WTO Patent Rules and Access to Medicines:

The Pressure Mounts

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This briefing was prepared by the Policy Department of Oxfam (Great Britain) for Oxfam International as part of the 'Cut the Cost of Medicines' campaign. All campaign reports are available on the Oxfam GB website (www.oxfam.org.uk). These include more detailed analyses of the issues concerning access to medicines, particularly in relation to patent rules and corporate social responsibility.

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Executive Summary

Public outrage over the exorbitant prices of HIV/AIDS drugs in Africa is focussing public attention on the harmful role of global patent rules in blocking poor people's access to vital medicines. In response to mounting public pressure, World Trade Organisation (WTO) members have taken an unprecedented step in agreeing to hold a special meeting to discuss the impact of global patent rules on access to medicines. They will meet on 20 June at the WTO in Geneva.

The WTO has the power to change patent rules. As a result, this meeting, and the forthcoming WTO Ministerial in Qatar, offers the best opportunity yet to shift the balance of global patent rights in the interests of public health. The outcome of the meeting will have a critical effect on poor people's access to medicines.

Inventors need some protection but under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) they are getting far too much. Briefly stated, the Agreement, which is the product of one of the most successful corporate lobbying campaigns in history, creates effective legal monopolies for patent holders across the world, enforceable by trade sanctions. This will drive up the price of vital medicines in poor countries, benefiting narrow corporate interests at the expense of public health.

The winners will be the large northern-based companies where innovation is concentrated and which account for 90 per cent of pharmaceutical patents. The strengthened protection provided by the Agreement allows them to sell their new medicines at higher prices for longer periods in more countries. The losers are the millions of people in poor countries who will be further excluded from access to these vital medicines, and their cash-strapped government health services.

It is not suprising that the TRIPS Agreement is fast becoming the epicentre of a battle which pitches some of the world's most powerful pharmaceutical companies, backed by rich governments, against some of the world's most vulnerable people. More widely, there is a growing sense that the Agreement is fundamentally unfair and unbalanced – a fact which threatens to bring not only the patent system but also the whole multilateral rules-based system into disrepute, and which policy makers ignore at their peril.

What is certain is that TRIPS will need serious revision if it is to stem the growing public backlash against patent rules. The recent controversy over the attempts by 39 pharmaceutical companies to block a law which allowed the South African government to shop around for cheaper patented products in other countries, and which the companies claimed violated the TRIPS Agreement, gave the world a graphic illustration of why the rules need to change.

Oxfam is calling for TRIPS to be reformed so that developing-country governments have the unambiguous right to obtain the cheapest possible life-saving medicines without facing the threats of legal challenges or trade sanctions experienced by South Africa and Brazil. To this end, Oxfam is asking WTO members to agree to:

- an in-depth review of the health and development impacts of TRIPS, with a view to reducing the length and scope of pharmaceutical patent protection in developing countries, or exempting developing countries from pharmaceutical patenting.

- a moratorium on trade disputes with developing countries over TRIPS compliance until a review of TRIPS is concluded, and the concerns of developing countries about its implementation are addressed.

- a commitment by rich countries not to exert bilateral pressure on developing countries to implement unnecessarily strict and potentially harmful intellectual property standards (whether through bilateral or regional trade agreements, or by other means).

- outlaw the use, or threatened use, of bilateral trade sanctions for enforcing unnecessarily strict and potentially harmful levels of intellectual property protection in developing countries, such as the 'Special 301' provisions of the USA's trade act.

- stronger public-health safeguards and exceptions to give developing countries the option of reducing the length and scope of pharmaceutical patenting on public health grounds. These should include:

  a strengthened and meaningful public-health safeguard in Article 8;
  the option to exempt vital medicines from patenting on public-health grounds under Article 30;
  an easing of the conditions for compulsory licensing, including restrictions on the production of medicines for export to another country where a compulsory licence has been issued, and the development of fast-track procedures for public-health purposes.

- longer transition periods for developing countries before they have to implement TRIPS, based on their attainment of development milestones rather than arbitrary dates.

These are modest proposals. If agreed, they would merely mark a return to the situation for poor countries prior to TRIPS. This would not, as the pharmaceutical companies claim, significantly reduce R&D into the diseases of poverty, nor jeopardise patent protection in richer countries.

Of course, reforming TRIPS is not a panacea. A broad package of measures is needed to improve access to medicines and to ensure adequate R&D into treatments for poverty-related diseases. These include massive investment in public-health services, public funding of R&D, and comprehensive systems of tiered pricing.

Nor will reform of TRIPS provide any guarantee that all governments will take positive action to improve poor people's access to medicines. It will, however, remove a key legal obstacle that currently constrains poor governments from obtaining the cheapest possible medicines for their citizens, and allow market forces to reduce prices through generic competition.

However, attempts by developing countries to change TRIPS so that it better reflects broader social and developmental objectives have been blocked by some rich countries, particularly the US. These countries continue to repeat pharmaceutical industry scaremongering that any tampering with new global patent rules will reduce company profits and undermine R&D.

If the USA or other rich countries block proposals to reform patent rules aimed at protecting public health, developing countries should push the issue to a vote at the forthcoming 4th Ministerial. They

have little to lose. It is true that if the USA believes its commercial interests are being prejudiced at the WTO, it's commitment to multilateralism may weaken. But it would be far more damaging for public health and the multilateral system if developing countries renounced their efforts to seek pro-health and development reforms of TRIPS on these grounds. Moreover, the USA is already using bilateral pressure, including the threat of trade sanctions to ratchet up intellectual property standards outside the WTO.

Introduction

The decision by WTO members to support the African nations proposal for a Special Session of the TRIPS Council on patents and access to medicines is a welcome response to developing country and public concern about the issue. It offers a unique opportunity to change the rules in favour of public health.

The TRIPS Agreement was championed by Northern governments under the influence of powerful corporations, with the pharmaceutical industry providing much of the leadership and finance. It requires all 140 WTO members to provide a minimum of 20-year patent protection for products and processes in all sectors, or risk the threat of trade sanctions.

At a time when millions of people in poor countries are already unable to afford essential medicines, and when public health is being threatened by a combination of new diseases and drug-resistant variants of old killers, the Agreement will further reduce access to new medicines by effectively extending the monopolies of drug companies and restricting generic competition.

The recent controversy around the excessive price of patented HIV/AIDS medicines South Africa graphically illustrated the negative impact of TRIPS on access to medicines. The legal complaint by the 39 pharmaceutical companies also demonstrated the way in which powerful corporations use legal pressure to reinterpret TRIPS in their own interests.

A similar pattern of commercial and political pressure is now being repeated in Brazil, where international pharmaceutical companies are pressing for reforms in Brazil's patent law in order to further their business interests. As well as claiming that the law does not comply with TRIPS, they object strongly to the price controls on medicines and to the way in which the Brazilian government has warned that it will suspend patent rights on AIDS drugs unless prices come down.

The companies have threatened to stop investing in Brazil unless these policies change. They have also persuaded the USA to exert diplomatic pressure, backed by the threat of trade sanctions, and to request the establishment of a WTO dispute settlement panel to rule on the alleged violations of the TRIPS agreement. Although the law in question does not specifically refer to pharmaceuticals, and has not been applied to the industry, it can be used by the Brazilian government to help ensure secure and affordable access to vital medicines. [i]

In the run up to the 3rd WT0 Ministerial at Seattle, developing countries put forward concrete proposals which aimed to reform the TRIPS Agreement in the interests of public health. Similar proposals were raised again at the UN General Assembly on Social Development by the Group of 77 countries, which represents most of the developing world. Various options have been proposed, ranging from proposals to exempt essential medicines from TRIPS or to shorten the patent period for pharmaceutical products. Such proposals have been blocked by rich countries.
Due to the sheer weight of public opinion, and the international outcry around the South Africa court case, there are now signs of a more enlightened pro-health position on TRIPS by some European Union governments. On 14 May this year, the EU Council of Ministers passed a resolution on

communicable diseases which endorses governments' use of the public-health safeguards within TRIPS. It also states that the European Commission should 'report its findings to the Council' once it has investigated what needs to be done to 'ensure consistency' between international patent rules and public health. This opens the door to possible future changes to the EU position on TRIPS. But while the resolution was carried unanimously, some governments inside the EU are seen as blocking more enlightened positions.

However there is a risk that any meaningful attempts to reinterpret or change WTO rules in the interests of public health at the June TRIPS Council or at the 4th WTO Ministerial in Qatar, will be blocked by US stonewalling. Even more reprehensibly, the USA is using bilateral pressure including the threat of trade sanctions to ratchet up intellectual property standards outside the WTO. One tactic is to negotiate higher standards in bilateral or regional trade agreements with developing countries which, under WTO rules on Most Favoured Nation, then have to be extended to all other countries. The US-Jordan free trade agreement, for example, restricts the grounds for compulsory licensing and places conditions on its use for imports.

The strength of the corporate lobby has also helped keep the issue of patents off the agenda of a number of a high-level initiatives which have recently sprung up to help combat communicable diseases in poor countries. But with media attention now focusing on the special session of the TRIPS Council discussing patents and access to medicines, it will be increasingly hard for rich governments to duck the issue. Indeed, the level of public awareness is such that the companies risk further damage to their reputation if they are they are seen to be complicit in blocking reform proposals behind the scenes at the TRIPS Council.

Why the rules need to change

Public officials from rich countries often present TRIPS as an agreement which has struck a delicate balance between the need to maintain incentives for R&D, and the need to ensure the greatest possible diffusion of technology. Both the UK government and the EC argue that TRIPS contains sufficient flexibility to allow governments to adapt it to their needs and address health considerations and other social goals. Oxfam, on the other hand, believes that the Agreement needs fundamental reform.

The central problem is that TRIPS represents a significant expansion in the length and scope of patent protection for many developing countries. The introduction of 20-year patents on all products and processes, even with safeguards, can hardly be considered flexible. The limited public interest safeguards will not on their own off-set the potentially disastrous effects of rising prices associated with the extension of monopolies and restrictions on generic production under TRIPS.

Poorer countries cannot absorb the higher prices associated with strengthened patent protection. For the 1.4 billion people in the world living on or near the poverty line, even marginal increases in patent prices can place effective treatment of life-threatening treatments out of reach. Drugs typically represent the single biggest item in household health spending, accounting for over 80 per cent of the total in countries such as India.

Prior to TRIPS, countries were free to strike their own balance between encouraging innovation and maximising the availability of affordable medicines to their people. Many developing countries used this freedom to exempt drugs from patenting or to grant short patent periods allowing low-price generic versions of new products to enter the market within a few years of the launch of the originals. Other countries, such as India, provided only process patents rather than product patents, thereby allowing local manufacturers to develop equivalent products using alternative processes.

TRIPS will severely curtail the use of such measures. That is why Oxfam is calling for a fundamental review of the Agreement with a view to reducing the length of pharmaceutical patenting in developing countries, or exempting developing countries entirely from the pharmaceutical patenting.

Why Brazil's success in controlling AIDS could not be repeated under TRIPS

Brazil is renowned for its success in tackling AIDS. One important factor in significantly reducing transmission, morbidity, and deaths has been the free distribution of anti-retroviral drugs since 1996, including those needed to stop mother-to-child transmission. Currently, the health service provides free ARV treatment to 95,000 people. This is only possible because ten of the twelve drugs needed are not patented in Brazil and can therefore be produced as generics, without paying the royalties or monopoly prices that have to be paid in industrialised countries. Brazil is now spending just over US$3,000 per patient per year. Thanks to hard bargaining with the companies, the price will fall further. These figures contrast sharply with the US$10,000 cost per patient in the USA.

Why can Brazil produce or import low-cost generic versions of some of the drugs that are so expensive in rich countries? The answer is simply that Brazil did not adopt pharmaceutical patenting until 1996. It could therefore legally produce equivalents of expensive medicines patented before that date in the industrialised countries, or import them from India, which also did not have patenting on pharmaceutical products. However, both countries are now obliged by the TRIPS agreement to provide patent terms of at least 20 years for all products and processes. If TRIPS had been agreed just a few years earlier, thousands of Brazilians with AIDS would not have had access to treatment and would be dead today. This dramatically illustrates the public health problems that will flow from excessive patent protection in developing countries.

Strengthening the public-health safeguards

It is true that the TRIPS Agreement does contain some important hard-won public-health safeguards. It is vital that the TRIPS Council defends the rights of governments to use these, and ensures that a pro-public-health interpretation of the Agreement prevails. But the safeguards are insufficient and need to be strengthened if governments are to feel safe from the threat of legal challenge or trade sanctions.

While in principle the safeguards give governments the right to override patents in the interests of public health through such means as compulsory licensing, in practice it is extremely difficult for poorer countries to make use of these. It is significant that not one developing country has issued a compulsory licence for medicines using the TRIPS safeguards.

First, the provisions are hedged with conditions that make them difficult to operate, especially for poorer countries. Moreover, poorer countries often lack the legal resources to interpret and implement the agreement in favour of public health and development objectives.

Second, powerful companies and rich countries use this legal ambiguity in TRIPS to interpret the rules in their own interests, and to limit the use of the public interest safeguards. While the 39

pharmaceutical companies recently dropped their case against the South African government, this was an example of the kind of corporate bullying to which countries can be subjected when they seek to use TRIPS-compliant provisions, such as parallel importing, in the interests of public health.

The US administration's decision to take Brazil to the WTO disputes settlement panel, is designed to deter other countries from following Brazil's example and starting to question drug patents. The action sends a clear message to other developing nations such as India and Argentina, that the US will take firm action on any apparent deviation from the TRIPS-mandated levels of protection, for all kinds of intellectual property. The US has also used the threat of trade sanctions against India, the Dominican Republic, and Egypt to enforce TRIPS-plus measures.

Developing countries need a permanent guarantee that that they can put the public health and welfare of their citizens before private patent rights, without having to face these kind of legal pressures or the threat of trade sanctions. To achieve this the public-health safeguards need to strengthened.

The South African case

The South African case provided a graphic illustration of the problem of excessive prices of patented medicines and the vital role played by generic competition in reducing these prices. The US-patented price for triple therapy for HIV/AIDS is approximately US$10,000 per person per year. As a result of growing public concern about the harmful effects of patents, and because of the presence of cheaper generic competition, the large companies recently cut their prices to African governments to around US$1000 per person per year. But this was still more than three times higher than the cheapest offer from the Indian generic company, Aurobindo, of US$295 per person per year. The offers from generic companies have played a vital role in bringing down patented prices. But the effects of TRIPS in India and elsewhere will mean that this important source of generic competition will disappear for new medicines. Oxfam believes that the TRIPS Agreement needs to be revised in order to allow market forces to lower the high price of patented medicines through generic competition.

The case for special treatment for developing countries

TRIPS will largely benefit the big Northern-based transnational corporations where pharmaceutical innovation is concentrated, not poorer countries which are principally importers of modern technology. For the latter, TRIPS will raise the cost of protected and imported technologies such as medicines. It will also reduce their scope to produce cheaper generic equivalents for their own consumption and export to other poorer countries.

Yet industrialisation usually relies on reproducing the technologies of the more advanced companies. Patenting only becomes of interest to a country when it has developed the capacity to innovate. Many European countries, including Switzerland, home of many innovative pharmaceutical companies, resisted providing pharmaceutical product patents until their industries had reached a certain degree of development. France introduced patent products in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977, and Italy and Sweden in 1978.

Advocates of TRIPS argue that the costs of strengthened patent protection are outweighed by the benefits of increased foreign investment in developing countries. But this is an assumption based on little if any evidence. Nor will strengthened patent protection do much to promote innovation in poorer countries, since the main constraint on innovation is the lack of industrial and technological capacity, not weak patent protection.

For these reasons, Oxfam is arguing for longer transition periods for developing countries to comply with TRIPS, based on their attainment of development milestones rather than arbitrary dates. This would free them from the administrative costs of implementing TRIPS and enable them to produce or import cheap generics without having to issue compulsory licences or risk the threat of legal action.

Will changing WTO TRIPS rules reduce R&D?

Pharmaceutical companies and Northern governments have repeatedly argued that strong patent protection in developing countries will increase R&D into neglected diseases which afflict poor people. The lack of R&D into these diseases is certainly a serious problem. Pneumonia, diarrhoea, tuberculosis, and malaria – a group of diseases that claim approximately 11 million people every year mostly in developing countries – account for less than one per cent of the global health research budget. In contrast, diseases which primarily affect the rich world account for 85 per cent of global drugs sales, and are consequently the target for the bulk of R&D spending.

Strengthening patent protection in developing countries will not change this basic market reality. Simply stated, purchasing power in developing countries will remain too small, even with longer patent protection. The entire African market, for example, represents only one per cent of the multinational pharmaceutical companies' sales. This is why increased public investment will be needed to correct the current imbalance in R&D.

The drug companies also justify TRIPS by arguing that strengthened patent protection is needed to reward R&D. But the minimum 20-year period required by TRIPS is arbitrary, and could be reduced in developing countries without prejudice to R&D. Moreover, pharmaceutical R&D is not as costly as often claimed. Evidence presented by a local campaign group, the Treatment Action Campaign, to the South African courts exploded the myth that strong patent protection is needed to recoup the costs of R&D. It showed that a large proportion of HIV/AIDS drugs were developed with funding by public money. [ii] Moreover, company calculations of the cost of R&D often include research into copycat drugs rather than therapeutic breakthroughs, market research costs, and the opportunity cost of capital, while also glossing over the tax benefits involved. [iii]

Do voluntary initiatives and tiered pricing help?

In response to rising public concern about the harmful impact of patents on poor people's access to medicines, pharmaceutical companies have tried to stem the damage to their reputations by increasing voluntary initiatives such as donations, discounts, and tiered-pricing arrangements. These initiatives are a welcome way of helping alleviate some of the problems of access to medicines, and an important recognition by companies that price does affect access.

Nevertheless, reliance on these schemes leaves governments dependent on companies' charity, providing only an adhoc, temporary, and disease-specific approach to the problem. Nor do these schemes necessarily offer the best obtainable price. As such, they do not offer a systematic or sustainable solution to the problem of affordability. They should not therefore be seen as substitutes for the use of compulsory licensing, parallel importing, or, most importantly, reforms to the TRIPS

Agreement which aim to reduce price through generic competition. Moreover, companies need to be aware that the media and the public will ultimately judge them on the basis of their net development impact, which includes their influence over patent rules.

Corporate influence and big-stick trade diplomacy

The WTO is a multilateral forum which ought to reflect the public interest of all its members. Yet it is being used to advance the private interests of extremely powerful corporations, with adverse implications for public health[iv]. The TRIPS Agreement produced revolutionary changes in intellectual property rules with minimal participation and understanding by developing countries and, until recently, almost no public debate. This is why Oxfam and many NGOs are now calling for the TRIPS Agreement to be opened up to critical public debate. It is also why these NGOs are increasingly focussing their campaigns directly at the large companies.

US, European, and Japanese drug companies and other businesses played a particularly significant role behind the scenes of the 1986-94 Uruguay Round negotiations. The recommendations of the US industry's Advisory Committee for Trade Negotiations and the Intellectual Property Committee were fundamental to the development of the US strategy for intellectual property protection. Edmund Pratt, Chief Executive Officer of Pfizer, was quoted at the time as saying, 'Our [the industry's] combined strength enabled us to establish a global private sector-government network which laid the groundwork for what became TRIPS'.[v]

These committees convinced the US government that the 'theft' of US technology and profit could be halted only by creating global rules, enforced by the threat of trade sanctions. The US companies skillfully enrolled their European and Japanese counterparts to put pressure on the other rich-country governments, which together dominated the negotiations.

By contrast, developing countries had very little understanding of the implications of TRIPS and were for the most part excluded from many of the decisive negotiations in the WTO. The USA also used bilateral pressure to break developing-country resistance to TRIPS. Under the influence of the corporate lobby, it developed and used the Special 301 provisions of its trade legislation to target developing-country leaders such as India and Brazil. This legislation allows the US government to take retaliatory action against countries that fail to give what the USA considers to be adequate protection to intellectual property. This can go far beyond the requirements even of the TRIPS Agreement. The legislation also makes resistance to the USA in a multilateral forum one of the conditions that could lead to a Special 301 investigation. [vi]The US government also placed conditions on access to its trade preferences programme (GSP) on adequate intellectual property protection.

The failure of the TRIPS negotiations to meet the minimum conditions for democratic negotiation may well prove to be the Agreement's Achilles heel. Increasing numbers of people are questioning why the WTO, an organisation charged with developing rules for 'free trade', is providing a legal framework for the development of effective corporate monopolies. There is increasing concern that its 'one size fits all' approach is prejudicial to welfare and innovation in many developing countries and in certain industries and sectors. Distinguished scientists have argued that the limited benefit to innovation arising from stronger global patent protection does not justify the health risks. Thousands of NGOs signed a statement before Seattle calling for TRIPS to be removed from the WTO altogether.

What is certain is that TRIPS will need serious revision if it is to stem the growing public backlash against patents. But the USA and other rich countries are unlikely to agree to reform and to change their ways unless public pressure is strong enough to counterbalance the powerful corporate lobby.

Concerted public campaigning helped persuade the USA to refrain from exerting bilateral pressure against African countries trying to address the HIV/AIDS crisis. The question is whether public pressure can also stop it from using blocking tactics in the WTO, and bilateral trade agreements to ratchet up IP protection outside the WTO.

Decision making in the WTO

The WTO has the power to change pharmaceutical patent rules for poor countries and to stop intimidation by rich countries and large companies. The TRIPS Council, which will hold a special session on health, comprises all WTO members. On the basis of a recommendation from the TRIPS Council, the Ministerial Conference of the General Council could adopt a formal, binding interpretation of the TRIPS Agreement, or change the rules.

The formal WTO rules provide for one person, one vote, based on the universal participation of members in all meetings. Decisions are to be taken by consensus. That is reached when 'no Member, present at the meeting when the decisions are taken, formally objects to the proposed decisions'. If consensus should fail, the issue can be pushed to a vote. However, a majority vote has never been used in the WTO. Working by consensus is supposed to make decisions more acceptable to all members.

In practice, lack of consensus has meant that meant that the status quo prevails, and that WTO members have effectively abandoned much of their policy-making role to the dispute settlement body. Lack of consensus can work in developing countries' favour when it prevents rich countries seeking to further strengthen intellectual property standards. But it has a negative effect when it allows rich countries to block pro-health and pro-development reforms to WTO rules.

Oxfam believes that if the USA or other rich countries block proposals to interpret and reform patent rules in favour of public health at the special session, WTO members should push their proposals to a vote at the 4th Ministerial. The Ministerial Conference has the power to adopt binding interpretations or amendments of any of the multilateral trade agreements.

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[i] The law allows the government to require a company to manufacture a patented product locally. Where the patent holder does not do this, the Brazilian government reserves the right to issue a compulsory license which would allow a generic company to manufacture an equivalent, or to import the patented product from another country where the price is cheaper. If the WTO panel rules against Brazil it will have to change the law or face trade sanctions. Changing the law will have a significant negative impact upon public health. It would limit the technology transfer necessary to build up a strong domestic pharmaceutical industry, narrow the scope for reducing the foreign exchange cost of medicines, prevent the government from using parallel importation to gain access to cheaper medicines, and weaken the government's bargaining position over the high price of medicines.

[ii] See Hwww.tac.org.zaH.

[iii] See Oxfam briefing paper, *Implausible Denial, Why the Drug Giants'Arguments on Patents Don't Stack Up*, April 2001, (www.oxfam.org.uk/cutthecost)

[iv] Much of the evidence in this section comes from a paper by Peter Drahos written for an Oxfam International seminar, 'What Future for the WTO TRIPS Agreement', held in Brussels on 20 March 2001, and called 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue'.

[v] Edmund T.Pratt Jr., Pfizer Forum, 'Intellectual Property Rights and International Trade', *The Economist*, 27 May 1995, p.26

[vi] Under Special 301 a state can be identified as a priority foreign country if it is not 'entering into good faith negotiations; or making significant progress in bilateral or multilateral negotiations

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