

## Viewpoint

## The role of civil society in protecting public health over commercial interests: lessons from Thailand

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In October, 2002, two Thai people with HIV-1 won an important legal case to increase access to medicines. In its judgment in the didanosine patent case against Bristol-Myers Squibb,<sup>1</sup> the Thai Central Intellectual Property and International Trade Court ruled that, because pharmaceutical patents can lead to high prices and limit access to medicines, patients are injured by them and can challenge their legality. This ruling had great international implications for health and human rights, confirming that patients—whose health and lives can depend on being able to afford a medicine—can be considered as damaged parties and therefore have legal standing to sue.

The complexities of pharmaceutical intellectual property law are most poorly understood by those most affected by their consequences—the patients who need the drugs. The Thai court case was the outcome of a learning process and years of networking between different civil society actors who joined forces to protect and promote the right of access to treatment.

Our Viewpoint, based on key interviews and published reviews, summarises the efforts of civil society in Thailand to achieve a fair balance between international trade and public health. These efforts have focused on didanosine, an essential antiretroviral drug that in Thailand has become symbolic of how multinational companies and governments of industrialised countries protect their own interests at the expense of access to essential medicines for the poor.

### Early efforts to provide treatment

Thailand is a low-to-middle income country with a population of 63·5 million, of whom about 603 000 have HIV/AIDS (adult infection rate is 1·8%). The country is noted for an effective response to the epidemic.<sup>2-4</sup> The Thai Public Health Ministry began to provide antiretroviral monotherapy in 1992 and dual therapy in 1995 for an estimated 25% of symptomatic patients attending public hospitals. However, in 1995 specialists concluded that continuing the programme would be costly with minimum effectiveness,<sup>5</sup> although their analysis did not take into account the possibility of lower prices due to generic competition or of the greater effectiveness of triple therapy. In 2000, the Public Health Ministry began to promote triple therapy as the norm, using mostly brand name drugs. However, coverage was limited by the price of medicines.

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For several years, the only antiretroviral drugs commonly available in Thailand were zidovudine and didanosine. By 1996, generic zidovudine was available at a reasonable price, but generic production of didanosine was blocked by the patent holder Bristol-Myers Squibb (panel 1)<sup>6-15</sup> and the brand drug cost more per month (US\$136) than the average wage of an office worker (US\$120).<sup>16</sup>

Since 1975, the US pharmaceutical industry has claimed that lack of product patents acts as a barrier to market entry in Thailand, and the US government has put trade pressure on the country to introduce stronger patent protection through trade sanctions, representing US\$165 million in lost export revenue for Thailand.<sup>17</sup> In response to this pressure, Thailand has introduced a series of measures,<sup>16</sup> which maximise the rights of the multinational pharmaceutical industry while minimising the rights of patients, with little benefit to the national industry in terms of foreign investment and technology transfer.<sup>18</sup>

Civil society groups are strong and numerous in Thailand, and have been central to defending and promoting access to medicines (panel 2). In 1999, the Didanosine Working Group was formed as a result of concern about Thailand's patent laws, which they believe constituted a major barrier to access to HIV/AIDS drugs, a view confirmed by the findings of a joint UNAIDS/WHO fact-finding mission to Thailand in 1999. The mission recommended that the Public Health Ministry review its patent provisions on compulsory licensing and institute a means of monitoring drug prices, with assistance from WHO.<sup>19</sup>

In November, 1999, the Thai Government Pharmaceutical Organisation (GPO) submitted a request for a compulsory licence (a legal measure that allows governments to over-ride patents and produce generic medicines) to the Thai Department of Intellectual Property. This request was supported by several local non-governmental organisations, by the Thai network of people living with AIDS, and by Médecins Sans Frontières (MSF). The occasion represented the first in Thailand when people infected with HIV braved stigmatisation to stage public demonstrations, and proved to be a watershed event in terms of awareness and self-confidence for people with HIV/AIDS. At the same time, US AIDS activists demonstrated in Washington, DC, against Bristol-Myers Squibb and the US government, regarding their repressive trade policy with respect to drugs for HIV in Thailand and South Africa.

A letter from the US Ambassador in Bangkok to the US Trade Representative stated that the Thai government “certainly don't want to be the cause of a trade dispute just before the Seattle Meeting [1999 World Trade Organisation (WTO) Ministerial], which is what we have always told them would happen if the compulsory [*sic*] licensing clause should be invoked”. The USA was concerned that this would “set a worrisome precedent for the rest of the drug industry”.<sup>20</sup>

In January, 2000, Thai activists submitted a letter to the US government, demanding that they not retaliate with trade sanctions if a compulsory licence was issued. This correspondence was backed by the Washington based Consumer Project on Technology.<sup>21</sup> The US government responded, “the United States will raise no objection, provided the compulsory license is issued in a manner fully consistent with . . . TRIPS [trade-related aspects of intellectual property rights]”.<sup>22</sup> But this reply did not assuage fears of US trade retaliation. A senior official at the commerce ministry said, “Thailand has committed to the international community not to use poverty and sickness as an excuse in international trade”. He expressed concern that, “if a compulsory license were to be issued, just one million people will benefit, while the rest of the country’s 61 million people will have to pay the price if the US retaliates.”<sup>23</sup>

The use of compulsory licensing was rejected.<sup>24</sup> Instead, the GPO began to produce a non-patented formulation of didanosine—a citrate-phosphate buffer formulation with more gastrointestinal side-effects than the patented drug.

### **Bristol-Myers Squibb taken to court**

A lawsuit was filed in May, 2001, at the Thai Central Intellectual Property and International Trade Court by the AIDS Access Foundation (a Thai foundation that

provides social support to people with HIV/AIDS) and two patients with HIV against Bristol-Myers Squibb. The plaintiffs alleged that Bristol-Myers Squibb and the Thai Department of Intellectual Property had “conspired to intentionally delete” the dose restriction to the didanosine patent. The court summoned the Department of Intellectual Property as a co-defendant.

One of the central questions in the case became whether individuals have the right to challenge a patent. The defendants claimed that the plaintiffs “do not have the objective to manufacture didanosine, and can choose other medicines to cure the disease, and are therefore not injured or interested parties”.<sup>1</sup> However, in the final verdict, the court noted that “Medicine is one of the fundamental factors necessary for human beings, as distinct from other products or other inventions that consumers may or may not choose for consumption” and that “lack of access to medicines due to high price prejudices the human rights of patients to proper medical treatment”.<sup>1</sup>

The court went on to assert the primacy of human life in trade agreements, as recognised internationally at Doha where “it was insisted that TRIPS be interpreted and implemented so as to promote the rights of members to protect public health, especially the promotion and support of access to medicines”.<sup>1</sup> This occasion is believed to be the first time a court decision has used the Doha Declaration to protect public health and the rights of patients. It concluded that “injured parties . . . are not limited to manufacturers or sellers of medicines protected by patent. Those in need of the medicine are also interested parties to the granting of the patent.” The AIDS Access Foundation was also noted as an interested party,<sup>1</sup> affirming the important role of civil society groups.

Furthermore, the court noted that the removal of the restriction on dose range extended the patent protection beyond the scope of the initially described invention. The court ruled this amendment unlawful. This ruling

#### **Panel 1: Privatisation of a public drug**

February, 1998—US National Institutes of Health (NIH),<sup>6</sup> which invented didanosine, grants a licence to Bristol-Myers Squibb (BMS) to produce the drug in a limited list of countries, excluding Thailand, for an initial period of 10 years, with option of 5-year extension. Licence includes fair-pricing clause, stating that “there be a reasonable relationship between licensee’s pricing of licensed product and the health and safety needs of the public and that this relationship be supported by evidence”.<sup>7</sup> Despite repeated requests by MSF and others, NIH has never enforced fair pricing clause, nor has BMS honoured it. Thus, attempts by the Thai Public Health Ministry’s AIDS division to negotiate the price of didanosine have been unsuccessful<sup>8</sup>

July, 1992—BMS files patent application for formulation of didanosine in Thailand, containing different antacid buffer to original preparation and with a specified dose range “from about 5 to 100 mg per dosing unit” (similar to 5–150 mg formulation patents in other countries<sup>9,10</sup>). Similar patent applications in USA in 1991<sup>11</sup> and 1992<sup>12</sup> rejected on the grounds of lack of novelty and inventive step, although new version of US patent finally granted in March, 1999.<sup>13</sup> Application made for a product patent 2 months before product patents recognised in Thailand

August, 1997—BMS files an amendment in which dose restriction omitted, thus seeking to expand scope of patent to all preparations, containing didanosine plus antacid buffer irrespective of dose

January, 1998—Thai Department of Intellectual property grants amends patent.<sup>14</sup> Amendment never published

April, 1998—Launch of generic didanosine 150 mg tablets by GPO planned. BMS threatens litigation and blocks production<sup>15</sup>

October, 2002—Omission of dose range in patent amendment found to be unlawful by Thai Central Intellectual Property and International Trade Court. BMS appeals

January, 2004—BMS withdraws appeal; judgment upheld in favour of plaintiffs

#### **Panel 2: Civil society groups and non-governmental organisations (NGOs) promoting access to medicines in Thailand**

##### **Thai Foundation for Consumers**

Founded in 1983

Lobbies on issues around patent protection and access to medicines

Played a key part in informing patient groups about such issues

##### **Thai NGO Coalition on AIDS (TNCA)**

Formed in 1989

Gained early success through the disbanding of an AIDS Bill proposed in 1990 that would have required compulsory HIV testing of any member of a high-risk group without their consent<sup>4</sup>

Comprises 168 national and international NGOs

##### **Thai Network for People Living with HIV/AIDS (TNP+)**

Established in 1998

Coordinates activities of groups of people living with HIV/AIDS across Thailand

##### **Médecins Sans Frontières**

Began working in Thailand networking in 1994 at invitation of local NGOs. Early work included support to local NGOs, including medical care for people with HIV/AIDS. Started to provide antiretroviral treatment in October, 2000

### Panel 3: Campaigning for access to didanosine—views of Thai activists

“Treatment is not only an issue for doctors. People with HIV/AIDS should be in the driving seat.”

Bunniam, TNP+

“If people do not have a good understanding of the issues they cannot say why they are there [at the demonstrations]. They need to do a bit of homework. It's a chance to strengthen the network. In the past people only talked about small issues, to do with themselves. This was a wider issue that brought people together. People who joined the protest feel that they are part of this change: they make the difference and they feel proud. Some people now only work at the policy level and have lost touch with their community. They must keep the support of people in the regions.”

Bandon Khamrangsi, MSF

“It's been a lot of work, challenging. It was a new issue, starting from zero, but it's been a pleasure because it has given hope in a situation where people couldn't previously access medicines. The movement is not just about demonstrations. There are other activities. It's a process. You need to explain clearly the goal of the movement and of each milestone and explain clearly what needs to be done. MSF is really a big help, especially the technical knowledge: you have to confront doctors and the Public Health Ministry and you really need the medical backup. Also MSF helps to simplify the medical stuff and make the knowledge easy so that it can then be passed on to and used by other patient groups. The response of government has generally been quite positive. They listen to us more. Before 1999 the Public Health Ministry didn't really think about access to antiretroviral treatment, only about small programmes and studies. Didanosine is just an example of the whole problem related to patent monopoly and access to medicines. It's not the solution but it's the point from where you make the case. The didanosine case is going to be a good example for other countries, as is this whole movement.”

Nimit Tienudom, AIDS Access Foundation

“I want to portray a positive image to show that people are still vibrant, driven and alive although they have HIV . . . It was a public challenge to the government. We wanted to show the government: we are here. There is a strong movement. We want you to act.”

Kamon, TNP+

Statements made during interviews for research of this Viewpoint.

has set an important precedent that essential drugs are not just another consumer product but a human right, and that patients are injured by patents. The defendants initially appealed, but withdrew this appeal in January, 2004.

Unsurprisingly, the parties involved had different views of the outcome. Although a spokesperson for BMS claimed they had decided to “dedicate the patent to the people of Thailand”, one of the plaintiffs said that “this did not happen because the drug company wants to be kind to people living with HIV/AIDS in Thailand. It is the result of our fight to improve access to medicine”.<sup>25</sup>

#### Thailand and beyond

The Thai Public Health Ministry has clearly stated that their ambitious antiretroviral treatment programme would not exist without generic drugs (Chitwarakorn A, Public Health Ministry, personal communication). The GPO produces seven antiretroviral preparations, which are two

(nevirapine) to 25 (stavudine) times cheaper than the cheapest brand equivalents.

The use of locally produced generics has allowed the government's treatment programme to expand more than eight-fold in the past 3 years with only a 40% increase in budget. As of May, 2003, 13 000 patients are receiving antiretroviral treatment; coverage is planned to increase to 70 000 people, using funds from the Thai government and from the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Thus almost 10% of people with HIV/AIDS in Thailand will receive treatment within 2 years; most of those in need of antiretroviral treatment, according to the Public Health Ministry.<sup>26,27</sup>

By 2005, developing country WTO members must implement the TRIPS agreement in full. Without the effective use of safeguards to ensure generic competition, the cost of all new medicines will largely depend on price setting by the patent holder.<sup>28</sup> The Thai didanosine patent is an example of the problems faced by developing countries, and intergovernmental organisations, such as the World Intellectual Property Organisation (WIPO), should be more active in helping them to overcome the formidable challenges in implementing patent protection, including examining patent applications properly.<sup>18,29,30</sup>

Countries also need assistance in meeting their obligations under the Doha Declaration and in implementing the TRIPS agreement in a way that protects public health and promotes access to medicines for all. The TRIPS agreement contains safeguards to protect public health, but in practice developing countries face political and practical obstacles to using these safeguards. In Thailand, the government has faced considerable trade pressure from the USA, and public health has suffered as a consequence.

World Health Assembly resolutions in May, 2003, strengthened WHO's mandate to promote policies that increase the availability of generic medicines.<sup>31,32</sup> WHO and WIPO should provide technical expertise to countries in the developing world with respect to the inclusion of effective public-health safeguards in national patent laws.<sup>15</sup> The constraints faced by countries in implementing these recommendations are exemplified by the fact that none of the recommendations of the 1999 UNAIDS/WHO fact-finding mission to Thailand, restated by a second UNAIDS/WHO mission in 2000,<sup>33</sup> has been implemented.

In Thailand, civil society groups have been key to establishing the human right to health by challenging the practices of the multinational pharmaceutical industry and governments of industrialised countries (panel 3).<sup>34,35</sup> However, there are few developing countries where civil society is strong in advocating for greater access to medicines (Brazil and South Africa are notable exceptions). Access to medicines for people in poorer countries risks being limited by monopolies, arising from over-restrictive patent laws and invalid but unchallenged patents for some time to come.

The pharmaceutical industry will continue to push for increased patent protection.<sup>36</sup> In Thailand, successful opposition has come from people with HIV/AIDS, who have fought for their rights by forming effective coalitions, bringing together a range of experience and expertise. Their experience has not only increased access to treatment, but has brought wider benefits in terms of self-image, confidence, and dignity of people with HIV/AIDS. Thailand's example can only be encouraged.

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