitis, a common cause of death among HIV-positive people in South Africa. The only version available in the country is known by the brand name Fungizone and is made by the multinational firm Bristol-Myers Squibb (BMS).

After conducting extensive research, a group of local civil society organizations including the Treatment Action Campaign (TAC) and the Southern African HIV Clinicians' Society realized a few years ago that a generic version of the drug was sold in Brazil at a far lower price than BMS charged in South Africa. They also uncovered numerous other pricing discrepancies indicating that the price BMS charged in South Africa for amphotericin B was far higher than nearly anywhere else. For example, the British public health system purchased the branded version itself at a price less than 30 percent of its cost in South Africa.

The two organizations contacted the AIDS Law Project (ALP), a local civil society group with extensive experience in legal issues related to access to medicines.[10] In February 2005, ALP sent a letter to BMS in which it outlined the civil society organizations' intention to file a formal complaint with the government's Competition Commission against the drug maker for excessive pricing. ALP based its actions on a provision in South Africa's Competition Act permitting the lodging of such a complaint against a company with a monopoly on a product.

According to media reports, BMS considered resisting. However, it ultimately capitulated and agreed to reduce the price of Fungizone by 80 percent and 85 percent, respectively, in the South African public and private sectors. Three weeks later, in April 2005, ALP notified BMS that it would not proceed with the complaint.

Example 2: Lawsuit leads to licenses with local manufacturer of generic medicines.[11] In September 2002, TAC and 11 parties, including people living with HIV, filed a complaint with the Competition Commission against two leading multinational drug makers, GlaxoSmithKline (GSK) and Boehringer Ingelheim. The complaint accused the two companies of violating the Competition Act by using their dominant positions to not only keep prices high, but also to restrict competition. Specifically, the complaint focused on what it called the companies' excessive pricing of four ARVs: ritonavir, lamivudine, ritonavir+lamivudine and nevirapine.

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[9] The following is the primary source for this information: Avafia, T., Berger, J. and Hartzenberg, T. 2006. "The ability of select sub-Saharan African countries to utilize TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: A study of producing and importing countries." Tralac Working Paper No 12. Stellenbosch, South Africa: US Printers.

[10] The following source contains additional recent information about ALP: Hassan, F. and Berger, J., "Health Service Delivery and Health Sector Transformation." AIDS Law Project, 18 month review: January 2006 to June 2007, Section 4.

[11] See www.keionline.org/index.php?option=com_content&task=view&id=41.

The commission took more than a year to investigate. But eventually, in October 2003, it released a preliminary finding stating that there was enough evidence to refer the case to a full Competition Tribunal hearing. The announcement prompted GSK and Boehringer to negotiate with the commission. Two months later, GSK reached a settlement that included granting three licenses for local production of generic versions of the company's branded ARVs.[12] A previously existing license for another ARV was extended to include the private sector as well as the public one. Other precedent-setting elements of the agreement did the following:

- allowed the new licensees to export the ARVs to sub-Saharan African countries
- permitted the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa
- allowed the licensees to combine the relevant ARV with other antiretroviral medicines
- restricted GSK from charging the new licensees royalties in excess of 5 percent of net sales of the ARVs

Some five years later, TAC and ALP continue to use a similar strategy. Most recently, in November 2007, ALP filed a complaint with the Competition Commission in response to what it considers the excessive high price of another ARV, efavirenz, sold by the South African subsidiary of Merck. Among other things, the complaint alleges that the two companies' "refusal . . . to allow sufficient generic competition contributes significantly to the high cost of the drug." The civil society groups said they wanted the commission to compel the companies "to issue multiple licenses on reasonable terms" as part of an overall effort to force down the price.[13]

6.2 Thailand

Key legal and regulatory issues:

Domestic laws and policies are in place specifically allowing the use of TRIPS flexibilities.

Mechanism(s) used to lower drug prices and increase access to essential medicines:

- Compulsory licenses
- Negotiations with patent-holders

Important factors:

Thai health authorities generally have sought to negotiate voluntary licenses and price discounts with patent-holding companies for vital medicines. However, beginning in

[12] The commission reached a similar agreement with Boehringer Ingelheim shortly after the GSK settlement was announced.
[13] For additional information, see TAC's electronic newsletter, November 7, 2007. Online: www.tac.org.za/nl20071107.html.

2006 the Thai government issued a series of compulsory licenses in cases where it believed no substantial progress was being made. Local and international civil society organizations are consistent supporters of both the Thai government's tactics and scope of action. They are particularly pleased that the government has not buckled under strong pressure from the pharmaceutical industry and key trading partners, notably the United States, to not break existing patents.[14]

A few other unique factors underpinned Thailand's recent inclination and ability to exercise its compulsory licensing rights. For one thing, according to Spring Gombe, a senior health policy advisor at KEI,[15] the country has long had committed and influential supporters of such steps within the health ministry. This has helped overcome reluctance or opposition among officials elsewhere in the government, including in the foreign and commerce ministries. In addition, the country has a well-organized civil society movement focusing on access to essential medicines. Some of the most educated, vocal, and influential groups were established by and continue to be run on behalf of people living with HIV.

Thailand also benefits from the fact that it is a fast-growing, middle-income country with relatively high education levels. It also has domestic capacity to manufacture pharmaceuticals. That capacity was enhanced in 2002, when the state-run Government Pharmaceutical Organization (GPO) began producing a generic version of a common first-line ARV regimen. At that time, policymakers were almost exclusively interested in local production of ARVs to treat the tens of thousands of HIV-positive Thais in need. Although the domestic manufacture of generics is still relatively new and limited in Thailand, its introduction has helped build a political culture in support of generic competition. The crucial expertise obtained from the initial experience with ARVs can now be utilized for domestic production of medicines for numerous other conditions as well.

Recent developments and achievements:

Beginning in late 2006, the Thai government exercised its right to issue compulsory licenses seven times in less than a year. Altogether those steps have marked the most extensive and far-ranging effort to date by one developing country to utilize that specific TRIPS flexibility.

The government's decisions followed failed efforts to lower the costs of branded drugs through negotiations with patent-holders. The government initiated negotiations because it wanted to hold down public-sector health care costs and thereby be able to provide the

[14] In early 2008 there were signs indicating a potential weakening of Thailand's commitment to utilize TRIPS flexibilities to ensure lower prices for essential medicines. Most notably, the country's newly appointed health minister, Chaiya Sasomsap, announced in February 2008 that he had formed a committee to review the legality of compulsory licenses issued by his predecessor. A few weeks later, the head of Thailand's Food and Drug Administration, who had played a central role in the issuing of the compulsory licenses, was removed from his post by Chaiya. In March 2008, however, Chaiya publicly announced that he supported the continuation of the government's compulsory license efforts.

[15] Interviewed in Geneva, Switzerland, November 6, 2007.

medicines to all who need them. (It should be noted that WTO rules do not require governments to undertake negotiations prior to issuing compulsory licenses; neither do relevant national laws in Thailand.)

The first drug in question was efavirenz, an increasingly important ARV used primarily in second-line regimens.[16] The drug's maker, Merck, had exclusive rights to sell it in Thailand. By the mid-2000s, the company reportedly had priced the drug at nearly $500 per patient per year, more than twice the cost of generic versions made in India. The relatively high cost of efavirenz meant that Thailand's health ministry could only offer it to about two-thirds of potentially eligible patients. That shortfall jeopardized the government's much-admired effort to provide free ARV treatment to all in need.

In November 2006, the health minister issued a compulsory license that allowed the government to import generic efavirenz and to permit domestic production. Shortly thereafter, the government refused to rescind its decision even though Merck offered to lower its price by almost half, to $288 per patient per year, if the company could retain exclusive rights. The first supply of generic efavirenz, imported from India, was available in Thailand just three months later.

In January 2007, the government followed suit by issuing compulsory licenses for two other drugs. One was for the ARV lopinavir+ritonavir, sold by Abbott Laboratories under the brand name Kaletra. The other was for clopidogrel bisulfate, a medicine used to treat heart disease and sold by Sanofi-Aventis under the brand name Plavix. In both cases, the government reportedly had negotiated regularly for significantly lower prices for more than a year. Both brand-name drugs were sold at prices far higher than generic versions elsewhere. At the time, for example, the price of generic versions of Plavix was less than 5 percent of the brand-name version.

The government's decision enraged both companies. Nevertheless, Abbott continued negotiating with the government in the hope of reaching an agreement that would maintain its dominant position in the Thai market for lopinavir+ritonavir. Over the next few months, the government rejected several options presented by Abbott, noting that the prices offered for Kaletra remained higher than potentially available generic versions.

Abbott subsequently announced that it would withdraw applications to sell at least seven new drugs in Thailand. The company's announcement sparked widespread rage among civil society advocates worldwide, with several groups calling for a boycott of its products.

The Thai government remained unwilling to accept Abbott's terms and withdraw the compulsory licenses. In May 2007, the then–health minister, Mongkol Na Songkhla, clarified the situation for Abbott, Sanofi-Aventis, and all other drug firms when he stated

[16] Additional information and background on all three compulsory licenses discussed in this section may be found at the following source: Ford et al, "Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand," *AIDS* 2007, 21 (suppl 4):S21–S29.

that Thailand would not issue compulsory licenses to produce reduced-cost versions of patented drugs if pharmaceutical companies offer prices that are roughly equal (within 5 percent) of those charged by generic drug makers.

Sanofi-Aventis, meanwhile, enlisted the support of European Union (EU) Trade Commissioner Peter Mandelson (Sanofi-Aventis is a French company). In July 2007, Mandelson publicly called the Thai government's actions "a matter of concern for the European Union."[17] He did not specify whether the EU was considering or would pursue any actions in response, but his statement was viewed as threat by many observers in Thailand and elsewhere.

The health ministry justified its decision to issue the compulsory license on the fact that Plavix's high price meant that fewer than 10 percent of the estimated 300,000 heart disease patients in Thailand could afford it. The ministry added that heart disease was the country's second leading cause of death after HIV/AIDS.[18]

The impact of the earliest licenses became clear within a very short time. According to one recent report, the availability of lower-priced generics meant that the number of HIV-positive people in Thailand receiving efavirenz and lopinavir+ritonavir had already tripled by January 2008.[19] That month the health ministry announced plans to issue compulsory licenses on four additional drugs, all used to treat cancer: docetexel (sold by Sanofi-Aventis under the name Taxotere); letrozole (sold by Novartis as Femara); erlotinib (sold by Roche as Tarceva); and imatinib (sold by Novartis as Glivec outside the United States).[20]

6.3. Brazil

Key legal and regulatory issues:

The national legislature passed a law in 1996 requiring the federal government to ensure that all people living with HIV received free treatment and care. The law and its subsequent enforcement have been hailed by the WHO, HIV/AIDS advocates, and human rights organizations as one of the most comprehensive and humane responses to the epidemic anywhere in the world, at least in terms of treatment. Because of the guarantees it contains, the law has prompted the government to consider options to reduce the cost of ARVs it provides to all who need them.

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[17] AFX News Limited, "Thailand to buy generic rivals to Sanofi-Aventis', Bristol-Myers Squibb's Plavix," August 22, 2007. Online: www.abcmoney.co.uk/news/222007122374.htm.
[18] Ibid.
[19] "Thailand lowers medicine prices; faces U.S./E.U. pressure," Essential Action's Global Access to Medicines Bulletin, Issue No. 3, April 14, 2008. Available online: www.essentialaction.org/access.
[20] Ibid. At the time this report was finalized, it was unclear whether all of the compulsory licenses would in fact be issued. The government reportedly was not planning on implementing at least one, for imatinib, because the manufacturer (Novartis) had agreed to donate supplies of the medicine as needed.

Brazil's patent law contains a few unusual post-TRIPS provisions and amendments:

- One amendment, passed in 2001, authorizes the country's drug regulatory agency to review patent applications for pharmaceutical products. This mechanism, known as "prior consent," gives health authorities a formal role in the process. As such, patent applications are regularly reviewed from a public health perspective in addition to the narrower perspective of patent authorities. (It is important to note, however, that the drug regulatory agency's consent is not required for the issuance of a patent by patent authorities.)
- Another provision is aimed at ensuring local production of crucial medicines. It specifically allows the government to issue a compulsory license to another manufacturer if the patent-holder does not produce the medicine in Brazil within three years of patenting. (As of January 2008, the government reportedly had not exercised the provision.)

Mechanism(s) used to lower drug prices and increase access to essential medicines:

- Negotiations with multinational drug firms
- Threats to issue compulsory licenses
- Compulsory licenses

Important factors:

Local production of nonpatented ARVs is one of the two main complementary strategies used by the government to lower drug costs. Brazil has a significant generics industry. In July 2007, for example, eight of the 17 ARVs purchased by the government were manufactured domestically.[21] They accounted for nearly one-half of all ARVs used in the country.

The other strategy focuses on price negotiations with pharmaceutical companies for newer drugs that are subject to patent. Over the years, the Brazilian government has wielded the threat of compulsory licensing, credible because of its domestic production capacity, during such negotiations as it tries to pressure patent-holding companies into reaching agreements for significantly reduced prices over a set period of years. That strategy has been used to reach settlements on price discounts with patent-holders in numerous cases, including in 2001 (for the ARVs efavirenz and nelfinavir); in 2003 (for the ARV lopinavir in addition to efavirenz and nelfinavir); in 2005 (for the combination ARV lopinavir+ritonavir); and in 2006 (for the ARV tenofovir and the cancer drug imatinib mesylate, which is commonly known by the brand name Glivec outside the United States).

Price discounts reached in such agreements have generally exceeded 50 percent of the original brand price. The total combined costs savings from this strategy—negotiations to reduce the price of patented drugs—and generic production have been massive.

[21] Ford et al, "Sustaining access to antiretroviral therapy in the less-developed world: Lessons from Brazil and Thailand", *AIDS* 2007, 21 (suppl 4):S21–S29.

According to one recent estimate, the Brazilian health ministry saved approximately $1.2 billion on ARV purchasing costs from 2001 to 2005 alone.[22]

However, most advocates believe that the government's negotiating ability weakened over the years because it never actually did issue a compulsory license. In their view, companies began to see the threat as hollow, a perception that prompted some firms to drive harder bargains. According to Judit Rius Sanjuan, a staff attorney at KEI, it was definitely a "problem" that "the country talked about issuing compulsory licenses for years but never acted."[23] She added that the lack of action by Latin America's largest economy had a "negative impact on other countries" in the region. Policymakers in those countries, she said, were reluctant to consider compulsory licenses in the absence of strong leadership from Brazil.

Rius Sanjuan's concerns were echoed by a local MSF representative, Michel Lotrowska.[24] He said the 2005 agreement with Abbott for the ARV lopinavir+ritonavir (sold under the brand name Kaletra) was particularly "bad" because it set a fixed price for several years that was "far too high."

Recent developments and achievements:

The Brazilian government finally followed through on its threat in May 2007 when it announced a compulsory license for efavirenz, an ARV sold and distributed by Merck under the brand name Stocrin.

At the time, some 75,000 people living with HIV—more than one-third of those on ART at the time in Brazil—reportedly were taking efavirenz as part of their treatment regimen. Moreover, health authorities expected that share to rise because efavirenz is considered an especially effective drug. Yet the medicine cost significantly more than most other ARVs purchased and distributed by the government. Most first-line medicines, for example, cost far less than $1 per person per day.

Prior to the compulsory license, Merck was charging the Brazilian government about $1.60 per dose for the medicine. That represented a deep discount over the drug's cost per dose in the United States (nearly $16). However, it was far less than what Merck had offered Thailand for the brand-name version ($0.65)—which the Thai government eventually rejected in favor of issuing its own compulsory license in November 2006—or the price of available generic versions from abroad ($0.45).

The government asked Merck to lower the price to match that offered in Thailand ($0.65). However, Merck refused to consider a price discount below $1.10. Civil society

[22] Nunn AS, Fonseca EM, Bastos FI, Gruskin S, Salomon JA (2007). "Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment." *PLoS Med* 4(11): e305. Online: http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040305&ct=1 (accessed February 15, 2008).
[23] Interviewed in Geneva, Switzerland, November 9, 2007.
[24] Interviewed in Geneva, Switzerland, November 6, 2007.

leaders were heartened by the fact that the government did not cave in this time, as they believe it did during negotiations a couple of years earlier with Abbott over Kaletra. The decision to issue the compulsory license is also expected to lead to additional significant cost savings for the public health system. According to one source, purchasing a generic version of efavirenz could save Brazil some $240 million by 2012, when Merck's patent on the drug expires.[25]

The comparison with Thailand is instructive. There are numerous similarities between the nations: Both are middle-income countries, and both are considered trailblazers in terms of ensuring public-sector access to free or reduced price essential medicines. Yet Brazil's government traditionally had been much more cautious about exercising the most aggressive mechanisms possible under TRIPS. Its eventual decision to do so took place several months after Thailand had issued three high-profile compulsory licenses. On the one hand, it is possible that Brazilian authorities were emboldened by Thailand's example and moved forward in a show of open solidarity and support. Some observers believe, however, that Brazilian policymakers felt comfortable taking their forceful step only because Thailand's aggressive steps shielded them from criticism and pressure from multinational companies and their developed country allies.

Regardless of the reasons, Brazil's step is seen as vital by civil society groups. According to Lotrowska, the development "is important because it means the government can likely get much better deals in the future through negotiating. Companies now realize it's capable of going through with its threat to issue compulsory licenses."[26]

Rius Sanjuan said she hoped as well that the decision "will open the floodgates for other countries in the region" to threaten—and perhaps follow through with—the issuing of compulsory licenses.[27]

6.4 Philippines

Key legal and regulatory issues:

Growing public demand, encouraged by civil society, for changes in the intellectual property code to improve access to essential medicines. A sweeping new law had passed the House of Representatives and Senate by December 2007 and was expected to be signed into law in 2008.

Mechanism(s) used to lower drug prices and increase access to essential medicines:

- Parallel importation
- Seeking to invalidate patents
- Drafting and passing new laws

[25] See www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44715.
[26] Interviewed in Geneva, Switzerland, November 6, 2007.
[27] Interviewed in Geneva, Switzerland, November 9, 2007.

Important factors:

Although not classified as an LDC, the Philippines is still a relatively poor country. Yet, according to Filipino government officials citing data from 2006, only Japan among other Asian nations had more expensive medicines overall than the Philippines.[28] According to media reports, some drugs were priced from 5 to 45 times higher than in India and Pakistan, for example, both of which are at a broadly similar economic level. The government reportedly concluded that the high cost of medicines is one of the main reasons that some 70 percent of Filipinos have no regular access to lifesaving drugs.[29]

Most medicines are far more expensive in the Philippines because the country has some of the most rigid intellectual property policies in the region. Partly in response to intense pressure from major allies such as the United States, the government over the years has acted far more cautiously than many of its nearby counterparts in considering laws that allow the utilization of TRIPS flexibilities and other legal options to increase access to lower-priced drugs.

In recent years, local civil society groups have redoubled their efforts to change the situation. Some have joined coalitions such as Effective Medicine for Affordable Prices, which has been especially scathing in its criticisms of the high drug prices charged by many patent-holding multinational pharmaceutical companies. The groups' successful efforts to draw attention to the problem have been bolstered by a classic case of industry hubris and overreach, as discussed below.

Recent developments and achievements:

Example 1: Background and lawsuit regarding Norvasc patent. One of the most effective medicines to treat hypertension (high blood pressure) is amlodipine besylate, a drug developed by Pfizer and sold by it under the brand name Norvasc. Until recently Pfizer had an exclusive patent on the drug in the Philippines. It thus faced little pressure or incentive to lower costs. As a result, the company in 2006 was charging the equivalent of $1.46 for a single 10 mg dose in the Philippines, according to KEI's Judit Rius Sanjuan.[30] That price was much higher than it was charging in India for the same dose ($0.18), where the company faced generic competition.

The public health system could not afford to purchase or supply Norvasc for the majority of the nearly 8 million Filipinos estimated to suffer from hypertension. Its high price also limited the number of needy individuals who could purchase it out of pocket. By 2006, health officials were anticipating the expiration of Pfizer's patent on Norvasc in the Philippines in June 2007. From that point on, the sale and distribution of cheaper generic versions would be legal under Filipino law.

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[28] Associated Press, "Philippines trying to cut medicine cost," June 14, 2006. Online: www.globalaging.org/health/world/2006/cutcost.htm .
[29] Ibid.
[30] See http://secondview.blogspot.com/2006/03/pfizer-is-suing-philippines.html.

In preparation for that date, authorities at two government agencies, the Philippine International Trading Corporation (PITC) and the Bureau of Food and Drugs (BFAD), took steps designed to ensure that generic versions would be available immediately upon the patent's expiration. Two officials therefore traveled to India, bought 200 doses of a generic version of Norvasc, and returned home. They gave the samples to the BFAD to test for safety and efficacy. The goal was to have the analysis completed in advance so the imported generic version would be properly registered by the time the patent expired.

The government officials' action was perfectly legal under TRIPS. Known as "early working," agencies are able to use a patented invention without the consent of the patent holder for the purposes of preparing a generic version in advance of the patent expiration. The goal in such cases is to have a generic version ready to go on the market upon patent expiration. Pfizer, however, did not see it this way and filed a lawsuit in March 2006 against the PITC, the BFAD, and the two officials themselves. A Pfizer press release stated the following: "Pfizer's position is that the agencies' dealing with Norvasc (amlodipine besylate) supposedly sourced from India, without the authority of the patent owner, violates the law. The complaint further states that BFAD and its officers induced the violation of Pfizer's patent rights by granting registration approval to PITC."[31]

Pfizer's action precipitated an outpouring of condemnation against the company and soon backfired spectacularly. It was seen as unnecessary, inappropriate, and mean-spirited. For one thing, according to numerous advocates and experts, although "early working" was not explicitly permitted by the country's Intellectual Property Code, it had been "standard practice for several years without previously being challenged."[32] It was also legal in most other countries, including the United States (where Pfizer has its headquarters).

It was not only civil society groups and consumers who were outraged; so were most government officials. They refused to return the doses and vowed to fight the lawsuit. The legislature, formerly mostly quiescent in regards to issues related to access to medicines, also got into the act. In a speech in the House of Representatives, Rep. Ferjenel Biron called for a boycott of all Pfizer products. He accused the company of "persecuting millions of Filipinos who simply could not afford to buy the said medicine and are left with no choice but just to die."[33]

In May 2007, meanwhile, Senator Mar Roxas and allies announced support for a petition filed by PITC to nullify Pfizer's Norvasc patent altogether, even before it expired. PITC based its petition to the country's Intellectual Patent Office on a March 2007 U.S. appeals court decision invalidating the company's patent for the drug in the United States. The U.S. court based its ruling, which reversed three lower court decisions, on a

[31] See www.pfizer.com.ph/corporate/news/main.php?page=3Drelease&ID=3D95.
[32] Leonard, A, "Pfizer's Philippine follies", April 4, 2006. Online at Salon: www.salon.com/tech/htww/2006/04/04/pfizer/index.html.
[33] Associated Press, "Philippines trying to cut medicine cost," June 14, 2006. Online: www.globalaging.org/health/world/2006/cutcost.htm.

determination that Norvasc was not a novel product.[34] The PITC subsequently said the continuation of Pfizer's patent was "contrary to public order and morality."[35]

The PITC's demand for Norvasc's patent revocation was purely symbolic in one sense because the patent was due to expire less than two months later, in June 2007. Lower-priced generic versions of the drug have since become available in the Philippines, thereby offering greater opportunity for those in need to afford regular treatment. Yet the agency's demand was much more than symbolic in other respects because it set a legal precedent for other patent invalidations in the future. The entire affair also represented a huge boost in confidence for government officials who previously would have been far more reluctant to take on a multinational pharmaceutical company with influential support in a key ally (the United States, in this case).

Example 2: Amending the Filipino intellectual property code. The Norvasc debacle led directly to another development that will likely have far-reaching implications on access to a wide range of essential medicines. With the support of civil society, some legislators had drafted a bill in 2005 to amend the country's intellectual property code. From the beginning, the bill aimed to lower the price of drugs by specifically permitting the government to utilize several TRIPS flexibilities, including parallel importation.

The bill languished in Congress over the next couple of years. It almost passed in 2006, but ultimately failed in the wake of strong pressure from multinational drug firms. Growing public outrage over Pfizer's lawsuit, stoked by civil society, helped turn the tide. Civil society groups highlighted that the constitution requires the government to "protect and promote the right to health of the people and instill health consciousness among them."[36] They organized demonstrations and found patients willing and able to meet with legislators.[37]

The bill was reintroduced in 2007. In December, the House of Representatives approved by a vote of 205–0 the third and final reading of the bill, with the Senate following suit shortly thereafter. The bill was expected to be signed into law by the end of 2008, although campaigners for access to medicines had raised concerns that the bill might be modified at the last moment.

The new law would remove various barriers to the issuing of compulsory licenses, empower the local generics industry to experiment on drug formulas even before their patents expire, and deny new patent protection for slightly modified versions of a patented medicine. In addition, it mandates the creation of a Drug Price Regulation Board

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[34] The appeals court's decision is available online in PDF format: www.cafc.uscourts.gov/opinions/06-1261.pdf.

[35] Bondoc, J, "Hypertensive Filipinos deserve price relief," *Philippines Star*, May 17, 2007. Online: www.abs-cbnnews.com/storypage.aspx?StoryId=77575.

[36] See www.gov.ph/aboutphil/a2.asp.

[37] Interview with Rohit Malpani, trade policy advisor at Oxfam America, in Geneva, Switzerland, November 6, 2007.

with the power to regulate retail prices of medicines and drugs. Medicines covered by the proposed price regulations would include the following:[38]

- drugs or medicines indicated for treatment of chronic illnesses and life-threatening conditions such as diabetes, endocrine disorder, gastrointestinal disorders, peptic ulcer, cardiovascular diseases, and hypertension
- drugs or medicines indicated for prevention of diseases, including vaccines, immunoglobulin and anti-serums
- drugs or medicines indicated for prevention of pregnancy, such as oral contraceptives
- anesthetic agents
- intravenous fluids
- drugs or medicines included in the Philippine National Drug Formulary (PNDF) Essential Drug list
- all other drugs or medicines which from time to time the board determines to be in need of price regulation.

6.5 Rwanda

Key legal and regulatory issues:

A government in a developed country (Canada) amended its national intellectual property law to implement the TRIPS waiver agreed to by WTO Members in August 2003.

Mechanism(s) used to lower drug prices and increase access to essential medicines:

- A special form of compulsory license enabling the export of generic medicines to a country where production is not economically feasible

Important factors:

According to UNAIDS, some 200,000 people in Rwanda are living with HIV.[39] The majority of those in need do not yet have access to ART. Although the country receives donor assistance for its HIV treatment and care efforts, the sheer number of those who need ART now continues to dwarf its resources. The situation will likely get only worse in the future as more HIV-positive people become ill. The government and local and international civil society groups are therefore keen to explore options available to obtain access to lower-priced ARVs.

As an LDC, Rwanda is not currently required under TRIPS to grant or uphold patents for medicines. However, the country's ability to exercise a full range of TRIPS flexibilities is somewhat limited by the fact that it does not have domestic pharmaceutical manufacturing capacity.

[38] As per e-mail correspondence received December 19, 2007 from Judit Rius Sanjuan of KEI.
[39] See www.unaids.org/en/CountryResponses/Countries/rwanda.asp.

Several developing nations and civil society groups worked over the years to broaden the provisions in TRIPS governing compulsory licensing. They identified the following as one of the key barriers to lower-cost, generic medicines: the restriction on using compulsory licensing only to produce "predominantly" for a country's own domestic market. That restriction limited the ability of a country with pharmaceutical manufacturing capacity to use compulsory licensing to export to countries without production capacity. The end result was a significant obstacle on the ability of the most resource-constrained nations to obtain the lowest priced medicines possible.

WTO members eventually listened. In 2003, they agreed on a waiver—which was made permanent in 2005—to the TRIPS compulsory licensing provisions. The waiver allowed countries with manufacturing capability to issue compulsory licenses on behalf of those without. A pharmaceutical company would then have the legal ability to make generic drugs in one country for export to another country. Taking such a step could require changing national patent laws in the country with manufacturing capacity to take advantage of this new flexibility: this would allow compulsory licensing to be used primarily (or even exclusively) to produce generic drugs for export to countries needing to import them.

As of the end of 2007, only a few countries had altered their national laws in such a way that would allow them to take advantage of the legal waiver. The handful of countries included Canada, Norway, China, South Korea, and India; in addition, the European Commission had adopted a policy allowing member-states to take advantage of the waiver.

The WTO waiver requires both participating countries to specifically notify the WTO when they use it. The generic firm, meanwhile, must create a public website providing information about (i) the quantity of medicine to be exported under the agreement and (ii) key distinguishing characteristics of the product that distinguish it from the brand-name product sold by or on behalf of the patent-holder, including packaging, shaping, and coloring. The latter requirement aims to ensure that the generics are not illegally diverted into other markets.

Recent developments and achievements:

The Rwanda case took years to reach fruition. Discussions began in 2003 as Rwanda policymakers began searching for access to cheaper generic drugs. These discussions resulted in them tentatively reaching an early deal with a Canadian pharmaceutical company, Apotex. The next steps depended on action by the Canadian Access to Medicines Regime (CAMR). That regime was created by the government specifically to implement the 2003 WTO waiver and, ultimately, to permit compulsory licensing of pharmaceuticals patented in Canada for the purposes of exporting lower-priced generic medicines to eligible developing nations.

Unfortunately, setting the guidelines and parameters of CAMR proved to be a bottleneck. The process took nearly three years following the establishment in 2004 of CAMR. Officials claimed that the slow pace stemmed from the need to understand and address every potential complexity in the TRIPS agreement, including the waiver. Critics, including leading civil rights groups in Canada, blamed those working on CAMR for being excessively cautious and adding unnecessary complexities themselves.

In any case, things eventually moved forward. In July 2007, Rwanda formally informed the WTO that it intended to import from Apotex 260,000 packs of a generic combination drug called ApoTriavir over a period of two years.[40] That corresponds to at least 15 million individual tablets, which would be enough to treat about 21,000 people over one year.[41]

Apotex also encountered obstacles that slowed down the process. As required under CAMR, Apotex approached the patent-holders with a request for a voluntary license. That effort was not successful in the end. Having satisfied the CAMR requirements nonetheless, Apotex then applied for and was issued a compulsory license by the Commissioner of Patents in September 2007. The following month, the Canadian government notified the WTO's TRIPS Council that it had authorized Apotex to make ApoTriavir for export to Rwanda. The notification contained mandated information about the license, the quantity to be exported, and the two-year duration of the agreement.

Apotex said initially that it would price ApoTriavir at about $0.40/tablet, which translates into less than $200 a year per person. The company added that it expected the price to decline once the pipeline was running and certain components of the product were sourced more cheaply.

Implications:

This example represents the first compulsory license for export issued anywhere in the world under the terms of the 2003 WTO waiver. In some respects, it is difficult to yet know how effective this strategy might be for countries in need. Nearly four years after the waiver was announced, Rwanda is the first country to actually use it. Moreover, no drugs had arrived as of December 2007. As this publication was being prepared, Rwanda was expected to issue an international tender for bids from potential suppliers. Apotex was expected to submit a bid now that it was in possession of the necessary legal authorization to produce the drug in Canada for export. If Apotex succeeds against other possible competitors in the tender, the first shipment of ApoTriavir would be expected to reach Rwanda sometime in 2008.

One thing seems clear: Although the waiver offers a potentially appropriate strategy, especially for the world's poorest nations, its first use was burdened with far too many unnecessary and inappropriate complexities. Some leading civil society groups in Canada

[40] ApoTriavir is a generic fixed-dose combination ARV comprising zidovudine, lamivudine and nevirapine.
[41] "Canada to manufacture antiretroviral for Rwanda," Kaisernetwork.org, August 13, 2007. Online: www.iolhivaids.co.za/index.php?fSectionId=1838&fArticleId=3978790.

concluded that the drawn-out process pointed to the need for the enabling national law in their country to be changed. If not, they said, the legislation would not be particularly useful for other countries in dire need of generic ARVs and other essential medicines.

In September 2007, for example, Richard Elliott, the executive director of the Canadian HIV/AIDS Legal Network, remarked, "It took nearly three years to get to this point." He added that it was "unlikely that Apotex, or any generic manufacturer, will want to go through this process again."[42] Elliott told the *Bridges Weekly Trade Digest* that he "recommended reforming the CAMR to create a 'one-license solution' that would authorize a company to produce the same drug for export to different countries that submit notifications to the WTO or Canadian government."[43]

A month earlier the network's former executive director, Joanne Csete, said, "What we've learned from this three-year, incredibly cumbersome process is that" CAMR is "not working well. It's almost a miracle Rwanda may be getting any drugs under this law."[44]

Other observers were more hopeful, arguing that future efforts to exploit this waiver are likely to be more streamlined and quicker based on lessons learned from this initial use. Stephen Lewis, the former United Nations Special Envoy for HIV and AIDS in Africa, called the deal a significant step. "Forgetting all the negotiations and shenanigans over the last few years," he said, "we can begin to save lives. That is what is crucial."[45]

6.6 Kenya

Key legal and regulatory issues:

The government has approved legislation that specifically addresses and permits TRIPS flexibilities, including parallel importation and the issuing of voluntary licenses. The most important law is the Industrial Property Act, which was passed in 2001 and came into force in May 2002.

Mechanism(s) used to lower drug prices and increase access to essential medicines:

- Voluntary licenses
- Parallel importation

Important factors:

Along with South Africa, Kenya has one of the more developed domestic pharmaceutical manufacturing industries in sub-Saharan Africa. That is important for the ongoing effort

[42] "Canada issues compulsory license for HIV/AIDS drug export to Rwanda, in first test of WTO procedure", *Bridges Weekly Trade Digest,* Vol. 11, No. 32, September 25. 2007. Online: www.ictsd.org/weekly/07-09-26/story2.htm.
[43] Ibid.
[44] "Canada to manufacture antiretroviral for Rwanda", Kaisernetwork.org, August 13, 2007. Online: www.iolhivaids.co.za/index.php?fSectionId=1838&fArticleId=3978790.
[45] Ibid.

by the government and other treatment providers to obtain and supply lower-priced generic medicines, especially ARVs for the hundreds of thousands of HIV-positive Kenyans in need.

Because of its domestic manufacturing capability, Kenya is also particularly well-placed (and not only geographically) to supply low-priced generics to other countries in eastern and central Africa. To date, though, the Kenyan export potential has been largely untapped. One main reason is that most neighboring countries that could greatly benefit have yet to take steps to hasten the import of generics.

Unlike most of its neighbors, Kenya is not classified as an LDC. It therefore was required to become TRIPS compliant within 10 years after January 1996, which was the date the clock began ticking for meeting the TRIPS obligations. The Industrial Property Act of 2001 was the primary law that made the country compliant. In addition to various provisions guaranteeing intellectual property rights (including those of patent-holders), that law also contains provisions permitting the government to utilize a range of TRIPS flexibilities, including compulsory licensing, parallel importation, and the "Bolar provision."

Civil society played a vital role in helping shape the final law and ensuring the inclusion of the measures aimed at giving the government substantial leeway to exercise numerous TRIPS flexibilities.

Recent developments and achievements:

Example 1: Issuing voluntary licenses for ARVs. Provisions in the Industrial Property Act enabled the government to work with the main domestic pharmaceutical company, Cosmos, to obtain two voluntary licenses in 2004. Both were for ARVs. One license was with GlaxoSmithKline (GSK) for three technically different products: zidovudine, lamivudine, and a combination of the two marketed as Combivir. The other license was with Boehringer Ingelheim for nevirapine. All three medicines are essential parts of standard first-line ART regimens.

Although both multinational companies reached agreement with Cosmos on terms for voluntary licenses, the local firm benefited far less than it anticipated. Both GSK and Boehringer subsequently reduced their prices for those ARVs in the Kenyan market, thereby making it economically unviable for Cosmos to produce and sell generic versions. Even so, the effort to obtain the voluntary licenses proved fruitful in the most important respect: it led to lower ARV prices, which in turn increased affordable access to these vital medicines among Kenyan consumers.

Moreover, as observed by one group of analysts: "This example also clearly shows the price benefits that can be obtained by having workable compulsory licensing provisions

in place as they can result in lower medicine prices without a compulsory license actually being issued."[46]

Example 2: Resisting efforts to change intellectual property laws. Most multinational pharmaceutical companies opposed the Industrial Property Act and lobbied against it. According to Sisule Musungu, an expert on trade and intellectual property issues in the developing world, the companies continue to claim the law is "too broad."[47] Among their main targets are provisions regarding parallel importation that specifically permit the importation of generics as well as branded drugs. Musungu refutes their complaints, arguing that the provisions are perfectly legal because TRIPS does not specify that parallel importation applies to branded versions only.

Musungu and other local activists suspect that multinational companies are responsible for recent efforts to tighten the law. In the past two years, for example, national legislators have been presented with proposals that would remove key provisions allowing wide usage of TRIPS flexibilities. Musungu said, however, that "no one knows who's behind" these proposals, adding that officials in the ministries of health and trade publicly oppose the changes.

The efforts have so far been unsuccessful, regardless of the source. According to Musungu, the lack of success is due in large part to tireless efforts by members of an umbrella group of civil society stakeholders, the Kenya Coalition for Access to Essential Medicines. He said members have organized public protests against the changes and hired experienced lawyers to discuss the law with parliamentarians. The latter step has proved to be especially important because many legislators previously did not understand the law's existing provisions or the potential ramifications of the changes. Musungu noted that the majority of them became firmly opposed to the proposed amendments after recognizing the negative impact they could have on public health in the country.

In Musungu's view, one important lesson over the past few years is that "you don't win and it's over." He said there is always a need for civil society, among other sectors, to have the ability and expertise to respond immediately to threats to hard-won gains in addition to pushing for new victories.

7. Glossary of key entities, terms, and concepts

Most of the entries in this list are referred to at various points throughout this publication, including in the case studies. Even if not mentioned, however, all provide background information regarding access to essential medicines globally, regionally, and nationally.

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[46] Avafia, T., Berger, J. and Hartzenberg, T. 2006. "The ability of select sub-Saharan African countries to utilize TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: A study of producing and importing countries." Tralac Working Paper No 12. Stellenbosch, South Africa: US Printers.

[47] All references to Musungu in this section stem from an interview conducted with him on November 7, 2007 in Geneva, Switzerland.

The entries are listed in a rough approximation of the most logical order, from relatively broad and general to more specific.

7.1 World Trade Organization (WTO)

Based in Geneva, Switzerland, the World Trade Organization (WTO) is a global institution that administers a set of trade agreements between nations. It was formally launched in January 1995, following the conclusion of eight years of negotiations under the aegis of a precursor body, the General Agreement on Tariffs and Trade (GATT). At the core of the WTO are negotiated agreements including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Most of the world's countries—more than 150 as of December 2007[48]—are members of the WTO. An additional 30 had observer status as of that date. Those countries are also expected to become full members eventually because WTO rules require observer nations to begin accession negotiations within five years of becoming observers.

7.2 TRIPS and patents

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes minimum standards for intellectual property rights and regulations. WTO members are obligated to pass and enforce laws that meet the standards.

The TRIPS agreement took effect one year after the WTO was officially founded in January 1995. Its drafting and passage were spearheaded primarily by developed countries keen to more thoroughly codify laws and expectations around the world. Not coincidentally, such countries are home to the vast majority of multinational companies, nearly all of which supported the pact.

Provisions of the TRIPS agreement cover a range of intellectual property issues including copyright, trademarks, and patents. They also specify that disputes between countries over these matters will be subject to WTO dispute-resolution mechanisms and procedures.

The provisions related to patents are the most relevant vis-à-vis medicines and other pharmaceutical products. The agreement aims to globally harmonize patent laws and protections to the fullest extent possible. Under the TRIPS agreement, "governments are required to recognize patents on products and processes in most areas of technology and to confer rights to the patent holder for a given period of time."[49] To that end, the agreement mandated that the majority of WTO member-states pass laws by 2005 providing patent protection to all new pharmaceuticals for a period of at least 20 years from the date of filing a patent application. That mandate applies to all new

[48] As per the WTO's website: www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

[49] Martin, G, et al, "Balancing intellectual monopoly privileges and the need for essential medicines," *Global Health*. Published online in June 2007: www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1904211.

pharmaceuticals, regardless of the patent holders' home country or type of product developed.

Subsequent revisions allowed important and notable exceptions to the 2005 deadline for the world's poorest nations, which are classified as least developed countries (LDCs) by the United Nations. LDCs currently have until 2016 to pass and implement patent-protection laws for pharmaceuticals. Until they do so, LDCs need not (under WTO rules) recognize, protect, or enforce patents on pharmaceuticals. (Countries are also permitted to seek extensions beyond 2016.)

The TRIPS agreement also outlines numerous steps and measures, commonly referred to as "flexibilities," that member-states may consider taking to improve access to patented pharmaceuticals. Among the specific flexibilities are compulsory licensing and parallel importing (both discussed elsewhere in this glossary). They are two of the most controversial flexibilities because, although legal under WTO rules, their use is often opposed by many pharmaceutical companies and national governments in developed nations. Opposition is usually based on the belief that such steps undermine patent-holders' ability to profit fairly from the products they have developed.

7.3 Doha Declaration

In November 2001, WTO members agreed to the so-called Doha Declaration on the TRIPS Agreement and Public Health—named after the Qatari capital where member-state representatives unanimously agreed to it. Several developing countries, including many in Africa, refused to proceed further with the WTO's ongoing Doha Round of global trade negotiations until after this initial declaration was agreed to. (Doha talks continue to this day.)

The Doha Declaration stemmed in part from developing countries' desire to counter strong pressure from developed nations and the pharmaceutical industry to prevent poorer nations' use of key "flexibilities" in the TRIPS agreement. These flexibilities are intended to help countries improve access to unobtainable or unaffordable medicines. Although the flexibilities are perfectly legal to exploit under WTO rules—and in fact they were created specifically to be utilized as needed—some governmental and industry opponents in the developed world consistently portrayed them as illegal.

The Doha Declaration did not formally alter the TRIPS agreement, although it did set in motion processes that were ultimately beneficial for developing countries, including some deadline extensions for LDCs. A key aim of the declaration was essentially to remind policymakers of the type and scope of flexibilities that member-states could potentially utilize—including the right to allow parallel importing and to grant compulsory licenses on the grounds determined by the original TRIPS agreement. The declaration also served to reinforce WTO members' commitment to these flexibilities and to address the problem of using compulsory licensing for export purposes. (The case study on Rwanda refers specifically to the latter issue.)

The Doha Declaration stated: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. . . . We affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all."

7.4 Compulsory license

The issuing of "compulsory licenses" by governments is one key TRIPS flexibility, and thus a WTO-sanctioned option for improving access to much-needed drugs. The term "is used to describe a number of mechanisms for non-voluntary authorizations to use patents."[50] The World Trade Organization defines compulsory licensing as follows:

> Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property—the TRIPS Agreement."[51]

Compulsory licenses can be issued for any medicine or patented invention. Moreover, contrary to common misunderstandings by some policymakers and analysts, a government is not required to declare a "national health emergency" when issuing one.

To date, the most high-profile usage of compulsory licensing has been for HIV drugs, including in Thailand and Brazil over the past couple of years (as discussed in this report).

7.5 Parallel importing

"Parallel importing" is another potentially useful TRIPS-approved mechanism to increase access to medicines in developing nations. It commonly refers to the import and resale of a product that is patented in an importing country and marketed and sold legally in the exporting country. This step may be taken without the consent of the patent holder. It is usually undertaken when a patented drug is sold in the importing country at a higher price than in the exporting country. The potential cost savings accrued by parallel importation of vital medicines—which Kenya, among other nations, has resorted to for certain HIV drugs—can be of critical importance to resource-constrained countries.

Prior to utilizing parallel importing, countries are generally required to draft and pass legislation specifically allowing it. They are then largely protected from legal retaliation by Article 6 of the TRIPS agreement, which was reaffirmed by the Doha Declaration. That article explicitly states that nothing in the agreement can be used to challenge a country at the WTO for allowing parallel imports under its own laws.

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[50] Love, J, KEI Research Note 2007:2, revised May 6, 2007. KEI (Knowledge Ecology International) is a civil society organization that has played a leading role in seeking to increase access to essential medicines worldwide. Online: www.keionline.org/index.php?option=com_content&task=view&id=41.

[51] As per the WTO's website: www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

7.6 Voluntary license

As described by South African civil society legal experts, a voluntary license is "a license issued by the patent-holding company that allows another company to manufacture a patented product subject to the payment of an agreed royalty fee to the patent holder."[52]

Agreements on voluntary licenses typically are reached following significant (and often time-consuming) negotiations between drug firms. Governments are often involved in such negotiations as well. They have a vested interest in the success of such arrangements because in most countries the public sector purchases and dispenses at least a small amount of drugs through government health systems. In such cases the drugs are usually provided free of charge or at very low cost.

Many advocates consider voluntary licenses to be viable as an access to medicines strategy only when countries have demonstrated their will, ability, or inclination to take more aggressive action by issuing compulsory licenses. In their view, it is only in such cases that patent-holding firms will negotiate voluntary licenses in which they relinquish monopoly supply of a medicine. The companies negotiating voluntary licenses are aware that failure to reach such an agreement, in which they still retain significant control over their patented products, could prompt the issuing of a compulsory license that strips away even more of their influence. (The Brazil and Thailand case studies highlight different strategies regarding actually issuing and merely threatening compulsory licensing.)

7.7 Patent pool

As defined by KEI,[53] patent pools "are one example of the collective management of intellectual property rights. A patent pool

- is an agreement involving two or more patent owners to aggregate (pool) their patents and to license them to one another or to third parties, and
- usually offers standard licensing terms to licensees and allocates a portion of the licensing fees (royalties) to patent owners according to a pre-set formula or procedure."

Patent pools may take many forms. In some instances, they are essentially collective voluntary licenses. Over the past few years in particular, KEI and other supporters have been promoting the use of patent pools to help increase access to affordable medical technologies and pharmaceuticals. They consider such mechanisms to be more efficient than individual licenses because they are broader-based and involve multiple stakeholders.

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[52] Avafia, T., Berger, J. and Hartzenberg, T. 2006. "The ability of select sub-Saharan African countries to utilize TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: A study of producing and importing countries." Tralac Working Paper No 12. Stellenbosch, South Africa: US Printers.

[53] Online in PDF format: www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf.

7.8 TRIPS-plus

"TRIPS-plus" is a term used to describe multilateral, regional, or national intellectual property rules and procedures that exceed the minimum standards established by the WTO's TRIPS agreement. The requirement to adopt and enforce such higher standards is often included in bilateral or regional trade agreements negotiated between developed nations, including the United States and the European Union, and developing countries.

"TRIPS-plus" measures typically delay the introduction of price-lowering generic competition. They may limit countries' ability to issue compulsory licenses or to utilize other TRIPS-approved mechanisms. They also tend to require regulators to issue patent extensions, among other restrictive measures.

Many advocates consider "data exclusivity" to be among the most powerful and restrictive TRIPS-plus measures, especially since it is often the first priority of the U.S. government and drug companies. As described by one legal advocate, "Data exclusivity is a rule preventing a drug regulatory authority from referencing or relying on an innovator's registration data or even on the fact of prior registration in order to establish the safety and efficacy of the follow-on product [a generic version of the same drug]."[54] Such provisions delay, sometimes for up to 10 years, the introduction of generic drugs. They effectively grant legal monopolies for brand-name drugs that are not able to obtain patent protection, and may extend the effective monopoly even for patented medicines.

The overall impact of data exclusivity and other TRIPS-plus provisions is decidedly negative in terms of increasing access to lower-cost, generic versions of essential medicines. That is the primary reason most civil society organizations and public health advocates strongly oppose TRIPS-plus measures wherever they are proposed or mandated, including national legislation and rules as well as trade agreements.

[54] This description was prepared by Brook K. Baker of Health GAP. It was included in *Missing the Target #5: Improving AIDS Drug Access and Advancing Health Care for All*, published in November 2007 by the International Treatment Preparedness Coalition. Available online: www.aidstreatmentaccess.org.

Annex: Advocacy and options for HIV treatment offer high-profile model

More than any other disease or factor, the HIV epidemic galvanized global attention as to the widespread disparities in access to medicines for all conditions—from TB to diabetes to heart disease to cancer. It is therefore instructive to consider the positive and negative effects of the ongoing effort to increase access to HIV drugs to those in need.

In the late 1990s, advocates from both the developed and developing worlds sought to focus the world's attention on the unfolding health and humanitarian disaster in the countries most in need—resource-constrained nations, mostly in Africa and Asia, where HIV infection was skyrocketing and deaths were mounting. The size and scope of the epidemic were obvious, but little had been done to help those in need. This was not because effective therapies did not exist: combination antiretroviral treatment (ART) had been introduced in 1996 in the United States and Western Europe, and death rates from AIDS plunged dramatically in response. The problem was the high price of drugs used in ART. The global cost per patient of a standard ART regimen generally exceeded $10,000 a year, with such costs nearly always covered in rich countries by private insurance companies or public-sector assistance. That amount is of course far more than patients and public health systems in developing countries could afford, however. For many years the result was a stark split: most HIV-positive people in wealthier countries had access to potentially life-saving drugs, while those in poorer nations did not.

Advocates therefore recognized that the only realistic way to reach those in need was to use every option available to lower the cost of ARVs and, subsequently, get those lower-cost drugs to patients as efficiently as possible. A major focus was on the production of generic versions, which eventually began most notably in India. They also launched multipronged strategies that included prodding national governments and multilateral organizations to take more proactive roles. As a result, numerous multilateral and non-governmental initiatives have been launched with the goal of boosting availability of medicines, information and awareness, and prevention tools and strategies. Among the most important are the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and treatment-enhancing initiatives by civil society entities such as the Clinton Foundation. Those high-profile initiatives helped speed up the introduction and availability of lower-priced generic drugs in developing countries, steps that in turn forced most brand-name companies to lower their prices as well.

The ongoing campaigns to improve access to HIV treatment and prevention services have indeed achieved notable successes. According to one leading civil society organization, Médecins Sans Frontières' Campaign for Access to Essential Medicines, "Generic competition for the older first-generation AIDS drugs has reduced their price in developing countries by more than 98 percent."[55] In a growing number of countries, ART is now available at a cost of about $100 per patient per year. The lower prices and increased donor support, especially through the GFATM, have allowed hundreds of thousands of people living with HIV to access ART for the first time over the past few

[55] See www.accessmed-msf.org.

years. More than 3 million people were on ART in developing countries by the end of 2007.

Such positive developments must be recognized and highlighted. Yet although they are likely to grow in number and scale, significant gaps persist. The most prominent is the lack of access to affordable second-line ARVs. The same battles that were initiated and fought (and are often still being fought) over first-line HIV drugs are now the focus of many advocates' efforts in developing countries.