Priced out of Reach

How WTO patent policies will reduce access to medicines in the developing world

The forthcoming WTO summit offers an unparalleled opportunity to change global patent rules, known as the TRIPS agreement, so that vital medicines are not priced out of reach of people living in poverty. Unfortunately, the US government is opposing the developing-country call for TRIPS to be clarified and interpreted in favour of public health. Oxfam urges industrialised countries, above all the United States, to support this call, agree to an in-depth review of the agreement, and cease putting pressure on countries to implement unduly restrictive patent measures. Action to prevent TRIPS from obstructing access to medicines is the litmus test for the WTO's commitment to make trade rules work for poverty reduction.

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Summary

The outcome of the World Trade Organisation (WTO) summit in November will have a major effect on the lives of people living in poverty. Will vital medicines be affordable in future, or will WTO patent rules price them out of reach? Unfortunately, the US government, backed by Japan, Switzerland and Canada, is blocking attempts by developing countries to reduce the harmful effects of these controversial rules, known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). On the eve of the ministerial conference in Doha, lack of progress on this issue threatens to further undermine public confidence in the WTO, alienate its developing-country members, and provoke deeper questioning of the patents system. More importantly, the US government's unwavering protection of patents threatens the health of millions of people in developing countries, which is why Oxfam is promoting a public campaign for WTO members to take urgent action.

Developing-country governments are currently asking for the rules to be clarified and interpreted in a way that improves the ability of governments to ensure access to affordable medicines. The developing countries want their specific proposals to be endorsed as a free-standing declaration at Doha. Sadly, the US administration is opposing even this modest demand. At the special WTO session held on 19 September 2001 to discuss the public-health impact of TRIPS, the US delegate denied there were any problems, despite growing evidence to the contrary.

The European Union is prepared to accept some of the developing-country proposals, with some important exceptions, and is engaged in an effort to bridge the gap between the US government and the developing-country bloc. However, senior European Commission trade officials are now voicing their frustration with US 'intransigence', which they fear is obstructing the path to consensus over a new trade round. Regrettably, the governments of the UK and Germany, both homes to major international pharmacuetical companies, are attempting to shift the EU position closer to that of the US.

Progress is still possible at Doha, thanks to public pressure world-wide and developing-country persistence, but the challenge is all the greater since corporate lobbies, led by the pharmaceutical sector, are out in force to defend the rules they designed and promoted. Transnational companies, by far the greatest beneficiaries of globalised intellectual property (IP) rules, have large interests at stake. Last year, US companies earned US$36.5bn abroad from royalties and licensing fees alone, more than half the world total.

Nevertheless, recent concern in the US about the cost and availability of Cipro, Bayer's patented medication for anthrax infections, may sensitise public opinion to the problems of access to medicines in the developing world, and thus influence government policy on TRIPS. The proposal from some US legislators to override the Bayer patent and immediately import generic equivalents from India at one-thirtieth the cost is precisely the kind of policy option the US government has opposed in poor countries, where the health crisis kills 37,000 people every single day. In line with the calls from

industry, the US administration is respecting the Cipro patent, though it has threatened to issue a compulsory licence if Bayer continues to charge exorbitant prices. This attitude contrasts sharply with US opposition to Brazil employing similar tactics earlier in the year to bring down the price of patented antiretrovirals supplied by Roche and Merck. Canada's authorisation of a compulsory licence to enable a local manufacturer to supply Cipro also exposes it to accusations of double standards, given its pro-industry stance in the debate over how medicines should be treated in the TRIPS agreement.

Two million children die every year from pneumonia, almost all of them in developing countries. US-based Pfizer's best-selling antibiotic, azithromycin (Zithromax), is particularly good for treating child pneumonia. It is under patent in Kenya, where it costs as much as in Norway. But Kenya only spends US$17 per head every year on healthcare, while Norway spends US$2300. Kenya is not allowed to import the generic equivalent available in India at one-fifth of the price. Indian companies manufacture azithromycin because the government has not yet implemented medicine patenting. If TRIPS-compliant rules had come in earlier, manufacture would have been impossible.

Why do developing countries object so strongly to TRIPS? Its essential flaw is to oblige all countries, rich and poor, to grant at least 20 years' patent protection for new medicines, thereby delaying production of the inexpensive generic substitutes upon which developing-country health services and poor people depend. And there is no upside: the increased profits harvested by international drug firms from developing-world markets will not be ploughed back into extra research into poor people's diseases – a fact some companies will in private admit.

Many rich countries counter-argue that TRIPS is a blend of principles and general rules which gives countries sufficient freedom in the design of national laws, and provides safeguards for protecting the public interest, such as leeway to override patents on health grounds. In practice, the US government presses developing countries into passing 'TRIPS plus' legislation based on the most restrictive interpretation of TRIPS, shorn of the already-weak safeguards that TRIPS allows, and containing levels of IP protection that go well beyond anything mandated by TRIPS.

These pressures, from which Brazil, South Africa, the Dominican Republic, and Thailand have all suffered, are backed by the threat of unilateral trade sanctions, which can be authorised either by Section 301 of the US Trade Act, or by successfully appealing to the WTO 'court'. The US administration also makes extensive use of treaties such as the Free Trade Area of the Americas and dozens of investment agreements to achieve the same aims.

Recommendations

What the WTO member states do about TRIPS and access to medicines at Doha is widely seen as a decisive test for whether global trade is managed

for people or merely for profit. For the sake of the millions of people in poverty, Oxfam urges the industrialised countries:

- to support the interpretation of TRIPS put forward by the developing nations for approval at Doha which affirms the primacy of public-health objectives and strengthens the safeguards
- to support a commitment at Doha for an in-depth review into the health and development impact of TRIPS, with a view to amending the length and scope of pharmaceutical patents and other IP rights, as recently proposed by the African group of nations and the European Parliament
- to cease putting pressure on developing countries to implement 'TRIPS plus' or unduly restrictive patent measures, whether through bilateral economic agreements or the threat of trade sanctions.

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This paper has seven sections. Section 1 looks at current controversies at the WTO. Section 2 examines why TRIPS poses a threat to public health, and why 'TRIPS plus' demanded by the US is even worse. The position of WTO member states is described in greater detail in Section 3. Sections 4 and 5 explain why and how the US government vigorously promotes high levels of IP protection world-wide, employing the threat of trade sanctions and systematic use of bilateral and regional economic agreements. Section 6 addresses the arguments the US and its supporters are using at the WTO. Oxfam's recommendations for changes in the TRIPS policies of the industrialised countries and of the US are presented in the final part.

1 The growing political controversy over TRIPS

The forthcoming WTO summit offers an unparalleled opportunity to shift global patent rules so that life-saving medicines are not priced out of reach of people living in poverty. At the Seattle ministerial conference in 1999, the concern about patents was restricted to a number of developing countries. Now, almost all member states recognise that there is a problem to be addressed. Public opinion around the world, shocked by the scandalous cost of patented AIDS drugs in Africa and the callous behaviour of pharmaceutical companies, is also calling for action. As a result, the WTO has finally begun to overcome its 'business as usual' attitude, and in June and September 2001 held its first-ever meetings to debate the impact of TRIPS on access to medicines. This changing political climate, combined with the imminence of the ministerial conference (the WTO's highest authority), offers the possibility of real progress in changing the agreement and the way it is implemented. However, this opportunity will be lost unless the US government has a change of heart.

At the September discussion of the TRIPS Council (the committee charged with oversight of the agreement, to which all member states belong), more than 50 developing countries led by the Africa Group presented proposals for ways in which TRIPS could better protect public health. The developing countries want the Doha conference to issue a definitive interpretation of TRIPS which reaffirms the primacy of public health over commercial interests, and clarifies a number of contested clauses. Remarkably, even this modest proposition was opposed by the US delegation, backed by Canada, Japan, and Switzerland, which continues to assert that there is insufficient evidence that TRIPS prejudices public health. The intense debate continues among member states, but as part of the broader discussion over the Doha agenda and declaration.

The European Union, while still essentially protective of TRIPS, recognises that there could be a problem over affordability of medicines as a result of patenting. Nevertheless, despite shifting over the last year towards a more pro-public health interpretation of the agreement, it has significant objections to the developing-country proposal for Doha. At the moment, the European Commission is attempting to broker a deal between the rival camps but with little success. In mid-October, exasperated senior Commission officials were publicly referring to 'US intransigence'.

However, the EU is also divided on the issues. The UK and Germany, in line with demands from their pharmaceutical companies, are attempting to move the EU closer to the US position, while other members, notably Holland, are more sympathetic to the developing countries. The European Parliament, in a comprehensive motion approved in October 2001 on the health crisis in developing countries, calls for a pro-public health interpretation of TRIPS and for the reduction of patent periods for medicines used to treat communicable diseases. While this welcome resolution does not bind the EU position at Doha, it increases the isolation of the UK/German position, and of US policy.

2 Why TRIPS should carry a health warning

There are growing fears about the negative impact of TRIPS on public health in the developing world, where 37,000 people die every day from treatable infectious diseases. And the reason is simple. TRIPS obliges countries to grant at least 20-year patent protection in all fields of technology, including medicines. These longer patent periods will delay the availability of the low-cost generic equivalents that traditionally supply developing-country needs; only the expensive, patented version of a new medicine will be available. At a time when millions of people are already unable to afford essential medicines, and when public health is threatened by a combination of new diseases and drug-resistant variants of old killers, WTO rules will further reduce access to modern medicines for people living in poverty.

Pfizer, which recorded profits of US$13bn last year, has long been in the firing line for refusing to drop the price of its anti-fungal fluconazole (Diflucan), which is vital for treating meningitis and thrush infections in people with HIV. In Kenya, thanks to patenting, Diflucan costs 30 times the price of generic equivalents produced elsewhere. After long public campaigns, Pfizer has finally agreed to donate Diflucan in Africa, but this is only shortly before the patent expires. The question now is what Pfizer will charge for its improved version, Vfend, which will soon reach the market, protected by patents spread throughout the world by TRIPS.

US trade negotiators say that the TRIPS agreement is sufficiently flexible to accommodate the needs of developing countries, citing longer deadlines for compliance: 2006 in the case of the least-developed countries. Critics are also assured that the agreement contains safeguards which permit government action in case of a conflict with the public interest. Specific provisions include the ability to issue compulsory licences, i.e. to override a patent and authorise a

third party to manufacture the product, such as a medicine. This is an important recourse in cases of refusal to supply a market, or abusive pricing. TRIPS also does not prevent a country from buying a patented product from the cheapest legitimate international source without the permission of the patent-holder – a practice known as parallel importing.

Unfortunately, these and other safeguards are not clearly formulated, nor easy to put into practice, particularly for smaller, less economically developed countries, which cannot risk litigation or trade disputes. Their benefit is further reduced by US insistence on narrow interpretations of the conditions attached to their use. This helps explain why no developing country has yet issued a compulsory licence for a medicine. It is not clear, for example, whether TRIPS allows a country to issue a compulsory licence to enable a manufacturer in another country to supply it with a needed medicine. The US government asserts that TRIPS does not, which would mean that a country without a pharmaceutical industry would have no last resort to deal with a company refusing to provide affordable medicines.

From any perspective, compulsory licensing is an exceptional administrative measure, which cannot be the everyday solution to the expanding problem of high-priced medicines. For this reason, the African nations, in their recent comment on the draft Doha declaration, insist that the WTO address the issue of reducing the length and scope of pharmaceutical patenting, in order to stimulate price competition.

‘TRIPS plus'

Problems with the TRIPS agreement are exacerbated by the policy of the US government to push developing countries into passing 'TRIPS plus' national legislation. These are laws based on the most restrictive interpretation of TRIPS, purged of the original safeguards, and containing levels of IP protection that go well beyond anything mandated by TRIPS. The aim of the US government is to provide the longest possible period of effective protection for its corporations. The threat to developing countries is unilateral trade sanctions, which can be authorised either by Section 301 of the US Trade Act, or by a WTO Dispute Settlement panel in the event of a TRIPS violation. The US government also uses bilateral and regional trade agreements to induce countries into accepting the patent rules sought by US companies, and then binds them into those commitments. (See Section 5 for further detail.)

The US administration, under considerable domestic and international pressure, has ostensibly eased up on these policies in the case of Africa. In May 2000, President Clinton issued an executive order stating that the US would not take action against countries in sub-Saharan Africa using compulsory licensing and parallel importing to improve access to AIDS drugs, provided that the measures were TRIPS-compliant. This order was re-confirmed by President Bush. Behind the scenes, however, the Office of the US Trade Representative and the large pharmaceutical companies continue to lobby African countries for the introduction of 'TRIPS plus' patent laws.

The Dutch minister for Development Co-operation, Eveline Herfkens, argues that the provisions for compulsory licensing and parallel importing in TRIPS are important. 'The agreement gives developing countries some freedom. And they must be allowed to make use of it without rich countries putting a knife to their throat. It is totally unacceptable for rich countries to put bilateral pressure on them to be stricter than TRIPS allows. Or to be stricter than the rich countries themselves.' (*Speech at The Hague, 12 October 2001*)

3 How the WTO members are lining up on TRIPS

Developing countries

At the WTO, most developing countries are pragmatically seeking to reduce the immediate damage caused by TRIPS by seeking approval at Doha for a binding, pro-public health interpretation of the agreement. They hope that this will give them more freedom in the design of national laws, a greater capacity to negotiate with pharmaceutical companies, and a reduced threat of trade disputes or court cases. The developing-country proposal lists specific TRIPS clauses for which definitive interpretations are needed, consistent with the imperative to protect public health. These include clear recognition of members' rights to determine the grounds for issuing compulsory licences, to allow production and export in response to a licence issued in a third country, and to allow parallel importing. Developing countries also call for a moratorium on trade dispute actions that might limit a country's capacity to protect public health, and for extension of the transition periods for TRIPS compliance.

Developing countries warn, however, that they will push for more substantial reform if this strategy does not deliver improvements. Privately, many delegations say that they would like to see a major revision now, especially if it were not part of the horse-trading associated with trade rounds. Less constrained by realpolitik at the WTO, the Group of 77, representing most of the developing world, has proposed that essential and life-saving medicines be excluded from patent rules. In October, the Africa group at the WTO argued that this reform could be introduced through the review process laid down in Article 71 of the TRIPS agreement.

The EU

As noted above, there has been a welcome shift in the position of some EU member states and the European Commission over the last two years. The EU has now accepted that there is a problematic issue to discuss, and has indicated that it will support some of the immediate proposals of the developing countries on interpreting TRIPS. It is also more circumspect in pressing for 'TRIPS plus' intellectual property protection in its bilateral dealings with developing countries, at least where these would impact on public health.

Although the EU still argues against more substantial reform of TRIPS, such as changing the patent term of pharmaceuticals, it will consider the possibility of amendments to the agreement in the context of a new trade round. It also calls for international drug companies systematically to reduce their prices in developing countries, with the Commission hinting at action on patents if this is not done. All this means that there is now clear water visible between the US and EU positions, improving the prospect of real changes in global patent policies and practices.

The US government

The US government remains adamant that TRIPS does not pose a problem for public health. Faithful to the line of the big pharmaceutical companies, it insists on the most restrictive interpretation of the agreement and will not endorse the modest proposals of the developing countries. It also attempted to limit any further discussion to the problem of access to HIV/AIDS treatments – a proposition with no rationale, since people with HIV commonly suffer from TB, fungal infections, meningitis, pneumonia, and other diseases. Moreover, other illnesses unrelated to HIV also generate a high toll of death and suffering among poor people.

It remains to be seen if the recent debate in Canada and the US over access to Cipro, Bayer's patented antibiotic for treating anthrax, will soften their governments' policy on TRIPS. The fact that Canada has issued a compulsory licence for Cipro as a precautionary measure should make it politically and morally untenable to deny developing countries similar powers when faced with the reality of huge loss of life. Under the US/Canada interpretation of TRIPS, developing countries cannot import generic medicines under a compulsory licence. This deprives all countries that lack a sophisticated pharmaceutical industry of access to affordable treatments.

The US government's minority position in the WTO on access to medicines is not unprecedented. In April 2001, for example, Brazil presented a resolution to the UN Human Rights Commission on the right to access to affordable medicines in the context of the HIV/AIDS pandemic. The motion was supported by 52 nations, with a single abstention: the US. At the World Health Organisation (WHO), the US delegation leads a small minority opposing a role for the organisation in monitoring the impact of TRIPS and in producing regular information on global drug prices.

US policy also stands in contrast to a substantial body of informed public and even business opinion in the US and throughout the world, which recognises that there are problems with the current excesses of the patent system, North and South. Leading members of the liberal establishment, including commentators in the *Financial Times* and *The Economist*, and renowned free traders such as Columbia University Professor Jagdish Bhagwati, have publicly expressed concerns about the economic inefficiency and social costs associated with IP monopolies. In addition, US public-health experts, medical associations, and civil-society organisations are actively voicing their concerns, and have even suggested that IP protection, which is anti-competitive by nature, has no place in the WTO.

4 What is good for Pfizer is good for the United States

Why is it that the US government promotes IP protection so fiercely, to the extent that it can find itself isolated in international fora? Its policy is a direct response to the interests of powerful US-based corporations and investors, and is rooted in the importance of technology and know-how to the US economy, which receives more than half the world's royalties and licensing fees. In 2000, the US earned US$36.5bn on its IP exports while paying out US$13.3bn to other countries, thus gaining a net surplus of over US$23bn. No other

country achieved a net surplus of even US$1bn. The US pharmaceutical industry has an annual turnover of nearly US$200bn, much of it derived from patents.

US policy is also the result of the direct influence in Washington of large high-technology companies, such as Monsanto, Boeing, Dupont, Pfizer, IBM, and Microsoft. They have succeeded in perpetuating a political culture that equates corporate with national well-being.

Behind the scenes, Pfizer and IBM were, in fact, the leading intellectual authors of the TRIPS agreement. Apart from being famously skilled in lobbying, the pharmaceutical industry often has people in key posts in the Department of Trade and the office of the US Trade Representative (USTR), and is one of the largest funders of political parties. In 1997-99, the industry spent US$236m lobbying Congress and the executive. During the 2000 US election cycle, Pfizer alone donated US$2.3m to party funds, 86 per cent of which went to the Republicans.

What else is wrong with TRIPS?

Apart from the threats to public health, developing countries are worried that high levels of IP protection will raise the cost of acquiring technology and knowledge-intensive goods. There are also fears that TRIPS will strengthen corporate power in agriculture, weaken farmers' seed-saving rights, and reduce national control over biological resources. When TRIPS was negotiated in the early 1990s, most governments were not fully aware of these consequences. They were cajoled into accepting the agreement as part of the much bigger and indivisible package of measures agreed at the end of the Uruguay Round. It was take it all, or leave it all. Many hoped that the promised access to rich-country markets for textile and farm products would compensate for losses due to TRIPS – a promise never honoured.

5 How the US TRIPS strategy works

The US government has a complex global strategy for securing laws in every country which provide the maximum possible protection for IP. Despite the high profile of some US policies, such as the use of trade sanctions to force countries to introduce patents on pharmaceuticals, much of the effort is tucked away from view in bilateral negotiations over trade and investment treaties. Apart from the threat to public health, the consequence of locking developing countries into absurdly high levels of protection with minimal safeguards will be a massive transfer of resources from the technology-poor to the technology-rich. The US strategy employs three mutually reinforcing instruments:

- unilateral US investigation and sanction under Section 301 of the US Trade Act
- bilateral IP treaties, and bilateral and regional trade instruments containing IP provisions which specify in detail what national laws should be
- TRIPS, backed by the WTO enforcement mechanisms

One worrying aspect of this strategy is the way that a web of agreements is growing rapidly and tying countries and regions into higher levels of IP protection, well beyond TRIPS provisions. Even if TRIPS rules are amended or interpreted in a pro-public health manner, nothing will change at the country level without unstitching these other agreements. Moreover, since a country in the WTO is obliged to offer similar trade terms to all member states (the principle of 'most favoured nation'), agreements reached in a bilateral deal with the US automatically become its global policy. In this way, the EU and other IP-rich countries free-ride on US agreements with other countries. EU bilateral agreements also oblige partner countries to strive for the 'highest possible standards' of IP protection, which acquires real meaning when standards are being ratcheted up around the world by the US.

Section 301

For over 20 years the 'Section 301' provision of the US Trade Act has underpinned the drive for higher IP standards, far exceeding the legitimate control of intellectual property rights. 301 requires the USTR annually to identify countries that deny adequate IP protection to US firms and, depending on the perceived severity, to warn those countries to shape up, to present them a plan for progress, or to apply trade sanctions. In the case of medicines, the office of the USTR bases its assessment and grading on information supplied by PhRMA, the US pharmaceutical industry association. Section 301 also allows the USTR to act against countries opposing the IP policies of the US government in multilateral organisations.

A large number of countries have felt the heavy hand of Section 301, including Thailand, South Africa, and Brazil. In Brazil's case, US trade sanctions in the late 1980s successfully pressured it to introduce patents on medicines, and broke its resistance to the inclusion of TRIPS in the Uruguay Round package. However, it does not usually come to that pass. As a deputy USTR told Congress, 'One fascinating aspect of the Special 301 process occurs just before we make our annual determinations, when there is often a flurry of activity in those countries desiring not to be listed or to be moved to a lower list.

IP laws are suddenly passed or amended, and enforcement activities increase significantly.'

Thailand and the Dominican Republic

Thailand, a past victim of 301 trade sanctions on its exports, has been visited three times in 2001 by special US envoys complaining about new IP regulations that will reduce the period of effective market monopoly for patented medicines. These provisions govern when manufacturers can start production of generic equivalents of patented medicines, and whether they can take advantage of clinical data presented to the regulatory authorities by the patent-holder. US trade officials claim that its bilateral IP agreement and the TRIPS agreement are being violated, though this is denied by Thai authorities.

The Dominican Republic was put on the 301 'priority watch list' in April 2001. In June 2001, PhRMA sought a review of the US trade preferences granted to the country. If these were withdrawn, the effects on income and employment, especially of women, could be devastating. PhRMA also wants the USTR to initiate a dispute process at the WTO. PhRMA complains that Dominican patent law has too many exclusions from patentability, too much scope for compulsory licensing, too little protection of clinical data presented to regulatory authorities, and a requirement that patented products be manufactured in-country. The real 'problem' is that the Dominican Republic has a local pharmaceutical industry, which grew up before the country was forced to introduce drug patenting, and which the government is trying to preserve. This industry is now starting production of anti-retrovirals to meet the country's pressing need for affordable treatment for HIV/AIDS.

Bilateral and regional agreements

For the last two decades, largely unobserved by the public and even by health authorities, the US has been linking trade and investment agreements to a country's acceptance of IP protection norms that go beyond US domestic standards, and beyond what are now TRIPS standards. This remains a key element in US strategy today, as demonstrated by the US stance in the negotiations for the Free Trade Area of the Americas (FTAA), a regional agreement covering 34 countries, through which the US government seeks to restrict the use of compulsory licences. Similarly, the Africa Growth and Opportunity Act (2000), heralded by the US as a generous response to poverty in the poorest region of the world, requires the US government to take account of a country's record on IP when deciding whether to grant preferential trade terms.

The US-Jordan free trade agreement

This new treaty reveals how the US intervenes to obtain the desired domestic patent regime. Jordan's 'TRIPS plus' obligations which impact on the price of medicines include:

- banning parallel importing (i.e. shopping abroad for the cheapest supplier of a patented drug)
- restricting the grounds for compulsory licensing to national emergencies
- extending patent periods in the event of delay by regulators in approving medicines for public use
- preventing repeat use of clinical test data submitted to regulators, thereby delaying approval of generic competitors and effectively extending the patent period
- removing an existing law which makes granting a patent conditional on the holder marketing an adequate supply of the patented product at reasonable prices

In agriculture, the agreement requires Jordan to ratify UPOV, an international convention on plant breeder rights which is highly unfavourable to developing countries, and to allow patenting of plants and animals, as well as essentially biological processes. Remarkably, the agreement also specifies the increased criminal penalties for theft of IP.

The US government also negotiates Bilateral Investment Treaties (BITS) with many developing countries. In these, and in the investment chapters of comprehensive economic agreements like the North America Free Trade Agreement (NAFTA) and the FTAA, the US includes IP clauses which further weaken the ability of governments to regulate patents in the public interest. Provisions on expropriation, for example, protect against compulsory licensing of pharmaceuticals, and the requirement that a patented product be manufactured locally is outlawed. The US government has also negotiated dozens of Bilateral Intellectual Property Agreements (BIPS), particularly with transition countries outside the WTO. The effect of these instruments is to extend effective patent periods by a series of devices, and to emasculate public-interest safeguards such as compulsory licensing.

TRIPS and the WTO

The multilateral TRIPS agreement, signed in 1994, and now binding on 142 countries (with more to come), was the greatest breakthrough in the globalisation of US patent norms, not least because it can be enforced by trade sanctions authorised by a WTO dispute settlement panel. In one fell swoop, dozens of transition and developing

countries were obliged to meet 'first world' standards of IP protection. It was introduced after wearing down resistance from countries like Brazil and India. It was presented to developing countries with the argument that it would replace the painful bilateral pressure to which many of them had been subjected by the US: a claim proved false by the extensive use of US leverage today.

The US government, often at the behest of the pharmaceutical industry, has since used the threat of WTO disputes to press countries to introduce 'TRIPS-plus' – Argentina and Brazil being the most recent targets. Although the US administration recently withdrew its WTO complaint concerning Brazil's 'local working' requirement as a result of adverse public reaction, it will continue its dispute though bilateral channels. Brazil remains on the 301 'watch list'.

6 The US view on the effects of patents

In debates at the WTO, the US government continues to deny that high levels of IP protection can damage public health in developing countries. It claims there is no proof for this, and that poor health is caused by a range of other factors, including lack of infrastructure. It also points out that developing countries have longer periods within which to comply with TRIPS, and stresses the positive effect of patenting on pharmaceutical innovation.

The US government is right in saying that the health crisis in developing countries requires a range of interventions, including greater investment in health infrastructure. But while medicines are not a magic bullet, they are an essential part of the solution. Access to medicines is particularly sensitive to price, since most poor people in developing countries pay for them out of their own pockets. And price is related to the presence of patent-generated monopolies, now greatly extended by the TRIPS agreement. The US government echoes industry arguments that patented drugs face price competition from close substitutes, and thus do not enjoy a monopoly. However, the fact that the price of a patented drug usually falls very sharply after generic competition kicks in is proof that a monopoly exists.

At a conservative estimate, TRIPS will shield new patented medicines from generic competition for nine or ten years longer than in the past. During this period, poor people and under-resourced health services will find themselves paying at least three times what they would otherwise have paid, particularly for new life-saving medicines for

which there is no off-patent substitute. For some products, prices could be 10 or 20 times higher. (For further information, see 'Fatal Side Effects: Medicine Patents under the Microscope': www.oxfam.org.uk/cutthecost/indepth/html).

In 2000, the European Commission accepted that 'several key products to prevent, diagnose, and treat HIV/AIDS, malaria, and tuberculosis, largely produced in industrialised countries, under patent, are still too expensive for the poor'. Products are also coming out to deal with drug-resistant strains of many common diseases such as pneumonia, meningitis, and gonorrhoea, but as the WHO Director Dr. Brundtland has said, 'newer treatments are proving too costly to the vast majority of those living in poor developing nations'. Looking further ahead, scientific advances will lead to novel medicines for treating existing or new infectious diseases, as well as for cancer, heart disease, and diabetes, which are increasingly prevalent in developing countries. Unless governments exercise rigorous control, all these drugs will be protected by patents and priced out of reach of the world's poor.

It is true that developing countries formally have longer to comply with TRIPS (2000, 2005, or 2006, depending on level of development and prior patent regime), but this at best postpones the problem. Transition to higher levels of IP protection should logically be based on economic progress, not arbitrary dates. In fact, all countries are required to offer 'market exclusivity' now to products for which patents were filed post-1995, and many countries have been brow-beaten into introducing TRIPS-compliant patent laws well before the deadline – nine years before, in the case of Brazil.

The US and other industrialised countries claim that TRIPS benefits pharmaceutical innovation. Unfortunately, there is no reason to believe that increased profits from the sales of patented drugs in developing countries will make a significant difference to research and development (R&D) decisions – a fact that some companies privately admit. Industry will still neglect treatments for the diseases of poverty because of the lack of 'effective demand' – or more accurately, high profit margins – hence Oxfam's call for greater public investment. Even in the industrialised world, many believe that the current patent system is an inefficient way of generating socially useful innovation. (For further information, see 'Implausible Denial: Why the Drug Company Arguments Don't Stack Up': www.oxfam.org.uk/cutthecost/indepth/html).

7 What the US and other industrialised countries should do about TRIPS

Proposals for ministerial endorsement at Doha

The US and other industrialised countries should support the modest proposals put forward in September by the developing countries for ministerial endorsement at Doha. These are:

- recognition of the paramount importance of the social and development objectives of TRIPS (Articles 7 and 8), including public health, and interpretation of all TRIPS provisions in that light
- reaffirmation of members' rights:
  - to determine the grounds for issuing compulsory licences
  - to allow production and export in response to a licence issued in a third country
  - to allow parallel importing
- agreement to a moratorium on trade dispute actions that might limit a country's capacity to protect public health, and to extension of the transition periods for TRIPS compliance.

The industrialised countries should also support an immediate in-depth review into the health and development impact of TRIPS, with a view to amending the length and scope of pharmaceutical patents and other IP protection. TRIPS should become the means for limiting the headlong advance of excessive protection and the threat it poses to public health and economic efficiency, rather than acting as its springboard.

The US government should change track

Oxfam believes that the US government should stop insisting that poor countries implement 'TRIPS plus' or unduly restrictive patent measures which will damage the prospects for improved public health and poverty reduction. Specifically:

- IP should not be the subject of regional bilateral economic agreements with developing countries
- access to US markets for developing countries should not be conditional upon their compliance with US IP protection norms

- the '301' provisions in the US trade act which allow the unilateral imposition of trade sanctions should be rescinded

If the US continues vigorously to promote high levels of IP protection around the world, it risks defeating its own objectives. The more far-sighted figures in the trade establishment have warned that unless the industrialised countries respond to the outcry about TRIPS, the patent system and the WTO will be brought further into disrepute. As a top WTO official admitted, 'how Doha deals with the issue of the impact of patents on public health is a litmus test for whether the WTO has a human face'. For the sake of the millions of people whose health is on the line, the major trading nations must help Doha pass that test.

For further information please email advocacy@oxfaminternational.org

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