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Regionalism, Bilateralism, and “TRIP Plus” Agreements: The Threat to Developing Countries

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Regionalism, bilateralism, and TRIPS plus-provisions on public health: the threat to developing countries¹

Fourth Draft, Background Paper for UNDP Ruth Mayne, November 2004,

This paper focuses on the political economic forces driving WTO-plus provisions in bilateral and regional trade and investment agreements, and the implications for multilateralism and access to medicines in developing countries.

1. The political and economic forces driving TRIPS –plus arrangements

Since the mid 1980s the US and EU have used a combination of unilateral pressure and forum shifting from bilateral agreements to multilateral standard setting and then back to bilaterals again as a way of securing trade concessions from developing countries, including stronger intellectual property (IP) protection for exported knowledge-goods.

Recently, there has been a resurgence of US and EU interest in bilateral and regional free trade agreements (FTAs). This is in part a response to the emergence of a strong and assertive group of developing countries at the WTO which has made it harder for the US and EU to achieve their negotiating goals in this forum.

The paper focuses on the way rich country are using bilateral and regional free trade and investment agreements to ratchet up global IP protection on new medicines with provisions that go beyond even the damaging requirements of World Trade Organisation (WTO) rules. These provisions, known as TRIPS-plus, may involve countries being made to apply more stringent standards, not use existing flexibilities or public interest safeguards, or to comply with TRIPS obligations before time. In addition, under the Most Favoured Nation provision in TRIPS (Article 4), once a member of the WTO agrees to a higher standard of intellectual property protection in a free-trade agreement with the US, it is obliged to ‘immediately and unconditionally’ extend those standards to the nationals of other WTO members. This is something that is often not appreciated by smaller developing countries. The paper assesses the implications of bilateral trade agreements for multilateralism and public health.

The main focus of the paper is on the US which is the most aggressive promoter of TRIPS-plus provisions in bilateral agreements. The European Community also make extensive use of bilateral FTAs and bilateral investment treaties (BITs) , but is not currently actively using them to ratchet up IP protection specifically on medicines, although it does benefit from TRIPS-plus measures in US FTAs (see below). The World Intellectual Property Organisation (WIPO) is another forum in which rich countries have

¹ This paper draws heavily on the work of Peter Drahos, Jennifer Brant, Mohga Kamal Smith, Michael Bailey, and owes a wider debt to the global community of analysts and experts working on these issues, although any errors are my responsibility.

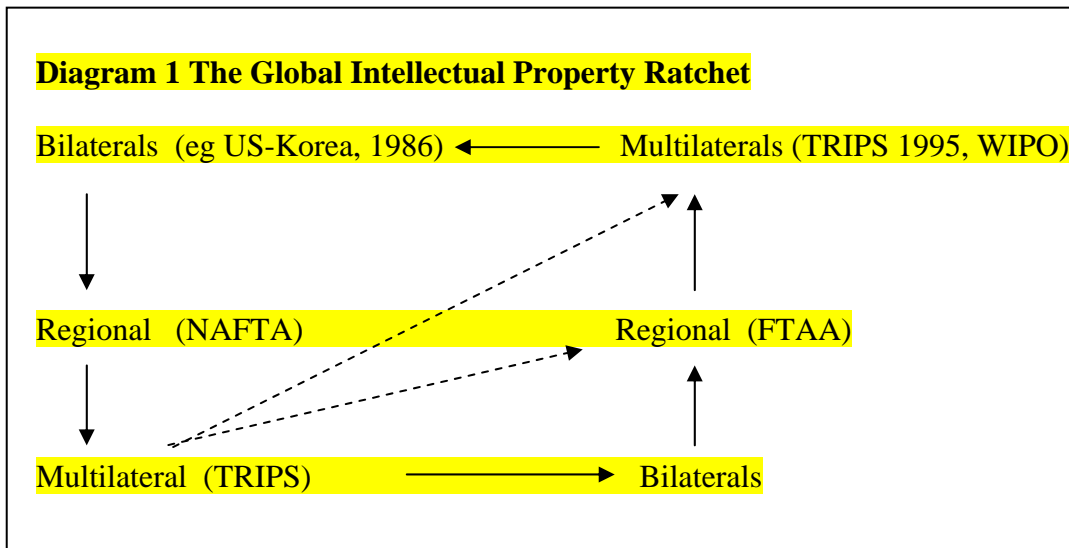
recently attempted to obtain an upward harmonisation of intellectual property standards. However, WIPO is beyond the scope of this paper.

This paper argues that current forms of bilateralism on IP has negative consequences for developing countries because:

- developing countries are weaker when negotiating bilaterally with powerful developed countries, than in the WTO where there is scope for coordinated action
- the TRIPS-plus in bilateral agreements, undermine implementation of Doha Declaration on TRIPS and Public Health and restrict access to medicines in poor countries

US bilateralism on IP

US bilateralism forms one part of a broader US strategy to raise global IP standards. This strategy has been characterised by Peter Drahos as consisting of waves of bilaterals on IP (beginning in the 1980s) followed by occasional multilateral standard setting (e.g. TRIPS, the WIPO Copyright Treaty).¹ Each wave of bilateral and multilateral treaties builds on previous agreements.



Source: Drahos Peter, *Temple Law Review*, forthcoming

US bilateralism on IP was initially largely a response to US failure to obtain an agreement on trade in counterfeit goods at the end of the Tokyo Round (1979) and the resistance of developing countries in the first half of the 1980s to include IP as a negotiating item in a new GATT round. During the 1980s the US reformed its 1974 Trade Act to include what became known as the 'Special 301' provisions. These require the USTR to identify countries that it considered were denying adequate and effective protection for intellectual property, and where necessary impose trade sanctions. The US

also linked the administration of its Generalised System of Preferences programme, which gave developing country access to the US large market, to the adequate protection of US IPRs. This was particularly significant as the key objectives of trade negotiations for many developing countries was to gain access to the closed and subsidised agricultural markets of developed countries. Finally, the US also linked its Bilateral Investment Treaty (BIT) programme to the goal of adequate and effective protection for intellectual property.

Because bilateral negotiations have high transaction costs the US develops prototype of the kind of bilateral treaty it wishes to have with other countries. Once a prototype treaty is ratified by Senate, US trade negotiators know that if they stick to its terms in other negotiations there is a good chance the treaties flowing from these negotiations will also be approved. When subsequent treaties are submitted to the Senate by the President they are usually accompanied by a statement pointing out that they are based on the relevant prototype.ⁱⁱ

Essentially these tools allowed the US to use its enormous market as a powerful source of bargaining and credible threats, and it used this to break the resistance of hard line developing countries in the TRIPS negotiations at the WTO – India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia - resulting in the signing of the TRIPS Agreement in 1994. However, rather than abating, US bilateral activity continued after the signing of TRIPS with the negotiation of a large number of FTAs and BITs in which it sought to achieved most of the new issues it had wanted in the early 1980s. The US has well over 100 bilateral agreements relating to intellectual property standards.ⁱⁱⁱ

US bilateralism has recently received a further boost following recent developments at the WTO which have made it harder for it to achieve its negotiating goals on IP and other issues in this forum. These events include the 2001 landmark WTO Declaration on TRIPS and Public Health and the emergence of strong group of developing country governments at the WTO in the form of the G20.

The Doha Declaration on TRIPS and Public Health reconfirmed the primacy of public health over private patent privileges. It also reconfirmed the rights of governments to use the safeguards in TRIPS to override patents for public health reasons without fear of legal challenge or trade sanctions. These safeguards include compulsory license, article 30 exceptions, and parallel imports.^{iv} This is significant because in 2005 all countries, except for least developed countries, will have to implement TRIPS which will restrict the routine production of generic versions of patented medicines. Generic versions of patented medicines will only be possible if companies grant voluntary licenses, or failing that if governments issue compulsory licenses.^v Generic competition is the key force driving down prices, as illustrated by the dramatic fall in the patented price of HIV/AIDS medicines following generic competition from Brazil and India.

The Doha Declaration and the paragraph 6 negotiations

The Doha Declaration was the outcome of asserted unified action by developing county, supported by

public campaigning from NGOs, and high media interest following the South African court case. It marked a set back for companies which had previously pressurised countries not to use the TRIPS safeguards, or to only do so in exceptional circumstances such as national emergencies. The pharmaceutical companies used their influence over the US government to try and reclaim this lost ground through the subsequent paragraph 6 negotiations. They attempted to restrict the solution to only certain diseases, emergencies, and the least developed countries^{vi}, in contradiction to the Doha Declaration.

Paragraph 4 of the Doha Declaration, which is the operational part, says that ‘ 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*’.

The Doha Declaration also mandated Trade Ministers to find a solution to a fundamental flaw in TRIPS which prevents drug-producing countries from manufacturing and exporting affordable generic versions of patented medicines on a large scale to countries which cannot produce them themselves. This became known as the paragraph 6 negotiations.

In August 30th following lengthy negotiations and intense wrangling, a modification to the TRIPS Agreement was finally agreed. WTO members agreed to lift TRIPS restrictions on the production and export of generic medicines to countries that lack manufacturing capacity. Unfortunately due to pressures from industry the agreed mechanism was unnecessarily complex and it was not clear it would provide the necessary economic incentives to allow generic competition of patented medicines in the long term. However, developing countries did defeat US attempts to restrict the agreement to only certain diseases.

More recently, the emergence of the G20 which emerged in the run up to the Cancun Ministerial Conference has posed a threat to US negotiating goals particularly in the area of agriculture. With leadership coming from Brazil, China, South Africa and India, the G-20 was seen by many commentators as a new power within the WTO that would help developing countries gain more positive outcomes in the WTO on critical development issues such as agriculture.

The US appears to have responded to the Doha Declaration and G20 by increasing its use of bilateral FTAs with developing countries. The aim of this strategy appears to be to gain greater market access for its exports with less trade-offs than would be possible at the WTO, ratchet up IP standards outside the WTO, and to break the power of developing countries within the WTO.

The US is currently negotiating or about to start negotiations with a range of countries, which according to the USTR account for two thirds of Western hemisphere GDP (excluding the US).^{vii} It is expected that Bush government will accelerate these negotiations following his November 2004 re-election .

Recent FTAs negotiated by the US include US-Chile (2003), US-Jordan (2000), US-Morocco (2004), US-Singapore (2003), and the US-Central America Free Trade Agreement (CAFTA–2004 includes the Dominican Republic, signed but not yet ratified by Congress). The US is also negotiating numerous new FTAs with other developing countries including the Free Trade Area of the Americas (which includes all countries of the Western Hemisphere except Cuba with a deadline 2005), Andean countries, Thailand,

Panama, Bahrain and Southern African Custom Union (SACU), Oman, and with others under consideration.

The US strategy has been summed up in a letter from Robert Zoellick to David Walker, Comptroller of the United States ^{viii}: 'At its most basic level, the competitive liberalisation strategy simply means that America expands and strengthens its options. If free trade progress becomes stalled globally - where any one of 148 economies in the WTO has veto power - then we can move ahead regionally and bilaterally. If our hemispheric talks are progressing stage-by-stage, we can point to more ambitious possibilities through FTAs with individual countries and sub-regions. Having a strong bilateral or sub-regional option helps spur progress in the larger negotiations. The recent disappointment in Cancun provides a case in point, A number of the 'won't do' countries that frustrated the 'can do' spirit of Doha are now rethinking the consequences as the US vigorously advances FTAs around the world'.

Poor countries tend to sign up to these free trade deals for political reasons, because they are desperate for greater access to vast US markets, and because they may not fully realise what they are signing away. President Chirac of France characterised the US strategy as 'tantamount to blackmail' . In a statement read out to International AIDS conference in Bangkok on July 13th 2004 Jacques Chirac wrote: ' Making certain countries drop these measures (i.e. to produce life saving generics) in the framework of bilateral trade negotiations would be tantamount to blackmail, since what is the point of starting treatment without any guarantee of having quality and affordable drugs in the long term'.

However, some developing countries have attempted to resist US attempts to introduce TRIPS-plus standards, and it has proved difficult for the US to get the bigger developing countries such as Brazil and Argentina to agree to these provisions. The Free Trade Area of the Americas (FTAA), the US-Andean FTA, and the US-SACU FTA are currently at a standstill partly in response to developing country resistance to the US agenda. On the other hand when middle power countries like Australia and ASEAN leaders like Singapore tactically support this strategy by negotiating bilaterals themselves, it creates an incentive for weaker developing countries to follow suit.

The US has also been using a combination of unilateral pressure and bilateral trade agreements to pressure developing countries to distance themselves from the G20. Shortly after Cancun several Latin American countries including Costa Rica, Colombia and Peru, announced they were no longer members of this group. This followed warnings by Senator, Finance Committee Chairman Charles Grassley that countries seeking free trade agreements with the US that Congress will not approve FTAs with G-21 members in the wake of the Cancun Ministerial. He warned that Costa Rica and Guatemala should be excluded from the US-CAFTA negotiations, unless they back out of their support for the G21. Grassley also said that Brazil and all other Latin American members of the G-21 should be excluded from FTAA negotiations. ^{ix}

Similarly, prior to President Bush's announcement of the possibility of an FTA with

Thailand, Grassley called on Thailand to first distance itself from the position taken by the G-21 on agricultural liberalization at the WTO's Cancun Ministerial. ^x The Costa Rican Trade Minister said that their decision to leave the G21 had nothing to do with US pressure, or the visit of the US trade representative, Robert Zoellick, a week prior to the announcement. ^{xi}

The table below reveals this strategy of divide and conquer.

DIVIDING AND CONQUERING
The use of FTAs by the US to break up developing country groups

	G20	Ex –G20	Cairns Group	FTA with US?
Argentina*	Y		Y	
Australia			Y	Y
Bolivia	Y		Y	Proposed
Brazil*	Y		Y	
Canada			Y	Y (NAFTA)
Chile	Y		Y	Y
China*	Y			
Colombia		Y	Y	Proposed
Costa Rica		Y	Y	Y (CAFTA)
Cuba	Y			
Ecuador		Y		Proposed
Egypt	Y			
El Salvador		Y		Y (CAFTA)
Guatemala		Y	Y	Y (CAFTA)
Honduras				Y (CAFTA)
India*	Y			
Indonesia	Y		Y	
Malaysia			Y	Proposed
Mexico	Y			Y (NAFTA)
New Zealand			Y	
Nicaragua		Y		Y(CAFTA)
Nigeria	Y			
Paraguay	Y		Y	
Pakistan	Y			
Peru		Y		Proposed
Philippines	Y		Y	
South Africa*	Y		Y	Y (SACU) Being neg.
Tanzania	Y			
Thailand	Y		Y	Proposed
Uruguay			Y	
Venezuela	Y			
Zimbabwe	Y			
	19	7	17	

•Leaders of the G-20.

Source: Drahos, Faunce, Goddard, and Henry 2004. The FTA and the PBS, A submission to the Senate Select Committee on the US-Australia Free Trade Agreement

There have also been recent attempts in the US to raise the eligibility conditionality on IP for developing countries to qualify for US GSP and other US trade preferences such as the Caribbean Basin Initiative or Andean Trade Preferences Act. The current standard requires countries to provide adequate and effective IPR protection, as defined by the US. A recent bill submitted by Hatch (R-UT) and Leahy (D-VT), with backing from the US Motion Picture Association and copyright industry, proposes explicitly ratcheting up and

linking this standard to specific provisions prescribed in Special 301 reports which are typically TRIPS-plus. This was defeated.

Implications for multilateralism

Many commentators have expressed concern that the TRIPS-plus measures in US bilateral FTAs will undermine implementation of the WTO Doha Declaration and the August 30th decision by restricting or eliminating vital TRIPS flexibilities such as compulsory licensing and parallel importation.^{xii} This in turn will erode the credibility of WTO as a key multilateral forum on trade. The TRIPS-plus provisions also violate the US's own trade negotiation mandate which under the US 2002 Trade Act instructs the USTR to respect the Declaration in all trade negotiations.

The US has responded to these criticisms by saying that it has included side letters in the CAFTA and Morocco agreements which contain a waiver for public health purposes. (See the Letter to Congressman Levin from John Veroneau, General Counsel USTR, July 19th 2004). But even with the side letters the effect of the FTAs will be at best to muddy the ability of countries to use the TRIPS flexibilities confirmed by the Doha Declaration and the WTO August 30th decision on access to medicines, and at worst undermine their implementation. Developing countries would therefore be better off without these provisions.

The August 2004 US-CAFTA side letter states that the obligations in the FTA 'do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning such cases as HIV/AIDS, tuberculosis, malaria and other epidemics, as well as circumstances of extreme urgency or national emergency', and that the FTA 'does not prevent the effective utilization of the TRIPS/health solution' reached in the WTO last year. The USTR also states in the letter to Congressman Levin that the side letter will have important interpretative value, and that 'the United States has no intention of using dispute settlement to challenge any country's actions that are in accordance with that solution'.

However, legal experts point out the side letters are likely to carry little legal weight as they are not in the main text of the agreement, and in the case of dispute they are unlikely to override the binding provisions in the main text. The effectiveness of the letter of understanding itself depends on the interpretation of what was agreed in the WTO. The US and Morocco may well come to different views about that matter. So the letter does not prevent the US from exerting pressure on countries, or bringing a trade action to clarify the understanding.^{xiii} A conflict between the text and the side letter would also, raise complicated questions related to international treaty law.

Second, the side letters introduce the term 'necessary' to protect public health, a term not used in the Doha Declaration, and which in international trade can be used in a very limiting way i.e. a measure may be necessary only if there is no other way to achieve the public health objective, even if the alternatives are not politically or financially feasible.

^{xiv}

In effect, the TRIPS-plus measures in US FTAs, even with the side letter, means that a signatory country's ability to take advantage of Doha will depend on the interpretative complexities generated by letters of understanding and the mixed signals that such devices send.

As the World Bank Global Economic Prospects 2005 says ' Notwithstanding the potential flexibilities provided by these side letters, they raise several question. How widely will the parties to the three agreements define the 'protection of public' health'- or, what definitions would an arbitration panel use ? Uncertainty, in this respect may become itself a barrier to making use of the flexibilities and may open the door for restrictive interpretations by vested interest. Also, several of the other U.S FTAs do not contain comparable side letters, raising questions about conflicts between intellectual property obligations and public health objectives in at least some of the affected countries'.

Industry Role

Industry has played a crucial role in defining trade strategy on IP, particularly in the US.^{xv} In 1974, as part of the US trade promotion authority, the US created the Advisory Committee for Trade Policy and Negotiations (ACTN) to ensure that US trade policy and trade negotiation objectives adequately reflect US commercial and economic interests. The ACTN involves more than 35 committees with over a thousand members from the private sector including a committee on intellectual property called the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3). (N.B It has recently been renamed the *Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15*, but will be referred to as IFAC-3 in this report). Under US Trade Promotion authority, the Executive branch is required to consult regularly with the Congress, and solicit advice from advisory committees and the public, as trade agreements are being negotiated. In return, the Congress agrees not to amend legislation implementing trade agreements, voting up or down on these agreements. In practice, regular consultation with Congress does not always happen.

The ACTN generated the strategic thinking behind the trade-based approach to intellectual property including the TRIPS Agreement.^{xvi} It remains central to current US strategy. At least 9 of the 15 members of IFAC-3 committee are associated with the pharmaceutical industry including PhRMA, Pfizer, Eli Lilly and Merck, and industry consultant group, the Gorlin Group.^{xvii}

The reports from this committee provide one of the clearest explanations of current US strategy. For example, the IFAC-3 March 12th 2004 report on the US-Central American Free Trade Agreement says: 'While IFAC-3 recognises that the negotiation of FTAs with individual countries and regions is labour-intensive, especially when compared with the negotiation of a multilateral agreement among the 146 Members of the WTO, 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, including the FTAA. This baseline is continually reflected in the model FTA agreements which are constantly changing based on what we learn through negotiating each of the FTAs....IFAC 3 recognises, that to a large extent, the negotiation of FTAs has become the primary focus of the US trade agenda and supports the use of all policy tools to gain worldwide improvement in intellectual protection..... IFAC 3 urges the US government to continue to maintain a strong bilateral program to deal with IPR deficiencies in non-FTA countries, many of which are critical markets for our industries and which may never be FTA candidates. It is therefore essential that traditional tools such as Special 301, the unilateral trade preference programmes and WTO dispute settlement mechanism be aggressively employed to lift levels of intellectual property protection in these countries'.

The report also points out the close relationship between industry and the US government:' IFAC-3 wishes to underscore the importance that it attaches to a close working relationship between IFAC-3 and industry, on the one hand, and U.S. negotiators, on the other, in ensuring that the model FTA intellectual property text, which has been carefully developed through the course of negotiation of six FTAs, continues to form the basis for these other agreements'.

Joseph Stiglitz has said that the US 'bilateral agreements reveal an economic policy dictated more by special interests than by concern for the well-being of our trade partners..... In all its bilateral agreements, the US is using its economic muscle to help big drug companies protect their products from generic competitors'.^{xviii}

Industry also have a large influence on USTR unilateral enforcement of IP through use of Special 301, and the GSP programme. A recent Oxfam report showed that US government included nearly 70 % of the countries recommended by PhRMA in its annual Special 301 2002 report.^{xix} A more recent concrete example of this influence is a letter dated September 22nd 2004 letter to the Deputy Assistant US Trade Representative to Latin America from Renard Aron Assistant Vice President of PhRMA in Latin America, requested the withdrawal of Peru and Ecuador as beneficiaries from the Andean Trade Preference Act, on the grounds of inadequate provision and protection of intellectual property. Various pharmaceutical companies have been at pains to publicly point out that poverty, rather than the price of medicines, is the main cause of lack of access to medicines. But withdrawing preferences would push these countries further into poverty.

Implications for Corporate Responsibility

It is a striking omission that recent IFAC-3 reports, such as the report on CAFTA, contain no reference to the recent international debate about the health and development impacts of a one-sized-fits-all approach to IP protection. There is no balancing of IP protection with internationally agreed human rights, health and development goals. There is no mention of the WTO Doha Declaration on TRIPS and Public Health. On the contrary, the IFAC-3 report on the Singapore FTA, for example, contains a complaint about the health officials interfering in patent matters.

Industry may well counter that IFAC-3's mandate is merely to assess whether trade agreements meet US economic interests, in particular to promote the adequate and effective protection of intellectual property rights on a global basis. As such, the onus should be on the US government to revise the mandate of the trade and industry advisory committees, and to include public interest groups and other experts in these committees, in order to ensure that trade agreements do not undermine multilateral agreements and internationally agreed development and human rights goals. The Federal Advisory Committee Act does require that each advisory committee be fairly balanced in terms of points of view represented and committee functions performed, including groups directly affected by the work of a particular committee, but the US Department of Commerce has taken no steps to address this despite recommendations from a 2002 US General Accounting Office (GAO) report. There is no public health representation on IFAC -3. It has also been pointed out that even for an industry committee IFAC-3 is highly unbalanced as there are no generic drug companies, the Internet Service Providers and consumer electronic companies, or innovative companies like IBM, Novell or Google, which are industry stakeholders with quite different views on intellectual public property policies.^{xx}

However, there is also an onus on industry to balance commercial considerations with social responsibility. It is widely recognised in mainstream business circles that companies' public lobby should not undermine corporate social responsibility objectives such as access to medicines. Merck and Pfizer, both members of IFAC-3, both claim to be responsible corporations.^{xxi} However, the effects of their advice to the US government on the FTAs is likely to undermine access to medicines by people in poor countries.

The EU

Like the US, the EU also uses bilateral trade agreements to obtain WTO-plus provisions on trade issues. In a recent meeting of trade ministers of the Association of Southeast Asian Nations (ASEAN) and the EU, Lamy was quoted as saying: 'We also use bilateral FTAs to move things beyond WTO standards. By definition, a bilateral trade agreement is 'WTO plus'. Whether it is about investment, intellectual property rights, tariff structure, or trade instruments, in each bilateral FTA we have the WTO plus provision'.^{xxii} But, the EC would contend that the rationale for bilateral agreements is not always solely or primarily for trade advantage, but may also be for geo-political reasons as is the case of the European Partnership Agreements with ACP countries .

Also like the US, the emergence of the G 20 at Cancun prompted the EC to re-think its bilateral strategy. Shortly after Cancun Pascal Lamy, EU trade commissioner, said 'We will have to a good, hard think amongst ourselves. Should we maintain multilateralism as our priority, which was the basic tenet of EU commercial policy?'^{xxiii} However, Lamy subsequently reconfirmed the EC's commitment to the WTO negotiations, and said that the EC will not launch any new bilateral trade negotiations as long as the WTO negotiations are running on track.^{xxiv}

In relation to intellectual property protection there is no evidence to suggest that the EC is

using current bilateral negotiations with developing countries to ratchet up IP protection on medicines post- Doha (although it may well try do so on other IP issues such as geographical indications, and on other issues such as services and investment). The Commission has committed itself to fully take the Doha Declaration on TRIPS and Public Health into account in its trade policy in its November 21st 2003 Communication to the TRIPS Council. Lamy and EC officials have also publicly commented on the dangers that bilateral FTAs can pose to the implementation of the Doha Declaration on TRIPS and Public Health and access to medicines.

That said, the implicit threat remains that the EC will revert to bilaterals if the WTO Doha negotiations flounder, as does the possibility for it to use free trade negotiations to raise IP standards. The negotiating mandates of many of its previous trade agreements contain commitments to provide 'adequate and effective provision' to the 'highest international standards' (EU Palestine 1997, EU-Mexico, EU Tunisia 1998, EU South Africa 1999), although EC officials have stated that the Commission no longer uses 'highest international standards' in current negotiations. However, the EC takes a different approach with EU accession countries. These countries are required to apply stringent EU standards on data protection and marketing exclusivity, which have a major impact on generic producers.

More significantly, the EC in effect is able to free-ride on the US bilateral strategy though the Most Favoured Nation (MFN) provision in TRIPS. This provision means that once developing countries agree to higher patent standards in a free trade agreement with the US, they have to automatically apply them to patent holders from other WTO members. Whether or not this is a deliberate policy from EU's perspective, it provides it with a considerable commercial advantage without having to face the kind of international opprobrium faced by the US. When countries are ranked in terms of total exports and imports of medicinal/pharmaceutical products, 9 of the top 10 countries are European. (The US is first, followed by Germany, UK, Switzerland, France, Belgium, Italy, Ireland, Netherlands, Sweden).^{xxv}

The EC also has developed a commercial policy instrument called the Trade Barriers Regulation.^{xxvi} The TBR is a legal instrument that gives the right to Community enterprises and industries to lodge a complaint, which obliges the Commission to investigate and evaluate whether there is evidence of violation of international trade rules resulting in adverse effects. International trade rules are taken to be primarily those established by the WTO Agreement, but can be another agreement to which the Community is a party. The procedure will lead to either a mutually agreed solution to the problem or recourse to the relevant dispute settlement procedure.^{xxvii}

Unlike the US 301 which empowers the US government to investigate countries that threaten commercial and economic interests generally, the EC regulation can only be used if a specific right of action can be established relating to a breach of international trade rules. Moreover, unlike the US 301 which allows for the possibility of unilateral trade sanctions, the TBR says it will refer cases to the relevant dispute mechanism. This could be either the WTO dispute settlement procedure or a bilateral mechanism.

However, there is nothing stopping the EC from unilaterally exerting unilateral political and diplomatic pressure on countries to implement and enforce IP.

The EC has initiated examination procedures in response to complaints from the European Federation of Pharmaceutical Industries and Associations (EFPIA) about discriminatory drug pricing and intellectual property issues in Turkey in 2003^{xxviii}, and Korea in 1999^{xxix}. The intellectual property issues in both the Turkish and Korean cases included industry complaints about inadequate data protection, and in the Korean case about patent extensions.

The EC has also recently launched a 'strategy for the enforcement of intellectual property rights in third countries', which includes 'making clear to trading partners that an effective protection of IP, *at least at the level set in TRIPs*, is essential'^{xxx}. It recommends reminding right holders of the possibility of using the TBR mechanism in cases of evidence of violation of TRIPS or of 'the highest standards' agreed in bilateral agreements between the EC and third countries, and also recommends making use of the WTO dispute settlement mechanism, or the dispute settlement tools included in the EC's bilateral agreements. It also recommends making use of Innovation Relay Centres dealing with transfers of technology to be used to collect information about enforcement problems in third countries. The strategy contains no mention of the Doha Declaration or the need for flexible enforcement on issues pertaining to Public Health.

2. TRIPS-plus provisions regional and bilateral agreements

IP provisions in the US FTAs agreements go far beyond the obligations required by the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). As mentioned above, critics have argued that by restricting or eliminating the public health safeguards in the TRIPS Agreement, such as compulsory licensing and parallel importation, US FTAs will undermine implementation of the Doha Declaration and the WTO August 30th 2003 decision. This will restrict production and trade of generic versions of new patented medicines and hence developing countries' access to affordable medicines.

Generic competition is a vital factor in driving down prices of patented drugs:

- The cost of treating HIV/AIDS patients with antiretrovirals fell from over \$10,000 per person per year in 2000, to between \$160- \$300 in 2004, due to a combination of generic competition from Brazil and India, and public pressure.
- Fluconazole was marketed under patent in Thailand by Pfizer until 1997. When the patent expired generic competitors entered the market, and within one year prices fell to 3 per cent of its original level
- In Costa Rica the cost of treating cancer patients with Paclitaxel dropped from \$160 per dose (when only one option existed) to \$25 per dose with the competition from a generic version.^{xxxii}
- Half the original brand medicines in South Africa cost from 11 to 62 times the international reference price.^{xxxiii}

When all countries comply with TRIPS after 2005, generic production will depend on companies issuing voluntary licenses, and failing that on government use of compulsory licenses. Voluntary and/or compulsory licenses will need to be issued in a routine manner in both large producing countries such as India or China (or other regional centres), and in importing countries without manufacturing capacity, in order to create adequate markets and economies of scale for generic companies to produce generic versions of patented drugs at affordable prices. Yet it is far from certain that this will happen.

Without sufficiently large and stable markets, generic companies are likely to move away from production and export of generic versions of patented medicines for developing countries, and focus either on the generic markets for off-patented products in industrialized countries, or move into joint ventures with multinational companies to focus on new patented products. This trend may be reinforced by the increasing complexity involved in reverse engineering new biotech drugs.

In the absence of generic competition, prices of new patented medicines are likely to be high and hence out of reach of majority of people in developing countries. This is of course particularly damaging for developing countries which have far fewer resources to spend on health: US \$ 4.4 per capita in low income countries compared to average of US\$ 396 per capita in high income countries (with much higher figures in the US, and EU).

Government financing of pharmaceuticals 2000

Income Clusters	Medicines share in government spending on health (%) 2000	Medicines share in total government spending (%) 2000	Per capita government expenditure at average exchange rate (US\$) 2000
WHO Member States	10.2	3.9	29
High-income	9.8	3.6	167
Middle-income	13.1	5.6	8
Low-income	16	3.6	1.1

Source WHO, 2004 The World Medicines Situation

Unlike in industrialized countries where most people are covered by insurance, in developing countries most people pay out of pocket for medicines: 72% of pharmaceutical spending in low income countries is private.^{xxxiv} Poor people are very sensitive even to small increases in price, and if prices rise sell assets, or take children (especially girls) out of school. When these options are exhausted people simply go without resulting in suffering, disability and/or death.

Where governments do provide health coverage medicines account for a higher percentage of overall health spending than in rich countries. The only way governments can meet high drug prices is to cut coverage.

Costa Rican officials have estimated, for example, that without generic options the Social Security system, which offers universal health coverage, would have to increase its

pharmaceutical budget from \$70 million to \$390 million to offer the same coverage. If the budget was fixed, coverage would be reduced to 18% .^{xxxv}

TRIPS-Plus Provisions in US FTAs ²

Objectives and Principles

The objectives and principles of the FTAs (e.g. Chile, Singapore, CAFTA) contain no reference to the kind of public interest language found in TRIPS, and makes no mention of the Doha Declaration on TRIPS and Public Health. This is relevant because the objectives and principles of international agreements are used when interpreting the provisions of agreements. When Andean negotiators requested the inclusion of language referencing the Doha Declaration in the US-Andean FTA, this was rejected by the US negotiators who reportedly said that the whole point of the FTA was to get TRIPS-plus provisions so incorporating wording of the Doha Declaration might contradict this aim.

Extension of patent term

Many of the recent FTAs (Chile, Singapore, and CAFTA) contain new requirements for governments to extend patent protection beyond the already excessive 20-year period required under TRIPS. Extending this monopoly period will further delay the introduction of affordable generic medicines. In CAFTA for example, the patent term must be extended under Article 15.9 (6), at the request of a patent owner, for delays that occur in granting the patent. Under Article 15.10 (2) the Parties must also extend the patent term to compensate the patent holder for delays in granting marketing approval.. Recent US proposals for language in the Andean FTA currently under negotiation go even further and require parties, where they have granted a patent on the basis of the granting of a patent in another territory, to extend their patent term if it is extended in that other country. There are no such requirement for extending patents under TRIPS which just states that ‘the term of protection shall not end before the expiration of a period of twenty years counted from the filing date.’ The minimum 20 year period required by TRIPS is already widely considered to be excessively long.

New restrictions on registering generic drugs

Many of the new FTAs (Chile, Singapore, CAFTA) contain provisions preventing national drug registration authorities (NDRAs) from registering generic versions of patented drugs during the entire patent period, unless the patent holder gives consent. In contrast, TRIPS says nothing about the need to link patent protection and drug registration. The fact that intellectual property rights are recognized as ‘private rights’ in the preamble, means that it is up to patent holders to enforce their rights.

² Much of the detailed analysis on TRIPS-plus measures in USA FTAs in this section was carried out by Jennifer Brant for Oxfam. See Oxfam, 2004, Undermining access to medicines: a comparison of 5 US FTAs , A technical briefing note

In most countries at present a drugs patent and its registration status are two separate issues, assessed by 2 different bodies. Patent offices assess whether a drug is innovative and novel enough to be patented, and NDRA's assess whether a drug is of sufficient quality, safe and effective to be given marketing approval. This means that a generic company can register its product or obtain marketing approval (following a determination that the product is safe and effective) before patent expiry enabling them to put their generic versions on the market as soon as the patent expires.

The provisions in the FTA new system convert the NDRA into enforcers of patent rights and mean that registration would probably not be granted to generic producers until after the patent expires, regardless of the quality, efficacy and safety of the drug. This will extend the patent period by the time it takes to get market approval, and thus prevent or delay access to affordable generic versions of new medicines. Moreover, the provisions could provide an insurmountable barrier to the use of compulsory licenses during the patent period.^{xxxvi}

An Indian generic manufacturer Ranbaxy was stopped by the NDRA in an African country where MSF works from registering the generic version of fluconazole, an important drug used to treat opportunistic infections associated with HIV. MSF learnt that the grounds for this refusal were that the NDRA has been informed by the originator drug company that it had a patent on the drug in the country. The NDRA had no legal obligation to refuse registration on such grounds, but it had been pressured to do so by the drug company

Under further investigation, it was revealed that the originator company's claim was false and that the patent had expired more than a year earlier. The NDRA eventually retracted its decision, and allowed the registration of Ranbaxy's low cost generic version of the drug. Under the terms the US is seeking, such instances of NDRA's blocking generic drugs on false patent grounds would become commonplace.^{xxxvii}

New restrictions on use of existing clinical trial data by generic companies (data exclusivity)

Many of the new FTAs (Chile, Singapore, CAFTA) prevent generic companies from using clinical trial data generated by brand name companies to obtain marketing approval which could delay or prevent generic competition even in the absence of patent barriers and even if a compulsory license is issued. The TRIPS Agreement (Article 39.3) only states that countries must protect undisclosed test or other data for new chemical entities against disclosure against 'unfair commercial use'. It does not detail what constitutes 'unfair commercial use', nor how WTO members must fulfill this obligation. Neither does it stipulate that they must provide *exclusive* rights to the originator of the data for a *specified* time period.

The TRIPS-plus measures in NAFTA, require countries to protect test data for between 5-10 years. This means that for the first five to ten years following registration of an innovator drug, even in the absence of patent barriers, government regulatory authorities

cannot rely on originator test data to approve a bio-equivalent generic product. If no generic suppliers can obtain marketing approval without repeating time-consuming and costly test on their product (which would be impossible during an emergency situation due to time constraints), then compulsory licensing is rendered useless. Such provisions undermine the Doha Declaration, and would render the WTO August 30th decisions useless . It is also unethical to subject patients to clinical trials unnecessarily.

New restrictions on compulsory licensing

Recent FTAs contain restrictions of the grounds for compulsory licensing, which could limit government's ability to promote competition by generic producers in order to increase access to medicines. TRIPS enshrines the rights of governments to determine the grounds for compulsory licensing, and this right was reconfirmed by the Doha Declaration. The Doha Declaration specifically affirmed that countries should be able to use the TRIPS flexibilities to the full to promote public health and access to medicines for all. In contrast, the Singapore FTA and draft provisions in the FTAA limit the use of compulsory licensing to remedy anti-competitive behaviour, to national emergencies and to public non commercial use. The FTAA also contains language which would prevent member states from exporting under a compulsory license. The Singapore FTA, and others, also contains a new higher standards of compensation when compulsory licensing is used - 'reasonable and entire' rather than 'adequate' as in TRIPS - and the Parties cannot require the transfer of test data of know-how in connection with production under a compulsory license. While, these restrictions do not appear in later FTAs such as CAFTA, the use of compulsory licensing is anyway threatened by provision on data exclusivity and drug registration.

New restrictions on parallel imports

Parallel importation is a vital flexibility in TRIPS which allows governments to shop around for patented medicines placed on foreign markets at lower prices. In practice most rich countries do not allow parallel importing from poorer countries, but it can provide significant savings for poorer countries. TRIPS allows countries to determine their own rules on parallel imports. But provisions in the Singapore FTA limits parallel imports by requiring governments to giving patent holders the means to block parallel importation if it contravenes a distribution agreement anywhere in the world. Patent holders could restrict all distribution agreements territorially with a view to blocking parallel importation into member countries. Provisions in the draft FTAA text oblige countries to prohibit parallel imports from outside the region, although it would be allowed inside the FTAA.

US response to criticisms

Countering these claims the USTR has argued that the US-FTA with Morocco, for example 'can advance Morocco's ability to address public health problems, both by putting in place incentives to develop and bring new medicines to market quickly and by raising standards of living more broadly'. ^{xxxviii} The USTR points to the US-Jordan FTA which it says has resulted in Jordan approving 32 new innovative medicines since 2000,

and it specifically links this to data exclusivity protection. However, it seems likely that an agreement signed less than 3 years ago could have already fostered sufficient new R &D to generate 32 new drugs. It is more likely that these drugs were already developed by US companies and have been newly registered in Jordan. Moreover, the data exclusivity provisions in the Jordan-FTA are far less TRIPs-plus than in other agreements. The link between strong IP protection and innovation is explored further below,

The USTR has also argued that many of the FTA provisions are already to be found in signatory country legislations. For example, Morocco had already decided in 2000, well before the FTA not to permit parallel imports. In contrast, in negotiations with other countries that do not have parallel import restrictions in their domestic law (e.g. Central America, Chile and Bahrain), the final negotiating texts do not contain provisions on parallel importation. (Executive Office of the President, Office of the USTR, Letter to Congressman Levin concerning US Morocco FTA, July 19th 2004). The fact that Morocco had already decided not to permit parallel imports, however, may itself have been the consequence of prior US pressure. Moreover, whereas under TRIPs Morocco has the choice of reversing this position in the future, it will not be able to do so under the FTA without risking a trade dispute. (FTAs tend to be made renewable every 3 to 4 years, at which point the US may ask for even higher standards).

In response to complaints that the provisions in the FTA on data exclusivity would prevent countries from using compulsory licenses the USTR argues that 'if circumstances ever rise in which a drug is produced under a compulsory license and it is necessary to approve that drug to protect public health or effectively utilize the TRIPs/health solution, the data protection provisions in the FTA would not stand in the way'...(Executive Office of the President, Office of the USTR, Letter to Congressman Levin concerning US Morocco FTA, July 19th 2004). In effect this means that if the US agrees that the relevant use of the compulsory license fits with *its* interpretation of TRIPs then it will not stand in the country's way. In other words public health policy in that country will be contingent on the approval of US trade officials.

The USTR has also defended data exclusivity by saying that companies won't enter the market if generic companies are allowed to use their data to make generics.

3. Implications of the US-FTA with Thailand for the Thai HIV/AIDS programme³

An estimated 695,000 people are living with HIV/AIDS in Thailand, and around 290,000 have died of AIDS since the outbreak of the epidemic. There are around 29,000 new infections each year, and of these cases approximately 4,200 are children. The Thai government has taken some important steps to contain the epidemic including the introduction of a strong preventative programme, medicines to prevent mother to child

³ Research for Oxfam by Dr Jiraporn Limpananont, Ph.D, September 2004, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand

transmission, and a treatment programme, with beneficial results for its population. But the future scale of the programme could be seriously threatened if the USA succeeds in pressurising Thailand to accept stringent new IP standards in the FTA currently under negotiation.

The treatment programme has been possible because the government has been able to manufacture affordable generic versions of some of the vital HIV/AIDS medicines recommended for first line treatment by the World Health Organisation. This has allowed the government to offer some key HIV/AIDS medicines to around 30,000 people with plans to scale up the programme in coming years. Local production of these particular drugs was possible because the drugs were not under patent.

One of the key locally produced medicines is a generic three-in-one HIV/AIDS tablet containing stavudine, lamivudine, and nevirapine which costs around ten times less than the brand-name patented versions made by Bristol Myers Squibb, Glaxo Smith Kline and Boehringer Ingelheim respectively. More generally, a comparison of first line AIDS drugs in Thailand shows that the price of brand name drugs are between 5.6 and 25.8 times higher than the prices for generic versions. The cheapest generic combination costs 40 Baht per day, compared with the cheapest brand-name combination, which costs 252 Baht per day. Considering that the minimum daily wage in Bangkok is 170 Baht (140 outside the capital), the generic fixed dose combination costs around a quarter of the wage, while the cost of the equivalent patented drug is almost one and a half times that wage.

However, although the Thai programme supplies some generic versions of the vital HIV/AIDS drugs, it lacks others that are vital for scaling up treatment, as these are currently patented and priced out of reach of the government, NGO and most patients. Currently the Thai Government has the option of issuing a compulsory license to authorise domestic production or import of these medicines (although it hasn't yet used this option), or use parallel imports to shop around for cheapest patented product in other countries. But if the US FTA is similar to previous ones such options may be closed down.

The missing HIV/AIDS drugs include some important alternative first line ARVS that are essential for people who develop side effects or resistance to the generic cocktail. For example, some patients develop adverse reactions to nevirapine, including liver and kidney damage, so they need to be given other drugs such as Merck's efavirenz. However, efavirenz is patented and is too expensive for the government programme. With efavirenz, the daily cost of HIV/AIDS medicines increases from 40 to 138 Baht (MSF estimates that at least 2-3 % of patients receiving first-line treatments through its projects will develop resistance and need second-line therapy.^{xxxix})

Moreover, as Thailand scales up treatment, its need for second line treatments, as well as alternative first-line treatments, will increase. Drugs such as lopinavir and indinavir are recommended for second-line therapy, but they are all patented and therefore very expensive. For example a bottle of lopinavir syrup (made by Abbott) costs 11,770 Baht,

and one Kaletra tablet (lopinavir combined with ritonavir made by Abbot) costs 100 Baht. As side effects and resistance increase over time, new medicines will be needed, or even better a vaccine. But under new patent rules these will be patented

The treatment programme also lacks certain vital drugs to treat opportunistic infections linked to HIV/AIDS. While ARV treatment reduces the incidence of opportunistic infections, treating those infections directly can also save patient's lives and reduce the number of hospitalisations. Thailand is able to provide treatment for cryptococcal meningitis, a fatal opportunistic infection, because it can produce a cheap generic version of fluconazole, a drug developed by Pfizer for which the patent had expired. But other medicines, vital for treatment of other opportunistic infections, are under patent and are therefore too expensive to be used as part of the government programme. For example, GSK's ganciclovir is needed to treat cytomegalovirus (CMV), a dangerous infection which can cause blindness and death, but because it is patented it is too expensive (2655 Baht per 500mg vial) to be included in the government's programme.

If the Thai government is unable to use compulsory licensing to negotiate lower prices or authorise production of cheap generics in the future, it is unlikely that it will be able to afford patented alternative treatment (first line or second and third line) for those people who have adverse reactions or who develop resistance to the existing first-line treatment cocktail. It is estimated that the incorporation of the alternative first-line, and second and third line medicines, into the Thai treatment programme at current patented prices would double or even triple the cost of the programme. The most likely outcome is that the government will simply not be able to buy these drugs and fewer patients will have access to life-saving drugs.

3. Beyond HIV/AIDS ⁴

The TRIPS-plus provisions will not only potentially restrict access to affordable generic versions of improved new medicines to treat HIV/AIDS, TB and malaria, but also other infectious diseases such as pneumonia and gonorrhoea, non-communicable diseases, such as cancer, diabetes, asthma and cardiovascular diseases which now account for at least 40 per cent of all deaths in developing countries, as well as for new emerging diseases.^{x1}

In all these cases there are current treatments which control the symptoms, but there are or will be more effective treatments produced which have fewer side effects and are easier to administer. However, global patent rules will mean many are patented and therefore out of reach of developing countries, and US FTAs will prevent countries from using TRIPS public health safeguards such as compulsory licensing to access them.

⁴ The information in this section is taken from Dr. Mohga Kamal Smith, 2003, Oxfam briefing note, TRIPS, the disease burden in developing countries and the need for new drugs, forthcoming

Global patent rules, the disease burden in developing countries, the need for new drugs

Diseases	Disease burden in developing countries	Promising but expensive drugs in the pipeline
Non Communicable Diseases		
Cervical Cancer	78% of new cases in developing countries 391,000 women in developing countries in 2000	Vaccine to prevent viral infection and cancerous changes
Breast cancer	In 2000: 59,000 women in Africa 503,000 in developing countries	New drugs including Bexaretone to enhance efficacy of currently used drug Tamoxifen
Diabetes	Around 8 million in Pakistan (i.e. 5.8 % of population)	Inhaled insulin: effective, better compliance compared with insulin currently injected more than once a day
Asthma	Increasing in developing countries due to pollution and urbanization 107,000 deaths in developing countries in 2001, compared with 119 in industrialised countries.	Xolair: effective treatment and possible prevention. New class of drug with fewer side effects
Infectious Diseases		
Pneumonia	3 million children die each year in developing countries	Prevanar vaccine available but expensive. New, effective vaccine is under development
Gonorrhoea	Increased drug resistance High incidence among women in developing countries	Need for new antimicrobial to fight drug-resistant infections

Source: Dr Mohga Kamal Smith, pre-publication Oxfam Briefing Note, TRIPS, the disease burden in developing countries and the need for new drugs

The WHO estimates that approximately 176 million people worldwide have diabetes (mellitus), including 115 million in developing countries. The number is predicted to double by 2025, with 70 per cent of the increase occurring in developing countries. Diabetes is the leading cause of blindness in people aged 20-74, and the disease has other serious complications, including heart and kidney problems.

Diabetes control is dependent on diet, exercise and medicines. Forty per cent of patients need oral medicines and the same proportion need insulin injections. Insulin is particularly difficult to administer, because of its relatively high costs and the need for daily injections. WHO estimates that only 3 per cent of people with diabetes in developing countries are treated. This figure reflects the fact that the majority of patients in developing countries must pay for drugs themselves. However, health services are also overburdened by the high cost of treatment. For example, in 1989-90 the estimated cost of treatment of diabetes in Tanzania was US \$2.7 million, out of the country's total health care budget of \$47.2 million

New drugs are under development that are effective and easily administered such as

inhalation insulin. They offer shorter hospitalization, fewer complications and a better quality of life. However, all new and pipeline drugs are under patent.

In 1993, 3 million children died of respiratory tract infections. This represented 28 per cent of all child deaths, and most of these were due to pneumonia. The main organisms that cause pneumonia are *Streptococcus pneumoniae* and *Haemophilus influenzae*. There have been safe and effective drugs, such as penicillin, to treat these deadly infections relatively cheaply, but in the last 25 years there has been a rapid rise in resistance to penicillin and other antimicrobials in many countries. Prevnar, a vaccine developed to prevent pneumococcus pneumonia infection, has been used for children in the US. However, the vaccine is patented (currently held with Wyeth) and the cost is prohibitive (around \$236/course/child) for widespread use for children in developing countries.

Cervical cancer, is one of the most common cancers in women and kills about a quarter of a million patients each year but scientists say that a new vaccine could prevent most cases of cervical cancer. Each year 470,000 women are diagnosed with cervical cancer. Treatment involves the removal of the cancer by surgical means which can be hazardous in advanced cases. Women in developed countries undergo screening for early detection and hence have a high rate of cure, with less drastic surgery. Poor women in developing countries do not have access to screening or affordable surgery. It is not surprising that eighty percent of deaths from the disease are in the developing world. The main hope is the development of an affordable vaccine to prevent the development of cancer altogether.

GSK has been developing a vaccine against two strains of the human papillomavirus (HPV) which are linked to more than 70 percent of cervical cancer cases. Following positive results from a study published in the *Lancet* medical journal, GSK, recently pushed forward the filing date for worldwide regulatory approval for a vaccine known as Cervarix which has been developing, from 2006 from 2008. Adrian Howd, an analyst with ABN AMRO, said sales of Cervarix could eventually exceed 1 billion pounds (\$1.84 billion), following its expected launch in 2007. Merck and Co Inc is also working on a similar vaccine, which industry analysts say could be filed in the latter part of 2005.

James Love, from the US based Consumer Project on Technology, commenting on the GSK vaccine said: 'When this vaccine hits the market, every young woman should have access. They should not have to wait 5 years for the rights in registration data to expire. GSK should be addressing how this will be priced in developing countries, and if they cannot move toward an "access to medicine for all" approach, this should be a prime target for compulsory licensing.'^{xli}

But under the TRIPS-plus provisions of the US FTAs, the US could take out a dispute if a country tried to compulsory licensing for diseases other than HIV/AIDS/TB or malaria, or if the disease had not reached epidemic proportions. This is even more probable if the country is a developing rather than least developed country.

5. The public health implications of US-Australia FTA ⁵

The USFTA with Australia (AUSFTA) was signed by both governments in May 2004. It sparked heated debate in Australia, and more recently in the US, about its impact on public health. Although it has been signed, ratification was held up due to the introduction of last minute amendments by the Australian government which drug manufacturers in both the US and Australia are opposing on the grounds that they conflict with Australia's obligations under TRIPS. The amendment introduced in response to public pressure imposes large fine on companies which submit frivolous patent applications. However, the agreement was subsequently ratified.

The AUSFTA follows a similar pattern to the FTAs outlined above and contains IP provisions that go beyond those in WTO and Doha Declaration, and which, among other things risk delaying entry of generic competition into the market. But AUSFTA is also significant because it challenges Australia's national health programme which provides inexpensive subsidized prescription drugs to its citizens.

The challenge to the Pharmaceutical Benefit Scheme (PBS) is a test case for the industry and US government drive to raise the price of drugs overseas and thus spread the burden of research and development which they believe is borne disproportionately by US consumers. 'The US Trade Representative Bob Zoellick reportedly told a US senate finance committee that the US trade deal with Australia was the first step in a campaign to raise global pharmaceutical prices. It would change the 'distribution' of prices and the relative prices of generic and patented drugs. Senator Jon Kyl, said ' one of the ways of addressing the causes (of high drug prices in the US) is to get the other countries of the world to help bear part of the burden of the R &D. ^{xliii}

In October 2003 President George Bush reportedly told Prime Ministers John Howard that raising Australian prices for pharmaceuticals manufactured in the United States was important for ensuring that consumers in all countries, not just US consumers, paid for the high research and development (R& D) costs. ^{xliii}

In January 2003 the Pharmaceutical Research and Manufacturers of America (PHRMA) lobbied the US negotiators for the Free Trade Agreement with Australia (AUSFTA) to seek a commitment from the Australian government to 'refrain from trade distorting, abusive, or discriminatory price controls' in relation to the operation of its Pharmaceutical Benefits Scheme (PBS). ^{xliv}

What is the PBS?

The PBS was established under the National Health Act 1953 and progressive amendments have emphasised that its basic principles relate to the need to ensure universal access to affordable, essential medicines. Under the PBS government officials decide which drugs to include in the recommended list for use in the national health

⁵ Much of the information in this section is taken from various publications by Drahos P, Lokuge B, Fuanca T, Goddard M and Henry D

system and how much to pay for them. The officials base their decision on recommendations from an expert committee that analyses the drugs clinical benefits, safety and cost-effectives. If a drug is considered not to be cost effective it will not be recommended for use in the national health system.

Australia only accounts for 1% of drug companies global market, and as such does not pose a big threat to drug industry. But US drug companies reportedly do not want PBS type schemes to be a model for other countries, including developing countries. They are also reportedly worried that US medicare, which provides health care for the over 60s in US and in future will include pharmaceutical benefits, may some day adopt a version of the Australian pricing system.^{xlv}. Weakening the PBS model through provisions in AUSFTA will set a precedent for future trade agreements between the US and developing countries, and will lock the US into same model.

Threats posed to PBS by the AUSFTA^{xlvi}

Experts have argued that that the PBS is threatened by the following provisions in the AUSFTA

- Interpretative principles which are heavily weighted to towards the rights of manufacturers of 'innovative' medicines, and contain no unqualified reference to universal access to affordable, essential medicines.
- Requirements for Australia to set up an independent review body which drug companies (but not consumer or public health organisations) can ask to examine drugs rejected by the Pharmaceutical Benefits Advisory Committee. It is feared that this may undermine the famously tough stance of this committee and pressure it to include drugs that may otherwise be left off because not sufficiently cost effective.
- An exchange of letters between the US and Australian that Australia shall provide opportunities for pharmaceutical manufacturers to apply for an adjustment to PBS prices. While this possibility already exist there is concern that if it is interpreted in the light of the narrow interpretative principles it will provide greater opportunities for US companies to seek price rises for innovation as distinct from cost-effectiveness criteria
- A dispute resolution procedure (chapter 21) which gives a panel of three trade lawyers nominated by the Parties (Article 21.7) the power to interpret compliance with obligations in AUSFTA, including the provisions that shift the focus of the PBS towards greater rewards for drug 'innovation'. The US and Australia could will take different views of Australia's obligations to provide an 'independent review' of decisions made by the Pharmaceutical Benefits Advisory Committee, because the meaning of this term? has not yet been specified. If this happens the panel will rely on the narrow interpretative principles (see above). The dispute resolution procedure also allow for non-governmental persons or entities to make submissions, that the industry, and lawyers, will no doubt use
- A damages claim if a 'benefit' the US could reasonably have expected to accrue under AUSFTA is not realised, even though no specific provision has been

breached. The upshot of this is that PBAC decisions not to 'list' innovative new US drugs (because they are not cost effective) will be made in the shadow of a possible US trade retaliation in other sectors affected by the trade agreement such as manufacturing and agriculture.

Other IP provisions

The AUSFTA also follows the template that the US has used FTAs with other countries by introducing new TRIPS-plus provisions. IFAC-3's March 2004 report on the US-Australia says 'IFAC-3 is particularly gratified that AFTA (Australia free trade agreements) preserves these strong precedents set forth in these other (free trade) agreements and now, with high-level agreements with both small developing countries in the CAFTA and a strong and mature developed country like Australia, it will prove much easier to convince future FTA countries that strong intellectual property protection is in the interest of all countries regardless of their economic circumstances. Accordingly, IFAC-3 urges the U.S. government to keep this in mind when negotiating with countries such as those in the SACU, which have much to gain from maintaining the high levels of protection negotiated to date'.

The TRIPS plus provisions in the AUSFTA are:

- Locking in of existing 5 year protection of disclosed data
- Preventing market registration during the life of the patent;
- Patent term extensions for pharmaceuticals to compensate for 'unreasonable' delays in issuing the patent (This is in addition to the five year extension of term that Australia already grants to pharmaceutical patent holders);
- Compulsory licensing of patents is prohibited except in three circumstances;
- Locking in of existing legislation which allows patent holders greater control over the importation or re-importation of their products by means of contracts.

It is interesting that while the public health implications of these provisions provoked heated debate in Australia, US lawmakers were only alerted to some of the implications for health care in the US later in the day. For example, many democrats, supported by consumer groups and a substantial number of Republicans, are promoting legislation to lower drug costs by parallel importing cheaper patented medicines from Europe, Canada, Australia, Japan and other countries where prices are regulated. But the FTA would allow pharmaceutical companies to prevent imports of drugs to the US. Drug companies and US administration officials oppose legalising imports of inexpensive prescription drugs, citing safety concerns.

Impact of AUSFTA on access to medicines

An Australian Senate report on the AUSFTA finds that patent provisions in the deal could delay the introduction of generic drugs to the Australian market and would increase drug prices to the Australian market and would increase drug prices in Australia as multinational pharmaceutical companies continue to sell higher-priced proprietary

products.^{xlvi}

Even though the PBS pricing scheme does not make maximum use of generic competition, a study in 1993 by the Australian Institute of high-cost drugs that had recently become subject to competition found that the PBS made savings of around 35% by the fourth year after the entry of generic competition. Research at the Australian Institute in Canberra has estimated that if provisions in the FTA succeed in delaying by 24 months market entry of generic versions of just the top five PBS expenditure drugs due to come off patent, this could increase the cost of the PBS by \$1.5 billion over 2006-2009. The budgetary cost could easily swamp the \$53 million a year in economic gains from the agreement estimated by modeling work commissioned by a Senate Committee investigating the FTA.

This amount would be multiplied many times as these delays applied to more and more drugs. Because the PBS provides a powerful price benchmark in the Australian market, delayed entry of generic drugs will not only affect the prices of PBS-listed medicines and hospital medicines supplies, but also non-PBS products sold in Australia. These include pharmaceuticals purchased by private and public hospitals and over-the-counter medicines not covered by government subsidies or safety nets. To compensate for the drain on their budgets public hospitals are likely to cut back on drug availability and on non-drug services such as elective surgery. Private hospitals will pass the costs onto patients and insurance funds, and private health insurance premiums will rise.^{xlvi}

The end result will be much higher pharmaceutical costs for the federal and state governments as well as consumers and the potential collapse of the PBS.^{xlix}

Is Australia paying its way with pharmaceutical R & D?

Australian experts have contested the assumption underlying the US approach that Australia is not paying its way with pharmaceutical R & D. It is true that Australian drug prices are currently about three to four times lower than those in the US. But the PBS has kept Australian drug prices low for various reasons. Pharmacoeconomic analysis and reference pricing are used to determine the true worth of the benefits of a new drug, while national bargaining power is used to counter the increasingly prolonged price-setting monopoly accorded to pharmaceutical patent holders. The Australian Productivity Commission has established that the greatest price differences between Australia and the US are for aggressively marketed new drugs involving small molecular variations and minor additional patient benefit (so called 'me-too' drugs). PBS prices for new drugs providing genuine benefit are much closer to US prices. Further over the past few years the Australian Department of Industry, Tourism and Resources has administered a \$300 million Pharmaceutical Industry Investment Program that provides additional rewards for those pharmaceutical manufacturers undertaking R & D in Australia. From 1st July 2004, a Pharmaceuticals Partnerships Program will take over from the Pharmaceutical Investment Program and provide an additional \$150 million over the next 5 years.¹

6. Are TRIPS plus measures in developing countries necessary to

promote R & D?

The big pharmaceutical companies argue that the high levels of intellectual-property protection demanded by TRIPS, and the even higher levels sought in FTAs, are necessary to allow companies to recoup the high costs of R & D. But for medicines needed for both rich and poor countries such as anti-retrovirals for HIV/AIDS, companies recoup their expenses in the profitable market in developed countries – Sub Saharan Africa accounts for only 1 % of global drug sales, and over 90% of GSK's global revenues are from the rich OECD countries. ^{li}And for ‘poor country’ or ‘neglected’ diseases there is little private R & D because low purchasing power in these countries means the markets are simply not big enough to provide the necessary financial incentives.

More widely policy makers are increasingly questioning the efficiency of current forms of private sector R & D and are looking for more cost effective methods^{lii}. And while the industry does indeed invest substantially in research and development (although such expenditure is only half the expenditure on marketing), it also gets a very high return. Profits on assets of the nine largest pharmaceutical companies were 4 ½ times greater in 2003, than the average profits for the Fortune 500 companies. ^{liii}

It is also important to remember that the key question for many developing countries is whether IP protection will help them develop their own domestic technological capacity. This is vital as technology capacity not only brings important health and development benefits but is also vital for long run poverty reduction, and effective participation in the global market. In the majority of poor countries without innovative capacity, patents won't by definition stimulate innovation. The key problem here is that they are poor and therefore lack scientific know-how, a technological base and infrastructure – rather than IP protection. It is not surprising that more than 80 percent of patents granted in developing countries go to residents in rich countries. For poor countries in the early stages of building technological capacity, strong patents inhibit domestic innovation by restricting the scope for creative imitation and reverse engineering.

While stronger patent protection may increase the willingness of companies to invest in advanced NIEs which have the ability to copy technologies, according to the CIPR evidence is lacking for most poor countries. Even for advanced NIEs stronger patent protection may actually encourage companies to export rather than invest directly in the country. IP protection is not the main determinant of location decisions of companies – this depends more on market size, skilled and flexible work force, natural resources, necessary infrastructure etc. Some of the countries which receive the largest FDI flows such as Brazil, China and Argentina are top of PhRMA's hit list for ‘inadequate’ IP protection .

Copying is not necessarily considered to be a bad thing in economic theory unless it completely destroys incentive for R & D . Indeed it is seen by many economists as a vital stage in the development process. The US copied extensively from Britain, France only introduced product patents in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977, and Italy and Sweden in 1977, Spain in 1992. Korea and Tawain combined weak

IPRs with investments in skill development, strong export orientation, ample inflows of foreign capital goods, and strong governments incentives for R & D

As the CIPR concluded ‘ it is not likely that the benefits of IP protection will outweigh the costs in the foreseeable future for most developing countries’. This is a conclusion shared by the World Bank ‘ The promise of long term benefits seems uncertain and costly to achieve in many nations, especially the poorest’. ^{liv} For some more technologically advanced countries, there may be some long-term gains, but these must still be balanced against the human costs of higher prices.

This does not mean that developing countries should never introduce patent protection – indeed it may make good sense to do so when a country has developed a technological and innovative base. But the point is that countries need flexibility to introduce IP rules in accordance with their development needs just as rich countries did in their earlier stages of development.

Public funding is needed to promote R & D into neglected diseases. For this reason last year’s G8 initiative on financing R & D for an AIDS vaccine is very welcome. There are also important new proposals from public health experts for a new R & D convention or treaty on priority health care research that would promote R & D but in areas of greatest need^{iv}, but also galvanise funding but also promote scientific and technical exchanges between countries but also support access to medicines for all, the transfer of technology, and development. It is proposed such a treaty would identify and provide for:

- Minimum levels of support for priority research among member nations,
- Measures that provide transparency and measurement of investment flows, and scientific and economic data,
- Mechanisms and incentives to support technology transfer to less developed economies
- Access to publicly funded research,
 - Obligations to provide incentives for open access publishing
 - Equitable pricing of government funded inventions,
 - Mechanisms to provide patent holidays on inventions which are derived from open public databases (HapMap issue),
- Exceptions to patent laws for research

ⁱ Drahos, Peter 2001, Bilateralism in Intellectual Property, A paper prepared for Oxfam by Peter Drahos, Herchel Smith Senior Fellow in Intellectual Property, Queen Mary College, University of London.

ⁱⁱ Ibid

ⁱⁱⁱ Ibid

^{iv} Compulsory license provides a vital tool for governments to override patents when prices of the patented product are too high or supply limited and authorise production or import of affordable generic versions of patented medicines. In practice governments have used the threat of a compulsory licensing as a bargaining chip to get companies to lower prices, or issue voluntary licenses, without actually issuing a compulsory

license. Parallel importation allows governments to purchase cheaper patented medicine from other countries.

^v Originator companies may increasingly issue voluntary licenses as a way of avoiding compulsory licensing. Voluntary licenses still gives them control over production and prices as they control the grant and terms of the license.

^{vi} ‘We urge you to negotiate a solution that is specifically limited to the diseases that were the focus of the Doha Declaration, namely HIV/AIDS, TB and Malaria and other epidemics of similar scale. In addition, it should be clear that only truly disadvantaged countries, such as those countries in sub-Saharan Africa, be the recipient of the changed rules’ Letter from PhRMA to members of Congress, November 14th 2002.

^{vii} www.ustr.gov/releases/2003/12/2003-12-03-letter-gao.pdf

^{viii} *ibid*

^{ix} Inside US Trade, 2003, Grassley threatens FTAs Post-Cancun; Aldonas offers softer tone, September 19th

^x Inside US Trade, 2004, Bush Announces FTA with Thailand as it puts G-21 at Distance, Inside US Trade, October 24th.

^{xi} BBC news, Costa Rica abandons el G-20-plus

http://news.bbc.co.uk/1/hi/spanish/business/newsid_3179000/3179748

^{xii} See for example

(a) Oxfam, 2004, Undermining access to medicines: a comparison of 5 US FTAs , A technical briefing note http://www.oxfam.org.uk/what_we_do/issues/health/undermining_access_ftas.htm

(b) Oxfam, 2004, Free Trade Agreement between the USA and Thailand Threatens Access to HIV/AIDS. Briefing Paper, treatment http://www.oxfam.org.uk/what_we_do/issues/health/bn_fta_hiv_aids.htm

(c) Reports from various UN Human Rights Committees warning various developing countries that they may breach the right to health if they introduce TRIPS plus provision US FTAs www.3dthree.org

(d) World Bank, 2005, Global Economic Prospects: Trade, Regionalism & Development,

(e) Stiglitz, J, 2004, New Trade Pacts Betray the Poorest Partners, New York Times July 10

<http://www.nytimes.com/2004/07/10/opinion/10STIG.html?ex=1090435917&ei=1&en=0aabdc37ae8913e2>

(e) Eugui, D.V, “Regional and Bilateral Agreements and a TRIPS plus world: the case of the FTAA”

<http://www.geneva.quino.info/pdf/FTAASupptableA4.pdf>

(f) Various reports by Robert Weissman. attorney and co-director of Essential Action, a Washington, D.C.-based corporate accountability group www.essentialaction.org

(g) MSF, 2004, Access to Medicines at Risk Across the Globe: What to Watch Out For in Free Trade Agreements with the United States, MSF, May.

^{xiii} Drahos, Peter, 2004, personal communication, October

^{xiv} Weissman, Robert, <http://www.cptech.org/ip/health/c/morocco/weissman04082004.html>

^{xv} Drahos, Peter, 2001 *Ibid*

^{xvi} Drahos, Peter, 2001 *Ibid*

^{xvii} Members of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) include Chairman Mr. Eric H. Smith President International Intellectual Property Alliance; Ms. Mary A. Irace Vice President, Trade and Export Finance National Foreign Trade Council, Inc; Vice-Chairman Mr. Jacques J. Gorlin President, The Gorlin Group; Jeffrey P. Kushan, Esq. Trade Counsel, Sidley, Austin, Brown & Wood LLP Representing Biotechnology Industry Organization; Ms. Catherine P. Bennett Vice President, Federal Tax and Trade Policy **Pfizer**, Inc; Shira Perlmutter, Esq. Vice President and Associate General Counsel, Intellectual Property Policy Time Warner Inc; Hope H. Camp, Jr., Esq. Consultant, Law Offices of Hope H. Camp, Jr., P.C. Representing **Eli Lilly and Company**; Timothy P. Trainer resident international AntiCounterfeiting Coalition; Susan K. Finston, Esq. Associate, Vice President for Intellectual Property Pharmaceutical Research and Manufacturers of America; Neil I. Turkewitz, Esq. Executive Vice President, International Recording Industry Association of America; Morton David Goldberg, Esq. Part Cowan, Liebowitz & Latman, P.C.; Mr. Herbert C. Wamsley Executive Director Intellectual Property Owners Association; Mr. Francis (Frank) Z. Hellwig, Esq. Senior Associate, General Counsel Anheuser-Busch Companies, Inc; Ms. Deborah E. Wiley Senior Vice President, Corporate Communications John Wiley and Sons, Inc. Association of American Publishers, Inc.; Dr. Joseph Anthony Imler Director, Public Policy **Merck & Company**, Inc.

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- ^{xviii} New York Times, 2004, New Trade Pacts Betray the Poorest Partners, July 10.
- ^{xix} Oxfam, 2003, US bullying on drug patents: one year after Doha, Briefing paper No 33, November.
- ^{xx} Love, James, Consumer Project on Technology http://www.ip-watch.org/weblog/index.php?p=5&res+1024_ff&print=0
- ^{xxi} ‘We hear you saying more people around the world need medicines, but can’t get access to them. Due to the complexity and scale of health care issues, we are working with a broad range of public and private sector partners to help address this. Ultimately our goal over time is to be a partner in identifying, creating and implementing comprehensive sustainable health care solutions.’ (www.pfizer.com/subsites/corporate_citizenship/index.html). ‘‘We are striving to be the company that does more good for more people than any other company on the ‘planet’ – Dr Henry McKinnell, CEO, of Pfizer, April 2001
- ^{xxii} Jakarta Post, September 9th 2004.
- ^{xxiii} Buck, Tobias 2004, EU may rethink multilateral trade rule. FT.com.site, 16th September
- ^{xxiv} . European Commission, 2004, Mr. Hiddo Houben, Deputy Head of Unit, Free Trade Agreements Unit, Personal communication, 25th September
- ^{xxv} WTO IP/C/W/345, Annex 3
- ^{xxvi} TBR, 1994, EC No 3286/94, December
- ^{xxvii} <http://europa.eu.int/comm/trade/issues/respectrules/tbr/legis/adgreg06a.htm>
- ^{xxviii} EN 20.12.2003 Official Journal of the European Union C 311/31
- ^{xxix} http://trade-info.cec.eu.int/doclib/docs/2003/april/tradoc_112198.pdf
- ^{xxx} European Commission, 2004, Directorate General for Trade Brussels, 23rd June
- ^{xxxi} Pharmacotherapy Department of the Costa Rica Social Security System, 2003
- ^{xxxii} Health Action International www.haiweb.org/medicineprices
- ^{xxxiii} A study on the difference in price between 30 essential generic and original brand medicines found that in Ghana, brand medicines were more expensive than generic medicines by a factor of 18 in public facilities, 11 in private facilities, 10 in pharmacies, and only 50 per cent in NGOs and religious missions. In Cambodia the differences were two to threefold in private pharmacies and private facilities, and about 100 per cent in public facilities and in the pharmacies of NGOs and missions (Strategies for enhancing access to medicines, Management Sciences for Health, Boston (www.msh.org/seam/3.1.3.htm in *WHO The World Medicines Situation*, WHO 2004 p 69) In 2000, a patented antiretroviral for the treatment of HIV was found to be 20 per cent more expensive in real terms in Africa than in ten advanced industrialised countries. (Perez-Casas, 2000, in *Medicine Prices: a new approach to measurement*, 2003 edition, WHO and HAI)
- ^{xxxiv} WHO, 2004 The World Medicines Situation
- ^{xxxv} Pharmacotherapy Department of the Costa Rica Social Security System, 2003
- ^{xxxvi} Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Health Economics and Drugs EDM Series, No 16, WHO, Essential Drugs and Medicine Policy.
- ^{xxxvii} MSF, 2004, Access to Medicines at Risk Across the Globe: What to watch out for in free trade agreements with the United States, MSF Campaign for Essential Medicines, Briefing Note, May
- ^{xxxviii} Executive Office of the President, 2003, Office of the USTR, Letter to Congressman Levin concerning US Morocco FTA, July 19th.
- ^{xxxix} Reuters, 2004, Mitchell, Deborah. Doctors’s Group Calls for More HIV Drug Price Cuts, July 12th
- ^{xl} WHO fact sheet 106, [Http://www.who.org](http://www.who.org)
- ^{xli} http://story.news.yahoo.com/news?tmpl=story&ncid=751&e=1&u=/nm/20041112/hl_nm/health_cancer_vaccine_dc
- ^{xlii} Garnaut, John, Sydney Morning Herald, Drug Costs will rise with deal: US official, March.
- ^{xliii} Colebatch T. The Age, 2003, Bush wants end to medicine subsidies. The Age, Melbourne, 24 Oct: 5
- ^{xliv} PhRMA, National Trade Estimate Report on Foreign Trade Barriers (NTE) 2004, PhRMA, 2003 www.phrma.org/international/resources/2003-12-17.466.pdf
- ^{xlv} Sydney Morning Herald, 2004, Why US drug firms want us to swallow their bitter trade pill, January 27th

^{xlvi} See (a) Drahos, Faunce, Goddard, Henry, 2004: The FTA and the PBS: A submission to the Senate Select Committee on the US-Australia Free Trade Agreement (b)

^{xlvii} . http://www.aph.gov.au/Senate/committee/freetrade_ctte/

^{xlviii} Drahos, P, Faunce, T, Goodard M, Prof Henry D: The FTA and the PBS, A submission to the Senate Select Committee on the US-Australia Free Trade Agreement, (<http://www.drs.org.au/articles/2004/FTA/Doc/drahos%20et%20al%20senatesub.htm>)

^{xlix} Drahos P, Lokuge B, Faunce T, Goddard M and Henry D, Prometheus, 2004, Pharmaceuticals, Intellectual Property and Free Trade: The case of the US-Australia Free Trade Agreement, Vol 22, No 3 September

^l Ken J Harvey KJ, Faunce TA, Lokuge B and Drahos P, MJA, 2004, Will the Australia-United States Free Trade Agreement undermine the Pharmaceutical Benefits Scheme? 25th July

^{li} Outterson, Kevin, Associate Professor of Law West Virginia University 304 293 8282

^{lii} Fears that cheap generics made in developing countries will flow back to rich countries and undermine prices and profits there are exaggerated. Rich countries are already rightly regulated- and there is no evidence of significant diversion of cheap generic medicines to rich countries. The G8 has also recently agreed that that it will not benchmark prices in their countries against those in poor ones.

^{liii} Light, Donald Ph.D, 2004, News Release, October 7th

^{liv} World Bank 2001

^{lv} Love, James and Hubbard Tim, Bridges, June 2004, Makes Drugs Affordable: Replace TRIPs-plus by R & D-plus, <http://www.ictsd.org/monthly/bridges/BRIDGES8-6.pdf> Bridges No.6 | June 2004 | www.ictsd.org | 3