

TRIPS and Public Health

The next battle

The Declaration on TRIPS and Public Health agreed at the WTO Ministerial in Doha in November 2001 was an important step forward in the campaign for affordable medicines. It affirmed the primacy of public health over intellectual property rights, and the rights of governments to make full use of the public health safeguards in TRIPS. Ministers also recognised a fundamental imbalance in the TRIPS Agreement and promised to find a solution before the end of 2002. This concerns the way the TRIPS Agreement, by restricting countries like India from exporting cheap generic medicines, will prevent many developing countries from finding affordable sources of vital new medicines. There is a simple solution to this problem in TRIPS. However, rich-country governments, under pressure from large companies, are backsliding on their promises and seeking to water down potential solutions. This issue will test the commitment of rich countries to allow poor people access to the cheapest possible medicines. Failure will strengthen calls for a fundamental redesign of TRIPS.

Summary

The Declaration on TRIPS and Public Health agreed at the World Trade Organisation Ministerial at Doha in November 2001 is an important step forward in the global campaign for affordable medicines. It should give developing countries greater confidence to use the public health safeguards in TRIPS in order to improve access to affordable medicines. This in turn could help bring about real benefits in the health of poor women and men. The Declaration also gives least-developed countries more time before they are required to implement pharmaceutical patenting.

However, there is some important unfinished business in the Doha Declaration. Ministers recognised a fundamental imbalance within the TRIPS Agreement and committed themselves to finding an expeditious solution before the end of 2002.¹ This concerns the way the TRIPS Agreement, by restricting countries like India from exporting inexpensive generic versions of new medicines, will prevent most developing countries from finding affordable sources of new improved medicines to treat diseases such as HIV/AIDS, malaria, and tuberculosis.

Many developing countries cannot afford expensive patented medicines yet neither can they produce cheaper generic versions. Currently they can import these generic copies from a handful of other developing countries which do have the capacity to produce them, but which have not yet fully complied with TRIPS.

The key problem is that these cheaper supplies of medicines will begin to dry up once India and other developing-country generic producers comply with TRIPS, which they have to do by January 1st 2005, at the latest. This is because TRIPS prohibits producer countries from exporting cheap copies of patented medicines, whatever the health needs in other countries, and even when there is no patent in force in the importing country.

This represents a fundamental imbalance in TRIPS. TRIPS allows countries to override a patent, for example if prices are too high, or supplies limited, if certain procedures are followed. Countries with their own production capacity, mainly the rich and industrialised,

¹ The Doha Declaration says 'We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licencing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002'.

can take advantage of this to produce their own cheap generic versions of medicines. However, the majority of poor countries are not able to because they lack manufacturing capacity. Nor will they be able to override a patent to import medicines, because TRIPS stops generic-producing countries from exporting to them.

Some developing countries and NGOs, including MSF, CPT, HAI and Oxfam, argue that the simple solution to this problem is to lift TRIPS restrictions on exports of public-health related products. Under Article 30, the TRIPS Agreement allows governments to make exceptions to the exclusive rights conferred by a patent. WTO members could therefore agree an interpretation of Article 30 that would allow countries to export cheap generic versions to countries that cannot manufacture them themselves.

But there are challenges ahead. First, at the March 2002 TRIPS Council Meeting, it was evident that the US was backsliding on the commitment to find an 'effective' solution by proposing a temporary moratorium on WTO disputes over the issue. Other industrialised countries, also under pressure from powerful corporate lobbies, are seeking to water down potential solutions. Public pressure is vital to ensure that solutions are not limited to a small number of countries, or only to health emergencies, or made so cumbersome as to be effectively unworkable.

Second, developing-country governments will need help in integrating the TRIPS public-interest safeguards into their legislation. Least-developed countries will also need advice on how to take advantage of the extended deadlines for pharmaceutical patenting, since many have already implemented, or are in the process of implementing, TRIPS-compliant rules. For example, in its recent, first patent law, Cambodia has failed to avail itself of the extended transition period agreed at Doha. To this end, organisations such as the WTO, WIPO, and WHO, will need to ensure that the Doha Declaration is fully integrated within their technical assistance programmes.

Third, pharmaceutical companies must ensure that their patent policies, practice and lobbying are compatible with the Doha Declaration, and the US government must also adapt its intellectual property enforcement policies accordingly. This means respecting the rights of governments to use the TRIPS public health safeguards. However, in February 2002, as if Doha had never happened, the pharmaceutical giants' club, PhRMA, recommended that the US government should designate four new countries as 'Priority Foreign Countries' for monitoring and potential trade sanctions under the

‘Special 301’ provisions of US trade law, for ‘their failure to protect patented pharmaceutical products’. The countries are Argentina, Colombia, India and Turkey.

Finally, a massive increase in public financing is needed to help strengthen health services and subsidise the purchase of medicines. The funds currently committed to the Global Health Fund, for example, are inadequate and should be increased. However, the Fund is unlikely to receive widespread public backing unless it is allowed to purchase medicines from the cheapest source, in particular generic manufacturers. Otherwise it risks being viewed as another expensive public subsidy for the giant pharmaceutical companies.

Effective follow up to the Doha Declaration is a crucial next step in making patent rules compatible with public health and development needs. Half-baked solutions will indicate that rich-country governments are not serious about allowing developing countries the right to buy the cheapest medicines, and will merely strengthen the calls for a fundamental redesign of TRIPS.

The Doha Declaration on TRIPS and Public Health

Growing international condemnation of the excessive price of patented HIV/AIDS medicines finally forced trade ministers to address the thorny issue of global patent rules at the WTO Ministerial Conference held in Doha in November 2001. NGOs had campaigned vigorously on the issue, arguing that the global patent rules known as the TRIPS Agreement would exacerbate the health crisis ravaging poor countries. By obliging all governments to grant minimum 20-year patents, TRIPS shields pharmaceutical companies from generic competition globally. This results in higher prices for vital, new, medicines in rich and poor countries alike. Oxfam believes this will seriously restrict poor people's access to new medicines for treating diseases such as HIV/AIDS, and to newly improved medicines for drug-resistant versions of old killers, such as malaria and tuberculosis.

Encouraged by the success of public campaigns on patents and medicines, and by the South African government's victory against 39 pharmaceutical companies over its Medicine Act, developing countries seized the initiative. They tabled a proposal at the Doha summit which sought to ensure that the TRIPS Agreement supported rather than undermined public health. The issue dominated much of the discussions, and trade ministers finally approved a text, known as the Doha Declaration on TRIPS and Public Health. If developing countries now integrate the Declaration into the design and implementation of their national legislation, this could bring real improvements to the health of their citizens.

The Declaration states that 'the TRIPS Agreement does not and should not prevent governments from taking measures to protect public health'. Although this wording is not as strong as that in the original developing-country proposal, it clearly affirms the primacy of public health over intellectual property rights.

The Declaration also clarified some of the key public-health safeguards in TRIPS that had been contested by the US and by large Northern-based pharmaceutical companies. It affirmed the rights of governments to:

- authorise use of a patent without the consent of the patent holder (compulsory licensing), and determine the grounds upon which such licences are granted. These may include public-health objectives.

- determine what constitutes a national emergency – including, but not limited to, the HIV/AIDS pandemic, in which case the procedure for issuing a compulsory licence becomes faster and easier.
- authorise imports of patented goods from the cheapest legitimate international source (parallel imports) without challenge.

In principle the Declaration also grants least-developed countries an extra 10 years (until 2016 rather than 2006) before they are required to implement pharmaceutical patent protection, without prejudicing their right to further extensions. In practice, however, they will need active encouragement and support to avail themselves of the extended deadline, as many have already implemented pharmaceutical patenting. Moreover, the TRIPS Council must confirm that the extension also covers 'mailbox' provisions and patents on processes as well as products.

These political agreements, along with the huge profile given to the issue at Doha, should give developing countries greater confidence to make full use of the existing public-health safeguards in TRIPS, and make it more difficult for the US or the big drug companies to bully them over their patent policies. Experts have suggested that the Declaration will also have positive interpretive value in any future dispute settlement proceedings at the WTO. The Declaration also provides developing countries with an important yardstick for negotiating intellectual property clauses in bilateral or regional trade agreements.

Unfinished business

However, a crucial problem identified at Doha remains unresolved. This concerns the way in which the TRIPS Agreement restricts countries from producing and exporting cheap generic versions of new medicines. This will prevent countries without their own manufacturing capacity from finding affordable sources of new medicines to treat diseases such as HIV/AIDS, malaria, and tuberculosis. This includes the vast majority of developing countries.

Developing countries cannot afford adequate supplies of expensive patented medicines, and unlike rich countries, most cannot produce cheaper generic versions. Currently, they can buy imports of generic medicines from a handful of other developing countries that have not yet fully complied with TRIPS, such as India. Many important medicines are off-patent and can be produced and sold freely. However, vital new medicines for diseases such as HIV/AIDS that are ravaging developing countries are on patent in many countries.

At the moment, if there is no patent granted in the importing country, it can import generic equivalents freely. If there is a patent, TRIPS allows a government to override it by issuing a 'compulsory license' for import from a country where a patent is not in force, such as India. (A compulsory licence is when a government authorises local manufacture or importation of copies of medicines without the consent of the patent holder but in compliance with certain procedures and in exchange for a reasonable royalty.) Even if poor countries don't actually import these generic versions, the option to do so is an essential bargaining tool in negotiating price reductions for patented medicines with the big international drug companies. This was seen when the US government negotiated a low price from Bayer for their anti-anthrax medicine in October 2001, and when Brazil halved the price of anti-retrovirals from Roche in the summer of 2001.

The problem is that when India, and the few other developing countries which currently produce generics, comply fully with TRIPS, which they must do by January 2005 at the latest, they will no longer be able to produce or export cheap generic versions of new medicines. This means that the last source of affordable new medicines for developing countries will dry up. At this point, unless a way can be found of easing TRIPS restrictions on generic exports, countries without sufficient manufacturing capacity will become entirely dependent for new treatments on expensive patented medicines.

How TRIPS restricts exports of cheap generic medicines

TRIPS not only stops competitors producing and exporting cheap generic versions of patented drugs, its rules also say that compulsory licences can only be granted 'predominantly' to supply the domestic market. So although India, once fully compliant with TRIPS, could issue a compulsory licence to address its own health problems, it could not grant a licence in order to address the health problems of other countries, however desperate their needs.

This represents a fundamental unfairness within TRIPS. Countries with their own production capacity, mainly rich industrialised countries with large markets, can override a patent to produce their own cheap generic versions of medicines if prices are too high, or supplies limited. However, the majority of poor countries will not be able to use compulsory licences to produce their own medicines because they lack the capacity to do so. Nor will they be able to use a compulsory licence to import medicines, because TRIPS stops generic-producing countries from exporting to them.

Trade Ministers at Doha recognised this problem and agreed in paragraph 6 of the Ministerial Declaration on TRIPS and Public Health that: 'We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licencing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002'. This is a commitment that it should be difficult for any country to renege on, but there were worrying signs at the March 2002 TRIPS Council meeting that this might indeed happen.

TRIPS restrictions on exports: the future threat

Imagine that the year is 2007, and that Chad wants to import a cheap Indian generic version of a vital new medicine from India. If the medicine had been patented in India after 2005 – the latest date by which India can introduce pharmaceutical product patenting – India would need to issue a compulsory licence to produce the medicine. And because TRIPS also says that compulsory licences can only be granted predominantly for the supply of the domestic market, India would have to find a domestic reason for issuing the licence.

If the medicine were for a disease such as HIV/AIDS, which is common to both India and Chad, it is quite probable that India would be able to cite domestic health reasons for issuing the licence. Under this scenario, India may then be allowed under TRIPS to export to Chad a proportion of the production, perhaps up to 49% but probably much less. This may or may not be enough to supply Chad's needs, but it would almost certainly be insufficient to supply the needs of many other developing countries.

If Chad wanted a medicine for a disease which was not so common in India, it is doubtful that India would have a domestic health reason to issue a compulsory licence. In this scenario, India would be unable to export to Chad. In either case, this would be a very convoluted way for Chad to gain access to affordable generics. No country should have to depend in this way on another government for its health security.¹

Which countries will be affected?

Almost all developing countries rely on imported medicines to a lesser or greater extent, and will therefore be affected by the imminent restrictions that TRIPS will place on generic exports. Only a handful of developing countries, including Argentina, China, Korea, and Mexico, have innovative capabilities and can produce new drugs by a process of reverse engineering. Brazil has a limited innovative capacity. The rest of the developing countries either have insufficient or no manufacturing capacity to produce new generic equivalents themselves.

In developing countries, a large proportion of the population live below the poverty line, and most medicines are paid for by individuals, so higher medicine prices resulting from TRIPS restrictions on the production and export of cheap generic medicines will have grave consequences for people's health. These countries also carry some of the highest burden of disease.

Studies in Rwanda have shown that households with an HIV/AIDS patient spend on average 20 times more on health care each year than households without an AIDS patient. Families often remove girls from school to care for sick relatives or to assume other family responsibilities. Some 20 per cent of rural families in Burkina Faso are estimated to have reduced their agricultural work or even abandoned their farms because of AIDS. Almost everywhere the extra burdens of care and work are deflected on to women, especially the young and elderly.²

In sub-Saharan Africa there are 28 million adults and children living with HIV/AIDS, around 70 per cent of the global total. Of these, 55 per cent are women. AIDS killed 2.3 million people in 2001. Over 12 million African children had lost their mother or both parents to the epidemic by the end of 2000. These figures are forecast to double over the next decade. Without adequate treatment and care, most of those infected will not survive the next decade. Access to affordable anti-retrovirals would both prolong the lives of parents, and give children precious more years with their parents.³

Most of these countries cannot afford the expensive patented versions of HIV/AIDS medicines.⁴ Although generic competition and public pressure helped bring down the price of a patented brand-name triple antiretroviral (ARV) drug cocktail from around US\$10,400 to around US\$930 per person per year in sub-Saharan Africa, the brand-name medicines are still largely out of reach of poor countries. Currently, these countries still have the option of importing cheaper generic versions from India, or at least using this option as a negotiating tool with the large pharmaceutical companies. The cheapest generic version of a triple anti-retroviral (ARV) drug cocktail is available from an Indian firm, Ranbaxy, at US\$295 per person per year. Even at these prices sub-Saharan countries will need financial assistance to subsidise purchases, but use of imported generics would allow governments to treat three times as many people than with the brand-name medicines.

It is not only the least developed countries that will be hurt by higher prices. It is also true of middle-income developing countries, many of which have high levels of poverty and face crippling health problems. One illustration of this is Colombia. Despite a relatively high per capita income, inequality means that one in five Colombians live below the nutritionally defined poverty line. Around half of

health spending is made by households, with medicines accounting for 40 per cent of their total outlay. Major causes of death in Colombia are cardiovascular disease and cancer. The medicines to treat these diseases are relatively costly in relation to average incomes, so that even modest increases in price have major implications for families and government health budgets. The Colombian generics industry can produce low cost versions of many basic anti-infective drugs. And the government has encouraged the importation of low-cost generic drugs, which has drastically reduced costs in a number of areas. The price of a patented version of insulin, for example, fell by half in the early 1990s. With the progressive implementation of TRIPS around the world, such sources of generic new medicines will gradually dry up.⁵

Even upper-middle-income developing countries such as South Africa can face great inequality and devastating health problems. South Africa has 4.7 million people living with HIV/AIDS, and a very high incidence of tuberculosis, a growing proportion of which is drug-resistant and will require new forms of antibiotics.

Follow up to the Doha Declaration

The US is trying to backslide on the commitment of Ministers at Doha to find an effective solution to TRIPS restrictions on production for export. Both the US and EC are under pressure from powerful corporate lobbies to restrict solutions to a small number of countries, to health emergencies, to narrow definitions of manufacturing capacity and to introduce cumbersome procedures that could effectively make solutions unworkable.

However, the Doha Declaration adopted a broad public health perspective and confirmed 'that TRIPS does not and should not prevent governments from taking measures to protect public health'. In this light it is incumbent on the WTO to help ensure that poor people, wherever they live, have the opportunity to find affordable health care. It is also important for the WTO to ensure that any solution allows countries to export 'health products' such as testing kits rather than just pharmaceuticals. TRIPS Council members must also avoid restrictive definitions of health needs or manufacturing capacity as this will increase rather than reduce the uncertainty for governments and generic firms wishing to use the measures to export generics.

In March 2002, the WTO TRIPS Council initiated discussions on follow-up to Doha. At the meeting the US tabled a paper rejecting the proposed solutions put forward by the EC and developing countries (see below). Instead it proposes a moratorium on WTO disputes in

cases where a government allows compulsory licences for export to selected developing countries. The US proposal is unacceptable as it provides a temporary, rather than a permanent solution. As a moratorium can be ended at any time, it will increase rather than reduce current uncertainty and inhibit generic production. It can hardly be considered an 'effective' solution and has been rejected by Brazil and other countries.

Also, the US paper, based on an extremely partial reading of the Doha Declaration says that solutions must be focused on improving access to pharmaceuticals to treat diseases referred to in the Declaration, such as HIV/AIDS, malaria, tuberculosis or other *epidemics*. The US paper also says that the phrase 'countries with insufficient or no manufacturing capacities' should not be extended to encompass developed countries or to countries that choose not to manufacture certain drugs based on policy, economic or other reasons. The paper also questions whether there are any circumstances under which solutions should be employed by commercial entities on a for-profit-basis. This restriction would exclude company and private medical schemes that would have considerable capacity to provide ARVs if they had access to cheap generic supply.

The European Commission presented a much more positive paper with two possible solutions. One is the option, proposed by some developing countries and NGOs prior to Doha, that WTO members should simply agree an interpretation of Article 30 of TRIPS to allow countries to export health products.⁶ Article 30 allows governments to make exceptions to the exclusive rights conferred by a patent.

The second approach suggested in the EC paper is to amend the compulsory licencing provisions of TRIPS (Article 31) by 'carving out an exception, under certain conditions, to Article 31(f)'. This article states that compulsory licences 'shall be authorised predominantly for the supply of the domestic market'.

Unfortunately, the preamble to their paper talked about restricting solutions to countries facing serious health problems and 'exceptional circumstances'. On the other hand, a positive element in the EC paper is that it says that it is ready to discuss production for export to countries that do not provide pharmaceutical patents, as well as those that do. This is a crucial step as paragraph 6 the Doha Ministerial Declaration only refers to countries with pharmaceutical patents that issue compulsory licences. Restricting solutions to these countries would exclude least-developed countries that choose to avail themselves of the extended transition periods granted by the Doha Declaration, as well as very poor countries like Afghanistan that are

not yet members of TRIPS and therefore not party to the TRIPS Agreement. It would be absurd, damaging, and quite contrary to the intentions of the Ministers at Doha, if the US or others insisted on excluding these categories of countries from solutions.

Fortunately, the developing countries remained solidly united at the March TRIPS Council. The African Group (41 members) made a statement supported by many developing countries including Brazil, India, Peru, Ecuador, Malaysia and Indonesia. Their paper proposes that the key options are either to delete Article 31(f) of TRIPS, or to agree an interpretation of Article 30 to allow production to address health needs in other countries. The statement opposes any narrow interpretation of paragraph 6 of the Doha Declaration, or attempts to limit solutions to a certain category of countries, although they point out that developing and least-developed countries are naturally expected to be the main beneficiaries. The developing-country paper also proposes the introduction of a 'general exception' clause along the lines of those in other WTO Agreements,² and puts great emphasis on the need for technology transfer. China was supportive of many of the developing-country proposals.

Lifting TRIPS restrictions on exports

In the run-up to Doha, NGOS and developing countries proposed that the simplest solution to the problem of production for export would be an interpretation of Article 30 which allows exports of health products without the consent of the patent holder. This approach has the following advantages over Article 31 approach⁷:

- It provides the simplest and most direct solution to the problem for developing countries.
- It can be limited to the health problems the Doha Declaration seeks to address by restricting its application to exports of health products
- It allows the decision for a compulsory licence to remain in the country of consumption. It is neither logical or desirable for an

² Article 8.1 of the TRIPS Agreement authorises the adoption of necessary public health measures provided they are 'consistent' with the terms of the TRIPS Agreement. There is no justification for the TRIPS safeguard to be more restrictive than the safeguards applicable to WTO Agreements on goods and services. Developing countries therefore propose that the current weak wording in Article 8:1 should be replaced by the unqualified statement that 'nothing in the Agreement shall prevent the adoption of measures to protect public health'.

importing country to have to rely on an exporting country to issue a compulsory licence on its behalf, which would be the case under an Article 31 solution.

- It allows compensation to be paid to the patent holder in the country of consumption, if a patent exists. If a patent does not exist in the importing country, then logically no compensation should be paid. It does not make sense for compensation to be paid in the exporting country where the product is not consumed which would be the case under the Article 31 solution. The Article 31 approach may also result in double compensation.

Counter-arguments

Some rich countries and companies argue, at a general level, that changes to, or reinterpretations of, the TRIPS rules will not solve the root causes of ill health in poor countries, which relate to poverty, inadequate health services, and lack of political will on the part of governments. It is true that these are all important barriers, and that action is urgently needed to overcome them. Oxfam has consistently campaigned for aid and debt relief for health and education. But as the earlier example from sub-Saharan Africa shows, the use of cheap generic imports would allow governments to treat many more AIDS patients than with brand-name medicines, even after the big pharmaceutical companies dropped their prices.

Industry also argues that some of the key HIV/AIDS drugs will be off-patent by 2005, and that India will be able to continue manufacturing generic versions even after it complies with TRIPS. However, the drug market is dynamic and new ARVs or fixed-drug combinations are likely to come on to the market and will be patent-protected in India. There will also be new improved medicines in the future for many other diseases including drug-resistant versions of old killers, as well for new diseases not yet foreseen. These will effectively be denied to poor countries unless a solution is found now.

On the specific issue of export restrictions, the US and industry argue that an exemption within Article 30 could undermine the TRIPS Agreement by allowing countries to start producing and exporting generic versions of a whole range of other products to other places. There are also concerns that consumers in smaller, wealthy countries without sufficient manufacturing capacity may also demand the use of this exception. This is essentially scare mongering. First, the exception could easily be restricted to exports of health products. Second, rich countries governments can always refuse to use the exception, and customs measures can be agreed to prevent re-

exportation to third countries. Third, patents will still be respected in markets where they are in force, and compensation paid. Fourth, large pharmaceutical companies will not necessarily lose significant markets to generic companies. Many of them are pursuing a high-value, low-volume strategy in these markets, targeted at better-off groups. If the large pharmaceutical companies want to expand their markets to poorer sections of the population and to governments, or avoid compulsory licences, they could always reduce their prices.

Some legal commentators have suggested that an Article 30 exception will conflict with previous panel rulings and/or with Article 27.1 of TRIPS (which prevents countries discriminating in their patents laws as to the field of technology). However, there are also sound legal reasons to argue that Article 30 is not subject to this rule.⁸ Moreover, such concerns should not block action, as Trade Ministers have the power to issue a definitive interpretation of TRIPS and this would take precedence over previous rulings.

Other challenges

The Doha Declaration on TRIPS and Public Health should help give developing countries that have granted patents on ARVs and other vital new medicines greater confidence in using compulsory licence provisions to import cheaper generic versions without the threat of trade sanctions or litigation. However, for a variety of reasons countries are still reluctant to use these safeguards.

In many cases countries have already implemented unnecessarily restrictive legislation due to bilateral pressures or because they are bound by restrictive bilateral or regional trade agreements. These countries will need to revise their legislation to take advantage of the Doha Declaration. In other cases, the technical and legal advice developing countries are receiving from organisations such as WIPO do not yet reflect the Doha Declaration. For example, in the process of passing its first patent law, Cambodia has failed to avail itself of the extended transition period agreed at Doha, despite receiving technical assistance from WIPO. In other cases, governments have included the necessary safeguards in their patent laws but continued fears about provoking retaliation from the US and pharmaceutical giants, prevents them using them. Fear of potential litigation costs and lack of political will can also contribute to the problem. In Thailand, for example, activists and sympathetic government officials report that there has been no change in the stance of the Thai Government on compulsory licencing since Doha.

The case of Thailand

There are an estimated 30-50,000 new cases of HIV a year in Thailand but currently only five per cent of 1.5m HIV-positive people receive any significant treatment. (Government estimates of HIV-positive people range from between 750,000 and 1.5m). Thailand does produce and use some ARVs that have come off patent and have completed Thailand's Safety Monitoring Programme. But health ministry insiders argue that it would help their treatment programme – and enable a limited budget for drugs to reach far more people - if the Government issued a compulsory licences for recent, more effective ARVs. But in January 2002, a US Embassy official questioned Thai government officials and was reassured that compulsory licencing was not on the agenda in Thailand. 'The political will for compulsory licencing still does not exist, despite Doha - Thailand is just too frightened of America', says one health ministry official. US officials have also been taking an active interest in a Thai government/WHO scheme to transfer drug production technology from Thailand to five African countries. While the Thai government began dialogue with NGOs in December about ways of including HIV drugs under government health care schemes, the discussions did not include compulsory licencing. At a meeting between officials and NGOs on 25th March the head of the Thai Food and Drug Administration said that compulsory licencing would be 'impossible' unless Thai law was amended.

The South African government, despite the devastation of HIV/AIDS, has still not used its compulsory licence provisions to import cheap generic versions of ARV triple-therapy cocktails. Critically, in India, the National Working Group on Patents Laws report that the revised patents bill that will bring India into compliance with TRIPS does not fully reflect the spirit of the Doha Declaration, despite the fact that the Indian government fought so hard for it. However, in nearly all cases, even if governments import generic ARVs, they will still need financial assistance to subsidise the purchase.

These kind of problems pose several challenges if the Doha Declaration on TRIPS and Public Health is to translate into real health gains for poor people. First developing-country governments will need active encouragement and support to help them integrate the TRIPS public-interest safeguards into their national legislation. Least developed countries will also need advice on how to avail themselves of the extended deadlines for TRIPS compliance, since many have already implemented pharmaceutical patenting.⁹ This task will fall to organisations such as the WTO, WIPO, and WHO, which must ensure that the Doha Declaration is integrated into their technical assistance programmes. The TRIPS Council must also confirm that the extension covers mailbox, exclusive marketing rights and process patents.

Second, pharmaceutical companies should ensure that their patent policies, practices and lobbying are compatible with the Doha Declaration, and the US government must also adapt its intellectual enforcement policies accordingly. This means respecting the rights of governments to use the TRIPS public health safeguards, and of least-developed countries to avail themselves of longer extension periods.

Finally, a massive increase in public financing is needed to help strengthen health services and subsidise the purchase of medicines. The funds currently committed to the Global Health Fund, for example, are inadequate and should be increased. However, the Fund is unlikely to receive widespread public backing unless it is allowed to purchase medicines from the cheapest source, in particular generic manufacturers. Otherwise it risks being viewed as another expensive public subsidy for the giant pharmaceutical companies.

Deeper concerns with TRIPS

Allowing production for export of health products to countries is an important step. However, even this would not fully solve the public-health problems caused by the Agreement. The deeper problem is not just the restrictions TRIPS places on the *export* of cheap generic versions of patented medicines, but also on their *production* more generally.

With the extension of 20-year patenting to all countries, generic production of new medicines for domestic use and export risks becoming dependent on a complicated web of compulsory licensing and exceptions. This will be a nightmare for poor countries and generic firms, but a dream come true for lawyers.

Many poor governments do not have the legal and administrative capacity to implement TRIPS or use the safeguards adequately, and all are vulnerable to diplomatic and economic pressure, above all from the US. It remains an open question whether rich countries and companies will view compulsory licencing as an exceptional, rather than a routine, measure.

It will also be difficult for generic companies, under this system, to find sufficiently large or stable markets to guarantee the economies of scale necessary to produce *affordable* generics. The likelihood is that, in the long term, generic production of new medicines will be progressively curtailed, allowing large pharmaceutical companies to consolidate their hold over markets. The resulting lack of generic competition will increase the tendency for patent holders to set high prices everywhere.

Oxfam's concerns about TRIPS go further than health, and also relate to its broader development impact on poor countries. TRIPS will raise prices and restrict poor people's access to knowledge-rich goods such as seeds, research materials, textbooks, and computer software. The World Bank estimates that developing countries will transfer an additional US \$20 bn abroad in technology-related payments when they comply with TRIPS. It will also result in huge trade losses to developing countries, as they are all net importers of such goods. It will also restrict their scope to imitate technologies from richer countries, which is a necessary step on the path to developing an innovative capacity. Despite the claims of its defenders, TRIPS will do little to promote foreign investment in poor countries, nor will it promote much global research and development of interest to poor countries because of the low purchasing power, and thus lack of market incentive, in these countries.

There is increasing consensus that the benefits of intellectual property depend on a country's level of development,¹⁰ and a growing concern that the one-size-fits-all approach of the TRIPS Agreement is damaging for poor countries. As well as campaigning for effective follow-up to the Doha Declaration, Oxfam is also calling for a review of the development and health impact of TRIPS, with a view to granting greater flexibility for developing countries to determine the length and scope of intellectual property protection. There is growing consensus that simplest way to do this would be to grant developing and least-developed countries much longer transition periods to comply with TRIPS, based on their achievement of agreed development milestones rather than arbitrary dates (as at present).

Notes

¹ Our thanks to Christopher Garrison at MSF for helping clarify this issue. Any errors of interpretation are ours.

² Ibid

³ UNAIDS/WHO, AIDS Epidemic Update, December 2001

⁴ A recent study by Dr Attaran and Mr Gillespie-White argued that the main barrier to medicines in Africa is lack of finance rather than patents. The study purported to prove that patent coverage in Africa for antiretroviral medicines was modest. But MSF, Oxfam and other NGOs argued that the data actually proved the opposite, namely that *the most affordable and appropriate* ARVs were blocked by patents. Patents on zidovudine block these ARV combinations in 33 of the 53 countries surveyed in the study, while nevirapine is patented in 25 of these countries. These countries represent 81 per cent of Africa's AIDS burden. It is also pertinent to note that the vast majority of least-developed countries in Africa have already introduced pharmaceutical patent legislation.

⁵ Oxfam press release, June 2001

⁶ Joint NGO letter to TRIPS Council Members, 28 January 2002

⁷ Adapted from the Joint NGO letter and a conference presentation by Jamie Love from the Consumer Project on Technology.

⁸ Frederic Abbot, February 2002, 'Compulsory Licensing for Public Health Needs; The TRIPS Agenda at the WTO after The Doha Declaration on Public Health'.

⁹ The TRIPS Council will also need to confirm that the extended deadlines for least developed countries refer to 'mailbox' and exclusive marketing rights.

¹⁰ See for example, World Bank, Global Economic Prospects and the Developing Countries, 2001.

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