

**Patents, Compulsory Licences
and Access to Medicines:
Some Recent Experiences**

Martin Khor

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Third World Network

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The paper draws from various other documents. Chapters 1 and 2 draw on Khor (2004). The framework and parts of Chapter 3 are from Sangeeta (2007a), while material on the various country cases is drawn from Chee (2006a) for Thailand, Chee (2006b) for Malaysia, Love (2007) for Italy and the United States, Lutfiyah and Hira (2006) for Indonesia, and Sangeeta (2007b) for Brazil. Chapter 4 draws from Khor (2007) and Medecins Sans Frontieres (2004) on FTAs, and from Smith (2007) on the report of the Thai Human Rights Commission.

Chee Yoke Ling updated the paper.

1

Background

ACCESS to medicines, which is part of the human right to health services, has emerged as a major public health issue, especially with the impact of patents on the prices of drugs. The patenting of medicines has become more prevalent after the establishment of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in the World Trade Organization (WTO) in 1995. That agreement made it compulsory for WTO member states to include medicines in their regime for product and process patents.

A few years ago, there was a public outcry after public health and development organizations highlighted how the monopoly granted by patents enabled the maintenance of excessive prices of medicines for HIV/AIDS. The cost of treating a patient with patented drugs was US\$10,000-15,000 a year in developed countries, whereas some producers in developing countries were able to provide generic versions for as low as US\$300. The cost of generic drugs has now dropped to US\$100-150. If developing countries are able to make or import these generic drugs at lower cost, that would significantly increase access to medicines.

Whilst mandating that WTO members have to allow patenting for medicines, the TRIPS Agreement does contain flexibilities. For example, if patented drugs cost too much, the government authorities can take measures such as issuing a compulsory licence to an agency or company to manufacture or import a generic version of that patented drug, which can then be made more available to patients more cheaply.

At the WTO's Ministerial Conference in Doha in 2001, the Doha Declaration on the TRIPS Agreement and Public Health was adopted as a response to the public concerns. The Declaration reaffirmed and clarified the flexibilities available under the TRIPS Agreement, and proclaimed: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health ... [W]e 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.” The Declaration spells out several flexibilities that WTO members can use to the full, such as the right to grant compulsory licences and the freedom to determine the grounds for these.

Two important and influential studies that emphasize the crucial importance of TRIPS flexibilities for developing countries are:

- “Integrating Intellectual Property Rights and Development Policy” – Report of the Commission on Intellectual Property Rights established by the United Kingdom (2002)¹; and
- Report of the World Health Organization (WHO) Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) (2006)².

The two commissions comprised international experts on intellectual property, development and public health.

If the Doha Declaration is to benefit AIDS patients and those afflicted with other ailments in developing countries, these countries now have to establish appropriate provisions in their national patent legislation by using “to the full” the flexibilities in the TRIPS Agreement. They also need to formulate and implement national policies aimed at providing access to medicines for all. In doing so, they would be operationalizing, at national level, the aims of the Doha Declaration. If such laws and policies are not introduced, the gains made at international level through the Declaration will not translate into actual benefits for patients.

In other words, whilst in recent years the goal of access to medicines has been significantly pursued at the international level, action is now equally or even more important at the national level, where policy makers should focus on policy and practical measures to get medicines to poor patients.

¹ www.iprcommission.org.

² www.who.int/intellectualproperty/documents/thereport/CHPublicHealthReport.pdf.

2

National Public Health Measures that are TRIPS-Consistent

GOVERNMENTS can take a range of policy measures to facilitate access to affordable medicines, including the following:

Importing the Drug

A country can import a generic version of a patented drug by issuing a **compulsory licence** to a company or agency to import the drug, and the government has the freedom to determine the grounds upon which such licences are given. The imported drug can be from a country in which the drug is not patented, or in which the drug is patented (in which case the exporting country also has to issue a compulsory licence). The applicant has to firstly negotiate to obtain a voluntary licence from the patent holder (except in cases of public non-commercial use, situations of extreme urgency and national emergency) and if that fails, then a compulsory licence can be granted. Adequate compensation has to be paid to the patent holder.

A generic version of the patented drug can also be imported for “**public non-commercial use**” by the government. Under this “government use” procedure, the prior consent of or negotiations with the patent holder are not required, but adequate compensation has to be paid. This method is suitable if the imported drug is to be used by the government.

There can also be “**parallel importation**”, i.e., the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. It is a very important tool enabling access to affordable medicines because there are still substantial price differences for pharmaceutical products in different markets. Parallel importation is allowed under Article 6 of the TRIPS Agreement (on “exhaustion” of intellectual property (IP) rights), and the Doha Declaration affirms this by stating that each WTO member is “free to establish its own regime for such exhaustion without challenge”. There is no need for an importer to obtain a compulsory licence or to pay compensation to the patent holder.

Local Manufacture

If a drug is patented in a country, generic versions of the drug can be locally manufactured by a local company or agency that has been granted a **compulsory licence**. The applicant has to have negotiated with the patent holder for a voluntary licence and failed to obtain such a licence, before applying for a compulsory licence. This requirement does not apply, however, if the compulsory licence is issued on grounds of public non-commercial use, for national emergency or situations of extreme urgency, or to remedy anti-competitive practices. Compensation has to be paid.

The government can also assign to a public or private agency the right to locally manufacture a patented product without the patent holder's permission, provided it is used for a **public non-commercial purpose**. Compensation has to be paid.

Export, Including to Countries with Inadequate Manufacturing Capacity

A local producer of generic versions of patented products under a compulsory licence or government-use provision may export a portion of its output. However, Article 31(f) of the TRIPS Agreement requires that this production be “predominantly for the supply of the domestic market” and thus there is a limit to the amount that can be exported. This restriction does not apply when the compulsory licence is granted to correct anti-competitive practices.

The restriction on export quantity has posed a problem for developing countries with insufficient or no drug manufacturing capacities, as they may find it difficult to import the required medicines since there is a limit to the amount the potential exporting countries can supply to them.

The Doha Declaration recognized this problem could also affect access to medicines, and mandated the WTO to find an “expeditious solution”. After lengthy negotiations, the WTO's governing General Council in August 2003 adopted a decision on a “temporary solution” in the form of an interim waiver to the Article 31(f) restriction, such that countries producing generic versions of patented products under compulsory licence would be allowed to export the products to eligible importing countries without having to limit the exported amount.

However, the decision also obliges importing and exporting countries that wish to make use of the waiver to undertake several measures and fulfil several conditions. It has been pointed out by some experts and non-governmental organizations (NGOs) that these measures and conditions are difficult for the relevant companies and governments to comply with.

There are additional requirements under a “Chairperson’s Statement” linked to the decision, such as that the system should be used in good faith and not pursue a commercial policy objective, and members concerned about how the decision is implemented can bring matters for review in the WTO’s TRIPS Council.

As the waiver and the conditions for its use are only an “interim solution”, the WTO has mandated a “permanent solution” to this problem. In December 2005, the WTO General Council adopted a set of amendments to the TRIPS Agreement that was basically a reiteration of the August 2003 “interim solution”. This amendment will come into force only when it has been ratified by a sufficient number of countries. As of June 2009, this number has not yet been reached. Thus the “interim solution” of August 2003 is still in force.

Conclusion

Patents can and often do affect the access of patients (especially the poor) to medicines, and the TRIPS Agreement also does affect the space available to developing-country members of the WTO to formulate the drug patent policies of their choice.

However, despite these problems, developing countries can and should take full advantage of the measures that *are* permitted by the TRIPS Agreement in pursuit of the goal of promoting access to medicines for all.

In order to exercise their right to “use to the full” these flexibilities in the TRIPS Agreement (in the words of the Doha Declaration), developing countries can study the policy options available to them, and introduce the appropriate laws and concrete measures. In the longer term, revisions to the TRIPS Agreement may also be desirable, in order that the existing flexibilities be expanded to meet the needs of patients and consumers. As millions of lives are at stake, both the shorter- and longer-term tasks are urgent.

3

Use of TRIPS Flexibilities: Some Recent Experiences

IMPLEMENTATION of the flexibilities in the TRIPS Agreement is vital if a country is to achieve the objectives and abide by the principles outlined in the Agreement. Article 7 of the Agreement unequivocally expresses the “objective” of protection and enforcement of intellectual property rights as contributing “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 8 (on “principles”) recognizes that IP right holders can abuse the rights granted to them and/or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, wherein governments may need to take “appropriate measures” consistent with the TRIPS Agreement to prevent this from happening. It also recognizes that governments may “adopt measures necessary 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 TRIPS Agreement.

For many years, even before the TRIPS Agreement came into force, several developed countries have on many occasions made use of compulsory licences.

In comparison, few developing countries have implemented TRIPS flexibilities. This is due to a variety of reasons, e.g., lack of awareness or understanding about the available flexibilities, lack of legal expertise on IP-related issues (in particular with a pro-development perspective) in government departments, inappropriate or inadequate laws on TRIPS flexibilities and, finally, pressure from developed-country governments and industry, in particular the multinational pharmaceutical industry, to not use these flexibilities.

An example of such pressure was seen in 2001 when 39 pharmaceutical companies brought an action against the South African government for amendments it wished to make to its law (Medicines and Related Substances Control Amendment Act No. 90 of 1997) to incorporate provisions on compulsory licensing and parallel importation to increase access to affordable medicines. Later the industry capitulated by withdrawing the suit after it faced severe criticisms nationally and globally.

It was criticism of the effects of patents on prices which led to the adoption of the Doha Declaration in 2001. As stated above, the Declaration recognized “that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and affirmed 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”.

Very importantly the Declaration reaffirmed “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.

Since the adoption of the Doha Declaration, many more developing countries have exercised their rights and made use of the available flexibilities to access affordable medicines, despite the continuing pressure. The initial focus was on antiretroviral medicines for HIV/AIDS treatment but this has now expanded into other much-needed medicines.

Below are examples of the use of TRIPS flexibilities by developing countries. The recent use of compulsory licences in the US and Italy is also highlighted.

Malaysia

In 2003, Malaysia became the first country in Asia following the adoption of the Doha Declaration to issue a government-use licence. The health authorities initiated the measure after considering various options (i.e., between compulsory licensing and government-use order) and after consultations with other government departments.

The government-use authorization was for the import of generic versions of patented antiretrovirals or ARVs (to treat AIDS) from the Indian company Cipla for use in government hospitals and clinics.

The patented ARVs were didanosine (ddI) 100 mg tablet (patent holder: Bristol-Myers Squibb); didanosine 25 mg tablet (patent holder: Bristol-Myers Squibb);

Table 1**Malaysia: Comparison of cost of treatment per patient per month before and after import of generic ARVs under a government-use order**

Treatment	2001 price for patented ARV (US\$)	2004 price for patented ARV (US\$)	2004 price for generic ARV (US\$)	Percentage of cost reduction
Stavudine + didanosine + nevirapine	261.44	197.10	45.32	83%
Combination of zidovudine and lamivudine + efavirenz	362.63	136.34	115.14	68%

Source: Ministry of Health, Malaysia.

zidovudine (AZT) 100 mg capsule (patent holder: GlaxoSmithKline); lamivudine 150 mg + zidovudine 300 mg tablet (Combivir; patent holder: GlaxoSmithKline).

The authorization, which was for a period of two years beginning 1 November 2003, was obtained from the Ministry of Domestic Trade and Consumer Affairs (DTCA) for the import of AZT, ddI and Combivir.

The government-use authorization was initiated by the Ministry of Health (MOH) and the licence was issued by the DTCA. In November 2002, the MOH had presented a paper to the Malaysian Cabinet with a recommendation to import generic ARV drugs, under a section in the Patents Act that allowed the Minister to exploit a patented invention where it is required by the public interest. The Cabinet approved the import on the basis of this provision.

As a result of the government-use licence, the average cost of MOH treatment per patient per month dropped significantly from 2001 (before the government-use measure) to 2004, as can be seen from Table 1.

For one combination of drugs (stavudine, didanosine and nevirapine), the cost of treatment per patient per month fell from US\$261 (for the patented ARV) to US\$45 (for the generic ARV), an 83% decline. For another combination of drugs (zidovudine and lamivudine and efavirenz), the cost fell from US\$363 to US\$115, or a decline of 68%.

Also as a result of the exercise of the right of government use, the patent holders dropped their own prices, leading to considerable reduction in the cost of treatment, as seen in Table 1.

The much lower cost encouraged the MOH to consider free treatment for more people who needed treatment. Previously, free treatment had only been provided to a few selected categories of patients. In addition, the number of patients that could be treated in government hospitals and clinics increased from 1,500 to 4,000, according to the MOH.

In June 2004, the MOH began prescribing the imported generic medicines, which were distributed through government hospitals. Then Health Minister Dr Chua Soi Lek announced on 6 June 2004 that the monthly cost of treating a patient would be reduced from RM1,200 to RM200-220, after the drugs were imported from India. “With the cheaper cost, we can treat at least 4,000 HIV patients compared to the present 1,500,” he said. (*The Star*, 7 June 2004).

According to news reports, there are 59,000 people in Malaysia infected with HIV, only 6,000 have gone for follow-up treatment in government hospitals, and up to a few years ago only 1,500 of the estimated 4,000 HIV-positive people on the verge of developing full-blown AIDS were receiving treatment (*Sunday Star*, 4 July 2004).

The MOH proposed to the patent holders a remuneration level of 4% of the value of stocks actually delivered. As of February 2006, it was reported that the patent holders had not shown interest in claiming the offered compensation.

Indonesia

Indonesia became the second Asian country in the post-Doha Declaration period to issue a government-use authorization. On 5 October 2004 a Presidential Decree was issued in accordance with Article 5 of the Indonesian Government Regulation No. 27 of 2004 regarding the Mechanism of Patent Exploitation by the Government. This was in light of “the urgent need of the community in the effort to control the HIV/AIDS epidemic”.

The Presidential Decree No. 83 of 2004 Regarding Exploitation of Patent by the Government on Antiretroviral Drugs empowered the Minister of Health to appoint a “pharmaceutical factory” as the patent exploiter on behalf of the government, taking into account the recommendations from the head of the National Drug and Food Authority. The two ARVs in question are nevirapine (for seven years) and lamivudine (for eight years) and the exploitation period covers the remaining patent protection term.

The decree also set the “compensation fee” at 0.5% of the net selling value of the ARVs concerned to the patent holder. According to an interview with a staff member at the Indonesian Patent Directorate, the patent holder has not provided any comments on the release of the Presidential Decree.

Production of the ARVs has resulted in cheaper ARVs in government hospitals, as seen in Table 2.

Patients who need the ARVs can now get free or partly subsidized medicines from the hospital. The price per package per month for the first-line fixed dose combination (lamivudine, zidovudine and nevirapine) produced by Kimia Farma, the authorized generic manufacturer, is US\$38. The government provides a subsidy of US\$20 per month, so patients pay only US\$18 per month per package.

In comparison, the price of lamivudine produced by GlaxoSmithKline is about US\$290 per 60 tablets and of nevirapine produced by Boehringer Ingelheim is US\$96 per 60 tablets. Table 2 provides a summary of the relevant ARV prices compared with prices of patented equivalents in 2000 as a baseline.

Table 2
Indonesia: Prices of patented ARVs compared with prices of the generic version

ARVs	Price of patented ARV <i>before</i> 2000 (per 60 tablets) (US\$)	Price of patented ARV <i>after</i> 2000 (per 60 tablets) (US\$)	Price of generic ARV after government-use authorization (per 60 tablets) (US\$)
Lamivudine + zidovudine + nevirapine	800-1,000	600	18-65*
Lamivudine (3TC)	NA	290-330**	28
Nevirapine (Viramune)	NA	96	28
Lamivudine + zidovudine (Combivir)	NA	400	48.60

Source: Lutfiyah and Hira (2006). Data obtained through interview with PT Kimia Farma, the Indonesian generic manufacturer.

Note: The brands of the patented ARVs are in brackets.

* The range of subsidized and full-cost prices that patients have to pay.

** The price range in different pharmacies. Indonesia does not have price control on medicines and therefore pharmacies and hospitals charge different prices.

According to the Working Group on HIV/AIDS of the Faculty of Medicine, University of Indonesia (Pokdisus), the price of patented ARVs has not decreased substantially even though the generic drugs are in the market. Almost all the PLWHA (people living with HIV/AIDS) treated under the Pokdisus programme have turned to generic drugs. Pokdisus currently provides to about 2,000 persons free generic ARVs sourced from the domestic production under the government-use decree.

In early 2007, the Indonesian government issued Presidential Decree No. 6/2007 on Revision of the Presidential Decree No. 83/2004 on Implementation of Patent by the Government for Anti Retroviral Drugs. This was in recognition of the need “to increase the number of ARVs whose patents are to be implemented by the government in order to enhance access to ARVs”.

The decree added efavirenz to the other two ARVs listed in the previous decree. The patent holder is Merck & Co. Inc., and the duration for the patent implementation is until the patent period expires on 7 August 2013.

Thailand

On 29 November 2006 Thailand’s Ministry of Public Health announced a five-year government-use authorization for the domestic manufacture of efavirenz. This drug is recommended by the World Health Organization for HIV/AIDS treatment and is commonly used and considered by doctors as one of the best components for first-line therapy because it results in fewer side-effects and is more suitable for those co-infected with other diseases such as tuberculosis or liver infections. Although the drug has been in the market for many years, it still remains very expensive.

Originally developed by DuPont Pharma, the medicine is now marketed by Bristol-Myers Squibb. However, Merck, another pharmaceutical giant, has marketing licence rights in a number of countries including Thailand and China.

The government-use authorization was issued by virtue of Section 51 of Thailand’s Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), which states that any ministry, bureau or department of the government may, by themselves or through others, exercise the compulsory-licensing right “in order to carry out any service for public consumption or which is of vital importance to the defence of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service”.

The authorization grants the Government Pharmaceutical Organization (GPO) of Thailand, a government-linked pharmaceutical manufacturer, the authority to exercise the rights under the Act.

A royalty fee of 0.5% of the GPO's total sale value of the imported or locally produced efavirenz will be paid to the patent holder.

The authorization took effect immediately following the announcement and the GPO is expected to start mass production of a generic version of the drug by mid-2007. In the meantime, imports of generic efavirenz from India under the same authorization will start.

This importation of the generic version from India is expected to reduce the cost of the drug for treatment to US\$22 per month from US\$41 per month (the price of the patented product). The cost of the locally produced drug is also expected to reduce the price to about half that of Merck's product.

Minister of Public Health Dr Mongkol na Songkhla told a national daily newspaper *The Nation* that there were about 500,000 HIV-infected people who needed to use antiretroviral treatments, yet only about 100,000 had access to the drugs because of the high prices as well as insufficient budgets. "Of course, the company [patent holder/licensee] will do something to oppose this but we're doing everything according to not only the country's law, but also international law," said Mongkol in the news report.

The Thai Network of People Living with HIV/AIDS (TNP+) and other HIV/AIDS activists hailed the Thai government's decision. They have been at the forefront of efforts to advocate for the government to use the flexibilities in the TRIPS Agreement.

In issuing a licence to temporarily override the patent barrier to enable the GPO to first import, and then locally manufacture, generic efavirenz, Thailand has further strengthened its policy to ensure access to affordable HIV/AIDS medicines. This move will allow more patients to switch from the current triple therapy (which could result in serious side-effects) to efavirenz. Eventually, if the cost of efavirenz were to drop further, the Thai government hopes to replace the triple-therapy formulation with an efavirenz-based one for all patients, according to Dr Suwit Wibulpolprasert, Senior Adviser on Health Economics to the Thai Ministry of Public Health, in a recent interview with the international medical humanitarian aid organization Medecins Sans Frontieres (MSF).

Since Thailand's decision was announced, there have been commercial pressures on the government. There has also, however, been widespread support from international health networks and organizations, including MSF and the Consumer Project on Technology, which have written separately to the US government calling on it not to put pressure on the Thai government. About 22 members of the US House of Representatives have also sent a letter to US Trade Representative Susan Schwab asking the USTR not to interfere in Thailand's decision to issue the government-use licence on efavirenz.

Table 3
Thailand: Comparison of prices before and after the government-use authorization

Medicine	Price (US\$)			
	Patented drug before GU	Patented drug after GU	Generic drug	Percentage of cost/price reduction
Efavirenz	58/month	24/month	7.5/month	87%
Lopinavir/ritonavir	1,800/year	1,000/year	600/yr	67%
Clopidogrel	3	1.3	0.06	98%
Docetaxel	900	450	37	96%
Letrozole	7	2.2	0.1	98%

Source: Dr Suwit Wibulprasert, Ministry of Public Health, Thailand.

In January 2007, compulsory licensing for government use was authorized for the GPO to manufacture lopinavir+ritonavir combination (second-line ARV) and clopidogrel (for coronary illness). This was the first time a developing country issued a non-ARV compulsory licence.

The benefits are clear. The price of efavirenz declined by more than 7 times, lopinavir/ritonavir by 3 times and clopidogrel by 50 times, while the price of the anti-cancer drugs docetaxel decreased by 24 times and letrozole by 70 times (see Table 3). As a result, access to essential ARVs has increased significantly. The prices of the patented drugs also decreased due to the competition from the generic versions, but these are still very high.

Zimbabwe

In 2002, in view of the HIV/AIDS pandemic affecting Zimbabwe, a notice of “Declaration of Period of Emergency (HIV/AIDS)” was issued by the Minister of Justice, Legal and Parliamentary Affairs for a period of six months.

The notice was intended to allow the state or a person authorized by the Minister to: (a) make or use any patented drug including any antiretroviral drug; and (b) import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.

The period of emergency was extended to 31 December 2008 in a Statutory Instrument 32 of 2003. During this period the state or any person authorized by the Minister of Justice would be able to manufacture or use patented medicines or import any generic medicines used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.

Varichem Pharmaceuticals (Private) Limited, a Zimbabwean generic company, applied under Section 34 of the Patents Act for the authority to make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the state.

Following the application, the Minister of Justice, Legal and Parliamentary Affairs in April 2003 granted Varichem the authority to “produce ARVs or HIV/AIDS related drugs and supply three quarters of its produced drugs to State-owned health institutions”. The licence that was issued also states that the prices of the drugs shall be fixed subject to price control mechanisms that are to be determined by the Minister.

According to a Varichem representative, the company produced its first ARV in October 2003 and it has seven generic versions of ARV medicines on the market (i.e., Combivir, Nevirapine (200mg tablets), Stalanev-40 (fixed dose combination comprising Stavudine 40mg, Lamivudine 150mg and Nevirapine 200mg), Stalanev-30 (Stavudine 30mg, Lamivudine 150mg and Nevirapine 200mg), Stavudine (30mg capsules), Stavudine (40mg capsules) and Lamivudine (150mg tablets)).

Ghana

In October 2005, the government of Ghana issued a government-use order to import (from selected generic pharmaceutical companies in India) generic versions of selected ARVs that are patented in Ghana. The HIV/AIDS drugs will be used to treat people without commercial purpose and will be for government use, accord-

ing to the Ministry of Health. According to an official source, the cost of the ARVs dropped more than 50% from US\$495 to US\$235 for one year's treatment.

Brazil³

The Brazilian President, Luiz Inacio Lula da Silva, on 4 May 2007 signed a decree sanctioning the compulsory licensing of the antiretroviral drug efavirenz. The ARV was declared to be of "public interest" in an ordinance issued by the Minister of Health on 24 April 2007. Brazil has stated that its decision is in "absolute compliance with international requirements and with Brazilian legislation".

The patent holder, Merck, was given time in which to make a new proposal on the price it would charge for the ARV. Merck offered the ARV to Brazil at a 30% discount on the current price of US\$1.59 per tablet (i.e., at US\$1.11 per tablet) but the Brazilian MOH reported that it could obtain the product elsewhere for US\$0.45 per tablet.

Efavirenz is the most used imported ARV in AIDS treatment in Brazil. Currently, 38% of AIDS patients take efavirenz as part of their treatment scheme. It is estimated that by the end of this year, 75,000 of Brazil's 200,000 AIDS patients will be taking the ARV.

At the current prices charged by Merck in Brazil, the annual cost per patient is equivalent to US\$580, representing budgeted expenditure of US\$42.9 million for the year 2007. The prices charged for the generic product result in an annual cost per patient that varies between US\$163.22 and US\$166.36. Based on these amounts, under compulsory licensing, expenditure reduction in 2007 will be around US\$30 million. Savings of US\$236.8 million are estimated to be made by the year 2012, when the efavirenz patent expires.

News posted on 4 May 2007 on the website of the Brazilian national STD and AIDS programme (at www.aids.gov.br) gives the following background on the negotiations with drug companies on other drugs:

"In August 2001, the then Minister of Health, José Serra, requested the compulsory licensing of the Nelfinavir patent (made by Roche). The decision was taken following nine months of negotiations with the laboratory. However, on the same day as the announcement was made, the Minister further announced that the process had been

³ For the official Brazilian government decree, see: http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717.

interrupted. This happened because Roche agreed to reduce the price of the drug by 40%.”

“In December 2003, Health Minister Humberto Costa announced that compulsory licensing could be adopted for the production of Nelfinavir in Brazil. On that occasion, Humberto Costa explained that he expected to negotiate with Roche, but that compulsory licensing would be decreed if necessary. In January 2004 the Health Minister was successful in obtaining a price reduction for five drugs: Nelfinavir, Lopinavir, Efavirenz, Tenofovir and Atazanavir. The agreement resulted in a 37% reduction in the prices previously paid for these antiretroviral drugs.”

“In June 2005, the President of the Republic, Luiz Inacio Lula da Silva, and the Minister of Health, Humberto Costa, signed a declaration of public interest in relation to the antiretroviral drug Kaletra (Lopinavir + Ritonavir), made by Abbott Laboratories. In July of the same year, the Minister of Health issued a statement on the conclusion of the negotiations with Abbott, which ensured a reduced price for the drug for six years, access to the new Kaletra formulation (known as Meltrex) and the transfer of the technology for the formulation of Lopinavir + Ritonavir. The laboratory agreed to reduce the unit price of Kaletra capsules from US\$1.17 to US\$0.63 each, with effect from March 2006, representing a saving of US\$339.5 million between 2006 and 2011.”

United States

Cases involving government use under 28 USC 1498

28 USC 1498 is the law on the use of patents or copyrights when the use is by or for the government. Under this law, the US government does not have to seek a licence or negotiate for use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright. The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government to prevent the use. The use of patents or copyrights by any contractor, subcontractor, person, firm or corporation who receives authorization from the federal government is construed as use by the federal government, and the authorized party cannot be sued for infringement.

In 2001, then Department of Health and Human Services (DHHS) Secretary Tommy Thompson used the threat to invoke 28 USC 1498 to authorize imports of generic ciprofloxacin for stockpiles against a possible anthrax attack.⁴

⁴ For more information: www.cptech.org/ip/health/cl/cipro/.

In a November 2005 Congressional hearing, then DHHS Secretary Michael Levitt testified before the House of Representatives that he had effectively required the patent owners for Tamiflu (Roche/Gilead) to invest in US manufacturing facilities for the product, so that the US government would have access to Tamiflu if confronted with an avian flu pandemic.⁵

Cases involving merger reviews

In 2002, the US Federal Trade Commission (FTC) ordered⁶ a compulsory cross-licence of the Immunex tumour necrosis factor (TNF) patent to Serono, including the “freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States”. There was permission to export, which is anticipated by Article 31(k) of the TRIPS Agreement. In this case, the compulsory cross-licence allowed a Swiss firm to compete with the US patent owner.

In 2005, the FTC ordered a compulsory licence of Guidant’s intellectual property surrounding the RX delivery system for Drug-Eluting Stents (DES) as a condition of Guidant’s acquisition by either Johnson & Johnson or Boston Scientific.⁷ Boston Scientific, which eventually won the bidding to acquire Guidant, was required to license DES patents to a potential entrant, Abbott.

Italy

Merck antibiotic (imipenem cilastatina) patents

On 23 February 2005, the Italian Competition Authority (Autorità garante della concorrenza e del mercato – AGCM) opened an investigation into abuses of a dominant position by refusals to license rights to active pharmaceutical products by two large pharmaceutical companies – GlaxoSmithKline and Merck & Co. Inc. (cases A363 and A364).

On 21 June 2005, the AGCM ordered a compulsory licence for Merck patents on antibiotics that use the active ingredient imipenem cilastatina.

⁵ See video excerpts from 8 November 2005 hearings of the Subcommittee on Health of the House Committee on Energy and Commerce: www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html.

⁶ For more information: www.ftc.gov/opa/2002/07/amgen.htm.

⁷ For more information: www.ftc.gov/opa/2006/04/bostonscigui.htm.

Glaxo patents on migraine drug

On 8 February 2006, the AGCM closed the investigation into the Glaxo Group's refusal to grant a licence to Fabbrica Italiana Sintetici SpA (FIS), a chemical company, for the manufacture in Italy of an active ingredient, sumatriptan succinate, used in the production of migraine medicines.

According to the AGCM press release, "To remedy the earlier refusal to license, Glaxo granted the licences originally requested by FIS, but also set conditions such as to allow the time to be made up which had been lost because of the original refusal. Those conditions include the granting of a number of additional procedural licences, whereby Glaxo has allowed FIS to save the time otherwise required to research and test an efficient manufacturing process for sumatriptan succinate. FIS will thus be enabled to offer the active ingredient to manufacturers of generics as early as if Glaxo had never refused the original request for a licence."⁸

The AGCM sought to prevent delays in bringing generic pharmaceuticals to market, thus paving the way for substantial price reductions.

FIS initially used the compulsory licence entirely for the export market, supplying generic firms that were selling products in markets outside of Italy (such as Spain), where the patents had expired. It did so outside of the framework of the WTO August 2003 decision on exports of medicines manufactured under a compulsory licence, which Spain and other EU members had "opted out" as an importer. This was possible in part because the TRIPS Agreement waives all restrictions on exports in cases where the licences were issued to remedy anti-competitive practices.

Merck patents on prostate and male-pattern baldness drug

On 21 March 2007, the AGCM required Merck to "grant free licences to allow the manufacture and sale in Italy of the active ingredient finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate". Finasteride is the active ingredient of a drug marketed initially under the brandname Proscar and Propecia. It is used to treat hypertrophy of the prostate, cancer of the prostate and male-pattern baldness. The Merck royalty-free compulsory licences were remedies to Merck's earlier refusal to license the patents to Italian manufacturers of active pharmaceutical ingredients. Again, the licences anticipate exports to "other European countries".

⁸ AGCM, 21 February 2006 press release, "Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued. Granting of licence opens way for manufacture of generic migraine drugs." Proceeding reference n. A363, case GLAXO-PRINCIPI ATTIVI.

4

Implications of Bilateral FTAs on Implementation of TRIPS Flexibilities Regarding Public Health

Increasing Awareness of IPR Problems in Multilateral Context

THE introduction of intellectual property rights (IPRs) as an issue subject to binding rules within a trade agreement was very controversial, and remains so, after the TRIPS Agreement was incorporated within the WTO. Since then, many economists, ranging from Joseph Stiglitz to Jagdish Bhagwati, have decried the inclusion of IPRs and TRIPS in the WTO. There is a growing realization that high IPR standards, as contained in the TRIPS Agreement, are inappropriate to the development needs of developing countries. In particular, the former head of the World Bank's trade research department, Michael Finger, estimated that the cost to developing countries of implementing their TRIPS Agreement obligations amounts to US\$60 billion annually, and that this more than offsets the gains they may expect to obtain from expanded market access in the agriculture and textiles sectors under other WTO agreements.

There is now a movement by developing countries to clarify some aspects of the TRIPS Agreement or to amend them, in order to reduce the more developmentally negative aspects. For instance, the Doha Declaration has clarified that developing countries can make use of flexibilities such as compulsory licences to offset the monopoly privileges of patent holders.

(Developing countries are also trying to have the TRIPS Agreement amended to deal with the problem of "biopiracy", by requiring that patent applications involving biological resources be accompanied by disclosure of the countries of origin of the resources and evidence of benefit-sharing arrangements with these countries.)

As negotiators in the WTO have become more aware of the development dimensions of IPRs, the developed countries have tried to introduce even higher IPR standards globally through another forum, the World Intellectual Property Organization (WIPO). However, many developing countries have now started a move-

ment to establish a “development agenda” within WIPO. They have also resisted attempts at harmonizing patent and copyright laws at even higher standards.

Dangers of Bilateral FTAs in Eroding TRIPS Flexibilities

Thus, there is now an attempt by some of the developed countries to use the forum of free trade agreements (FTAs) to: (a) remove or reduce the flexibilities in the TRIPS Agreement; and (b) establish even higher IPR standards in developing countries. IP is thus a major item covered in bilateral FTAs, and countries like the US and Japan are keen to further their interests in this area beyond what is in the TRIPS Agreement. The FTAs threaten the use of TRIPS flexibilities in relation to patents and access to medicines, as well as other aspects of IP, including biodiversity.

On IP and public health, the FTAs will have serious implications. Implementation of the right to use TRIPS flexibilities like compulsory licensing and government-use orders can be eroded or even erased through provisions in an FTA. Thus it would also affect the developing-country FTA signatory’s ability to implement the Doha Declaration which spelt out the flexibilities available for policy measures to promote access to affordable medicines.

Bilateral FTAs signed by the US with several countries or groupings are limiting the flexibilities or measures that are permitted in the WTO through the TRIPS Agreement. The result is that the developing-country partner in the FTA would now find it more difficult or impossible to undertake measures such as compulsory licensing or government use to provide cheaper generic drugs to patients. Examples (in the Medecins Sans Frontieres paper, “Access to Medicines at Risk Across the Globe”) include:

- (a) **Data exclusivity.** The WTO does not require “data exclusivity”, i.e., that data submitted by a patent holder to drug regulatory authorities (to obtain marketing approval for safety) cannot be made use of as part of the drug regulatory approval process undertaken by other applicants. Thus, a generic producer (which is given permission, for example under a compulsory licence, to sell or produce a generic version of a patented drug) can make use of that data when it seeks safety approval from the drug regulatory authority. However, in bilateral FTAs the US seeks to establish or expand “exclusive rights” over test data provided by the originator companies to prevent generic companies from registering an equivalent generic version of the drug, thus preventing or making it difficult for a compulsory licence to take effect, and effectively curbing the supply of generic drugs. This limitation is contained in the US-Singapore FTA.

- (b) **Extending the patent life span.** Patents on drugs last 20 years from the date of filing in most countries; this is also the WTO requirement. However, the US is seeking to “compensate” drug companies for any “unreasonable” time a national drug authority or patent office takes to examine or approve an application. The life of the patent would be extended by the “unreasonable time” taken. This extension measure is in the US FTA with Central American countries (CAFTA).
- (c) **“Evergreening” the patent.** Drug companies try to renew patents after they expire by applying for new patents for “new uses” of the same product. Under the WTO rules, members are not obliged to grant patents on new uses of existing substances. The US wants provisions in FTAs to allow companies to apply for new patents for each “new use” of a product, thus allowing the patent protection to continue beyond the expiry date of the original patent. This provision is in the US-Morocco FTA.
- (d) **Limiting the grounds for compulsory licensing.** The TRIPS Agreement allows countries to issue compulsory licences and does not restrict conditions for their use. The Doha Declaration confirms that countries have “the freedom to determine the grounds upon which such licences are granted”. However, the US seeks limitations on the circumstances under which compulsory licences on drugs are issued. For example, the US-Singapore FTA allows compulsory licences only for remedying anti-competitive practices by the patent holder; for public non-commercial use; and in the case of national emergency or circumstances of extreme urgency.

Thailand’s Human Rights Commission Report

In January 2007 the National Human Rights Commission of Thailand issued a draft report on a human rights assessment of the FTA that Thailand has been negotiating with the US.

It concluded that such an agreement would violate the human rights of Thai people and affect the country’s sovereignty, and thus that the negotiations should not resume until a thorough review of its impact is undertaken. [For a detailed article on the report, see Smith (2007).]

The Commission based its findings on a human rights assessment of the intellectual property chapter proposed by the US as well as on other chapters of the FTA based on the texts of other bilateral deals signed by the US.

The Commission found that “an FTA is like a tsunami that crashes to the shore without warning when one is not prepared to deal with it”.

In its investigation of the IP chapter, the Commission focused on the impact on public health and farmers’ rights. The Commission charted the history of US pressure on Thailand to increase its IP protection and the protests against such a move by academics, public health officials and NGOs.

The report also explains demands made by the US that go beyond the requirements under the TRIPS Agreement. These “TRIPS-plus” provisions include: the patenting of plants, animals and methods of treatment; patent term extensions beyond the 20 years required by the TRIPS Agreement; data exclusivity; linkage of patent status and medicine registration; prohibition on patent pre-grant opposition; and limitations on the use of compulsory licences. These last two (i.e., pre-grant opposition and compulsory licensing) have been recently successfully used in Thailand to ensure access to medicines used to treat AIDS.

The Commission highlighted research that showed that in Thailand the price of branded/originator medicines can be 10 times higher than that of the generic version. It concluded: “The impact [of] the market monopoly will be that the costs of drugs will be too expensive or beyond the purchasing power of people.

“On top of this, the estimated increase of expenses over 100,000 million Baht, more than the annual budget for public health, will definitely undermine any earnest attempt to manage the health system in Thailand, particularly the health insurance scheme ... In the final analysis, the people in Thailand will be denied access to drugs, causing endless public health and social problems...”

“Doing so would amount to undermining the universal health care system and popular health insurance scheme and destroying the chances for Thailand to develop its own potentials in this pharmaceutical field and to be self-reliant in manufacturing and distribution of quality pharmaceutical products at reasonable price.”

Among the Commission’s many recommendations in the report are the following:

- All sectors of society should be involved in the negotiating process for the FTA and the matter must go through Parliament.
- Thailand should delay the negotiations for the time being to be able to carefully scrutinize important issues. FTA negotiations with every country should be suspended for a one-year period during the administration of the current

temporary government, because the negotiations and the signing of FTAs will be legally binding on Thailand in the long term.

- On matters relating to medicines and public health services, the government must adhere to the principles of the rights of patients and consumers, and self-reliance in terms of drugs and public health. If the US demands impact on health conditions and access to drugs and public health services, they must be rejected without being compared to benefits offered by the US.
- As every person has fundamental rights to good health, the issue of IPR protection relating to drugs and public health services should not be considered in the bilateral trade negotiations. This can be compared with the US not agreeing to include its agricultural subsidies on the agenda.

Appendix: Some Recent Cases of Compulsory Licensing

Country	Type of Compulsory Licence (CL)	Reason	“Adequate Remuneration”
Malaysia	CL to local company to import for use in public hospitals	Government use	Offer 4% to patent holder
Mozambique	CL to Pharco Mocambique Lda for local manufacture	Condition of national emergency and extreme urgency	Not to exceed 2% of sales
Zambia	CL to Pharco Ltd for local manufacture	Condition of national emergency and extreme urgency	Not to exceed 2.5% of the total turnover of the products
Indonesia	Licence for Ministry of Health to appoint a pharmaceutical factory as patent exploiter	Government use	Compensation fee of 0.5% of the net selling value of the ARVs to the patent holder
Zimbabwe	CL to Varichem to exploit patent	Emergency	
Thailand	CL to Government Pharmaceutical Organization to manufacture efavirenz	Government use	0.5% of the sale price of the generics to patent holder
Ghana	CL to import generic ARVs	Government use	
Brazil	CL to manufacture efavirenz	Government use	
United States	CL to Swiss company to research, manufacture and sell in the US products using Immunex tumour necrosis factor patent (exports also permitted); CL on intellectual property surrounding the RX delivery system for Drug-Eluting Stents	To correct anti-competitive practices	
Italy	CL to manufacture active ingredients: imipenem cilastatina used in antibiotics; sumatriptan succinate used in the production of migraine medicines; finasteride used in products to treat hypertrophy of the prostate, cancer of the prostate and male-pattern baldness	To correct anti-competitive practices	

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PATENTS, COMPULSORY LICENCES AND ACCESS TO MEDICINES: SOME RECENT EXPERIENCES

High prices of patent-protected medicines have become a major public health concern in developing countries, especially since the coming into force of the World Trade Organization (WTO)'s TRIPS Agreement, which sets stringent patent norms for WTO member states. Nevertheless, despite providing for the patenting of medicines, the TRIPS Agreement does allow certain exceptions and flexibilities which are in line with the public interest.

This paper examines the TRIPS-permitted flexibilities – compulsory licensing, government use and parallel importation – which developing countries can make use of to override drug patents and make available more affordable medicines.

Recent examples (from Malaysia, Indonesia, Thailand, Zimbabwe, Ghana, Brazil, the United States and Italy) are provided of individual countries' use of compulsory licences or government-use orders or other flexibilities to produce and import cheaper generic versions of patented drugs.

The author also cautions, however, that a new wave of bilateral “free trade agreements” (FTAs) between developed and developing countries effectively erode these flexibilities by imposing even stricter patent standards than those in the TRIPS Agreement. If left unchecked, the trend towards such “TRIPS-plus” FTAs threatens to undermine access to essential medicines by poor patients throughout the developing world.

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