High prices of medicines is often the major cause of inaccessibility of medicines for poor patients in developing countries. The monopoly protection provided by patents on medicines under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) is one of the main causes of the high prices. However, there are avenues, for example, through the use of the TRIPS flexibilities, by means of which developing countries can ensure accessibility to medicines by their poor patients. A large number of developing countries have not made effective use of these flexibilities due to a number of reasons. Thailand, which has made successful use of the TRIPS flexibilities and ensured the affordability and accessibility of medicines for its poor patients, is an exemplary case study for other developing countries.
In developed countries, the cost of medicines is largely public funded through reimbursement and insurance schemes. In contrast, up to 90 percent of the population in developing countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food. Poor patients in the developing world will thus not have access to new, patented medicines, if the prices are not kept affordable.

The effect of generic competition on medicine prices is well illustrated by the case of antiretroviral (ARV) medicines for HIV/AIDS. The first triple combination ARV medicines cost over US$10,000 per patient per year—well out of the reach of much of the developing world—when it was first introduced in the late 1990s. The introduction of generic ARV medicines by Indian drug manufacturers since 2001, however, has triggered massive reductions in the cost of ARV treatment. There has been a 99 percent reduction in the price of ARV treatment; and generic first-line triple combination ARV medicines are available today at US$87 per patient per year. These price reductions have enabled treatment programmes to be established in many developing countries, thereby facilitating access to treatment by HIV patients.

The coming into force of the TRIPS Agreement has made it mandatory for WTO members to provide patent protection for processes and products, in all fields of technology, for a minimum of 20 years. In the pharmaceutical context, this means that countries can no longer exempt pharmaceutical products from patent protection—a practice of a number of developed and developing countries, prior to the coming into force of the TRIPS Agreement. Nor can they limit pharmaceutical patents to process patents only, although a number of developing countries like India were allowed to do so until 2005 as they had previously not provided product patent protection prior to the TRIPS Agreement.

After 2005—the deadline for full compliance of the TRIPS Agreement—all developing-country WTO members, including those that manufacture and supply generic medicines, are obliged to provide patent protection for pharmaceutical products; hence they may no longer be able to manufacture generic medicines. In the absence of competition, significant and sustained price reductions may be more difficult to achieve. This is already the case for the new second- and third-line ARV medicines: second-line treatment can be 9 to 17 times more expensive in those countries where the medicines are patented and no generic equivalents are available.

Aware of these concerns, developing-country WTO members had pressed for a legal clarification that the TRIPS Agreement does not prevent them from taking measures to provide access to affordable medicines. In 2001, after acrimonious debate, the trade ministers adopted the Ministerial Declaration on the TRIPS Agreement and Public Health at the WTO Ministerial in Doha. The Declaration confirmed that members are permitted to take measures to limit exclusive patent rights, where the interests of public health and the need to ensure access to affordable medicines so require. These measures, which include compulsory licensing and parallel imports, are now often collectively referred to as the TRIPS flexibilities.

Despite the legal clarity provided by the Doha Declaration, only a small number of developing countries have made actual use of the TRIPS flexibilities. In contrast, in developed countries, compulsory licensing has been “part of the law and practice” for over a century. One reason why developing countries have not made greater use of the TRIPS flexibilities is that their use may require expertise and experience on legal issues, as well as an institutional and administrative system for effective implementation, which may be absent in these countries.

**South Asian context**

Between 2 million and 3.5 million of South Asia’s 1.5 billion people are living with HIV/AIDS. Although it appears that the overall adult HIV prevalence in India and Nepal has stabilized, the epidemic is rapidly increasing in other countries like Bangladesh. Therefore, it is still crucial to ensure the establishment and sustainability of HIV treatment programmes in all the countries of the region to prevent the further spread of the virus.

South Asian countries are also witnessing the emergence of non-communicable diseases—including heart diseases, stroke, cancer, chronic respiratory diseases and diabetes—as a major cause of death and disability. Patients with chronic diseases require a reliable supply of affordable medicines, but essential medicines used to treat such diseases in low- and middle-income countries have limited availability and may not be affordable. As a result, non-communicable diseases account for almost half of the adult disease burden in South Asia.
The provision of public sector health-care in South Asia is still lacking and health insurance schemes provide very limited coverage. According to the World Development Indicators 2006 of the World Bank, people in South Asia meet 96 percent of their total health expenditure through out-of-pocket payments. A 2007 study by Mendis et al. of six low- and middle-income countries (including Bangladesh, Nepal, Pakistan and Sri Lanka) found that although many medicines for chronic diseases are theoretically provided free or at low cost in the public sector, their availability is poor. Hence, the majority of patients must purchase medicines from the private sector or forego treatment if they cannot afford them.7

The study also found that patented or originator products were generally priced higher than generics: compared to the lowest-priced generics, they were 34 percent higher in Bangladesh, 40 percent higher in Nepal, 90 percent higher in Pakistan, and 175 percent higher in Sri Lanka. There were also cases where the costs of the originator brands were 10 times higher than their generic equivalents. Because patients with chronic diseases require multiple medications for adequate management, the monthly treatment costs of such chronic diseases may be equivalent to several days’ wages of the lowest-paid government worker. The treatment is unaffordable for most patients in South Asia, home to 47 percent of the world’s population living on less than US$1 a day.

It is thus crucial for South Asian countries to ensure that they avail themselves of the flexibilities permitted under the TRIPS Agreement, in order to be able to take all necessary measures to make medicines affordable. The World Health Organization (WHO) has noted that one of the pressing regional issues is the lack of awareness in the health sector, especially regarding the implications of the WTO Agreements, and inadequacy of legislation to optimize the flexibility provisions allowed by the TRIPS Agreement, such as compulsory licensing and parallel importation.8

There are various options available for the use of the TRIPS flexibilities (see Box, next pages). Although India has been in the forefront in making effective use of the TRIPS Agreement to facilitate access to medicines, other South Asian countries have not made any such attempts. In this respect, they need to incorporate the TRIPS flexibilities in their national legislation and build their capacity to make appropriate use of the flexibilities to ensure access to affordable medicines. The case of Thailand can be an important lesson in this regard.

Case of Thailand

In 2006 and 2007, the Government of Thailand granted a series of government use authorizations to enable the import of generic equivalents of seven patented medicines at a fraction of their cost. The medicines were: efavirenz and lopinavir/ritonavir combination (both of which are ARV therapy for HIV); clopidogrel (which is used in the treatment of coronary artery disease); and imatinib, erlotinib, letrozole and docetaxel (cancer medicines used in the treatment of leukaemia, lung and breast cancers).

Legal validity

Since 2002, Thailand has provided universal health coverage to its 64 million people. Thais are covered by one of the three national public health insurance schemes, entitling them access to medicines on the National List of Essential Medicines (NLEM). Initially, ARV medicines were not included in the NLEM due to their high prices and inadequate government budget. In 2003, the government sought to provide universal access to HIV/AIDS treatment; however, the sustainability of the programme became a major concern given the cost of the patented medicines and the need to provide life-long treatment to HIV patients. Meanwhile, epidemiological evidences also indicated a rising trend of cardiovascular diseases and cancer, which were becoming major causes of deaths in Thailand.9 Yet, due to high prices, the public health insurance system was not able to ensure sufficient access to proven and effective treatments.

The use of generic equivalents of patented medicines was thus identified as a sustainable cost-containment measure for the public health system. One study also found that the use of generic ARV medicines and clopidogrel (for heart disease) would lead to a substantial cost savings of 800 million baht per year.10 The Thai government, however, maintains that the government use authorizations are not intended to reduce health expenditure but to enable greater access to medicines under its health insurance scheme.

Under the provisions of the TRIPS Agreement, WTO members are only limited with regard to the procedures and conditions to be followed in the grant of
compulsory licences or government use authorizations, such as the requirement of prior negotiations with the patent holder for the grant of a voluntary licence and payment of adequate compensation. In the case of the government use of patents, where it is for public non-commercial purposes, the condition of prior negotiations is waived. In Thailand, government use authorizations are also provided for in its domestic legislation. While Article 52 of the Thai Patent Act 1979 provides broad powers to the Prime Minister to order the use of any patent necessary for national defence and security during war or emergency, Article 51 authorizes the government use of patents in the general public interest, so that “any ministry, bureau or department of the Government” may exercise the rights in any patent “to carry out any service for public consumption”. It further provides that the government may use a patent, either by itself or through others, subject to the condition of a royalty payment to the patent holder. While Article 51 requires prompt notification to the patent holder about government use authorization, it does not require negotiations with the patent holder prior to the grant of government use authorization.

The grant of the government use authorizations were thus in compliance with the provisions of the domestic law in Thailand, as well as the TRIPS Agreement. Also, since the generic medicines imported under the government use authorizations were only for the use of patients under the public health insurance scheme, the authorizations comply with the TRIPS Agreement’s requirement of public non-commercial use, and with the Thai law’s provision that the use of the patent be for “public consumption”. Moreover, in accordance with the legal provisions, compensation ranging from 0.5 percent to 5 percent of the sale value of the generic medicines would also be provided to the patent holders.

Type of disease

Significantly, Thailand granted the government use authorizations not only for HIV/AIDS medicines, but also for medicines to treat heart disease and cancer. A popular misconception about the use of the TRIPS flexibilities is that they may only be used to address public health crisis in pandemic or emergency situations. In fact, neither the TRIPS Agreement nor the Doha Declaration places any restrictions on the type of disease or product for the use of the TRIPS flexibilities.

Some parties argued that Thailand’s government use authorizations for clopidogrel and the cancer medicines did not meet the criterion of an “urgent public health concern”. It should be borne in mind, however, that in line with the Doha Declaration on the TRIPS Agreement and Public Health, they were used to protect public health and promote access to medicines for all. The decision has been challenged neither in Thailand’s domestic courts nor at the WTO.

Decision-making and implementation

The decision to grant the government use authorizations took a considerable length of time. This was because the Thai authorities had sought to negotiate price discounts with the patent-holding pharmaceutical companies before considering the use of the TRIPS flexibilities, although there was no legal requirement to do so.

In 2005, the Ministry of Public Health (MOPH), Government of Thailand, established an Ad Hoc Working Group on Medicine Price Negotiation, chaired by the Secretary General of the Food and Drug Administration (FDA), to undertake negotiations for price discounts on the needed medicines. The Working Group identified a list of priority medicines. The Working Group

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**Box** Available options for the use of the TRIPS flexibilities

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Option 1: Importing generic medicines from abroad

One option is to allow the import of generic medicines that have been manufactured abroad through compulsory licensing or government use authorization. Where the medicine is patented in the importing country, a compulsory licence can be granted to a third party (such as a private company) to import the generic medicine from the country of manufacture. A government use authorization, which is a form of compulsory licensing, can be used when the medicine imports are undertaken for public and non-commercial purposes. Many national patent laws permit both compulsory licensing and government use of patents (which are often framed in broad terms and are procedurally much simpler). Developing countries and international medicine procurement programmes, such as those under the Global Fund, currently import substantial quantities of ARV generic medicines from India, where generic manufacturers are able to legally produce generic versions of older medicines that have not been patented in the country. With the expiry of the 2005 TRIPS Agreement deadline, however, generic producers in countries like India will only be able to produce generic versions of new patented medicines under compulsory licence or government use authorization.
medicines for which access was lacking, including treatments for cancer, cardiovascular diseases and HIV. When negotiations to reduce the prices of the priority medicines did not succeed, the National Health Security Office (NHSO) set up a sub-committee to develop recommendations for the implementation of the government use of patents. Chaired by the Secretary General of the NHSO, the sub-committee’s membership comprised senior officials from MOPH, FDA, the Department of Intellectual Property, as well as representatives from health- and consumer-protection groups in Thailand. The sub-committee was tasked with considering the need for government use authorizations as well as developing the criteria for the selection of medicines, and the conditions for the implementation of government use authorizations.13

The fact that the decision-making process involved different agencies in developing the criteria and guidelines for implementation helped to delineate and define the roles and responsibilities of different government agencies. This, in large part, ensured the speedy and effective implementation of the government use authorizations when they were eventually granted.

Transparency and accountability

The government use authorizations, not surprisingly, provoked strong objections from the patent-holding pharmaceutical companies whose products were affected, and the governments of the countries where the companies are headquartered. The strongest reaction came from Abbott Laboratories, which decided to withdraw its applications for market registration of 10 new medicines in protest of the government use authorization on its product. This raised concerns in Thailand about the risk of losing access to new medicines, particularly if other multinational pharmaceutical companies also followed suit. However, Abbott Laboratories eventually reinstated its applications for market registration after the protests and boycotts of its products organized by civil society groups in Thailand and elsewhere gave it much negative publicity. The inclusion of civil society groups in the decision-making process for the grant of the government use authorizations played a critical role in organizing the protests and boycotts.

On the political front, the Office of the United States Trade Representative (USTR), in its annual review of the state of intellectual property right (IPR) protection and enforcement, downgraded Thailand’s ranking from the Watch List to Priority Watch List, indicating its concerns over deficiencies in IPR protection and enforcement in Thailand. A reason given for this change in Thailand’s status was that “in late 2006 and early 2007, there were further indications of a weakening respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products."

Option 2: Enabling local production

A second option is to enable local production of the required medicines. A compulsory licence or government use authorization can be granted to permit the manufacture of generic versions of medicines patented in the country. This option is relevant for those countries with the requisite pharmaceutical manufacturing capacity. Since new medicines are likely to be patent protected with full implementation of the TRIPS Agreement (after the expiry of the 2005 TRIPS deadline), generic producers such as those in India may no longer manufacture new patented medicines without a compulsory licence or government use authorization. Other countries may import such medicines produced under compulsory licence or government use authorization, but if the product is patented in the importing country, a compulsory licence is also required in the importing country. In such situations, the scenario envisaged in the WTO Decision on Article 31bis of the TRIPS Agreement arises, which permits the local production of a generic medicine for export.

Option 3: Parallel importing

A third option is parallel import of patented medicines from markets abroad where they are sold at lower prices. Parallel importing is based on the international exhaustion of rights theory, which means that the intellectual property rights holders’ rights over the pharmaceutical product ceases when the said product is placed for the first time in any market. Since some patented products are sold at different prices in different markets, parallel importation can enable the import of patented products from countries in which they are sold at lower prices into those countries where the same patented products are being sold at a higher price.
products. While the United States acknowledges a country’s ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. In addition, in a move widely speculated to be retaliation against the government use authorizations, the USTR announced that privileges under the Generalized System of Preferences (GSP) would be removed for three Thai export items.

In an effort to inform the public and to garner support, MOPH and NHSO published a series of so-called “White Papers” which detailed the rationale for, and the legal issues and decision-making process of the government use authorizations. These White Papers were widely circulated both within and outside Thailand. A further detailed study was conducted by an independent research arm of MOPH, the International Health Policy Program (IHPP), with the aim of documenting the policy processes involved in the decision to grant the authorizations.

The Minister of Public Health also sought support from WHO members at the World Health Assembly (WHA) in 2007. It is significant that the same year the WHA adopted a resolution which urged the WHO Director-General to provide technical and policy support on the use of the TRIPS flexibilities. Thailand became the first country to request WHO support under this resolution. The mission led by the WHO, comprising experts from the WTO, the United Nations Development Programme (UNDP) and the United Nations Conference on Trade and Development (UNCTAD), produced a technical report in 2008, which has been widely interpreted to confirm the authorizations’ validity and compliance with the TRIPS Agreement.

Aware that the decision would be much scrutinized, the government authorities were at pains to ensure that the decision-making and implementation processes were well-documented and transparent. The government also sought the technical and legal advice of international organizations and civil society groups. These efforts were aimed at demonstrating the transparency of the policy decision and the accountability of the government. These factors were extremely helpful in eliciting support for the authorizations and in countering the criticism leveled against it.

Impact assessment

A study by a research arm of the MOPH has sought to provide an evidence-based assessment of the public health and economic impacts of the government use authorizations. Of interest are the study’s findings related to the increase in the number of patients with access to medicines, and the effect on Thailand’s economy, particularly with respect to exports and foreign investment flows.

The study found that the government use authorizations were expected to result in the increase in the number of patients with access to the seven medicines. The study also estimated that over a five-year period, 17,959 more patients would have access to efavirenz; 3,421 to lopinavir/ritonavir; and 40,947 to clopidogrel. For the cancer medicines, the increase in the number of patients in the five-year period would be 8,916 for letrozole; 10,813 for docetaxel; 1,846 for imatinib; and 256 for erlotinib.

The study also undertook a calculation of the incremental benefits of the authorizations by comparing the scenarios with and without such authorizations, and using an assessment methodology that calculated the impact on national productivity (where patients who have access to treatment are assumed to contribute to national productivity) and the changes in health expenditure (greater costs assumed when more patients have access). The incremental benefit of the government use authorizations was estimated to be approximately US$132.4 million over five years. This figure represents a significant benefit, given the fact that the authorizations will permit the purchase of increased quantities of the seven medicines by the government, which would enable the access of a significant number of patients in Thailand to those medicines.

The impact on trade and foreign investment was also assessed, given the concerns of the domestic critics in Thailand that the export and foreign investment flows
figures were not affected, and in fact, during the 10-year period from 1998 to 2008, the overall export values had actually risen.

The study found no evidence of a link between the grant of the government use authorizations and the level of both short- and long-term foreign direct investment flows into Thailand. There was also little evidence to link the authorizations with changes in the level of investor confidence. Using the changes in activity in the Stock Exchange of Thailand (SET) Index as an indicator of the level of investor confidence, the study found that the Index activity responded more to factors such as the economic conditions of the US market, the Thai political climate and fluctuations of the Thai Baht, rather than the grant of the authorizations.

**Conclusion**

Contrary to the USTR’s view that there was “lack of transparency and due process” in the use of the government use authorizations by the Government of Thailand, much effort had been made in ensuring transparency and accountability in the process of granting and implementing the authorizations. Thailand’s case, however, is not the norm. Detailed information regarding the use of the TRIPS flexibilities and the effects thereof is not always readily accessible for a variety of reasons. Government authorities do not generally publicize their intention to grant compulsory licences or government use authorizations for reasons similar to those that prevent them from using the TRIPS flexibilities: the wish to avoid external political pressures and concerns about the potential impact on foreign investment. In that regard, the approach taken by Thailand demonstrates that openness and greater involvement of external parties such as the United Nations (UN) agencies and civil society groups can be constructive and helpful.

Although the legal clarity for the use of the TRIPS flexibilities has been confirmed by the Doha Declaration and various UN resolutions, the use of these flexibilities has been variable. In this context, the 2009 Report of the UN Special Rapporteur on the Right to Health, in cautioning against the adverse impacts of the TRIPS Agreement and other trade agreements on the prices and availability of medicines, recommends that developing countries and least-developed countries (LDCs) seek the assistance of UN bodies to build their capacity for the implementation of the TRIPS flexibilities so as to promote the right to health.

Since the passing of the 2005 deadline for developing countries to fully comply with the TRIPS Agreement, the ability of these countries to make effective use of the TRIPS flexibilities has gained increasing importance. Since all developing-country WTO members, including those that manufacture and supply generic medicines, like India, have now to provide patent protection for pharmaceutical products, the continued supply of generic medicines may be in doubt. This has already become a matter of great concern in the case of ARV medicines, given that many, if not all, of the second- and third-line ARV medicines are under patent protection.

Much will depend on governments to take the necessary measures. A first step is to ensure that national legislation and regulations permit the use of the flexibilities. Ensuring that the appropriate legislative
provisions exist to enable the use of the flexibilities will permit the prompt introduction of generic medicines. This also includes the flexibility extended by the Doha Declaration to LDCs to delay providing product patent protection for pharmaceuticals until 2016. In the South Asian context, LDCs like Bangladesh, the Maldives and Nepal should consider the means for using this flexibility effectively to facilitate access to affordable medicines. Aside from the necessary legal provisions, these countries should also consider establishing clear guidelines for decision-making, which designate specific responsibilities to government authorities or bodies for the various stages of decision-making.

A number of countries have negotiated, or are in the process of negotiating, regional and bilateral free trade agreements that may contain new intellectual property obligations that go beyond those currently existing in the multilateral agreements. Recently concluded free trade agreements have included “TRIPS-plus” provisions that have the effect of negating the spirit and intention of the Doha Declaration, and may further hinder access to generic medicines. Therefore, countries should be extremely cautious while negotiating international and regional agreements.

Notes
3 ibid.
10 ibid.
11 See Article 31 of the TRIPS Agreement.

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