LOWY INSTITUTE
FOR INTERNATIONAL POLICY

PERSPECTIVES

The Bangkok Challenge: From Conflict to Cooperation and Beyond

Outcomes Report

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OUTCOMES REPORT

The Bangkok challenge:
From conflict to cooperation and beyond

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Lowy Institute for International Policy
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with the George Institute for International Health

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On 15 May, the Lowy Institute co-hosted with the George Institute for International Health (www.thegeorgeinstitute.org) a half-day seminar looking at the potential ramifications of the 26 January decision by the Thai health authorities to issue a compulsory licence for the heart drug Plavix.[1] This was the first time that a developing country, and a large middle-income one to boot, had applied the World Trade Organization (WTO)-based rules on the compulsory licensing of patented drugs outside of the HIV/AIDS area.

The Thai decision on Plavix sparked an immediate torrent of comment as it has the potential to set a precedent for other developing countries facing rising public health care costs. This first use of the compulsory licensing rights outside of the HIV/AIDS area and in the area of chronic disease has reignited debates over patent rights and public access to life-saving medication that previously had been largely contained within HIV/AIDS circles. These earlier debates and the global focus on the HIV/AIDS pandemic played a central role in the development of the November 2001 Doha Ministerial Declaration on TRIPS and Public Health which clarified the rights of lesser developed countries to use compulsory licensing exceptions to patent rights.[2]

[1] The World Trade Organization defines compulsory licensing this way: 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 (Trade-Related Aspects of Intellectual Property Rights) Agreement.

[2] The declaration can be downloaded at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

This time around though, the debates themselves and their impact on public health policy and the pharmaceutical industry could be much larger. Chronic diseases are much larger in scale than HIV/AIDS and the patented drugs used to treat them account for a significantly larger share of the pharmaceutical companies' income. Presently, the costs of treating cardiovascular diseases exceed $1 trillion dollars a year globally.

The half-day seminar attempted to first understand the reasons behind the Thai decision (*the Bangkok challenge*) and what it might mean for the future of international and national policies dealing with chronic diseases in developing countries (*from conflict to cooperation and beyond).* The seminar analysed the difficult tension between property rights of drug innovators and the right to accessible medicines as expressed in the Thai situation, and the much larger structural challenges facing developing countries attempting to deliver better public health outcomes.

The Bangkok challenge

The Thai decision on Plavix restoked the arguments, and their resulting passions, over the patent rights of drug companies, the role of generic manufacturers and countries', especially developing ones, need for greater, more equitable access to essential medicines. Differences of opinion over these issues gain so much attention as they are a relatively new global trade issue, a new component in the North-South divide and involve large sums of money on both the side of the patent-holding drug companies and the public and private drug purchasers.

At the heart of the patent system lies a strong tension/paradox. The patent system attempts to maximise the provision of public goods through the reliance on exclusive mechanisms (intellectual property rights) and research and development efforts by private firms requiring a profit. In this system, how do you promote necessary innovation while maximising the equitable availability of its results?

In the area of public health and drug innovation, this tension is exacerbated. First, the significant cost and lead time to develop an innovative lifesaving drug and the extremely low cost of reproduction creates a large free rider problem that the patent system must protect to ensure the viability of private sector-based innovation. On the other hand, the often prohibitive cost of treatment with patented drugs creates grave concerns for equitable availability, especially in financially challenged developing country public health systems. The inclusion of patent law into international trade negotiations has increased international attention on this difficult tension.

The Thai decision itself again heightened this inherent tension. This was the first time a developing country had used the WTO rules on compulsory licensing for a drug outside the HIV/AIDS area. Thailand, Southeast Asia's second largest economy, is a large, middle-income developing country that garners significant regional and global attention. Thai authorities, in their public explanation of the decision, discussed the budgetary benefits of the compulsory licence rather than simply the strict public health emergency grounds usually used to justify a compulsory licence.

Finally, many queried the choice of Plavix, as the World Health Organization (WHO) does not include it on its list of essential drugs. Studies show that despite its comparatively high cost (in Australia, Plavix is 33 times the cost of aspirin), it has limited applicability and additional health benefit. According to one speaker, taking Plavix and aspirin together will only stop 1 out of 100 patients from suffering a hear attack when compared to patients at risk who take only aspirin. The pharmaceutical industry is concerned that a shift to a more regular use of compulsory licences to lower the cost of drugs is unsustainable for their business model and goes against their understanding of the spirit of the WTO's 2001 agreement on compulsory licences, which it sees as justifying compulsory licences only in extreme cases.

On the Thai side, the concern is more with the rising cost of addressing cardiovascular disease and the conflict between WTO law and their constitution. The Thai constitution requires the state to provide universal health care. Public Health Minister Mongkol Na Songkhla noted that, according to doctors at Bangkok's major chest hospital, up to 20% of their budget was spent on Plavix. Up to 300,000 Thais may be in need of Plavix treatment. While the Thai authorities contend that the Plavix decision falls within the limits of the 2001 WTO agreement that does not limit compulsory licensing to public health emergencies, the Thai state has felt a political backlash. The United States has relisted Thailand for the first time in over a decade as a priority country on the Special 301 watch-list of potentially erring trade partners and American authorities publicly queried the Plavix decision. There are also rumours that there is pressure to replace Mongkol Na Songkhla.

Chronic diseases and public health in the developing world

The seminar was very effective in making clear the huge challenges facing developing country public health systems in dealing with chronic disease and the limited, secondary role of drug patent issues in overcoming these challenges. Compulsory licensing is definitely a

hot-button issue that garners worldwide attention but the real problems with chronic disease in the developing world are much larger and more structural.

The number of individuals in the high-risk category for cardiovascular diseases is expected to double from 300 million to 600 million in the period from 2000 to 2020. Asia itself is expected to see a 150% increase during these two decades from 120 million people at risk to 300 million. Almost all the projected growth in deaths from cardiovascular diseases will come from the developing world and are closely associated with urbanisation, changing diets, longer lifespans and smoking.

Thailand itself is a good case-study of these problems. The strong demand for Plavix in some parts of urban Thailand is being driven by the rise in the numbers at risk of cardiovascular disease that itself is being driven by changing lifestyles. Problems with high cholesterol are twice as prevalent for both men and women in Thai urban areas than in rural ones. Almost half of all Thai men are current smokers. Only 5% of women smoke.

The inequity in health outcomes is particularly stark between rich and poor countries and between the wealthy and the poor in developing countries. Rural people in developing countries are particularly badly served by the public and private health care systems. Three-quarters of all doctors in the world live in urban areas, as do three-fifths of the world's nurses. Health worker absenteeism and the provision of counterfeit drugs are also greater problems in the poorer and rural areas of the developing world. It is estimated that 30% of all drug outlets in the Philippines sell counterfeits, while 25% of all drugs in Indonesia are pirated.

While the debate over patents and compulsory licensing focuses on the cost of drugs, the major problem facing developing country health care systems, especially in the poorest countries, is the lack of continuously functioning health care systems; systems that actually deliver essential medicines to those most in need in a timely and consistent manner.

Cooperation and beyond

The seminar as a whole had two sobering messages: 1) the problems facing developing country health care systems are deeply rooted and very hard to address at a time when the demand on these systems is growing, and 2) the existing system of drug patenting is inherently conflictual, with some participants wondering if the business model of the pharmaceutical industry is broken. Fortunately, the seminar also addressed some effective ways of dealing with these sobering messages and highlighted some areas of success.

Strengthening health care systems

The problem in many developing countries, especially the poorer, is the lack of a continuously functioning health care system to deliver care. It is estimated that three-quarters of maternal deaths could be avoided through the proper application of known cost-effective remedies. Drug innovation is not the problem here, health care delivery is. Aid agencies are focusing on strengthening the health care systems of their recipient countries.

Health care financing in particular is one area where there have been some noticeable, if not widespread, examples of successful programs that echo elements of the public health system in Australia. Health care financing assistance focuses on reducing the costs of inputs, improving the efficiency and coverage of the public health care system and reducing the financial burden (often catastrophic) to the poor of accessing the health care system. In rural China alone, three-quarters of rural people who opted out of hospitalisation nominated financial constraints as the reason. Bulk buying by public health authorities of approved essential medicines can help lower their cost and some donors like the Global Fund are pondering greater use of this cost reduction method.

- Cambodia highlights two successes in health care financing that may act as useful general models. The Cambodia authorities, with support from donors, have contracted out health services that used to be provided solely or largely by the state. Coverage rates have improved while health authorities have been freed up to work on areas other than service provision. User fee exemptions and subsidies for the poor can further improve coverage rates

  Cambodia has also benefited from the introduction of donor-funded health equity funds. These insurance schemes reduce the out-of-pocket expenses facing potential patients and assuage their very real fears that accessing the health care system may lead to impoverishment. Members of these funds are much less likely to go into debt when accessing the health care system and the larger the membership of these funds, the lower is the cost per beneficiary.

- Colombia has highlighted the potential preventative benefits of direct cash payments. Families pursuing effective preventative steps such as immunisation can receive direct cash payments from the health authorities. These direct payments and the actions they encourage have contributed to a reduction in diarrhoea and significant improvements in rates of up-to-date preventative care.

Cardiovascular disease

When it came to focusing on cardiovascular disease and the question of patent rights on Plavix, one of the speakers argued that this largely missed the point, particularly for developing countries. Rather, the 'polypill' is a better answer. This pill, at the cost of $20 a year per person, contains cholesterol and blood pressure lowering agents and aspirin. By itself, it can reduce the risk of heart attacks and strokes by 65%. This is a much better reduction than Plavix can deliver at roughly one-fiftieth the cost.

Patent rights and public health

The history of the struggle against HIV/AIDS showed that, at times, the interests of patent holders and patients are the same, particularly in the development and accessibility of new generation drugs. Rules for the release of new drugs on the national market can often delay the introduction of new generation drugs. The HIV/AIDS struggle also led to new, more cooperative approaches between pharmaceutical companies and public health authorities beyond these authorities' application of compulsory licences.

These include the issuing of voluntary licences after negotiation between the drug company holding the affected patent and local authorities enforcing the patent. Closely associated with this is the practice of differentiated pricing for patented drugs in response to the health needs of the country and their ability to pay for the essential drugs. Differentiated pricing is already widespread in the HIV/AIDS area even in first-line regime drugs like STOCRIN for which Thailand has issued a compulsory licence. Differential pricing schemes, however, raise the potential for greater parallel imports between countries in lower-income brackets to higher income ones.

The HIV/AIDS area has also spawned many public-private partnerships between pharmaceutical companies, donors and host governments. Many of these focus on public health systems issues like financing for the poor, strengthening health delivery mechanisms and developing long-term prevention strategies. In this sense, these programs bring the issue full circle from the focus on drug patents to developing and sustaining functioning health care systems.

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