The unravelling of compulsory licenses

Evidence from Thailand and India

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Introduction

Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Paragraph 4, states that "the agreement can and should be interpreted and implemented in a manner supportive of WTO (World Trade Organization) members' right to protect public health and, in particular, to promote access to medicines for all."[1] This short paper will examine two cases in which countries – Thailand and India – have threatened to issue compulsory licenses under Article 31. It will assess those potential applications against the criteria of "members' right to protect public health" and "to promote access to medicines for all." The central policy issues when issuing a compulsory license are:

- is access to medicines and price a barrier?
- will a compulsory license alleviate the health problem it sets out to solve?
- and, if it is being used for purposes other than those intended by Article 31, what is its life expectancy as a policy tool to increase access to essential medicines for the poor?

This paper considers these issues in the context of developments in late 2006 and early 2007 in Thailand and India.

The health environment in Thailand

In November 2006 the military government of Thailand threatened to issue a compulsory license for an AIDS therapy. A similar threat was subsequently issued in January 2007 for two additional licenses, this time for another AIDS drug and for a heart medication. In each instance, the government claimed the price of the patented medicines left it unable to fulfil its goal of achieving universal access to medicines.

Thailand has a population of 66 million whose annual growth rate is 1 per cent. Its life expectancy for both sexes is around 71 years. Two of the most sensitive indicators for the health of a nation are its under-5 mortality rate per 1,000 population and its maternal mortality rate per 100,000 live births. Respectively, they are 21 and 44, indicating that for a modest national investment in health, Thailand is reaping a very high return on investment. Because of the low rates of child and maternal mortality, and high life expectancy levels, it can be stated that Thailand is in the midst of an epidemiological transition, moving from relatively inexpensive parasitic and infectious diseases to more costly and long term chronic disorders.

In 2003, total national expenditure on health as a percent of GNP was 3.3 per cent, down from 3.5 per cent in 1999. However, government expenditures have increased from 54 per cent of total national expenditures in 1999 to 62% in 2003, while private expenditures have decreased in these same years.[2] Despite the fact that Thailand has received plaudits for its AIDS programme, only 61,000 of 135,000 elgible patients were receiving AIDS therapy at the end of 2005.[3] At the time of writing, the Global Fund to Fight AIDS, TB and Malaria alone has awarded Thailand $191.4 million. Since government is the dominant provider of health services, most AIDS patients rely on it for services.

The Government Pharmaceutical Organization (GPO)

In Thailand, the state-owned Government Pharmaceutical Organization (GPO) has been the main supplier of a triple dose antiretroviral (ARV) drug called

GPO-Vir. The Global Fund to Fight HIV/AIDS had granted the GPO $133 million in 2003 to upgrade its plant to meet international quality standards for this drug. In October 2006, the Fund withdrew the remaining monies, citing the GPO's failure to meet WHO standards. After four years of pre-testing, WHO still refused to list this drug in its pre-qualification program.

In September 2006, the Geneva-based coordinator for WHO's quality assurance and safety program publicly commented on this development, saying:[4]

- "Drugs that are not WHO pre-qualified may not directly kill people, but they could foster resistance to AIDS drugs.
- When pressed by GPO to approve this drug because it claimed it to be bioequivalent, the coordinator commented: "well, why should we believe you when there are no studies to prove it?"

Since 2002, WHO has recommended that this drug not be sold outside of Thailand because of the GPO's failure to prove bioequivalence, a critical test for acceptance into WHO's pre-qualification program.

On July 19, 2005 the U. S. Centers for Disease Control and Prevention reported on findings presented during Thailand's 10th National Seminar on AIDS in Bangkok. Scientists from Mahidol University's faculty to medicine at Ramathibodi Hospital said that the "rate of drug resistance to locally made GPO-Vir antiretroviral drugs treatment had increased dramatically over the past couple of years and is expected to get worse. They went on to comment that [drug] resistant patients would need to be switched to a more powerful regimen costing $239 per patient per month, compared to $24 for GPO-Vir. They said the high rate of drug-resistant HIV in their study indicates the spread of new infections already resistant to commonly used ARVs."[5]

The role of Médecins Sans Frontières (MSF)

The international humanitarian NGO MSF has publicly supported the military government of Thailand in its applications for compulsory licenses, and in so doing has lent its considerable institutional legitimacy to this development. It has previously also been a vocal supporter of the GPO's decision to manufacture and distribute GPO-Vir. Despite documented drug resistance from the use of GPO-Vir, and WHO admonitions, MSF continues to distribute this experimental drug to over 100,000 patients in Thailand, Cambodia and Burma – without providing them with Informed Consent provisions as required by the UN Universal Declaration on Human Rights.

MSF has calculated that the cost of treating 59 AIDS patients on expensive 2nd-line therapies is equivalent to treating 550 on inexpensive lst-line therapies. This is a 9.3 to 1 ratio in reference to the price of ARVs for patients on 2nd-line therapies. Since drug resistance is cumulative year by year, it is more than likely that of Thailand's 61,000 AIDS patients, at least 45 per cent – or 27,450 patients – are now drug resistant. Using the MSF ratio for the increased prices of 2nd-line treatments, the Thai military government is faced with an annual procurement price that is the equivalent of 255,285 AIDS patients (27,450 x 9.3). This would be more than four times the current AIDS patient load. But this does not include the higher ongoing costs of medical care treatment for patients on 2nd-line therapies with more complex health risks, such as hospitalizations, etc.

As long as both the Thai military government and MSF persist in treating AIDS patients with experimental ARVs, the drug resistance rate will continue to climb – independent of whether or not a compulsory license is issued for 2nd-line treatments.

In the past five years, the Thai government has threatened to issue other compulsory licenses for an AIDS drug and for Avian Flu. Both were to be produced at the GPO. To date, it has not produced one tablet of either drug, even when the rights holder of the AIDS drug surrendered its intellectual property to GPO. At present, pharmaceutical producers in India can supply the same AIDS drugs for which compulsory licenses are being sought, and all of them have been either pre-qualified by WHO or approved by the FDA as true, bioequivalent generics. The fact that their importation would threaten local production by the GPO and ruin its monopoly therefore suggests there may be other motivations aside from public health.

Meanwhile, the Thai military government is faced with rising healthcare costs for a rising burden of chronic diseases. The price for the therapies to treat these illnesses is the least component of total national expenditures: the bulk of those will come from ongoing medical care costs. This is a burden that Thailand's public health sector is ill-prepared to accept, yet from a political perspective, its government, with the encouragement of MSF and other NGOs, can in the short-term pin the blame on the pharmaceutical industry for its pricing policies.

There is enormous populist appeal to be gained by laying off this responsibility to pharmaceutical industries in this way. Yet, in time, when patients learn that they have obtained inexpensive experimental drugs which only produced adverse outcomes at higher and higher levels of medical care costs, then Thailand will find itself in a true national health emergency, compulsory licenses notwithstanding.

The health environment in India

India has a population of 1.2 billion, with an expenditure of 4.8 per cent of national GDP on health in 2003, down from 5.1 per cent in 1999. Of this, 76 per cent of expenditures are in the private sector. Life expectancy for both sexes is 63 years of age. In terms of the two most sensitive indicators for a nation's overall health, in 2004 India's under-five mortality rate is 85 per 1,000 per year, while its maternal mortality is unacceptably high at 540 per 100,000 live births.[6] For a country with an average annual GNP growth rate of 7 per cent since 2000, a greater national investment in public health would be expected.

India appears to be struggling to devote appropriate levels of resources to its AIDS problem. According to a November 2006 report by the International Treatment Preparedness Coalition (ITPC), only 49,864 patients were receiving ARV treatment out of 785,000 who were eligible."[7] This works out to 5.5 percent of those who are eligible. In an earlier report, ITPC found that "no significant steps – including negotiating with Indian pharmaceutical manufacturers to bring down the prices of second line ARV – have been taken by the [government's AIDS office] to ensure second-line regimens are available for those how are now taking first-line regimens. A new study has shown that as many as 20 per cent of ARV-naïve patients may be resistant to first line ARVs in southern India."[8]

India now has the highest number of AIDS patients of any country, making it the epicenter of the global AIDS pandemic. In the "government's budget allocation for 2005–2006, only $5 million was designated for AIDS patients,"[9] leaving the burden for treatment to the donor community, which has provided $600 million. Though India fails to treat its own patients, local Indian pharmaceutical companies are supplying 70 per cent of the antiretroviral AIDS drugs used in the rest of the developing world.

The Global Fund to Fight HIV/AIDS, TB and Malaria is one of the main financial supporters for AIDS in India, providing approved grants of $347.1 million. Nevertheless, the Fund "has no country or field offices, or regular contact with a range of key stakeholders in the country."[10] This may seem strange to some, but apparently not to Indian government officials who are not anxious to have on-site observers in a position to comment publicly on the lack of AIDS treatment.

The position of the union health minister on compulsory licensing

Over the past several months, MSF and Oxfam have been leading an emotive global write-in campaign against Swiss drug manufacturer Novartis, which applied under the Indian Patent Act for a patent on its cancer therapy Glivec. At least 40 other countries have granted patents on this same drug. When it was denied a patent, Novartis presented a legal challenge to India's High Court for a re-consideration. MSF, Oxfam and other NGOs sent an open letter to the president of Novartis, claiming that if this patent is granted, it could "negatively affect access to essential medicines (particularly HIV/AIDS medicines) not only in India but also in all developing countries that import Indian generic medicines."[11] Their claim is that a ruling in Novartis' favour would effectively prevent Indian companies from manufacturing and exporting cheap copy drugs to developing countries, leaving them at the mercy of the pricing policies of global pharmaceutical companies.

This global campaign has resulted in a tsunami of supporting e-mails to heads of state, heads of various ministries in the developed world, the U. S. Congressional leadership, and finally to the Indian Union health minister. Feeling the pressure of this campaign, the Indian health minister threatened in April 2007 to issue a compulsory license against Novartis unless it withdrew its legal challenge.

Glivec is used in the treatment of a cancer so rare that only 9,650 patients in India are affected out of a total population of 1.2 billion people. Novartis is providing this therapy to 7,100 of those needing it free of charge. Generics and other medications treat the remainder. It is therefore peculiar that this drug should be the subject of a compulsory license.

While the Union minister has little time for his AIDS patients, he has found ample opportunity to vocalize his support for MSF and Oxfam's demands that Novartis cease the free provision of this drug. Their pretext is that this program, while laudable in one regard, is nevertheless unsustainable in a larger sense.

There can be no doubt of any country's right to issue such a compulsory license – and Novartis does not contest this issue. The only pertinent question is this: does India, with the capacity to become one of the world's great pharmaceutical research and development centers, need to use a contrived mechanism simply to placate campaiging NGOs? Under TRIPS, compulsory licensing is a government-ordered expropriation of patent rights. If the Indian government accepts the recommendation of its Union health minister, then India would be the first WTO Member to have applied for an official compulsory license – on a drug that is not patented in the requesting country.

Novartis agrees with the interpretation of Article 31 and its provision "to promote access to medicines for all." It has taken immediate steps to ensure that most Indian patients needing access to a rare form of cancer therapy receive it. Yet, MSF and Oxfam have managed to detach the Union health minister from his responsibilities to protect the public's health in favour of pursuing their interests.

More importantly, if Article 31 were properly applied, it would require the Government of India to censure its Union health minister for his blatant disregard of international norms and standards by denying hundreds of thousands of Indian citizens access to AIDS therapies. One of the supporting requirements for the issue of a compulsory license under TRIPS is that the requesting country has to declare a "health emergency". There is one in India, but no such declaration has been forthcoming from the Union health minister for HIV/AIDS.

Lastly, TRIPS provisions are triggered when there are no local producers for the same drug. Since copies of Glivec are being produced by three local companies, the Union health minister needs to re-think the basis for his application for a compulsory license. If his threat is brought to fruition, there would be two losers: the Indian cancer patients now receiving Glivec free of charge; and international cancer patients because TRIPS severely limits the export of products made under a compulsory license.

The hidden issue with MSF and Oxfam

The same Indian drug companies that MSF and Oxfam contend will be harmed by a favorable outcome for Novartis now export and market more than 70 per cent of the AIDS drugs purchased for use in the developing world, extending the life-spans of more than 1 million poor patients, mainly in Africa. This will in no way change if Novartis prevails; indeed, sales by local Indian firms will continue to increase, and poor AIDS patients will maintain access to Indian-manufactured generic ARVs as they do now. Independent of the legal outcome of this case, currently available generic drugs launched before 2005 – including HIV/AIDS medicines and copy versions of Glivec – will continue to be available domestically and for export due to the grandfather clause in the Indian Patent Law.

MSF and Oxfam are of the mistaken belief that the new ARVs which will come on the market after 2005, especially those for 2nd-line therapies, cannot be produced by Indian companies as generics. At present, no rights-holder to the patents on lst-line therapies has presented a legal challenge to any Indian producer. It is highly unlikely that this unwritten policy will change with 2nd-line therapies.

But something more dramatic will change. Once India honors its WTO responsibilities, 2nd-line therapies will have to be produced to international standards if exported. The most fundamental standard will be bioequivalence to the reference products, which is not now required for drugs patented before 2005. A bioequivalent drug is also a true generic – rather than a copy of indeterminate quality.

Bioequivalence is important in that it proves that the copy drug is identical to the original product in terms of clinical benefit to the patient. A professor of molecular pharmacology at Stanford's Medical School noted: "successful treatment of infectious diseases is the result of complex interactions between the patient, the drug and the infectious agent. Drug concentrations that are too low can cause the therapy to fail, and equally important, promote the emergence of resistant forms of the infectious agent."[12]

High standards cost money and lesser-quality Indian companies would sooner avoid that required investment when developing countries are willing to buy their products in the absence of demonstrated bioequivalence, which is currently permitted under Schedule Y of the 1970 Indian Drugs and Cosmetics Law. Reputable Indian generic manufacturers, by contrast, do not shirk this responsibility.

WHO has pre-qualified several Indian companies that have stepped up to the plate and proven the high standards of their lst line AIDS drugs copies. Similarly, the U. S. FDA has Fast-Tracked their applications for approval as true generics. Before the FDA could extend this approval, the rights-holder was given an opportunity to present a legal challenge. None did so.

At present, more than 70 per cent of AIDS patients receiving ARVs via President Bush's Emergency AIDS Plan (PEPFAR) are being treated with true generics (as opposed to copies of indeterminate quality) from Indian producers, and increasingly from South African firms.

These same Indian companies that have accepted the quality challenge on lst-line therapies will most probably do the same for 2nd-line therapies on drugs patented after 2005. In many cases, these companies are operating under voluntary licenses from the rights-holders.

Because India is promoting efforts to implement measures which protect intellectual property, it has seen the number of copy-product brands launched in 2006 fall by a third compared with 2004, dropping from 2,878 to 2,076. "This is a strong indication that the legal copying of patented medicines is becoming tougher."[13] However, MSF and Oxfam, as expressed in their open letter in the global campaign against Novartis, support the continuation of drug production by copy firms in India – even though the government has taken measures to abide by WTO rules and protect intellectual property.

MSF and Oxfam are presenting a misleading case against Novartis, while lending their considerable moral authority to local copy drug producers who have turned their backs on poor AIDS patients in India. These are not principles befitting of humanitarian organisations. Nor should a Union health minister extend to MSF the legitimacy of his office to further an ideological campaign that is more about political theatre than improving healthcare.

The pricing of copies for a cancer therapy

The three Indian firms producing copies of Glivec do so at a price structure that is 4.5 times the annual income of an average citizen. Therefore, they mainly export this product because it is free of local taxes. Regardless of the outcome in the Novatis case, copy formulations of Glivec will remain available, but they will not necessarily be affordable for Indian citizens. Internal state taxes alone can add 30 per cent to the price when drugs are transported across local jurisdictions. The only difference will be that either poor cancer patients or the government will have to pay higher prices for locally produced Glivec, because a compulsory license against Novartis will spend the end of their philanthropic Glivec programme.

Is price a barrier to access for medicines?

The MSF/Oxfam case is predicated on the belief that future AIDS drugs for the poor will become more expensive if Novartis wins, thereby underming access to

medicines. In the initial scale-up to global AIDS treatment, price was indeed put forward as the main barrier to access for ARVs. Over the past few years, however, the WHO itself has dismissed this charge with convincing evidence based on well documented research:

- During the 2006 World Health Assembly in Geneva, WHO released a report on the price, availability and affordability of medicines. It stated: "One major finding was that taxes and duties levied on medicines, as well as the mark-ups applied, frequently contribute more to the final price than the actual manufacturers' price." It went onto comment: "There is evidence that some governments procure medicines efficiently, but charge markedly higher prices to patients, e.g., in Indonesia's public sector, patients paid 11 times the procurement price."[14]
- In July 2006, the director for WHO's HIV Division publicly stated: "Africa has been hardest hit by the AIDS epidemic … it is very obvious that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, and supply chains that don't exist."[15]
- In 2003, academic researchers conducted a study on the hidden costs of drugs in nine developing countries and concluded that they increased the cost of medicines, on average, by 68.6 per cent.[16]

Independent of WHO and other studies, one conducted by the EU Commission in 2003 "found that total duties and taxes (custom duty, value-added tax, and other duties) ran as high as 60 per cent in India."[17]

Companies have pricing strategies that allow them to sell at slightly above the marginal cost of production in the poorer countries, and even donate them outright, only to have the price driven up by tariffs. The WTO should exercise remedial actions beyond TRIPS, particularly where the barriers to promoting pharmaceutical access lie outside the patent system. "Pharmaceutical tariffs and taxes, for example, are non-TRIPS barriers to pharmaceutical access in poor countries, which the WTO can appropriately work to roll back under GATT and the rules for trade in goods."[18]

Patents and access to medicines

It has often been claimed that patents hinder access to medicines in poor countries by driving up prices. While theoretically plausible, there is little evidence to suggest this is actually the case. In a landmark study published in the Journal of the American Medical Association in 2001, the authors found that the poorest WTO members often had few or zero patents on antiretroviral medicines. In analysing the data, they determined that "it is wrong to categorically equate the mere existence of patents with a barrier to accessing AIDS treatment, because the relationship between patents and access is a complex and nuanced one, which depends on non-market factors, such as the medically accepted guidelines for antiretroviral drug treatment; offers by pharmaceutical firms to discount or donate medicines, notwithstanding patent status; and, above all, the availability of international aid finance to purchase drugs."[19]

The findings of the authors are particularly relevant to the MSF and Oxfam's concern that a victory for Novartis will spell the end for cheap HIV/AIDS for Africa. Most of these drugs are actually purchased by aid donors at a level which may well exceed $10 billion for 2007.

Conclusion

We would do well to revisit the basis of MSF and Oxfam's contention that compulsory licenses will solve the access problems of Thailand and India. In the first instance, WHO has dismissed price as an impediment to access, and a landmark study in the Journal of American Medicine has set aside patents as a barrier to access. Rather then improving patients' health, the GPO in Thailand would continue to provide them with experimental drugs, accelerating the rate of drug resistance, while India would persist in the production of copy drugs of indeterminate quality – and still be remiss in the treatment of its own AIDS patients. This latter factor in particular will undermine healthcare rather than improve it.

Compulsory licenses are a divergence from the real issue facing the global health community. "The prime mover of the epidemic is not inadequate antiretroviral medications, poverty or bad luck, but our inability to

accept the gothic dimensions of a disease that is transmitted sexually. Only when we cease to dodge this fact will effective HIV-control be established. Until then, it is no exaggeration to say that our polite behaviour is killing us."[20]

All of the parties in the pharmaceutical industry agree with Article 31 of TRIPS and the rights of countries to issue a compulsory license under its provisions. In Thailand's case, the only "health emergency" is the drug resistance caused by the continued production of the experimental GPO-Vir by a government-owned facility that has been unable to secure WHO pre-qualification. In India's case, the "access to medicines" issue has already been solved by Novartis' donations of Glivec and its production by three local companies. Despite this, India has persistently failed to provide "access to medicines" for its own AIDS patients. It is difficult to escape the conviction that MSF and Oxfam entered the fray with conviction borne of noble intentions rather than with hard facts.

If Thailand and India's current actions are to form the basis of future justification for the issuance of compulsory licenses, then these pretensions to the letter and purposes of TRIPS will become meaningless. Other provisions within TRIPS could rightly be employed to absurd effect For instance, Paragraph 6 expressly confers a political mandate in respect of countries with the problem of "insufficient or no manufacturing capacities in the pharmaceutical sector. Thus, highly affluent, healthy, but small countries without a pharmaceutical sector could apply for a compulsory license: Liechtenstein and Luxembourg come to mind."[21]

The central problem faced by global society lies not in the price of ARVs, which the current compulsory licenses seek to remedy. The real problem lies in patient costs after the drugs have been administered. Policy makers have drastically underestimated the medical costs involved in the sequential increases in the number of chronically sick people as a result of taking substandard ARVs. Their care and maintenance will ultimately prove financially unsustainable.

Using the flexibilities of TRIPS on these two spurious cases will strip Article 31 of its future legitimacy, and foreshadow the end of compulsory licensing as a justifiable tool for countries in real need of its provisions. On 6th May 2007, Brazil – the 6th largest economy in the world, with an HIV incidence rate of less than 0.1 per cent – read the tea-leaves and applied for a compulsory license for an AIDS therapy. TRIPS is thus in danger of evolving into a grab-bag of political opportunism, benefiting only to those who prioritise personal gain over the public's health. As used now, it is a contrived instrument of convenience to gain commercial advantage on the free movement of goods in international commerce, an imperfectly hidden discriminatory non-tariff trade barrier aimed solely at those firms that have provided to poor AIDS patients a life-line to the future.

Compulsory licensing can only succeed by disadvantaging other members of the WTO, especially the poorest ones, though each had pledged themselves to "the principle of sovereign equality of all its Members." When Article 31 becomes inoperative due to its profligate misuse, what then will those countries that really need this remedy do?

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In October 2006, the Thai military government applied for a Compulsory License (CL) on an AIDS therapy, following in January 2007 with two additional licenses. In April, the Union minister of health in India responded to an intellectual property law case brought by Novartis by threatening to issue a CL for a therapy for an extremely rare form of cancer – most of whose sufferers in India receive the drug free via philanthropic programmes. Then, on May 6, the Government of Brazil issued a CL for an AIDS drug.

In each case, the proponents of compulsory licenses argue that the manufacturer's pricing of medicines is the main barrier to access by patients. However, these claims have been contradicted by research from the World Health Organisation and other intergovernmental organisations. The reality is that other factors are more important in determining access to medicines, such as health infrastructure and government mark-ups on imported drugs.

Meanwhile, the manufacture of experimental copy drugs in India and Thailand is very likely contributing to worsening drug resistance amongst AIDS patients, which will lead to major economic and health problems. Based on past experience, compulsory licenses will only accelerate this process.

While governments are not in breach of TRIPS in their issuing of compulsory licenses, it is becoming clear that Article 31 is being devalued by countries that are using it for their own political purposes. When the flexibilities enshrined in TRIPS become meaningless due to this misuse, it will be the poorest countries that really need them that will lose.