

# Patents versus Patients

## Five years after the Doha Declaration

Five years ago, members of the World Trade Organisation (WTO) signed a ministerial agreement to ensure that intellectual property rules would no longer obstruct developing countries' efforts to protect public health. Since then, however, little has changed. Patented medicines continue to be priced out of reach for the world's poorest people. Trade rules remain a major barrier to accessing affordable versions of patented medicines (generic medicines). The prevalence of debilitating and life-threatening diseases in poor countries is growing, but medicines are simply not available. Urgent action is needed.

## Summary

Disease and ill health continue to ravage poor people worldwide. In 2005 there were approximately four million new HIV infections. Non-communicable diseases (NCDs) have unleashed a new epidemic of suffering across the developing world. Pandemics, such as avian influenza, are a serious threat to people in rich and poor countries alike.

Access to affordable, quality medicines is critical for patients in poor countries suffering a disproportionately high burden of disease. Most poor people pay for medicines out-of-pocket, so even slight price rises mean that life-saving medicines are unaffordable.

During the late 1990s, developing-country officials and civil-society groups grew increasingly concerned about the impact of intellectual property rules, introduced through the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, on access to medicines. Intellectual property rules create monopolies for medicines sold by multinational pharmaceutical companies, keeping inexpensive, generic medicines, which can reduce the cost of medicine in a sustainable way, off the market.

Responding to increased public outrage, developing-country governments demanded that the World Trade Organisation (WTO) address this critical issue as part of the launch of a new global trade round negotiation. As a result, WTO members unanimously enacted the 'Doha Declaration on the TRIPS Agreement and Public Health' on November 14, 2001, asserting that intellectual property rules should not prevent countries from protecting public health. The Declaration affirmed that developing countries could enforce public health safeguards to enable price reductions via generic competition. It also directed member countries to facilitate access to generic medicines by poor countries with insufficient drug manufacturing capacity, a measure known as the 'Paragraph 6 Public Health Solution'.

Since 2001, however, rich countries have failed to honour their promises. Their record ranges from apathy and inaction to a dogged determination to undermine the Declaration's spirit and intent. The USA, at the behest of the pharmaceutical industry, is uniquely guilty of seeking ever-higher levels of intellectual property protection in developing countries.

The USA has negotiated numerous bilateral and regional free trade agreements (FTAs) that impose what are known as 'TRIPS-plus' intellectual property rules, weakening or eliminating the public health safeguards allowed under TRIPS. Patented medicines thus have even higher levels of intellectual property protection than required under TRIPS, delaying the availability of affordable generics. The USA has also pressured countries for greater patent protection through threats of trade sanctions and through the WTO accession process.

While other rich countries, and particularly the member countries of the European Union, have not pursued a TRIPS-plus agenda, their inaction has left the USA free to impose stricter intellectual property rules on poor countries. This apathy is inconsistent with the EU's commitments under the Declaration, but is not surprising since EU pharmaceutical companies benefit from TRIPS-plus commitments that developing countries must enact through national legislation to comply with TRIPS-plus commitments in their agreements with the USA.

The 'Paragraph 6 Public Health Solution' has not facilitated delivery of affordable, generic medicines to poor countries with insufficient or no drug manufacturing capacity. Rich-country intransigence during negotiations created barriers that made the solution almost unworkable, and these countries are in no hurry to make the solution work. Canada, which first implemented the solution, made it even more complicated. The USA has not enacted legislation, while the EU only approved regulations implementing the solution in mid-2006.

The pharmaceutical industry has significantly benefited from the US trade agenda, as the US agenda reflects the industry's priorities by aiming to eliminate or weaken the TRIPS safeguards in order to extend its monopolies over medicines. The industry has also pursued TRIPS-plus rules in developing countries that have no obligation to implement higher levels of intellectual property protection. Having successfully lobbied the US government to impose these more stringent rules in developing countries, the industry is now actively pushing for their enforcement, including through the threat of trade sanctions.

This is the case in the Philippines and in India, which have not signed any TRIPS-plus trade agreements and are therefore only required to implement TRIPS standards of intellectual property protection. Yet the pharmaceutical company Pfizer is challenging the Filipino government's right to use TRIPS safeguards in an attempt to extend the company's monopoly on the hypertension drug, Norvasc. The pharmaceutical company, Novartis, which has made progress in some areas regarding access to medicines in developing countries, is challenging public health safeguards in Indian patent law. Furthermore, it is engaged in litigation to enforce a patent for a cancer drug, Glivec, for which generic versions could be available at one-tenth the originator's price.

Despite pressure from industry and rich-country governments, many developing countries – bolstered by effective civil-society groups and political will – are succeeding in introducing and enforcing TRIPS safeguards. Kenya introduced an Intellectual Property law in 2001 that drastically reduced prices for HIV medicines, and law-makers last year tabled an amendment to this law that would have repealed important TRIPS safeguards. In India, civil-society groups helped introduce TRIPS safeguards, preserving generic competition that is vital to millions of poor people in India and other developing countries.

Unfortunately, some countries that have used TRIPS safeguards in the past have now stopped doing so. Malaysia, which once used compulsory licensing (allowing governments to temporarily override a patent and authorise production of generic copies) to lower the price of antiretroviral drugs (ARVs), has now ceased challenging pharmaceutical companies' high prices. Countries that remain firm in their commitments, like Kenya and India, are threatened by external pressures.

On the five-year anniversary of the Doha Declaration, there is an urgent need to reinvigorate the spirit that produced the Declaration. The abysmal record of rich countries and the pharmaceutical industry remains a central concern of civil-society groups and developing-country governments. To ensure future access to inexpensive medicines for poor people, Oxfam recommends:

- Five years after the adoption of the Doha Declaration, the WTO review the impact of the TRIPs agreement on the affordability and availability of medicines in developing countries. The review should be supported by independent studies by the WHO and other relevant international organisations, in consultation with governments and public interest groups.
- The USA stop coercing developing countries into adopting 'TRIPS-plus' intellectual property protections through bilateral and regional trade agreements, threats of trade sanctions, and the WTO accession process.
- G-8 countries provide technical, political and economic support to poor countries to enact TRIPS safeguards and resist TRIPS-plus rules; encourage WTO talks to ensure that IP rules represent the interests and needs of poor countries; and ensure that the Paragraph 6 solution (which permits manufacturing countries to export generic versions of patented medicines to developing countries with insufficient or no domestic manufacturing capacity) is made workable.
- Rich countries incorporate the Paragraph 6 solution into their own national legislation and provide technical, political, and economic support to poor countries to enact and enforce TRIPS safeguards and resist TRIPS-plus rules.
- Developing countries, including India, China, Brazil, and South Africa, resist TRIPS-plus rules in FTAs, prevent introduction of TRIPS-plus rules in national legislation, and fully implement TRIPS safeguards to ensure production of generic medicines for domestic consumption and for export to other developing countries.
- Pharmaceutical companies stop lobbying rich-country governments to promote stricter intellectual property rules worldwide, and stop pressuring poor countries to accept stronger intellectual property rules that undermine public health.
- UN specialised agencies such as UNCTAD, WIPO, and WHO provide independent technical assistance and support to poor countries to enact TRIPS safeguards.

# 1. Introduction

In 1994, negotiators for the USA and other rich countries scored a major victory by inserting a global intellectual property rights agreement into the newly formed World Trade Organisation (WTO). The agreement, known as TRIPS (Trade-Related Aspects of Intellectual Property Rights), forced other countries to introduce a US-style intellectual property regime, including extending patent protection for medicines for 20 years. Claims that intellectual property protection and the resulting monopoly profits can sustain innovation remain debatable. On the contrary, intellectual property protection, by delaying competition with low-cost copies (called generics), results in higher prices for medicines, with disastrous consequences for millions of poor people.

At the same time as this new global intellectual property regime was being implemented, new threats to public-health were emerging – most notably the HIV epidemic. Many developing countries began addressing the HIV and AIDS crisis by providing low-cost medicines for their citizens. Some of these efforts encountered opposition from pharmaceutical companies, which sought to block production of generic equivalents of patented medicines in Brazil and Thailand.

Widespread public outrage resulted, and developing-country trade representatives insisted that the public-health consequences of TRIPS should be addressed as part of a larger ‘development round’ negotiation of new trade rules, launched in Doha in 2001. These efforts produced the ‘Doha Declaration on TRIPS and Public Health’, which asserted that the TRIPS Agreement should not prevent member countries from protecting public health. The Declaration reaffirmed the right of developing countries to use safeguards created under the TRIPS Agreement to reduce the price of medicines, and also instructed WTO members to find a solution for countries with insufficient generic manufacturing capacity.

The Doha Declaration is a subsequent legal agreement (to TRIPS) that can be relied upon to interpret the TRIPS Agreement, and can be used to lodge a complaint under the WTO Dispute Settlement Understanding.<sup>1</sup> Above all, it represents a political and moral commitment by all WTO members to ensure the TRIPS Agreement does not obstruct poor individuals from gaining access to inexpensive medicines.

Over the last five years, the health crises that prompted passage of the Declaration have worsened. Yet instead of enabling developing countries to implement the Doha Declaration, rich countries, and particularly the USA, have wilfully ignored their prior commitments. Through free trade agreements (FTAs) and unilateral pressure, the

USA has shackled developing countries with ever-higher standards of intellectual property protection that exceed the TRIPS Agreement. Other rich countries, and particularly member countries of the European Union, have silently watched and reaped the benefits of the US trade agenda. Pharmaceutical companies have also pressured developing countries not to use the TRIPS flexibilities and to enact stricter intellectual property rules.

Despite these pressures, some developing countries, such as India, Kenya, and the Philippines, with the strong support of local civil-society groups, have taken promising steps to promote public health and increase access to affordable medicines. Nevertheless, many other developing countries have not succeeded in improving affordability of life-saving medicines and have instead put in place more stringent intellectual property systems that are even more harmful to the health of their citizens than standard provisions under the TRIPS Agreement.

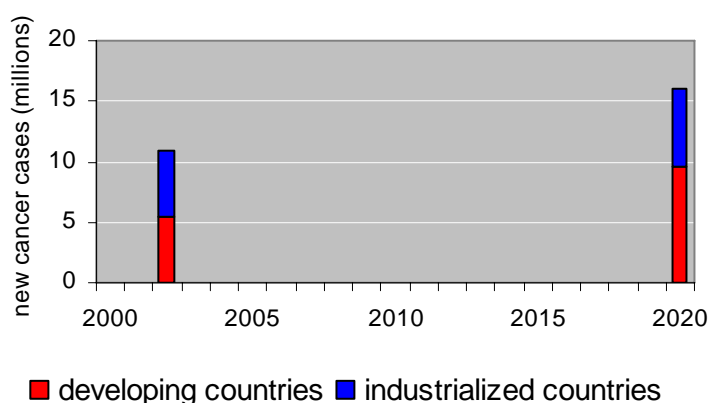
This paper argues that the concerns articulated in the Doha Declaration have not yet been resolved. Intellectual property rules continue to present obstacles to poor people's access to medicines and to the ability of countries to address public-health threats. Oxfam calls for a renewed commitment to defend public-health rights outlined in the Doha Declaration and recommends urgent actions by donors, developing countries, and pharmaceutical companies.

## 2. An urgent need for affordable medicines

In 2000, world leaders made health a priority of the Millennium Development Goals,<sup>2</sup> recognising that significant investments in health were essential for human development. Yet the health crisis that has devastated the developing world has shown no signs of abating. Infectious disease continues to kill millions of children and young adults.<sup>3</sup> Since the adoption of the Doha Declaration in November 2001, more than 20 million people have been infected with HIV, bringing the total number of people living with HIV and AIDS to 38.6 million people.<sup>4</sup> Other infectious diseases, such as tuberculosis and Hepatitis C, are a severe burden in many developing countries, while avian influenza threatens the lives of millions. Neglected diseases such as sleeping sickness are still endemic in poor countries.

Furthermore, non-communicable diseases (NCDs), once considered a 'burden of the rich', are increasingly affecting people in developing countries. In fact, over 80 per cent of deaths from NCDs occur in the developing world.<sup>5</sup> Cancer rates are expected to double between 2002 and 2020, with 60 per cent of these occurring in developing countries (Figure 1) <sup>6</sup>. Additionally, diabetes cases have risen from 30 million to 230 million over the last two decades, with most new cases occurring in the developing world.<sup>7</sup>

**Figure 1: Projected new cases of cancer by 2020**



Source: WHO

Besides causing illness and death, NCDs cripple poor people economically and socially because treatment means a lifetime of expenditures for medicines, with the burden of care most often falling upon women.

Improving health conditions in developing countries requires actions on many fronts by the international community and national governments. Insufficient funding and capacity, user fees for health services, and the lack of health services and health workers remain major impediments for poor people to access the services they need. The international community and national governments need urgently to improve health service delivery.<sup>8</sup>

However, the international community will not be able to reach its goals if it fails to tackle the problems caused by the high price of patented medicines, which keeps millions of people from receiving any treatment in developing countries.

The cost of medicine represents the greatest share of health-care expenditures for people in poor countries. Expenditure on pharmaceuticals ranges from 10–20 per cent of expenditure on health in the richest countries and 20–60 per cent in poorer countries.<sup>9</sup>

Unlike many rich countries, most developing countries lack universal health insurance. Across Asia, medicines comprise between 20 to 80 per cent of out-of-pocket health-care costs.<sup>10</sup> In Peru, where 70 per cent of expenditures on medicines are paid for out-of-pocket, only 52 per cent of the population has health insurance, and coverage mostly excludes those living under the poverty line.<sup>11</sup>



### 3. The Doha Declaration: patients over patents

Millions of women and men in developing countries make great sacrifices to buy the medicines needed for themselves and their families. The cost of health care, especially medicines, often drives them into poverty. The main proven mechanism to reduce the price of medicines is generic competition. In Colombia, where generics supply two-thirds of the national market, the cost of generic medicines is, on average, a quarter of the cost of brand-name equivalents.<sup>12</sup> Yet intellectual property rules included in the TRIPS Agreement restrict generic competition, thus keeping new medicines out of reach for all but a small elite in developing countries (Box 1).

#### **Box 1: How patent rules affected drug prices in Mexico**

In 1993, Mexico signed the North American Free Trade Agreement (NAFTA) with the US and Canada. Under NAFTA, Mexico implemented intellectual property rules nearly identical to those rules subsequently introduced under the TRIPS Agreement. By 1999, the prices for medicines in Mexico were nearly the same as those in European countries, and actually exceeded the average price for drugs in France and Canada.<sup>13</sup> However, Mexico's per capita income was less than one-third of the European Union, and, in 2000, approximately 20 per cent of the population earned less than two dollars a day.<sup>14</sup> Thus, there was 'dramatically lower per capita consumption of [medicines] in Mexico', which 'confirms that these drugs are unaffordable to most people'.<sup>15</sup>

The TRIPS Agreement represented the single greatest expansion of intellectual property protection in history. To allay the concerns of developing countries, the Agreement established that countries could adopt measures to protect public health, promote public interest, and prevent abuse of intellectual property rules. These measures, known as public-health safeguards, enable countries to obtain cheaper patented medicines or generic equivalents of patented medicines (Box 2). The importance of safeguards was recently affirmed by Pascal Lamy, the current WTO Director-General, who noted that '[safeguards] can make an important difference in saving life and ensuring more people can afford medical treatment'.<sup>16</sup> In addition, countries are empowered with flexibilities to determine the circumstances under which they apply safeguards. The TRIPS Agreement also provided developing countries with a 'transition period' for delayed implementation.

**Box 2: Some public health safeguards in the TRIPS Agreement**

Parallel importation (Article 6) allows countries to import a patented product marketed in another country at a lower price. Compulsory licensing and government use (Article 31) allows governments to temporarily override a patent and authorise production of generic equivalents of patented medicines in the public interest. This is broadly defined and at the discretion of each country. The 'Bolar provision' allows testing and regulatory approval of generic versions of drugs before the patent expires to ensure that generic copies can be introduced immediately upon patent expiry.

In the late 1990s, the HIV epidemic illustrated the need for flexible intellectual property rules, in addition to increased investment in health-care delivery.

In 2001, thanks to flexibilities in Indian patent law (India only implemented the TRIPS agreement in 2005), Indian generic producers were able to market antiretroviral medicines (ARVs) for a fraction of the price charged by multinational companies: \$360 per patient per year compared to \$10,000 per patient per year. Subsequently, prices fell even further to the current price of \$136 per patient per year. Due to such dramatic decreases in ARV prices, spurred by generic competition, the number of people receiving treatment has substantially increased, reaching 1.6 million in developing countries in 2006.<sup>17</sup> Furthermore, HIV and AIDS treatment has been simplified thanks to the efforts of Indian generic producers. Prior to TRIPS implementation in India, these manufacturers were able to combine three first-line ARVs into one tablet. These 'fixed dose combinations' (FDCs) simplify patient compliance with treatment regimes, and are now the basis for treatment programmes across Africa.

However, at the same time, rich countries, pushed by the pharmaceutical industry, tried to prevent countries from using TRIPS safeguards to increase access to medicines. In 1997, South Africa passed the Medicines Act to promote access to affordable medicines. In response, pharmaceutical companies brought a court case against South Africa, and the USA placed immense pressure upon South Africa to relent. At the same time, the USA launched a WTO dispute, challenging a Brazilian law that permitted local manufacturers to produce patented medicines if multinational companies did not locally manufacture them. This caused a worldwide public outcry. Eventually, the pharmaceutical companies dropped the South African court case and the USA withdrew its WTO complaint.

The enormous difficulties faced by developing-country governments trying to provide life-saving medicines to their citizens raised serious questions about the appropriateness of high levels of intellectual property protection in developing countries. Developing-country governments and civil-society groups, including Oxfam, pressured Northern countries to redress global imbalances created by

intellectual property rules. As a result, TRIPS and public health were key issues on the agenda of the Fourth Ministerial Meeting of the WTO in Doha, Qatar in November 2001, where WTO members launched the Doha 'Development' Round of trade negotiations.

These negotiations were intended to be 'pro-development' by addressing the mounting concerns of developing countries about global trading rules, such as the impact of TRIPS on access to medicines. From this meeting, the Doha Declaration emerged, which was unanimously approved by all WTO members. The commitment to address TRIPS' impact on public health, along with agricultural policies of rich countries, was critical in coaxing reluctant developing countries to sign up to a new Round of negotiations.

## 4. How does the Doha Declaration benefit public health?

The Doha Declaration unequivocally recognises and clarifies that the TRIPS Agreement should not prevent WTO member countries from taking measures to protect public health (Box 3).

### **Box 3: Doha Declaration on the TRIPS Agreement and Public Health**

Article 4 of the Declaration states: 'We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and, in particular, to promote access to medicines for all. In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose'.

Specifically, the Declaration recognises the legitimate need of countries to take measures to reduce the price of medicines, such as using TRIPS safeguards. The Declaration also acknowledges the need for WTO members to identify a mechanism that developing countries with insufficient or no drug manufacturing capacities could use to import generic versions of patented medicines under compulsory licenses. This is because TRIPS stated that compulsory licensing must be predominantly for the domestic market, which meant that poor countries without the necessary manufacturing capacity could not rely upon other countries to provide medicines. Finally, the Declaration extended the 'transition period' for least-developed countries to 2016, with each least-developed country retaining the right to apply for additional deferments.

Although the Declaration is a promising mechanism to mitigate the harmful effects of intellectual property rules, rich countries and

pharmaceutical companies have undermined its potential over the last five years.

## 5. Wrongdoing and inaction: the record of rich countries

Since 2001, the behaviour of rich countries has ranged from apathy and inaction to sheer determination to undermine the Doha Declaration. The USA, with the influence of pharmaceutical companies, is uniquely guilty of imposing higher standards of intellectual property protection (TRIPS-plus rules). These rules violate US commitments under the Doha Declaration and prevent developing countries from using safeguards to protect public health. The USA has accomplished this agenda through bilateral and regional trade agreements, WTO accession negotiations, and other forms of unilateral pressure. Other rich countries have not provided sufficient political, economic, or technical support needed for developing countries to enact and actively apply TRIPS safeguards. Furthermore, rich countries have collectively failed to make compulsory licensing workable on behalf of countries with insufficient manufacturing capacity.

### The US TRIPS-plus agenda

The USA has vigorously represented the commercial interests of pharmaceutical companies in trade negotiations with developing countries. For example, the office of the United States Trade Representative (USTR) announced an internal reorganisation to reflect 'our efforts to better support vital US innovations, including those in the pharmaceutical industry'.<sup>18</sup> Recently, the Bush administration has sought to stop World Health Organisation staff engaging in or publishing research or statements that critique the impact of US trade policy on public health.<sup>19</sup> In doing so, the USA seeks worldwide harmonisation of intellectual property rules on a level at or above US law, which is stricter than TRIPS.<sup>20</sup>

The US government's stance is not surprising given the close relationship between pharmaceutical companies and the USTR. Currently, 20 pharmaceutical-industry representatives are on USTR advisory committees.<sup>21</sup> Furthermore, the USTR has repeatedly delayed appointment of public-health representatives to industry advisory committees, as required under federal law.<sup>22</sup> A lawsuit was filed in the US federal court to compel the USTR to enforce these obligations. This suit has also led the US House of Representatives to pass legislation to withhold funding from these advisory committees until appropriate action is taken.<sup>23</sup>

The influence of the pharmaceutical industry over the US government position on intellectual property rights in developing

countries is particularly obvious when comparing annual surveys issued by the USTR and the Pharmaceutical Research and Manufacturers of America (PhRMA) on intellectual property frameworks in other countries. The annual government survey, known as the 'Special 301' report, is mandated by the US Trade Act and obligates the USTR to assess whether standards of intellectual property protection in other countries are consistent with the US preferred level of protection. It sends warnings to countries that infringe US standards, and these warnings include threats of trade sanctions. Many recommendations in the PhRMA survey and the Special 301 report are either identical or strikingly similar.

## Bilateral and regional free trade agreements (FTAs)

Even though the USA agreed to the Doha Declaration in 2001, US trade policy never actually changed. Instead, the USA has opted to rely upon other means to ensure that the strictest levels of intellectual property protection are imposed worldwide.

In 2002, Congress required the USTR to 'respect the [Doha] Declaration on the TRIPS Agreement and Public Health' when it granted the USTR authority to negotiate FTAs.<sup>24</sup> Yet every FTA signed or currently under negotiation has disregarded the fundamental obligations of the Declaration by maintaining or imposing higher levels of intellectual property protection that further restrict generic competition,<sup>25</sup> even though many US trading partners are developing countries with millions of poor people unable to afford expensive medicines.<sup>26</sup>

The FTAs contain the following TRIPS-plus rules:

- Expanding the scope of pharmaceutical patents, including to new indications (new therapeutic uses of existing medicines) and formulations;
- Enhancing protections for clinical trial data by providing at least five years of marketing exclusivity for the data (also known as data exclusivity);<sup>27</sup>
- Limiting the grounds for issuing compulsory licences to emergencies, government non-commercial use, and competition cases;
- Barring parallel trade of patented medicines sold more cheaply elsewhere;
- Extending patent monopolies for administrative delays by patent offices and drug regulatory authorities;

- Linking drug registration to patent status, thereby preventing registration and sale of generics during the patent term;
- Enforcing patent violations and granting pharmaceutical companies investor-based rights to sue, including for improvidently granted compulsory licences;
- Prohibiting pre-grant patent oppositions, and making it more difficult to revoke invalid patents.

## Public health consequences of TRIPS-plus FTAs

The FTAs signed between the USA and developing countries will have severe consequences on the health and welfare of people in those countries. Studies confirm that if FTAs with developing countries are enforced, the price of new medicines will increase and remain higher over time, with potentially devastating effects upon poor people. Colombia and Peru, for instance, recently concluded FTA negotiations with the USA. Both FTAs include stringent TRIPS-plus rules, including extension of patent term, data exclusivity, and patent linkage (Box 4).

Higher drug prices also threaten the financial viability of public-sector health programmes. A recent World Bank study predicts that a potential US-Thailand FTA would severely undermine the Thai government's national HIV and AIDS treatment programme, which provides HIV-related services (including ARVs) to 80,000 Thais, with an aim to achieve universal coverage.<sup>28</sup>

Over time, some patients on 1st line ARVs develop drug resistance or suffer from side effects and must switch to patented 2nd line ARVs, which are approximately 15 times the cost of generic 1st line medicines (\$6737 compared to \$482).<sup>29</sup> Compulsory licensing allows the Thai government to manufacture generic 2nd line ARVs or negotiate lower prices, a tactic often used by the Brazilian government. Issuing a compulsory licence for 2nd line drugs would be consistent with TRIPS and the Doha Declaration, and according to the World Bank, would significantly reduce Thailand's future budgetary obligations to treat HIV-positive individuals (Table 1).<sup>30</sup> An FTA would severely restrict the use of compulsory licensing and threaten the programme's sustainability.

**Table 1: Long-term public health burden of FTAs on access to affordable medicines in Colombia, Peru, and Thailand**

Relevant FTA	Source	Public Health Impacts
US–Colombia FTA	Pan American Health Organization <sup>31</sup> (2005)	By 2020, the Colombian health system would pay an additional \$940m per year to cover the cost of medicines, and approximately 6 million users would have no access to medicines through the health system.
US–Peru FTA	Peruvian Ministry of Health <sup>32</sup> (2005)	Prices for medicines would rise 9.6 per cent on average in the first year, 100 per cent in 10 years and 162 per cent in 18 years. In 10 years, Peru would incur additional medicine expenses of \$199.3m – of which \$110m would have to be met by Peruvian households.
US–Thailand FTA	World Bank <sup>33</sup> (2006)	Compulsory licensing, which is threatened by an FTA, could otherwise reduce the cost of 2 <sup>nd</sup> line ARVs – which most patients will eventually need – by 90 per cent. This would represent a saving of \$3.2bn <sup>34</sup> for the Thai national health budget over 20 years.

The USTR claims that public health ‘side letters’, which have been included in some FTAs, would allow developing countries to take measures needed to protect public health. A side letter is a ‘Memorandum of Understanding’ signed by the USA and a trading partner that clarifies the parties’ mutual understanding of relevant provisions in an FTA text. Yet side letters do not limit TRIPS-plus rules in the main text since the side letters do not constitute legally binding exceptions to clear obligations set out in the agreement.<sup>35</sup>

### **Other forms of US pressure**

In addition to FTAs, the USA exerts other forms of pressure on developing countries to implement higher levels of intellectual property protection. This includes monitoring other countries’ intellectual property rules in relation to US standards (Special 301 reports) and introducing TRIPS-plus rules during the WTO accession process.

#### **a) Special 301 reports**

The USA continues to exert unilateral pressure upon poor countries through the Special 301 process, an annual report that evaluates



intellectual property protection in other countries. If a country does not comply with US standards, it can be placed on the 'Priority Watch List', meaning the country could face unilateral trade sanctions. Armed with FTAs that legally bind countries to TRIPS-plus provisions, the USA and pharmaceutical companies can now use the Special 301 process as an additional tool to enforce strict TRIPS-plus rules.

For instance, the USA initiated a Special 301 review of Chile in May 2006. Chile signed an FTA with the USA in 2003, forcing it to adopt TRIPS-plus rules, including patent linkage and data exclusivity. Yet because Chile interpreted these commitments in a manner displeasing to the pharmaceutical industry, the industry recommended that the USTR place Chile on the Special 301 Priority Watch List.<sup>36</sup> Chile's status is currently under review by USTR.

The USA has also used the Special 301 process to pressure countries to unilaterally implement TRIPS-plus rules. In 2006, the USA placed India on the Special 301 Priority Watch List for not granting monopoly rights for clinical trial data (data exclusivity) that would give the patent holder five years of marketing exclusivity.<sup>37</sup> Some pharmaceutical companies also pressured the Indian government.<sup>38</sup> This occurred even though India's current law is TRIPS compliant. It allows the Indian drug regulatory authority to use the patent holder's clinical data to approve generic medicines rapidly.

An Indian inter-governmental committee has reconsidered the country's test data law, but has not made firm recommendations.<sup>39</sup> A legislative proposal is expected to be presented before Parliament.<sup>40</sup>

Implementing data exclusivity would reduce generic competition and devastate the ability of poor Indians to access affordable medicines. For example, Colombia granted data exclusivity for clinical trial data in 2002. As a result, research estimates that, by 2020, Colombia will incur an additional \$535m in expenses for medicines with no generic equivalent. Furthermore, at least 86 forms and indications of medicines are without a generic equivalent due to data exclusivity.<sup>41</sup>

Besides obstructing domestic access to generic medicines, introducing data exclusivity in India would also affect millions of people in least developed countries who rely upon Indian generic medicines, including ARVs. Recent studies have noted that generic production of ARVs such as atazanavir and heat-stable ritonavir could be precluded by implementing a data exclusivity regime.<sup>42</sup> Indian companies remain an essential source of affordable ARVs; even the US global HIV and AIDS treatment programme, PEPFAR (President's Emergency Plan for AIDS Relief), purchases and distributes ARVs manufactured by Indian generic companies.<sup>43</sup>

Above all, data exclusivity either prohibits generic competition for a specified period of time or requires generic manufacturers to repeat

clinical trials, which is unethical because some patients would be given placebos when the safety and clinical validity of the medicine being tested is already established.

### **b) WTO Accessions**

Countries acceding to the WTO must abide by WTO rules. In addition, existing WTO members may ask for additional concessions, often exceeding their own WTO commitments. Without the support of countries like the USA, entry is impossible since it requires consensus among all WTO members. The process of accession includes confidential bilateral negotiations with rich countries, during which aspiring members are pressured into accepting WTO-plus commitments in many areas, including intellectual property.

Since passage of the Doha Declaration, the USA has used the accession process to force poor acceding countries to forego their rights under the TRIPS Agreement. In particular, the USA used the process to pressure Cambodia and Nepal to forego the transition period allowing least-developed countries to wait until 2016 to provide intellectual property protection for medicines.<sup>44</sup> Only concerted resistance by Cambodian trade negotiators ensured that Cambodia could benefit from the transition period and other safeguards.<sup>45</sup>

The same process could force countries currently negotiating WTO entry to implement TRIPS-plus rules, including Vietnam, Ethiopia, and Laos.

## **Indifference by other rich countries**

There have been a few public statements from other rich-country leaders decrying the TRIPS-plus agenda pursued by the USA. During the 2004 World AIDS Conference, French President Jacques Chirac derided the USA for 'blackmailing developing countries into bartering their right to produce generic HIV drugs for free trade agreements'.<sup>46</sup> The UK reaffirmed the importance of TRIPS safeguards in multiple high-level government reports, including the Reports of the Commission on Africa and the Commission on Intellectual Property Rights (CIPRH). However, on the whole, rich countries have quietly consented to US action, leaving poor countries without support or leverage to resist stronger intellectual property protection.

Other rich countries may choose not to interfere with the US trade agenda because their pharmaceutical companies reap the benefits of TRIPS-plus rules. Although PhRMA is a US industry group, its members include US subsidiaries of European drug companies, including Glaxo-Smith Kline (UK), Sanofi-Aventis (France), and Bayer (Germany).<sup>47</sup> Furthermore, when developing countries

negotiate TRIPS-plus rules in an FTA, they must alter national intellectual property laws to fully implement TRIPS-plus terms. Thus, all pharmaceutical companies selling medicines in a developing country, including European companies, benefit from these changes, essentially 'free-riding' on US efforts to introduce TRIPS-plus rules.

## Failures to use the Paragraph 6 'Public Health Solution'

One objective of the Doha Declaration was to find an appropriate solution to ensure that countries with insufficient or no domestic manufacturing capacity could import generic medicines under a compulsory license. Rich-country intransigence during negotiations created barriers and bureaucratic hurdles that made the solution almost unworkable.<sup>48</sup> Although the Director-General of the WTO called the Paragraph 6 solution 'a historic agreement' that 'proves once and for all that the [WTO] can handle humanitarian as well as trade concerns',<sup>49</sup> NGOs, including Oxfam, derided it as a solution 'wrapped in red tape'.<sup>50</sup>

To date, the solution has not produced the desired results. According to a recent TRIPS Council report, no qualifying member has notified the WTO to use the system created to implement the solution.<sup>51</sup> For potential importing countries, this is probably because of the complexity of the process, lack of technical capacity, and fear of reprisal. Instead, such countries seem to have relied so far on ad hoc donations, non-notified imports or other safeguards, such as parallel importation.

Rich countries, for their part, seem to be in no hurry to make it work. Many have been slow to implement the deal, and no country has successfully used the mechanism to export medicines to countries with insufficient manufacturing capacity. The USA has not enacted legislation to implement the solution,<sup>52</sup> while the European Union only approved regulations implementing the public health solution in mid-2006.<sup>53</sup>

Rich countries that did implement the law made it more complicated. Despite the efforts of civil-society groups and generic manufacturers, Canada enacted legislation that has proved 'unworkable' according to Médecins Sans Frontières, which spent two years trying to export generic ARVs under Canada's legislation.<sup>54</sup>

The inability of the Paragraph 6 solution to deliver medicines is a serious threat to the legitimacy of the WTO. The current WTO Director-General has just started to acknowledge the solution's present weakness.<sup>55</sup> Civil-society scepticism towards Paragraph 6 is shared by most countries. By October 2006, only three countries, the

USA, Switzerland, and El Salvador, had formally accepted the solution.<sup>56</sup>

## **6. An unrelenting campaign: the record of pharmaceutical companies**

Pharmaceutical companies did not interpret the Doha Declaration as a signal to stop pursuing stronger intellectual property rules in developing countries; instead, they saw it as a signal to change tactics.

### **Shaky justifications for stricter intellectual property rules**

The pharmaceutical industry makes two primary justifications for stronger intellectual property protection as a benefit for poor countries: first that intellectual property rules provide an incentive to develop innovative drugs, and second that they allow the industry to recoup significant investments made for research and development (R&D).

While IP protection may be one method to promote innovation in rich countries, intellectual property rules do not stimulate innovation in or on behalf of poor countries. Quite the contrary – between 1975 and 2004, only 21 of the 1556 new chemical entities marketed were targeted at poor country diseases like malaria and Bilharzia.<sup>57</sup>

Moreover, the huge financial returns linked with intellectual property protection seem to have nurtured rent-seeking behaviour in the pharmaceutical sector rather than a drive towards innovation. In fact, the majority of research conducted by industry is for higher-priced and similar versions of existing medicines ('me-too' medicines with little added therapeutic benefit), or monopoly extensions for new uses of old medicines.<sup>58</sup> These medicines are rarely innovative: only 15 per cent of the new drug applications approved by the US Food and Drug Administration (FDA) from 1989 to 2000 were identified as clinical improvements over products already on the market.<sup>59</sup>

In fact, the role of intellectual property rules in promoting research is dubious. Research for many innovative drugs relies upon substantial contributions from government-funded research. A 2000 US Congress report found that of 21 innovative drugs introduced between 1965 and 1992, 15 were developed applying knowledge or techniques derived from federally-funded research.<sup>60</sup>

Even when pharmaceutical companies secure stronger intellectual property protection in poor countries, there is no profitable market to encourage companies to conduct R&D to produce medicines that

would predominantly benefit developing countries.<sup>61</sup> Nearly 90 per cent of pharmaceutical sales are in North America, the European Union, and Japan, with the remaining sales in all other countries combined.<sup>62</sup> No amount of intellectual property protection is going to make poor women and men in Africa a lucrative target for the pharmaceutical industry.

Even without generating many innovative medicines, the pharmaceutical industry has been one of the most profitable, returning an average profit of 19 per cent annually, compared to a 5 per cent average for the world's five hundred richest companies as ranked by the Fortune 500.<sup>63</sup> Despite claims of spending on R&D, 2004 figures show that companies spend, on average, only 14 per cent of their revenues on R&D, compared to 32 per cent on marketing and administration.<sup>64</sup> This includes, for instance, nearly \$25bn a year on glossy magazine pull-outs.<sup>65</sup>

## From lobbying to bullying

Lobbying the US government to impose TRIPS-plus rules has reaped major benefits for pharmaceutical companies. Companies are now enforcing their new-found 'rights' in the courtrooms of developing countries. For example, as Chile undergoes a Special 301 review, the government must also contest injunctions filed by pharmaceutical companies seeking to enforce their interpretation of patent linkage obligations introduced under the US–Chile FTA.<sup>66</sup> Even in countries with which the USA has not signed an FTA, pharmaceutical companies are trying to enforce TRIPS-plus rules (see Box 4).

### **Box 4: Pfizer's attempt to enforce TRIPS-plus rules in the Philippines**

Eight million Filipinos are hypertensive, and heart disease is the country's number one killer.<sup>67</sup> Norvasc, a hypertension medicine manufactured by Pfizer, is unreasonably expensive in the Philippines compared to neighbouring countries. Since most Filipinos pay for medicines out-of-pocket, any additional expense can be financially devastating. Anticipating patent expiration of Norvasc in mid-2007, the Filipino drug authority imported cheaper versions of the patented drug to establish bio-equivalence between the two versions. This practice, known as "early working", is legal under the Bolar provision and facilitates marketing approval and introduction of inexpensive equivalents of a medicine on the first day of patent expiration (since marketing approval can take 18 months). The Bolar provision is consistent with TRIPS and with Filipino legislation, and is used in other countries, including the USA and Canada. Yet Pfizer filed a lawsuit against the Filipino government, asserting that: parallel importation of a patented version of Norvasc prior to patent expiration, even if only to conduct early working, is illegal; registration of imported versions of Norvasc should not be permitted until the patent expires (a rule known as "linkage" that goes beyond what is required by TRIPS and is prohibited under Filipino law); and a temporary restraining order should be issued to ensure that the government does not import any additional samples of Norvasc until the patent expires.<sup>68</sup> If Pfizer succeeds,

it would severely limit future access to inexpensive medicines and would challenge the government's independent right to enforce TRIPS flexibilities.<sup>69</sup>

## 7. TRIPS safeguards: signs of hope and lingering threats

As the five-year anniversary of the Doha Declaration passes, there are signs that countries can still enforce TRIPS safeguards. Malaysia issued one compulsory license, but pressure precluded further use. Other countries, such as the Philippines, Kenya, and India, are trying to either introduce or apply TRIPS safeguards, despite the pressure and threats of the pharmaceutical industry and the USA. These countries' successes are due in large part to energetic civil-society pressure.

Although there are bright spots, the overall landscape is dark. Most developing countries have not exercised their rights, and many have not even introduced legislation that would permit the use of safeguards.<sup>70</sup> In fact, only 31 per cent of developing countries have implemented the Bolar provision facilitating rapid introduction of generic medicines, and only 53 per cent have introduced a parallel importation clause that allows importation of patented versions of medicines from anywhere in the world.<sup>71</sup>

### Malaysia's use of compulsory licensing

Malaysia issued a compulsory licence in 2003 to import ARVs from India. Previously, the pharmaceutical industry pressed Malaysia to negotiate lower prices instead of enforcing a compulsory licence. Nevertheless, the Ministry of Health demonstrated political will and enforced the country's rights under the TRIPS Agreement to use compulsory licensing, reducing the price of 1<sup>st</sup> line ARVs by 81 per cent (from \$315 to only \$58).<sup>72</sup> Yet Malaysia stopped using compulsory licensing, and is currently negotiating an FTA with the USA that would severely limit its future ability to enforce a compulsory licence.

### Philippines: a new push for TRIPS safeguards

In 2005, the Philippines introduced a new law that would implement TRIPS safeguards, including provisions legalising parallel importation and government-use licenses. It also confirmed the existing right of the government to use the Bolar provision to test and register a generic medicine in advance of patent expiry.<sup>73</sup> Implementation of this law would reduce medicine prices. For

example, Norvasc, a hypertension medicine manufactured by Pfizer (Box 4), would cost the government about one-tenth its current price (via parallel importation from Pakistan). The bill has progressed through the Filipino legislature, despite opposition by PhRMA and the US government.<sup>74</sup>

## Kenya: successful use of TRIPS safeguards

In Kenya, civil-society pressure succeeded in introducing an IP law with TRIPS safeguards in 2001. This law permits imports of generic versions of medicines presently patented in Kenya, but which are produced legally as a generic elsewhere.<sup>75</sup> Usually, parallel importation is limited to imports of branded medicines from other countries where those medicines have been sold onto the open market. As a result, generic competition reduced the prices of 1<sup>st</sup> line ARVs to one-third of the price of the patented version,<sup>76</sup> a huge gain for a country with nearly 3.1 million people living with HIV and 200,000 under treatment.<sup>77</sup>

Yet in 2006, the government introduced an amendment that would modify the law by requiring prior consent of a patent holder to use parallel importation.<sup>78</sup> This measure would effectively ban parallel importation and also undermine a government plan to abolish user fees for publicly distributed ARVs.<sup>79</sup> A local civil-society coalition has organised demonstrations, educated the media, and engaged members of Parliament in opposition to the proposed law. The amendment has yet to be voted upon in Parliament, and Kenya continues to import affordable medicines.

## India: enforcement of TRIPS safeguards under threat

India became TRIPS compliant in 2005, but civil-society pressure ensured inclusion of crucial safeguards. In particular, Section 3(d) of the Patents Act excludes patent protection for new forms or new uses (indications) of already patented medicines, a permissible limitation under TRIPS.<sup>80</sup> By narrowing the scope of patentability, the government prevents the pharmaceutical industry from abusing the patent system via 'evergreening', or by introducing 'new' medicines that are only second forms or indications of older medicines and are neither novel nor inventive.

The law also permits any individual or entity to contest patent applications filed by pharmaceutical companies. There were nearly 10,000 applications registered between 1995 and 2005. Since India qualified for a 'transition period' under TRIPS, these patent applications were treated as 'mailbox' applications.<sup>81</sup> Although generic competition was allowed during these intervening years,

patent holders now have a right to enforce their patents, thereby jeopardising generic production.<sup>82</sup> The patent opposition process provides any individual with an opportunity to prevent the patenting of medicines that are not truly innovative, and preliminary data indicates that many mailbox applications fall into this category.<sup>83</sup>

Nevertheless, the Swiss pharmaceutical company Novartis, in a recent court appeal, has asserted that denying patents for second uses or second indications of old medicines is illegal under the TRIPS Agreement (see Box 5).

**Box 5: Novartis challenges the Indian patent law**

Using the patent opposition process, the Cancer Patients Association submitted a request to oppose a Novartis patent application for Glivec, a medicine that treats chronic myeloid leukaemia – a blood cancer. Since Glivec is merely a new form of an old medicine, and thus under Section 3(d) is not patentable, the application was rejected.<sup>84</sup> This decision was crucial to ensuring treatment access. When Novartis had exclusive rights to the medicine, they charged nearly ten times more (\$27,000/year) than the generic price (\$2,700/year) in India.<sup>85</sup> Unsatisfied, Novartis has filed two appeals, one to challenge the patent examiner's decision to invalidate the patent on Glivec, and a second appeal to invalidate Section 3(d) of the Indian patent law.<sup>86</sup> Novartis's appeal directly challenges India's right to interpret TRIPS.<sup>87</sup> A victory by Novartis would have severe adverse implications on access to medicines in India and other developing countries, given that India is a major exporter of generic medicines to other developing countries.

## Threats to an effective HIV and AIDS programme: the case of Brazil

Brazil has been at the forefront of using safeguards to reduce ARV prices since guaranteeing universal access to treatment in 1996. Brazil repeatedly threatened to use compulsory licences to override patents on ARVs. Rather than lose such a large market, major pharmaceutical companies agreed to price reductions, lowering the average price of ARV therapy from \$6240 to \$1336 per patient per year.<sup>88</sup> These savings allowed Brazil to expand ARV treatment and increase investment in prevention. Brazil's programme has been one of the few successes worldwide to combat HIV and AIDS. Experts estimated that Brazil would have 1.2 million infected people by 2000. Yet by the end of 2005, 620,000 Brazilians were HIV-positive, a modest HIV prevalence rate of 0.5 per cent.<sup>89</sup>

However, the price of new ARVs has steadily increased, so that Brazil now pays, on average, \$2,500 per patient per year. As more patients develop intolerance or resistance to 1st line therapies, Brazil must use new and 2nd line medicines that are under patent. Brazil's Ministry of Health estimates that of its \$445m budget for HIV treatment, over 80 per cent will be spent on imported ARVs, with more than half on



only three medicines: efavirenz, Lopinavir/Ritonavir (Kaletra), and tenofovir.<sup>90</sup>

Brazil reduced the price of Kaletra and tenofovir by threatening to issue a compulsory licence. Issuing a compulsory licence for all imported ARVs would further reduce prices, saving the government \$769m by 2011.<sup>91</sup> Nevertheless, the government did not act and, while no patient is currently denied medicines, the strain of higher prices may eventually make Brazil's commitment to universal treatment unaffordable.

## New ways forward to promote patients over patents

Besides strict intellectual property protection, other mechanisms, such as public finance and prize money, can play an important role in promoting innovation. In 2006, the World Health Assembly passed a resolution, introduced by Brazil and Kenya, instructing the World Health Organisation to establish an inter-governmental working group to examine mechanisms to bolster R&D for diseases primarily affecting the developing world.<sup>92</sup> The resolution acknowledged that intellectual property rules are not a sufficient incentive to develop innovative medicines where the potential market is small or uncertain, that high medicine prices are a concern to ensuring treatment, and that the Doha Declaration affirms public health should take primacy over IP rules.<sup>93</sup>

Developing countries should collaborate to stop introduction of stronger intellectual property rules. For example, the African Union issued a declaration in April 2006 instructing the EU, which had begun to negotiate Economic Partnership Agreements with various African countries, to 'refrain from seeking obligations that exceed those under the TRIPS Agreement'.<sup>94</sup> In addition, the Declaration calls upon the EU to fully implement the Paragraph 6 solution.

Rich countries should heed these declarations from developing countries as they move towards the G-8 summit in 2007. The German government announced that the agenda would include intellectual property issues, without specifying whether it will address concerns regarding access to medicines.<sup>95</sup> G-8 members should support an assessment of the Doha Declaration and consider new steps to ensure access to medicines for poor people and flexibilities for developing countries to address public health needs. Because TRIPS safeguards have rarely been used in developing countries, the G-8 should also consider ways to assist developing countries to fully implement TRIPS safeguards, to ensure that the Paragraph 6 solution is both workable and used, and to review whether the TRIPS Agreement requires further modification to ensure that public health can truly be protected.<sup>96</sup>

## 8. Recommendations

Access to medicines is a basic human right. Poor people, particularly women, carry the burden of lack of access in terms of mortality, morbidity, socio-economic devastation, and caring for the sick. In 2001, the Doha Declaration was agreed upon by all WTO members to ensure that public health overrides commercial interests. Developing countries and civil society accepted the Declaration in good faith, believing that Northern governments and the pharmaceutical industry had finally acknowledged the harm strict intellectual property rules caused in developing countries. Yet five years later, as the health crisis in developing countries grows unabated, rich countries and pharmaceutical companies continue undermining poor people's rights to medicines.

To reduce the burden of intellectual property rules, Oxfam recommends that:

- Five years after the adoption of the Doha Declaration, the WTO review the impact of the TRIPs agreement on the affordability and availability of medicines in developing countries. The review should be supported by independent studies by the WHO and other relevant international organisations, in consultation with governments and public interest groups.
- The USA stop coercing developing countries into adopting 'TRIPS-plus' intellectual property protections through bilateral and regional trade agreements, threats of trade sanctions, and the WTO accession process.
- G-8 countries provide technical, political and economic support to poor countries to enact TRIPS safeguards and resist TRIPS-plus rules; encourage WTO talks to ensure that IP rules represent the interests and needs of poor countries; and ensure that the Paragraph 6 solution is made workable.
- Rich countries incorporate the Paragraph 6 solution (the solution permits manufacturing countries to export generic versions of patented medicines to developing countries with insufficient or no domestic manufacturing capacity) into their national legislation and provide technical, political, and economic support to poor countries to enact and enforce TRIPS safeguards and resist TRIPS-plus rules.
- Developing countries, including India, China, Brazil, and South Africa, resist TRIPS-plus rules in FTAs, prevent introduction of TRIPS-plus rules in national legislation, and fully implement TRIPS safeguards to ensure production of generic medicines for

domestic consumption and for export to other developing countries.

- Pharmaceutical companies stop lobbying rich country governments to promote stricter intellectual property rules worldwide, and stop pressuring poor countries to accept stronger intellectual property rules that undermine public health.
- UN specialised agencies such as UNCTAD, WIPO, and WHO provide independent technical assistance and support to poor countries to enact TRIPS safeguards.

## Notes

<sup>1</sup> C. Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', WHO, June 2002.

<sup>2</sup> Of the eight MDGs, three address issues of health: reduction of child mortality; improvements in maternal health; and combating HIV and AIDS, malaria, and other diseases.

<sup>3</sup> WHO Report on Infectious Diseases, 'Removing Obstacles to Healthy Development', 1999, <http://www.who.int/infectious-disease-report/index-rpt99.html>.

<sup>4</sup> UNAIDS, Report on the Global AIDS Epidemic, 2003, 2004, 2005 and 2006.

<sup>5</sup> WHO, 'Chronic diseases and their common risk factors', [www.who.int/chp/chronic\\_disease\\_report/media/Factsheet1.pdf](http://www.who.int/chp/chronic_disease_report/media/Factsheet1.pdf).

<sup>6</sup> WHO, *World Cancer Report*, 2006.

<sup>7</sup> 'Poor nations struggle to cope with diabetes surge', *Detroit Free Press*, 11 June 2006.

<sup>8</sup> Oxfam International and WaterAid (2006) *In the Public Interest: Health, Education, and Water and Sanitation for All*, [http://www.oxfam.org.uk/what\\_we\\_do/issues/debt\\_aid/public\\_interest.htm?searchterm=In+the+public+interest](http://www.oxfam.org.uk/what_we_do/issues/debt_aid/public_interest.htm?searchterm=In+the+public+interest).

<sup>9</sup> WHO, 'The World Medicines Situation', Chapter 5, 2004. <http://hinfo198.tempdomainname.com/medicinedocs/library.fcgi?e=d-0edmweb--00-1-0--010---4---0--0-10l--1en-5000---50-about-0---01131-00115ERnz+VC9ee84d6400000000436f372a-0utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.6&d=Js6160e.7>.

<sup>10</sup> E. Van Doorslaer et al., 'Paying out of pocket for health care in Asia: Catastrophic and poverty impact', Equitap Project: Working Paper #2, May 2005. In India, 80 percent of out of pocket expenditures on health are for medicines. See

[http://www.whoindia.org/LinkFiles/Commision\\_on\\_Macroeconomic\\_and\\_Health\\_Access\\_to\\_Essential\\_Drugs\\_and\\_Medicine.pdf](http://www.whoindia.org/LinkFiles/Commision_on_Macroeconomic_and_Health_Access_to_Essential_Drugs_and_Medicine.pdf)

<sup>11</sup> G. Valladares Alcalde (coordinator), R. Cruzado Ubillús, J. Seclén Palacín, Z. J. Pichihua Serna, 'Evaluación de los potenciales efectos sobre acceso a medicamentos del Tratado de Libre Comercio que se negocia con los Estados Unidos de América', Lima: Health Ministry, April 2005. Also in: [http://www.forosalud.org.pe/estudio\\_minsa\\_evaluacion\\_efectos\\_del\\_tlc\\_en\\_medicamentos.pdf](http://www.forosalud.org.pe/estudio_minsa_evaluacion_efectos_del_tlc_en_medicamentos.pdf).

<sup>12</sup> Germán Holguín Zamorano, 'La Bolsa y la Vida: Impacto de la agenda norteamericana para el TLC sobre el acceso a medicamentos y la salud pública', Misión Salud, 2004. <http://www.misionsalud.org/la-bolsa-y-la-vida-german-holguin.pdf>

<sup>13</sup> P. M. Danzon and M. F. Furukawa, 'Prices and Availability of Pharmaceuticals: Evidence from Nine Countries', *Health Affairs*, October 2003, <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w3.521v1>.

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<sup>14</sup> World Bank Group's World Development Indicators.

<sup>15</sup> Danzon and Furukawa, *op.cit.*

<sup>16</sup> A. Jack, 'WTO head flags trade rules as way to reduce drug costs', *Financial Times*, October 12, 2006.

<sup>17</sup> UNAIDS, Report on the Global AIDS Epidemic, 2006.

<sup>18</sup> Office of the United States Trade Representative, 'Schwab moves to strengthen focus on Innovation and Southeast Asia', 9 September 2006.

<sup>19</sup> See press release from Senator Edward Kenney and Congressman Henry Waxman and their accompanying letter to the US Secretary of Health and Human Services, Michael Leavitt, 13 October 2006, <http://www.democrats.reform.house.gov/story.asp?ID=1126>.

<sup>20</sup> According to the Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15), which is part of the USTR's formal advisory committee structure and represents the pharmaceutical industry, 'The Committee seeks to establish strong precedents in these FTAs in order to raise the global level of protection and enforcement globally, nationally and in regional and in multilateral agreements. The FTA process has become the principal process through which the IPR-based industries are able to ensure that the standards of protection and enforcement keep pace with new developments.', ITAC 15, *The U.S.-Colombia Trade Promotion Agreement (TPA) The Intellectual Property Provisions*, September 20, 2006.

<sup>21</sup> Center for Policy Analysis on Trade and Health, 'Campaign for public health representation in trade policy', <http://www.cpath.org/id4.html>.

<sup>22</sup> *Ibid.*

<sup>23</sup> *Ibid.*

<sup>24</sup> United States Trade Promotion Authority, Public Law 107-210, August 6, 2002, § 2101(b)(4)(C).

<sup>25</sup> See 'The US-Peru Trade Promotion Agreement (TPA): The Intellectual Property Provisions', Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), February 1, 2006. In the report, ITAC-15 states that 'FTA negotiations provide the most effective approach currently available to the United States for improving global intellectual property protection... Our goal in the negotiation of an FTA is to set a new baseline for all future FTAs'.

<sup>26</sup> Since TPA was passed in 2002, the USA has concluded negotiations for FTAs with Australia, Bahrain, Chile, Central American countries, the Dominican Republic, Colombia, Peru, Morocco, Oman, and Singapore. It is currently negotiating bilateral FTAs with South Korea, Thailand, Malaysia, the United Arab Emirates, Ecuador and Panama, and attempted to pursue regional negotiations in Southern Africa and the entire Western hemisphere (FTAA).

<sup>27</sup> Drug regulatory authorities generally rely upon clinical trial data produced by patent-holding pharmaceutical companies to approve generic versions of medicines. The TRIPS Agreement, pursuant to Article 39.3, only requires protection of clinical trial data against unauthorised public disclosure. This means that a government drug regulatory authority can rely upon the trial

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data to establish the effectiveness and safety of a generic version of a patented medicine. Thus, when a generic version of a medicine is produced or imported, a generic manufacturer only has to establish 'bio-equivalence' between its medicine and the patented version, and the regulatory authority can rely upon the previously submitted clinical trial data to establish the drug's efficacy and safety. A data exclusivity law precludes use of clinical trial data of an originator company by a drug regulatory authority, even establishing marketing approval, normally for a period of five years. As a result, when a generic producer wishes to introduce a generic version of a patented medicine, it cannot rely upon the already produced data. Thus, the company would have to produce new clinical data to establish a drug's efficacy and safety, which would be both costly and unethical, since patients would be required to take placebos when a known treatment is already available. Since generic manufacturers rely upon narrow margins to produce cheap medicines, they would be precluded from entering the market to produce affordable, generic versions.

<sup>28</sup> Oxfam, 'Public health at risk: A US Free Trade Agreement could threaten access to medicines in Thailand', Briefing Paper No. 86, 2006. [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/bp86\\_thailand.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/bp86_thailand.pdf)

<sup>29</sup> A. Revenga, M. Over, E. Masaki, W. Peerapatanapokin, J. Gold, V. Tancharoensathien, and S. Thanprasertsuk, *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*, World Bank, 2006.

<sup>30</sup> *Ibid.*

<sup>31</sup> Pan American Health Organization, 'Impacto de fortalecer las medidas de Propiedad Intelectual como consecuencia de la negociación de un Tratado de Libre Comercio con Estados Unidos: Aplicación del modelo a Colombia', November 2005. See <http://www.recalca.org.co/AAdoceducativos/2006.01.31%20Impacto%20de%20fortalecer%20las%20medidas%20en%20prop.%20intel.doc>

<sup>32</sup> G. Valladares Alcalde (coordinator), R. Cruzado Ubillús, J. Seclén Palacín, Z. J. Pichihua Serna, 'Evaluación de los potenciales efectos sobre acceso a medicamentos del Tratado de Libre Comercio que se negocia con los Estados Unidos de América', Lima: Health Ministry, April 2005. Also in: [http://www.forosalud.org.pe/estudio\\_minsa\\_evaluacion\\_efectos\\_del\\_tlc\\_en\\_medicamentos.pdf](http://www.forosalud.org.pe/estudio_minsa_evaluacion_efectos_del_tlc_en_medicamentos.pdf).

<sup>33</sup> A. Revenga, M. Over, E. Masaki, W. Peerapatanapokin, J. Gold, V. Tancharoensathien, and S. Thanprasertsuk, *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*, World Bank, 2006.

<sup>34</sup> This was calculated as discounted dollars.

<sup>35</sup> The letters make no explicit reference to the ability of a country to use to the full the public health safeguards provided by TRIPS. The letters state that 'obligations...of the Agreement do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.' Yet since these side letters are not explicitly integrated into the agreement, they merely give the impression that public health is given preference, without affirming that such public-health

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safeguards have the same legal standing as the TRIPS-plus provisions contained in the agreements.

<sup>36</sup> Inside US Trade, 'US Announces Chile out-of-cycle review after PhRMA complaints', May 12, 2006. In fact, the form of patent linkage demanded by USTR in its dispute with Chile actually exceeds the US standard and is not clearly established in the US-Chile FTA. See J.R. Sanjuan, 'Response to 2006 PhRMA "Special 301" Submission for Chile', Consumer Project on Technology, March 2006, <http://www.cptech.org/publications/cptech-response-phrma301chile.doc>.

<sup>37</sup> See 2006 Special 301 Priority Watch List, [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2006/2006\\_Special\\_301\\_Review/asset\\_upload\\_file353\\_9337.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file353_9337.pdf).

<sup>38</sup> According to news reports, Pfizer's ex-CEO, Hank McKinnell, made a trip to India in 2006 to lobby for India to enforce data exclusivity. See 'Pfizer Chairman McKinnell meets PM', *The Hindu*, 4 May 2006, <http://www.hinduonnet.com/businessline/blnus/14041706.htm>.

<sup>39</sup> Center for Trade and Development (CENTAD) press release, '5 year market exclusivity for non-patented drugs: Government decision ignores Ministry of Health concerns', 19 September 2006.

<sup>40</sup> *Ibid.*

<sup>41</sup> Mision Salud and IFARMA, 'La Propiedad intelectual en el TLC acordado entre los gobiernos de Colombia y Estados Unidos', August 2006 (unpublished).

<sup>42</sup> T. Amin et al., 'The impact of Article 39.3 in India: a practical perspective', Initiative for Medicines, Access and Knowledge (2006).

<sup>43</sup> D. G. McNeil, 'F.D.A. produces new AIDS pill to treat people in poor countries', *New York Times*, 6 July 2006.

<sup>44</sup> K. Alcorn, 'Compulsory licensing struggles continue: Cambodia loses rights as Brazil seeks new rights', *Aidsmap*, 13 September 2006.

<sup>45</sup> Summary Record of the Fourth Meeting, Ministerial Conference, 5<sup>th</sup> Session, 10–14 September 2003, WTA/MIN(03)/SR/4.

<sup>46</sup> D. Sontag, M. Wines and S. LaFraniere, 'Early tests for US in its global fight on AIDS', *New York Times*, 14 July 2004.

<sup>47</sup> See [http://www.phrma.org/about\\_phrma/member\\_company\\_list/members/](http://www.phrma.org/about_phrma/member_company_list/members/), accessed on 26 September 2006.

<sup>48</sup> For a review of the major problems with the Paragraph 6 decision, see 'Neither expeditious, nor a solution: The WTO August 30<sup>th</sup> Decision is unworkable', Médecins Sans Frontières, August 2006, <http://www.accessmed-msf.org/documents/WTOaugustreport.pdf>

<sup>49</sup> 'Decision removes final patent obstacle to cheap drug imports', [www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm).

<sup>50</sup> This included an effort by the USA to limit the types of drugs which could be produced and exported under Paragraph 6, even though the TRIPS

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Agreement does not limit which drugs qualify for export. See <http://www.cptech.org/ip/wto/p6/cptech03052003.html>.

<sup>51</sup> WTO, 'Annual review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health', 2006.

<sup>52</sup> However, a Senate bill was introduced by Senator Patrick Leahy in May 2006 to implement the Paragraph 6 public health solution, entitled 'The Life Saving Medicines Export Act'. See <http://leahy.senate.gov/press/200605/052506a.html>.

<sup>53</sup> 'EU accepts compulsory licensing of pharma patents for countries in need', 2 May 2005, <http://www.euractiv.com/en/health/eu-accepts-compulsory-licensing-pharma-patents-countries-need/article-154874>, accessed on 26 September 2006.

<sup>54</sup> See "The WTO August Decision is unworkable", Medecins San Frontieres, August 2006 at <http://www.accessmed-msf.org/documents/WTOaugustreport.pdf>.

<sup>55</sup> A. Jack, 'WTO head flags trade rules as way to reduce drug costs', *Financial Times*, 12 October 2006.

<sup>56</sup> 'Annual review of the decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', Draft Report to the General Council, October 2006. Two-thirds of WTO members are supposed to accept the Paragraph 6 Solution by the end of 2007 for it to enter into force. The deadline can be extended beyond December 2007 by general agreement of WTO members if the requisite number of signatories has not been obtained.

<sup>57</sup> T. Richards, 'The great medicines scandal', *BMJ* 332: 1345–346, 10 June 2006, <http://bmj.bmjournals.com/cgi/content/extract/332/7554/1345>.

<sup>58</sup> H. Mintzberg, 'Patent Nonsense: Evidence tells of an industry out of social control', *Canadian Medical Association Journal* 175 (4), 15 August 2006, [www.cmaj.ca/cgi/content/full/175/4/374](http://www.cmaj.ca/cgi/content/full/175/4/374).

<sup>59</sup> National Institute for Health Care Management, 'Changing patterns of pharmaceutical innovation', May 2000. See <http://www.nihcm.org/finalweb/innovations.pdf>

<sup>60</sup> Mintzberg, *op.cit.*

<sup>61</sup> WHO, *Public Health, Innovation and IP Rights*, 2006.

<sup>62</sup> Figures provided in presentation by Fabiana Jorge, MFJ International LLT, which were obtained from IMS Health.

<sup>63</sup> Public Citizen, 'Rx R&D Myths: The Case Against the Drug Industry's R&D Scare Card', Congress Watch, July 2001.

<sup>64</sup> See Families USA (2005), "The Choice: Health Care for People or Drug Industry Profits", September 2005 at [www.familiesusa.org/resources/publications/reports/the-choice.html](http://www.familiesusa.org/resources/publications/reports/the-choice.html)

<sup>65</sup> Geneva Forum on Health, 'Solving the health equation: Improving public and private contributions to bridge the gap between rich and poor countries', 2006.



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<sup>66</sup> See transcript of speech by John Murphy, US Chamber of Commerce, at the American Enterprise Institute, 23 May 2006 at <http://www.aei.org/events/eventID.1323.filter.economic/transcript.asp>. See also: Inside Trade, "U.S. Announces Chile out-of-cycle review after PHRMA complaints", May 12, 2006. The article notes that "there have been a number of cases where copy drugs have received sanitary registration [...]. [The source] said about a half dozen U.S. companies are now seeking preliminary injunctions to prevent copies from circulating on the Chilean market."

<sup>67</sup> Philippines Ministry of Health, 'Why is hypertension a serious problem?', [http://www.doh.gov.ph/common\\_disease/hypertension.htm](http://www.doh.gov.ph/common_disease/hypertension.htm).

<sup>68</sup> In a letter addressed to Oxfam, on 10 November 2006, Pfizer while not contradicting our arguments, pointed out that they are currently providing Novarsc at a 50% discount price "based on this product's suggested retail price" to Filipino patients. They did not mention the number of patients benefiting from this discount (cf footnote number 85 for Oxfam's position on philanthropic programmes). Pfizer also said that they were "able to purchase amlodipine besylate products (purporting to be Novarsc) from a Philippine International Trading Corporation (PITC) outlet, evidencing actual sale of the product". This according to Pfizer, constitutes an infringement of their patent rights. PITC is a government owned international trading company that was given permission to import amlodipine besylate under the bolar provision. See [www.pitc.gov.ph](http://www.pitc.gov.ph).

<sup>69</sup> S. R. Smith, *Fact Sheet on the PITC Norvasc case*, Third World Network, 2005.

<sup>70</sup> C. Oh and S. Musungu, 'The use of TRIPS flexibilities in TRIPS by developing countries: Can it promote access to medicines?', April 2006.

<sup>71</sup> *Ibid.*

<sup>72</sup> C. Y. Ling, 'Malaysia's experience in increasing access to antiretroviral drugs: Exercising "Government Use" Option', Third World Network, Intellectual Property Rights Series No. 9, 2006.

<sup>73</sup> The draft Filipino law also: permits parallel importation, narrows patent rules to exclude new indications and uses of existing substances already patented, and simplifies government use licences. See M. Rojas, 'A just cause: Quality Affordable Medicines for all', sponsorship speech of Senator Rojas, 16 August 2006, Senate of the Philippines.

<sup>74</sup> 'PhRMA opposed pending Filipino patent law as undercutting research', Inside U.S. Trade, 4 August 2006. This was confirmed in meeting between Oxfam and a Filipino Senate staffer on 16 October 2006, who recounted how pressure has been exerted by the US embassy and USTR.

<sup>75</sup> See R. L. Lettington and P. Munyi, 'Willingness and ability to use TRIPS flexibilities', DFID Health Systems Resource Centre, 2004.

<sup>76</sup> ARV price comparison chart for Kenya, provided by Health Action International via e-mail on 15 September 2006.

<sup>77</sup> [http://www.unaids.org/en/Regions\\_Countries/Countries/kenya.asp](http://www.unaids.org/en/Regions_Countries/Countries/kenya.asp).

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<sup>78</sup> G. Gathura, 'Cost of drugs at stake in new row with firms', *Nation Newspaper Kenya*, 22 June 2006.

<sup>79</sup> S. Lone, 'Step up war against AIDS and malaria', *The Daily Nation*, 30 June 2006.

<sup>80</sup> A. Grover, 'Briefing Note: Novartis files case in India challenging Patent Controller's Order and Patent Law', Lawyer's Collective, August 2006.

<sup>81</sup> Since India was not obligated to grant patent protection for medicines until 2005, any patent application filed by a pharmaceutical manufacturer was placed in a 'mailbox' that would be examined after India achieved TRIPS compliance. Patent examiners across India must now assess thousands of applications filed by pharmaceutical companies during the ten-year interim period.

<sup>82</sup> Speech by C. S. Park, World AIDS Conference, 18 August 2006.

<sup>83</sup> A forthcoming study by the Center for Trade and Development (CENTAD) estimates that most of the drugs in India's mailbox are actually older medicines that were first patented before 1995, when India was not obligated to provide product patent protection for medicines. Most medicines for which patent applications are submitted in the Indian mailbox are only second forms of these older medicines, and should not receive patent protection.

<sup>84</sup> In particular, Glivec, imatinib mesylate, is a new form of an old substance, imatinib. Novartis applied for a patent on imatinib mesylate in the U.S. in 1993. Yet India did not have to grant patent protection until 1995 under TRIPS; thus, any compound patented in the U.S. in 1993 cannot be patented in India. Glivec, which Novartis patented in 1998, adds a salt to the original compound (imatinib mesylate) that was patented in 1993. The court ruled that "It is only a new form of a known substance. It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy. Pursuant to Indian patent law, under Section 3(d), new forms of old substances (such as those that only add a salt to an old compound), cannot be patented in India unless there is enhanced efficacy. Thus, Novartis was denied a patent for Glivec in India. See *Novartis AG vs. Cancer Patients Aid Association* (2005) at <http://www.lawyerscollective.org/updates/Novartis%20Decision.doc>.

<sup>85</sup> In a Novartis letter responding to a request from Oxfam International to withdraw its patent challenge for Glivec, Novartis stated that "In India, more than 99% of patients on Glivec – currently over 6,200 patients – receive it free through GIPAP". Letter from Novartis Corporation to Oxfam International, received November 7, 2006. (GIPAP refers to the patient assistance program run through a charitable foundation that provides Glivec free of charge to patients). But promoting access via philanthropic programs is not guaranteed to cover all patients and an access program can be curtailed at any time by the pharmaceutical company.

<sup>86</sup> 'Novartis files 2 patent suits in Chennai courts', *The Times of India*, 18 August 2006.

<sup>87</sup> In a Novartis letter responding to a request from Oxfam International to withdraw its lawsuit, Novartis stated: "In pursuing the case, Novartis is also seeking alignment of the Indian IP laws with TRIPS and the laws of other

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leading research-based countries – a goal to which India aspires.” Letter from Novartis Corporation to Oxfam International, received November 7, 2006. Yet the World Health Organization, in its Commission on Intellectual Property Rights, Innovation and Public Health, has stated that “the TRIPS Agreement gives freedom to WTO Members to determine the hurdle required for the inventive step.” The report cites India’s Patent Law, under Section 3(d), as one example of adopting legislation that requires a level of inventiveness that prevents the evergreening of patents. See WHO Report of the Commission on Intellectual Property Rights, Innovation and Public Health, p. 133-134, April 2006 at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

<sup>88</sup> J. Cohen, ‘Brazil: Ten Years After’, *Science* 313: 484–87, 2006.

<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> *Ibid.*

<sup>92</sup> Since passage of the resolution, there has been little progress planning and organizing a functioning Commission, although an initial meeting will be held in December 2006 with identified parties from each WHO region. Civil-society groups and developing-country governments must ensure that the Commission operates transparently, promptly, and closely adheres to the mandate that it was granted at the World Health Assembly.

<sup>93</sup> ‘Public health, innovation, essential health research and IP rights: towards a global strategy and plan of action’, 59<sup>th</sup> World Health Assembly, WHA 59.24, 27 May 2006. See [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_R24-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf)

<sup>94</sup> See ‘Nairobi Declaration on Economic Partnership Agreements’, AU Conference of Ministers of Trade, 4<sup>th</sup> ordinary session, 12–14 April 2006.

<sup>95</sup> B. Benoit and M. Schieritz, ‘Germany plans to shake up G8 agenda’, *The Financial Times*, 27 July 2006.

<sup>96</sup> To tackle other impediments to the right to health in developing countries, the following components are also needed: sustained investments in health services and an end to user fees for basic health care; fulfillment of donors’ promise to give 0.7 per cent of their national income as foreign aid and to allocate at least 20 per cent of that aid to basic services; full financing of the Global Fund to Fight AIDS, TB and Malaria; donors working with poor countries to recruit, train, and retain 4.25 million new health workers.

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This paper was written by Rohit Malpani and Mohga Kamal-Yanni. Oxfam acknowledges the assistance of Raquel Gomes, Jennifer Brant, Stephanie Burgos, Gawain Kripke, Helena Vines Fiestas, Elizabeth Wabuge, Gopa Kumar and Ruth Mayne in its production. It is part of a series of papers written to inform public debate on development and humanitarian policy issues.

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