

US bullying on drug patents: one year after Doha

One year after WTO trade ministers agreed the Doha Declaration on TRIPS and Public Health, the US government, at the behest of giant pharmaceutical companies, continues to bully developing countries to introduce unnecessarily high standards of patent protection on medicines. This continued bilateral pressure restricts and delays the production of cheaper generic medicines, with potentially devastating consequences for millions of poor people.



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Summary

Last November, developing countries succeeded in getting the World Trade Organisation (WTO) Ministerial Conference to issue a landmark Declaration stating that public health should take precedence over WTO patent rules. The so-called Doha Declaration reaffirmed the rights of governments to use WTO public-health safeguards or other measures to gain access to the cheapest possible medicines, without the threat of trade sanctions or the kind of corporate pressure exerted in Brazil and South Africa earlier that year.

One year on, Oxfam has commissioned a review of US government bilateral policies on patents and medicines to find out how far it has lived up to these promises. It also looks at the lobbying record of the giant pharmaceutical companies and their influence over US government policy. The findings are damning. Overall the number of complaints against developing countries relating to patents and medicines made by the pharmaceutical companies to the US government has not fallen; nor has the number of complaints which the US government takes up.

This is not a theoretical matter. Forty million people now live with HIV/AIDS around the world. Fourteen million people die every year of preventable, infectious diseases, most of them in developing countries. Most are also women and children. It is now widely acknowledged that WTO patent rules – set out in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) – further restrict poor people's access to life-saving medicines by raising their price. Yet, US bilateral policy seeks even higher standards of patent protection for medicines.

The review looks at the bilateral policies of the US government on patents and medicines both before and after the WTO Doha Declaration. It focuses on the annual trade report of the US government known as 'Special 301'. Special 301 is a section of the US Trade Act which requires the US Trade Representative (USTR) to identify countries it considers have inadequate intellectual property rights, to warn them to improve, and if not, to apply unilateral trade sanctions. It is a big stick widely feared by developing countries – not just because of the threat of sanctions, but also because of the associated diplomatic and political pressures.

The review also looks at the annual submission to the USTR of the Pharmaceutical Research and Manufacturers of America (PhRMA) – a major US lobby group on trade issues – and its relationship to the Special 301 report. Although PhRMA is based in the US, its membership includes the world's major pharmaceutical companies, including Pfizer, Novartis, GSK, and Merck.

The findings from the Oxfam review show that public pressure and the Doha Declaration have led to the following:

- The US government has reduced the number of complaints in its Special 301 report against countries that introduce or use WTO-compatible compulsory licensing or parallel import provisions.
- Neither the US government nor PhRMA has any official complaints against the 49 Least Developed Countries (LDCs).

These moves are welcome. However, their potentially positive impact on poor people's health is undermined by continued complaints by the US and PhRMA on other aspects of drug patenting. The findings from the Oxfam review show that, contrary to the spirit and the letter of the Doha agreement:

- US bilateral policy on patents and medicines is still heavily influenced by the narrow commercial interests of the giant pharmaceutical companies seeking to stave off generic competition for lucrative patented drugs. The US government included 66 per cent of the countries recommended by PhRMA's annual submission in its 2002 Special 301 report, compared with 61 per cent in 2001.
- The number of complaints submitted by PhRMA to the USTR against developing countries was more or less unchanged – 28 countries in 2001 and 27 in 2002. PhRMA actually increased the number of complaints against developing countries relating to compulsory licensing provisions, from 13 countries in 2001 to 15 in 2002.
- The US continues to use its Special 301 trade mechanism to bully developing countries on a wide range of other drug patenting issues, the most frequent complaint concerning the protection of test data. Overall, the number of complaints by the USTR against developing countries concerning pharmaceutical patenting has remained roughly the same pre- and post-Doha. It made complaints against about 18 developing countries in 2001, increasingly slightly to 20 in 2002. Many of the complaints are TRIPS-plus i.e. they go beyond the requirements in TRIPS. Many of the countries targeted are key generic producers, such as India, Brazil, Argentina, Thailand, and Colombia. Some, however, are simply poor countries with little production capacity, such as Vietnam and Bolivia.
- The US government continues to use bilateral and regional trade agreements outside the WTO to pressure developing countries to implement TRIPS-plus standards. The US has bilateral intellectual property agreements with approximately 28 developing countries and is seeking more.

These continued bilateral pressures against developing countries delay or restrict the production of cheaper generic versions of new medicines. This not only reduces poor people's access to medicines in these countries, but also chokes off the supply of cheap drugs to the vast majority of other drug-importing poor countries leaving them entirely dependent on expensive patented medicines.

If bilateral pressures do kill off generic capacity in India and other developing countries, then the fact that the US and PhRMA are no longer enforcing patent claims in LDCs will be little more than an empty gesture, as there will be no where for LDCs to import cheap generics from. The same will apply to

the WTO's decision at Doha to extend the deadline for LDCs to implement drug patenting. Similarly, bilateral pressures will also negate the commitment made by WTO ministers at Doha to lift TRIPS restrictions on exports of cheap generics to countries with 'insufficient or no manufacturing capacities in the pharmaceutical sector'.¹

But US hypocrisy goes further. The US has recommended that only developing-country members, not developed countries, should be allowed to export generic medicines to countries without manufacturing capacity. Yet they are simultaneously targeting these very countries in order to stop them producing cheap generics. Moreover, while maintaining its tough bilateral stance on generic production in poor countries overseas, the US is going soft on generic production at home. In October 2002 President Bush unveiled a plan to bring lower-cost generic medicines more quickly into the US market by closing the legal loopholes that allow companies to block them. When it comes to standing up to the drug barons, it is clear that votes at home count more than lives lost overseas.

Recommendations

Given the scale of humanitarian suffering in poor countries caused by HIV/AIDS and other diseases, US bullying against developing countries is inexcusable. It also counteracts the benefits of the Doha Declaration and undermines the multilateral trading system.

- Rich countries should make their bilateral policies fully compatible with the Doha Declaration. This means stopping pressurising governments in both developing countries and the LDCs to introduce patent provisions that run counter to the Doha Declaration, or that are TRIPS-plus.
- The WTO should play a more active role in ensuring rich-country compliance with the Doha Declaration in both developing countries and the LDCs. To this end, the TRIPS Council should require rich-country members to explain bilateral departures from multilateral standards based on annual reviews of their bilateral trade policies and agreements, focusing particularly on the US.
- Rich countries should make export guarantees, tax concessions, and other government incentives conditional on companies respecting the rights of both developing countries and LDCs to use the TRIPS public-health safeguards.
- Investment and pension fund holders should make their funds conditional on companies respecting the rights of both developing countries and LDCs to use the TRIPS public-health safeguards.
- Poor countries should use the longer deadlines for introducing pharmaceutical patents agreed at Doha, or the TRIPS-compatible compulsory licensing and parallel import provisions, to help increase access to vitally needed medicines. Additional commitments from the rich countries to the Global Health Fund, bilateral aid, and debt relief are all urgently needed to help make this possible.

1 Introduction

'I don't have the money to pay for both my wife and I to receive antiretrovirals. If I pay for my wife, my children cannot go to school and will have no future. If I stop taking the ARVs and my wife starts instead, I will die. What will happen to my family?'

John, a local fisherman living with HIV/AIDS in Uganda, married with 8 children

Forty million people now live with HIV/AIDS around the world. Fourteen million people die every year from preventable infectious diseases. Most live in developing countries, and many are children. Women are particularly affected by the lack of adequate health care and by the burden of caring for a sick family. Yet one-third of the world's population lack regular access to vital medicines, resulting in unnecessary sickness, suffering, and death.

Many factors restrict poor people's access to medicines in poor countries: poverty, lack of political will, inadequate finance, gender inequality, poor infrastructure, and weak drug policies. Oxfam and other NGOs have campaigned for years to eradicate poverty and increase the resources going to health services through debt relief, aid, and higher government expenditure. But the price of medicines is also a major barrier. In poor countries, most people have to pay for medicines out of their own pockets. In Oxfam's experience, poor people take their children out of school, and sell cattle and even land, to continue buying medicines.

Over the last few years public outrage has grown about the way in which WTO patent rules are set to further restrict poor people's access to life-saving medicines by raising their price. These rules, set out in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), require all countries to provide 20-year minimum patent protection for all new inventions, including medicines. This gives companies an effective global monopoly, allowing them to raise prices for the duration of the patent.

The most notorious illustration of how patents can price medicines way out of the reach of poor people is that of HIV/AIDS. While people in rich countries are routinely treated with antiretrovirals (ARVs), which have drastically reduced death rates, their high price means that only a tiny minority of people in poor countries receive treatment.

But the problems posed by WTO patent rules will extend beyond the high prices of patented HIV/AIDS medicines to future new and improved medicines needed to treat not just TB and malaria, but also drug-resistant variants of diseases that pose public-health threats, such as pneumonia, meningitis, diarrhoea, and sexually transmitted diseases.

Moreover, developing countries are increasingly suffering from non-communicable diseases, such as diabetes, hypertension, cancer, and heart disease, which were previously associated with rich countries. The World Health Organisation (WHO) has also pointed to mental illnesses and neurological diseases as growing threats to health worldwide. Since there are many reasons, including drug resistance, why the pattern of diseases threatening public health changes over time, it is essential that the issue of access to necessary medicines is resolved now, so that diseases yet to emerge as major concerns can be treated effectively in the future.

2 Patents and access to medicines

The TRIPS Agreement does contain some important public-health safeguards that allow governments to override patents in order to gain access to cheaper medicines. But rich countries and powerful pharmaceutical companies have a track record of using strong-arm bilateral pressure to prevent poor countries from using them, or to get them to introduce more stringent patent protection than that required by TRIPS (known as TRIPS-plus measures).² The most infamous case of corporate pressure was the attempt by 39 pharmaceutical companies to stop the South African government incorporating one of these safeguards into national law by taking it to the high court. With 4.7 million people affected by HIV/AIDS, international outrage finally forced the companies to drop the case.

Last year at the WTO Ministerial in Doha, and in an attempt to put an end to such pressures, developing countries succeeded in getting WTO trade ministers to adopt the Doha Declaration on TRIPS and Public Health. The declaration affirmed that public health takes precedence over private patent rights. It also reconfirmed, among other things, governments' rights to use the existing TRIPS public-health safeguards without challenge – in particular compulsory licensing and parallel importing.³ The Doha Declaration also extended the deadline by which the Least Developed Countries (LDCs) have to comply with TRIPS, from 2006 to 2016.⁴

The use of TRIPS safeguards, combined with more international finance, could significantly increase poor people's access to life-

saving medicines, thus reducing unnecessary suffering and death. If poor countries used compulsory licensing to import cheaper generic versions of HIV/AIDS medicines from India, for example, they would be able to treat three times as many people than with the patented brand-name versions. Patented prices of a triple cocktail of ARV were at first approximately \$10,000 per person per year. Due to a combination of public pressure and generic offers from Indian firms, companies then cut prices to around \$900. The lowest offer from Indian generic firms is approximately \$295.

Research by Oxfam in Uganda found that a major health clinic was able to increase the number of patients receiving ARV therapy by 200 per cent due to the import of lower-priced generics. Similarly, parallel imports can bring significant savings to governments since the same drugs are sold at very different prices in different countries.

However, nearly one year after Doha, not one poor country has issued a compulsory licence, and only a handful are using parallel imports, despite the devastation from HIV/AIDS and other diseases.⁵ Lack of political will, lack of finance to purchase drugs, and poor technical advice all play a part. But as this paper shows, bilateral actions by the US government and powerful pharmaceutical companies are also to blame.

3 The bullying continues

One year on from Doha, Oxfam commissioned a review to assess how far the US government and the large pharmaceutical companies have lived up to the Doha Declaration. The review compares their behaviour on patents and medicines both before and after Doha. It focuses on the 2001 and 2002 Special 301 report of the US government,⁶ and the annual reports of the Pharmaceutical Research and Manufacturers of America (PhRMA) to the US Trade Representative (USTR).⁷ The findings from the Oxfam review show that:

The combination of growing international public pressure and the Doha Declaration have led to the following:

- **The US government has reduced the number of complaints in its 301 report against countries introducing or using WTO-compatible compulsory licensing and parallel import provisions.**⁸ Its 2002 report cites only one country (India) for 'over broad compulsory licensing provisions', compared with three countries in 2001 and five in 1999, before public pressure

began. The 2002 report has no complaints against parallel imports in 2002, compared with one complaint in 2001.

- **Neither the US government nor the PhRMA reports contain any official complaint involving patents and medicines against the 49 LDCs.**⁹ There are also signs that individual companies are refraining from enforcing patent claims in the LDCs. For example, Uganda has not been legally challenged for importing cheap generic versions of ARVs from India.

These moves are welcome. However, their potentially positive impact is being undermined by continued complaints by US and PhRMA on other aspects of drug patenting. The findings from the Oxfam review show that, contrary to the spirit of the Doha Declaration:

1. US bilateral policy on patents and medicines is still largely influenced by the narrow commercial interests of the giant pharmaceutical companies. Companies are, of course, entitled to lobby. They represent millions of jobs, as well as producing products of use to billions of people. But they should do so in a legal, transparent, and non-coercive manner that respects international commitments on human rights and development. There is also a duty on governments, as the Doha Declaration made clear, to balance private commercial interests against the broader public interest, such as in public health.

- The US government included 66 per cent of the countries recommended by PhRMA's annual submission in its Special 301 report in 2002, compared with 61 per cent in 2001.

2. The US continues to use its Special 301 mechanism to target developing countries over a range of other issues relating to pharmaceutical patenting.

- The US government cited 27 countries for insufficient patent protection for medicines in its 2002 Special 301 report, 20 of which related to developing countries and five to transition countries. This compares with 25 countries in its 2001 report, 18 of which related to developing countries and six to transition countries. Many of these are generic-producing countries, such as India, Brazil, Argentina, and Egypt. But others are poor countries with limited capacity such as Vietnam and Bolivia.

3. Many of the complaints have the effect of restricting or postponing the production of lower-priced generic medicines in developing countries, which runs counter to the Doha Declaration. While some of these complaints relate to inadequate implementation of TRIPS obligations, many of them are TRIPS-plus.

- The US government's complaints relate to the protection of test data, local working requirements, discrimination against certain fields of technology, enforcement of existing intellectual property laws, backlogs or other delays at the national patent office, exclusion of subject matter from patentability, discrimination against process or product patents, bolar exceptions for research, trade mark issues, mailbox provisions, and exclusive marketing rights.¹⁰

India

Four million people in India are HIV positive. The country bears 30 per cent of the world's burden of TB, and malaria is widespread. 86 per cent of people live on less than \$2 per day. Average health expenditure is only \$20 per capita.

India is also one of the world's few remaining producers of affordable generic versions of new medicines, providing a vital lifeline for poor countries. Because of this, and because of the active role it plays in multilateral trade negotiations, India has been repeatedly targeted by the USTR 301 mechanism. It has recently come under pressure to introduce 'TRIPS-plus' data protection provisions that will hinder generic production and weaken the protections offered by the Doha Agreement.

The USTR Special 301 report for 2002 also criticises India for failing to provide patent protection for pharmaceutical and agricultural chemical products, an overly broad compulsory licensing system, a backlog of 30,000 patent applications, and a severe shortage of patent examiners. Yet under TRIPS, India has until 2005 before it must fully comply with pharmaceutical patenting.

One of the hottest fights is over the protection of test data that can be used to substitute for, or extend, patent protection. The US government has increased complaints on this issue, from 10 countries in its 1999 report to 17 countries in 2001 and 19 countries in 2002. When brand companies seek regulatory approval for a new drug they have to submit test data to the relevant government concerning the quality, safety, and efficacy of the drug, as well as information on its chemical composition. In many countries this data is kept confidential for a period. When this period expires, generic producers can gain regulatory approval without generating their own clinical data, by submitting bio-equivalence data that shows that their drugs are the same compound, which is much quicker and cheaper. The TRIPS Agreement requires that members must protect such data against 'unfair commercial use' but does not specify what this means, or the time period for protection. Nevertheless the USTR and PhRMA are pressurising developing countries to give exclusive rights over the test data to the brand companies and for countries to adopt a minimum five-year protection.

Guatemala: TRIPS-plus through the back door

Three-quarters of Guatemalans live in poverty, and 58 per cent live in conditions of extreme poverty. Tuberculosis, malaria, and pneumonia are common. Under the guidance of USAID-funded legal advice the Guatemalan congress recently passed a law providing for 15-year protection for test data. This is the longest period of protection in the world, and three times longer than the five-year period granted in the US. Guatemala does not have to implement pharmaceutical patenting until 2005, yet by preventing generic companies from using test data from brand-name companies, generic producers or importing companies would have to repeat all the trials to reproduce the data. This would delay the production or import of cheaper generic versions of new patented medicines, effectively granting the brand name companies a monopoly, and therefore substituting for patent protection. The law would also block the entry of generics relating to non-patented drugs. The new law also required Guatemala to implement pharmaceutical patenting ahead of the 2005 TRIPS deadline. The Guatemalan congress is now considering throwing out this iniquitous law.

4. The US government is still using bilateral and regional trade agreements outside the WTO to get developing countries to implement TRIPS-plus measures.

- According to a recent study, the US government has bilateral intellectual property agreements with around 28 developing countries,¹¹ many of which contain TRIPS-plus measures.
- The US and Chile are currently engaged in negotiations to set up a bilateral trade agreement which, among other things, would restrict the grounds for compulsory licences and ban parallel imports. Test regulatory data for medicines would have to be given up to five years' protection. The US also wants Chile to grant patent extensions to make up for any regulatory delays. This approach closely mimics the pre-Doha US-Jordan free trade agreement and makes no concession to the Doha Declaration.
- The US government is also seeking TRIPS-plus standards within the negotiations for the Free Trade Area of the Americas (FTAA) and with the South African Customs Union.

The US and the FTAA

'The U.S. negotiating objectives for FTAA aim to strengthen patent rights beyond what is required in TRIPS, and reduce the extent of the safeguards to the detriment of public health – they are clearly "TRIPS-plus." If the U.S. achieves its negotiating objectives, FTAA will negate the achievements of the Doha Declaration and could have devastating consequences in terms of access to medicines for millions of people in low- and middle-income countries in the Americas with HIV/AIDS and other neglected diseases. For them, this is a matter of life and death.' *Recent MSF testimony at a USTR hearing on the proposed FTAA.*

5. PhRMA has not reduced the overall number of complaints it makes against developing countries, and increased the number of complaints against developing countries related to WTO-compatible compulsory licensing into their laws.

- PhRMA cited 41 countries for insufficient patent protection for medicines in its May 2002 report to the US trade department, of which 28 relate to developing countries and nine to transition countries. This is almost identical to its 2001 report, in which it cited 41 complaints, of which 27 related to developing countries, and nine to transition countries. Its 2002 report included complaints against key generic producers, as well as El Salvador, Nicaragua, Vietnam, and Bolivia.
- PhRMA increased the number of complaints relating to compulsory licensing after Doha. It cited 15 countries for complaints about 'overly broad compulsory licensing' provisions relating to pharmaceutical protection – two more than in 2001 – but reduced the number of complaints about parallel importing from nine countries in 2001 to six in 2002.

PhRMA increased its complaints relating to inadequate protection of test data from 31 countries in its 2001 submission to 34 countries in its 2002 submission.

4. Health Consequences

The reduction of US government complaints about compulsory licensing and parallel imports, and the lack of complaints against the LDCs, are welcome. However, their potentially positive impact on poor people's health is undermined by the US and PhRMA's complaints about other aspects of drug patenting. Continued bilateral pressures of the kind documented in this report restrict the production of cheaper generic medicines in developing countries. This not only reduces poor people's access to vital new medicines in these countries, it also chokes off supplies of cheap generics to the majority of poor countries that cannot produce them themselves.

The Doha Declaration says that TRIPS can and should be interpreted to promote public health and access to medicines 'for all'. This means ensuring that poor people, wherever they are, can gain access to affordable medicines. In order to honour their Doha commitments, the US government and PhRMA should refrain from pressurising developing countries and the LDCs to introduce measures which run counter to the Doha Declaration, or which are TRIPS-plus.

Although developing countries are not as poor as the LDCs, they are still considerably poorer than developed countries. In the developing-country category, the USTR and PhRMA target countries as poor as Nicaragua, Bolivia, Vietnam, and El Salvador. Even middle- and high-income developing countries have large pockets of extreme poverty, and many are ravaged by disease. South Africa, previously targeted by the US and still targeted by PhRMA, is a middle-income developing country. Yet it 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. Moreover, some of the most frequently targeted developing countries, such as India, not only have a massive disease burden themselves, but are key suppliers of affordable generics to the LDCs.

Uganda

35 per cent of Ugandans live below the poverty line, and 51 per cent of households lack access to health care. Nearly one million Ugandans have died of AIDS-related causes since the disease was first reported in the country in 1983. Just a few years ago, Dr Peter Mugenyi was treating only a few hundred HIV-positive patients who could afford to pay the \$12,000 or so per year for their antiretroviral drugs. Now, by defying patent laws and buying cheaper generics from India, he is treating around 4000 people. This in turn prompted Merck and GSK to slash their prices.

But the use of cheaper imported medicines may become much harder if the new Industrial Property Bill is passed in Uganda. Even if official pressure stops, developing countries can find themselves at the mercy of TRIPS-plus pressures through the back door. Local sources say that the bill was drafted with bilateral assistance from USAID and rushed through. Even though Uganda has until 2016 to comply with TRIPS, the bill provides for immediate 20-year patent protection for new drugs. It also requires that the patent holder's consent be obtained before parallel imports can be made. Local sources point to the involvement of a USAID-funded consulting firm, Nathan Associates, in drafting the Bill, and say that it was sent to the US for checking. According to Nathan Associates website, the lead consultant in 2000 was the former Senior Deputy General Counsel of the US Trade Representative's Office and negotiator on the WTO's TRIPS Agreement. (<http://www.nathaninc.com/projects/projectdetails>, and <http://lists.essential.org/pipermail/ip-health/2002-June/003113.html>)

The US government and PhRMA may well argue that that their disputes against developing countries are legitimate because developing-country governments are not fully adhering to the conditions outlined in TRIPS. This may be true in some instances. But when the targeted measures prevent or postpone access to cheaper medicines they run counter to the spirit of the Doha Declaration. Moreover, in many cases the US government and PhRMA are pressurising developing countries to implement measures that go

beyond what is required in TRIPS, or to implement patent protection ahead of the TRIPS timetable.

For example, the Doha Declaration reaffirmed that TRIPS allows governments to determine the grounds for compulsory licensing. Yet in direct contradiction, PhRMA has cited the following specific complaints concerning these grounds against developing countries:

- Licenses due to slow market entry of patented goods
- Licences due to patent holder pricing 'above market price'
- Licences issued when inventions are considered not of significant merit
- Frequency with which compulsory licenses are issued
- Public-interest provisions that PhRMA considered vaguely defined
- Government authority simply seen as too strong when it comes to the issuance of licences.

Argentina

In Argentina, a country reeling from an unprecedented financial and economic crisis. 37 per cent of people live below the poverty line and 25 per cent are unemployed. Even the most basic medicines and supplies are unaffordable to many. PhRMA's 2002 report complains that Argentina's compulsory licensing provisions are a 'clear violation of TRIPS Article 31'. It says that 'the overly broad definition of anti-competitive practices allows for the issuance of compulsory licence when, for example, the manufacturer prices its products above market prices for legitimate commercial reasons, or when it rationalizes its operations in a way that results in a slowing of market production activities'.

Yet most of the conditions that Article 31 of TRIPS applies to the issue of compulsory licences can be lifted by a state where anti-competitive conduct is found. TRIPS does not prevent states from defining anti-competitive conduct, and, in the case of licensing practices, Article 40 expressly allows states to define cases that constitute an abuse of intellectual property. The PhRMA objection amounts to little more than a vague and unreasoned accusation.

Argentina has also been pressurised by the US to strengthen its data protection provisions, but in the face of Argentinian refusal to amend its laws, the US has had to back off.

The review also finds that PhRMA and the US government target developing countries because the judiciaries are overwhelmed and cannot handle the number of patent disputes, or because there are backlogs and delays at the National Patent Office. While PhRMA and the US government may believe backlogs are due to lack of

political will, in many cases their complaints punish countries for their poverty.

Conclusion

'Since I started treatment, I am no longer sick. I can work and am happy. Before I was very sick and now I am fine.'

Violet, a Ugandan shopkeeper receiving antiretrovirals thanks to cheap generic imports. Oxfam research, June 2002

Communicable diseases such as HIV/AIDS, malaria, tuberculosis, pneumonia, and bloody diarrhoea are creating a human and development catastrophe in developing countries. As a recent UNAIDS report showed, the HIV/AIDS epidemic has not yet peaked, and is erasing decades of development and cutting life expectancy by nearly half in the most affected areas. The report also said that treatment is now technically feasible everywhere in the world, and warned against viewing HIV prevention and care as competing priorities.

While many factors conspire to keep medicines out of reach of poor people, it is now widely accepted that unduly restrictive patent protection raises prices and therefore reduces access for poor people. Price discounts by companies can help but generic competition is the only sustainable way of reducing prices and increasing access. This in turn requires a more flexible application of patent law in developing countries. And for this to happen, the US government and pharmaceutical companies must stop their bullying.

Annex

Placement and designation of countries recommended by PhRMA in the USTR Special 301 report for the year 2002 (not including countries cited in the USTR 301 for complaints other than intellectual property and healthcare).

PhRMA Designation	Country	USTR Designation
Priority Country	Argentina	Priority Watch
	Colombia	Priority Watch
	India	Priority Watch
	Turkey	Watch
Priority Watch	China	306
	Korea	Watch
	New Zealand	
	Philippines	Priority Watch
	Thailand	Watch
	Hungary	Priority Watch
	Poland	Watch
	Egypt	Priority Watch
	Israel	Priority Watch
	Lebanon	Priority Watch
	Pakistan	Watch
	South Africa	
	UAE	
	Bolivia*	Watch
	Ecuador*	
	Peru*	Watch
	Venezuela*	Watch
	Brazil	Priority Watch
	Canada	Watch
	Chile	Watch
Dominican Rep.	Priority Watch	
Watch List	Australia	
	Indonesia	
	Taiwan	Priority Watch

	Vietnam	Watch
	Bulgaria	
	Croatia	
	Latvia	
	Lithuania	Watch
	Romania	Watch
	Russia	Priority Watch
	Slovenia	
	Spain	
	Saudi Arabia	Watch
	Costa Rica	Watch
	El Salvador	
	Nicaragua	

*These countries are included in the PhRMA submission as members of the Andean Community. PhRMA also cites Colombia alone as a Priority Foreign Country. Each country is cited individually by the USTR in its 301 report.

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Notes

¹ Paragraph 6 of the Doha Declaration states 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 licensing 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.'

² A TRIPS-plus standard is one where a country fails to introduce an existing TRIPS public-interest safeguard, introduces a higher standard than that required by TRIPS, or implements protection ahead of the TRIPS timetable. As a result of public

pressure on 10 May 2002, President Clinton issued an Executive Order stating that the US would no longer threaten sanctions against countries in sub-Saharan Africa if they were using TRIPS-compliant measures, such as compulsory licensing or parallel imports, to improve access to HIV/AIDS medicines.

³ The Doha Declaration states that 'the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and in particular, to promote access to medicines for all.' It specifically affirmed that 'each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted', and that 'each member is free to establish its own regime for such exhaustion (parallel importing) without challenge'.

⁴ Article 66 of TRIPS allows the TRIPS Council to approve further extensions for least developed countries upon a duly motivated request.

⁵ Parallel imports of pharmaceuticals are currently taking place, according to the 2002 PhrMA submission, in the Philippines, Thailand, Israel, and Lebanon. PhRMA is concerned about PI legislation in South Africa and Chile, although it stops short of targeting these two countries over the practice. Parallel imports take place widely for non-pharmaceutical products, and parallel trade in pharmaceuticals is a fact of life within the EU.

⁶ The US government's Special 301 report is issued annually (a requirement of the US Trade Act) and lists countries that the US government believes are not implementing adequate intellectual property protection (this can go far beyond TRIPS). It has been used for over 20 years by the US to underpin its push for higher intellectual property standards. Countries included in the report are designated Priority Foreign Countries, Priority Watch Countries, or Watch Countries, depending on the severity of the disagreement between those nations and the US government. Section 301 also allows the USTR to act against countries opposing the US government in multilateral negotiations on intellectual property. The US also uses bilateral trade and investment agreements and the WTO dispute settlement mechanism as part of its push for higher intellectual property standards.

⁷ The Pharmaceutical Research and Manufacturers of America (PhRMA) is a major US trade lobby group. Although based in the US, its membership includes all the world's major pharmaceutical companies. Each year industry groups including PhRMA submit reports to the USTR identifying nations which in their view have inadequate intellectual property protection and therefore should be included in the USTR report.

⁸ Compulsory licensing allows governments to issue a licence for the production or import of cheaper generic versions of medicines without the permission of the patent holder. A parallel import is a good that is sold by the patent holder and then resold in another country without the permission of the patent holder. Both practices are permitted under TRIPS.

⁹ The UN currently designates 49 Least Developed Countries and around 123 developing countries. The UN criteria determining the current list of LDCs are i) GDP per capita below \$800; (ii) weak human resources, as measured by a composite index of Augmented Physical Quality of Life Index; and (iii) a low level of economic diversification, as measured by a composite index.

¹⁰ See the full study for an explanation of these terms (ref).

¹¹ Drahos, P., 'BITs and BIPs, Bilateralism in Intellectual Property', The Journal of World Intellectual Property, November 2001

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