Thailand: American bullying puts pharmaceutical company profits before the health of millions

In November 2001, at the World Trade Organisation's 4th ministerial conference in Doha, the finance ministers of the world reaffirmed that governments are free to take all necessary measures to protect public health. That means that a government has a right to override patents in an "emergency". One method of doing this is through "compulsory licensing", a procedure under WTO rules whereby a government faced with a health emergency may grant a permit to produce a generic form of a crucial drug. As of April 2002, no developing country has ever instigated a compulsory licence, though in US and Europe the process is common.

Despite the Doha declaration, Thailand activists and sympathetic government officials report that there has been no change in the stance of the Thai government on compulsory licensing since last November, despite the critical HIV/AIDS problem in the kingdom. In January 2002 a US Embassy official questioned Thai health ministry officials and was assured that compulsory licensing was not on the agenda.

Thailand has a history of compliance with US pressure on trade issues. "The political will for compulsory licensing still does not exist, despite Doha - Thailand is just too frightened of America," said one official in February 2002.

Thailand has not beaten HIV/Aids. Government estimates of new cases are at 30,000-50,000 a year; figures for total HIV-positive range from 750,000 to 1.5m. It's thought that no more than 5 per cent of HIV+ Thais receives double therapy, let alone triple therapy, the standard treatment for sufferers in Europe or America. In March 2002 the Thai government announced production of a cheap triple-therapy HIV drug produced from three drugs not under patent in Thailand – it will cost patients about US$$27 a month (10 per cent of the cost of a patented triple-therapy), and could save governments much more money in reduced cost of treatment – simply because HIV-positive patients will have less need of care.

Latest news is that the Thai triple-therapy drug (GPO-vir) will be exported to Indonesia, and, starting in October 2002, made available to 10,000 Thai HIV/AIDS patients under a government pilot scheme.

Meanwhile, after a significant legal victory in September 2002, the anti-retroviral didanosine (ddI) may become more cheaply available in Thailand. The Thai NGO AIDS Access, an Oxfam partner, and two HIV+ patients had challenged the manufacturer Bristol-Myers Squibb, over a patent on ddI tablets it has held since 1998 (the powder form of the drug is much less efficient). The Thai court found against BMS, one of the largest multi-national pharmaceutical companies. (For more, see report on case below)

US Trade Pressure on Thailand

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Thailand has suffered from unilateral trade pressure from the US government for increased intellectual property protection of pharmaceuticals since 1985. Backing its pharmaceutical companies, which claimed losses of $30m a year in Thailand, the US pushed the Royal Thai

Government (RTG) by limiting Thai exports to America, until, in 1989 the RTG employed an "interim measure" allowing 2 years market exclusivity for all new pharmaceuticals entries.

In 1992, the Thai Patent Act was amended to include pharmaceutical product patent before the conclusion of the WTO-TRIPS agreement and 8 years ahead of the end of the transition period for developing countries to implement the agreement. Prior to this amendment the Thai Patent Act included only pharmaceutical process patent (ie, it allowed for the production of generic versions through alternative processes). It also extended the length of patent protection from 15 years to 20 years. Against the US's will, RTG introduced a safeguard mechanism in the form of the Pharmaceutical Patent Board, the mandate of which was to investigate and report any evidence of not distributing patented products or distributing at an unreasonably high price. Finally in 1997 under pressure from the US, the Thai Patent Act was amended again to abolish this Pharmaceutical Patent Board.

However, the US was still not satisfied with the new 1992 Thai Patent Act. Pharmaceuticals, which had been given patents in the US prior to 1992, would not have patent protection in Thailand. US therefore continued the unilateral pressure on RTG, in 1993 the "Safety Monitoring Program" (SMP) was implemented. The SMP is applied to "*a new drug*" that is either first introduced in the Thai market or a pipeline product that has been patented abroad between 1986 and 1991, for at least two years. During SMP period, other manufacturers can neither register a generic version, nor conduct bio-equivalence study of such product. Consequently, the SMP provides a company of "*a new drug*" to enjoy market exclusivity. Often times, this period of exclusivity was extended from 2 years, to 3 - 4 years. In addition, to produce a generic version, a bio-equivalence study would take at least 1 year, and the registration of the generic product would take up to 5 - 6 months. Practically, the period of exclusivity would therefore be 5 - 6 years before the generic drug could be marketed in Thailand .

The SMP system alone has caused significant delay in generic availability for drugs such as fluconazole, ganciclovir, stavudine, lamivudine, nevirapine and a number of life-saving drugs none of them patented in Thailand. Some drugs have completed SMP and have become affordable generics. For examples: fluconazole's price fell from $6.1 to $0.16 per 200 mg capsule in 1998; the cost of stavudine decreased from $2.2 to $0.34 per 40 mg capsule in 2000. These price differences can mean life or death in a country still in the aftermath of a catastrophic economic crash in 1997 and currently suffering the highest number of AIDS deaths in Asia.

Thailand has done little to undo the damage of US pressure. Only in January 2001 SMP was revised, removing the market exclusivity provision while strengthening the safety monitoring. This change is welcome but is not enough. Market exclusivity is abolished only for drugs already benefiting from the 1992 patent law and is preserved for exactly those drugs that the US government sought to protect.

Another disturbing experience has been the failure to issue any compulsory licenses. Despite President Bill Clinton's announcement in December 1999 for a new "flexible enough" trade and patent policy indicating that "people in the poorest countries won't have to go without medicines they so desperately need", (Clinton sent a letter to the Royal Thai Government explicitly guaranteeing this) the US government continues to warn the Royal Thai Government against the use of compulsory license. Demonstrations outside the US embassy in Bangkok in November, and lobbying in the US may have had some effect on the US government.

But the Thai Ministry of Public Health continues to reject activist calls for compulsory license. Thailand's position was summarized by a senior official at the Commerce Ministry's Department

of Intellectual Property who said that “Thailand has committed to the international community not to use poverty and sickness as an excuse in international trade”.

The Thailand case shows that solutions must come from both sides. Firstly, the US administration must stop bullying developing countries and should issue an explicit statement supporting countries that implement measures in response to health needs if they are compliant with the World Trade Organisation agreements. Secondly, the developing countries should resist US pressure in order to build up their capability to deal with the patent granting process and to protect the health of their populace as they have a right and duty to do.

For more on trade rules and the injustices of patent law see Oxfam’s Make Trade Fair report from page 207 *(Read the report at www.maketradefair.com)*

Thai NGO Legal Victory against Bristol-Myers Squibb

- Onanong Bunjumnong, Medecins Sans Frontieres, Thailand

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Black Case No. Tor Por 34/2544
Red Case No. Tor Por 93/2545
Subject: Thai Patent No. 7600 (Improved Oral Dosing Formulations of Dideoxy Purine Nucleosides)

AIDS Access Foundation and 2 HIV infected persons jointly filed a law-suit against Bristol-Myers Squibb Company Limited (BMS) as a Defendant and the Thai Department of Intellectual Property (DIP) as a joint-Defendant with the Central Intellectual Property and International Trade Court (IPIT
Court).

The background and legal justification of the case.

Currently, there are more than 1 million people with HIV/AIDS in Thailand. In addition, since the start of epidemic in 1984, about 300,000 people with HIV/AIDS have died. This situation is a crisis for healthcare in Thailand because many of those who have died or are currently being ill
are the wage earners for their families, and the workforce of the country.

Antiretroviral drugs are the best treatment for HIV/AIDS patients and are standard of care However, these life-saving medicines often cannot be accessed in developing countries because they are extremely expensive. The high price is linked with the monopoly on many of these drugs held by Multi-National Pharmaceutical companies. These monopolies are, in turn, linked with patent protection.

Where possible, the Thai Ministry of Public Health provides high quality antiretroviral drugs at reasonable cost - generic versions of antiretroviral that are not patent protected under Thai law are manufactured by the Thai Government Pharmaceutical Organisation.

The Government Pharmaceutical Organisation (GPO) has researched two

generic antiretroviral drugs since 1992: AZT (zidovudine) in capsule form and ddI (didanosine) in both tablet and powder forms. AZT then was marketed in 1995, but ddI tablet has never been produced because a patent for ddI was granted to Bristol-Myers Squibb (BMS) on 22 January 1998. The
GPO could only produce ddI in a powder form to avoid infringing the patent held by BMS. However, in practice the powder form has more side effects and is less convenient to take, so it is more difficult for patients to
comply.

On 7 May 2000, three Thai NGOs - the Thai Network for People Living with
HIV/AIDS (TNP+), AIDS ACCESS Foundation and the Centre for AIDS Rights -
wrote a letter of request for legal assistance from the Law Society for advice on the rights of People Living with HIV/AIDS to access ddI. In order to serve this request from civilians, the chairman of the Law Society then set up a working group of lawyers on 1 June 2000.

Further analysis of the ddI patent granted to Bristol-Mayer Squibb Co., Ltd. (BMS), revealed inconsistencies in the patent application file. When
the ddI patent application was first filed, the BMS claim was restricted
to a dosing range of 5 to 100 mg. This same claim was also published in the Thai Patent Gazette. However, after the publication period had lapsed
more than 3 years, BMS applied an amendment of claims to the DIP. In effect BMS made a broader claim without specifying the range of quantity
per dosage of ddI. Moreover this amended claim did not conform to the detailed description of the invention previously disclosed to the DIP

On 22 January 1998, the DIP granted BMS a patent for its ddI formulation,
under which BMS's exclusive rights are broader than its formulation originally filed for the patent.

Issuance of this amended patent gave BMS the exclusive right to produce and sell ddI tablet formulation regardless of the quantity of ddI per dosage. Other pharmaceutical producers could not produce or sell this ddI
formulation of BMS, even if they produced tablets containing more than 100
mg of ddI.

Therefore, AIDS Access Foundation and HIV infected persons considered that
they were damaged parties: they were effected by the ddI patent and had to
buy an antiretroviral drug produced under the patented formulation of BMS
in high price because no one else produced it.

Legal action against BMS on the range of ddI tablet was begun on 9 May 2001 at the Central Intellectual Property and International Trade Court,
Bangkok, Thailand. In the suit, the plaintiffs requested the Court to adjudicate that both Defendants had illegally amended BMS's claims under
its patent of ddI Formulation. This amendment gave BMS unlimited exclusive
rights under the issued patent.

On 1 October 2002, the CIPIT court ruled in its judgment that the Aids Access Foundation and the HIV infected plaintiffs are injured parties, who
have the power to sue the Department of Intellectual Property and BMS for
the reason that pharmaceuticals are important elements for human survival.
In addition, the Court adjudged that the DIP and BMS shall jointly amend
the Patent No.7600 with respect to the claims there under to the effect that the particulars on the quantity of the contents in the ddI formulation which were previously released be inserted into the claims.

In the said judgment, the Court reasoned that the dispute patent must specify the quantity of the contents. The deletion of the particulars in
the claims of BMS in the patent in connection with the quantity of the contents is considered as a material change made to the patent application.

This is because such deletion results in the unlimited protection of the
dispute patent. Another reason given in the judgment was that the said material change to the patent application was unlawful as such change was
effected after the patent application was published in the Patent Gazette
without the permission of the Director General of the DIP as required by
law.

As a result of the judgment, other pharmaceuticals producer may produce ddI using the formulation with different quantity from that specified in
the claims under the patent as amended in compliance with the judgment without any infringement of the patent of BMS.

The deletion (of claims) can be considered as an adding specification of
invention. As a consequence, the deletion of 'from 5 to 100 mg. per dosage' from the existing (patent) claims has significantly changed the scope of the patent claims as the patent holder will obtain patent

protection from the formulation without any limitation of the quantity per
dosage which will be broaden than the range specified in the previous claims.

<<Under this circumstance, the amendment (of the patent claims) has significantly changed the scope of invention to be protected according to new claims will be broaden or beyond the range discussed in the detailed description of invention which was disclosed at the range of 5 to 150 mg per dosage. Therefore, the deletion of '5 to 100 mg' per dosage from the patent claims is deemed to be adding addition of substance of invention which is prohibited by law.>>

Excerpted from the Central Intellectual Property & International Trade Court Judgement, page 16 Red Case No. 93/2545 given on 1st October, 2002

Key points to emerge from this case are

- Problems in the Thai patent registration processes lead to the issuing
of an invalid patent.

- Thai consumers have utilised their rights under Thai law to mount a legal challenge to a Trans-National Pharmaceutical Company.

- The court ruled that in this case the amendment which removed the dosing
range was a significant widening of the rights of BMS (and by implication
a narrowing of the rights of the consumer).

- This alteration would have gone unchallenged unless civil society took
an interest in the issue.

- Patent applications should be clear and transparent in order to protect
the rights of both manufacturer and consumer.

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Statement prepared by Medecins Sans Frontieres (Belgium) - Thailand Office, with technical assistance from legal experts, on behalf of the members of the Working Group on the ddI Patent:
- Thai Network for People Living with HIV/AIDS (TNP+)
- Thai NGOs Coalition on AIDS (TNCA)
- AIDS Access Foundation (ACCESS)
- Foundation For Consumer (FFC)
- Center for AIDS Rights (CAR)
- Medesins Sans Frontieres-Belgium, Thailand (MSF-B)
- The Law Society of Thailand
- Drug Study Group (DSG)

- Social Pharmacy Research Unit (SPR) Faculty of Pharmaceutical Sciences,
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