Oxfam International

Drug Companies vs. Brazil:

The Threat to Public Health

May 2001

1. Summary of issues

The access of impoverished Brazilians to essential medicines, including those required for treatment of HIV/AIDS, is under threat. International pharmaceutical firms, with the backing of the United States government, are trying to ensure that Brazil has to buy the expensive patented drugs that they manufacture, rather than have access to the cheaper generic drugs that the country is making for itself or could buy from countries such as India. The companies are also resisting tighter price controls on their products. Oxfam believes that higher prices for medicines will cause unnecessary sickness and death among the sixty million Brazilians living in poverty, and calls on the US government and the companies to stop putting pressure on Brazil to change its policies.

Brazilians are particularly concerned that their progress in controlling and treating HIV/AIDS will be reversed if the national health service cannot provide affordable medicines to the half-million people who have the virus. The country's impressive achievements since 1996 include halving the mortality rate, an 80 per cent fall in the hospitalisation rate, and a sharp reduction in mother-to-child transmission. The incidence of HIV is now considerably lower than earlier UN predictions of millions of cases. The policy of prescribing free anti-retrovirals (ARVs) has played a significant part in these successes. Broad public access to ARVs has been possible because of local manufacture of cheap generic equivalents of the medicines developed and patented in rich countries. By 1999, this supply strategy had knocked 70% off treatment costs, enabling the health service to treat three times as many people for the same outlay and saving tens of thousands of lives.

Double assault on public health

Brazil's capacity to ensure a secure and affordable supply of medicines is under assault from two directions. Firstly, the international drug companies are directly challenging the Brazilian government over its medicines policies, accusing it of excessive price control and of not respecting patent rights on drugs for treating HIV/AIDS and other illnesses. Companies are threatening to take legal action or to withdraw from the country if their demands are not met. Secondly, the US government is taking Brazil to the World Trade Organisation 'court' on the grounds that its patent law violates international intellectual-property (IP) rules. The law in question would help Brazil to develop its national pharmaceutical industry and reduce the price of medicines. Although the USA is not formally linking its WTO complaint to the specific issue of drug patenting, it is acting at the behest of the Pharmaceutical Research and Manufacturers of America (PhRMA), a powerful industry lobby representing the world's largest companies. The US government is also maintaining steady diplomatic pressure, backed by the threat of unilateral trade sanctions, for changes in the Brazilian patent regime and medicines policy that would favour American business interests.

The situation in Brazil has much in common with that faced by South Africa, whose 1997 Medicines Act was criticised by the USA and the European Commission, and later challenged in the courts by international drug companies, including GlaxoSmithKline (GSK), Merck & Co, and Hoffman-La Roche. Fortunately, public pressure forced them to back down in April 2001. The behaviour of the US government and the drug companies in Brazil is provoking a similar angry reaction within the country, from all points on the political spectrum, and is attracting increasing public criticism world-wide.

What is at stake?

By putting pressure on the Brazilian government, the international drug companies are seeking to further their commercial interests in a pharmaceuticals market worth US$6.5 billion a year. The US challenge to Brazil's patent law, initiated at the WTO in January 2001, is part of the companies' strategy to undermine the tough negotiating stance of the Ministry of Health on prices. However, the

companies are also concerned that Brazil's example of promoting local production of generic medicines, and denying companies absolute control over prices and patents on public-health grounds, will spread to other countries. Their fears are heightened because Brazil has taken a leading role in the developing world on the issue of access to medicines, and has raised concerns about how WTO patent rules affect AIDS drug prices. In April 2001, for example, Brazil presented a resolution to the UN Human Rights Commission on the right to access to affordable medicines in the context of the HIV/AIDS pandemic. The motion was supported by 52 nations, with a single abstention – the United States. If Brazil is forced to alter its domestic policies, the world-wide momentum generated by the South Africa case for needed changes in pharmaceutical industry practices and patenting in the developing countries could be endangered. This would damage prospects for making vital medicines of all kinds affordable to poor countries.

By opening a formal dispute at the WTO, the US administration is also sending a strong signal that it will act decisively to ensure high levels of intellectual-property (IP) protection throughout the developing world, whether for pharmaceuticals and other industrial products, or in sectors such as software. The message is particularly directed at larger developing countries with significant industrial capacity, notably Argentina and India, both of which are currently drafting new IP laws.

Corporate pressure on Brazil

The dispute between the drug companies and Brazil is currently focused on the price of two of the twelve anti-retrovirals (ARVs) needed by Brazil for effective treatment of the virus. The two medicines, efavirenz and nelfinavir, are expensive, consuming a third of the ARV budget. The price is high because they are under patent in Brazil, and therefore cannot be copied by local manufacturers or imported from generic suppliers. At the end of March 2001, after lengthy negotiation, Brazil finally reached agreement on price with one of the patent-holders, the US-based pharmaceutical giant, Merck & Co. Talks continue with the Swiss firm, Hoffman-La Roche, which has exclusive rights to market nelfinavir in Brazil under an agreement with Pfizer, the US patent holder. In both cases, the Brazilian government has warned the companies that, if they do not bring their prices down to affordable levels, it will override the 'market exclusivity' rights conferred by the patents, and authorise local production by Far-Manguinhos, the State-run Institute of Pharmaceutical Technology. It is important to note that this procedure, known as 'compulsory licensing', does not rescind the patent and, under WTO patent rules, requires payment of royalties to the patent holder. In order to be prepared for production, Far-Manguinhos has imported the necessary raw materials for testing and research from India. In March 2001, Merck wrote to say that it considered Far-Manguinhos was thereby infringing its patent rights. The Ministry of Health denied this allegation, and the matter remains unresolved to date.

The battle over these two drugs is the latest chapter in more than a decade of corporate pressure on Brazil to change its medicines policy and patent regime. Although PhRMA gives credit to Brazil for having introduced pharmaceutical patents in 1997, it maintains a steady barrage of complaints over important details of legislation and practice. In December 2000, it objected strongly to tougher price controls on medicines. The companies regularly use the threat of disinvestment to influence health policies, but through their close relationship with the Office of the US Trade Representative (USTR) they have a superior weapon at their disposal: US trade sanctions, either applied unilaterally or approved by the WTO.

US government action against Brazil at the WTO

The dispute at the WTO initiated by the USA places a considerable burden on Brazil and represents an intensification of US pressure on the country. The formal complaint focuses on aspects of Brazil's

1996 Industrial Property Law. If the US government wins the case, Brazil must amend its law, or face penal tariffs on its exports to the USA, authorised by the WTO. All other WTO member states will have to ensure that their legislation is consistent with the ruling. Oxfam is calling on the US government to withdraw the complaint. If the case proceeds, Oxfam believes the WTO should find in favour of Brazil on both legal and public interest grounds.

The technical arguments in the case are complex, but can be summarised as follows. Brazilian law permits the government to require a company in any industry to manufacture a patented product inside the country within three years of patent approval. If the patent holder does not meet this requirement, the government may override the patent and allow third-party manufacture, or liberalise the import of the patented product from the cheapest international source, without the patent-holder's consent. This legislation could be used to encourage drug companies to produce essential medicines inside Brazil, thus reducing the high foreign-exchange cost and ensuring the development of a domestic pharmaceutical industry. It can also be used as a negotiating tool to pressure companies to reduce the high price of imported medicines. The USA claims that the law discriminates against imported products and therefore infringes WTO patent rules, known as the Agreement on Trade-Related Aspects of International Property Rights (TRIPS). The Brazilian government argues that US trade lawyers are disregarding the fact that Brazil's provision for local manufacture of a patented product is a safeguard which can be invoked only in a case of 'abuse of rights or economic power' by a patent holder, and, as such, that it is TRIPS-compliant.

Political, economic, and legal pressure from the US government over Brazil's IP rules is not unprecedented. The subject has been a source of tension since the 1980s, and on several occasions the Office of the US Trade Representative (USTR) has threatened or applied unilateral trade sanctions to force Brazil to do its bidding. Nor is such bullying unique to relations between the USA and Brazil. The USTR has exerted pressure on numerous countries, such as Thailand and the Dominican Republic, to conform to its desired protection standards for pharmaceutical products. Its principal weapon has been the 'Special 301' provision in the US Trade Act, which allows Washington unilaterally to impose tariffs on a country's exports to the US market if such standards are not met. In response to domestic public protest over the US role in South Africa medicines dispute, the US government has said it will exercise restraint in the use of Special 301 in cases which involve vital pharmaceuticals. However, Brazil is still on the Special 301 'watch list', which is a warning shot about US government concern. The current political sensitivity over pharmaceutical pricing and patents is one reason why the US government is taking Brazil to the WTO 'court' over broader aspects of patent law, without making specific reference to medicines.

2. Oxfam's recommendations

Oxfam, in common with many public-interest groups in Brazil, calls on the US government and the international pharmaceutical companies to lift the pressure for changes in the country's policies on medicines and patents. The health needs of the Brazilian people should be the prime determinant of those policies and not the commercial interests of international big business. Oxfam also believes that global patent rules are in need of urgent reform if they are not to prejudice public health in the developing world. Oxfam's specific proposals are that:

- The US government should drop the case against Brazil at the WTO. It should also stop using 'Special 301' investigations and the threat of trade sanctions to oblige poor countries to institute levels of intellectual-property protection which prejudice public health and economic development.

- Merck and Roche should not sue Brazil for violations of patents on AIDS drugs. The companies should issue voluntary licences to allow local manufacture of these medicines by third parties, or should agree to sell them at prices comparable to those of generic manufacturers elsewhere, such as the Indian companies.

- Other industrialised nations should discourage the United States from aggressively promoting high levels of pharmaceutical patent protection. They should support Brazil's use of compulsory licensing as a last resort to ensure affordable essential medicines.

- WTO member states should immediately agree to bolster public-health safeguards in the TRIPS agreement, including strengthening the right to manufacture or import cheap generic versions of vital drugs.

- The scheduled review of the TRIPS Agreement should include in-depth analysis from a development and public-health perspective, with a view to making amendments that:

    - give developing countries greater freedom to decide the duration and scope of pharmaceutical patents, including the ability to exempt medicines from patenting;

    - allow countries to require local manufacture of patented products as part of their national development and 'health security' strategy.

Note: The next section of this briefing describes Brazil's medicines policy, particularly in relation to AIDS drugs, stressing the importance of generic production in ensuring affordability. The conflicts with the international drug companies over prices are explained in detail. The fourth section examines the arguments and issues arising in the WTO dispute initiated by the USA. It then looks at drug company pressure for reform of Brazil's patent rules. The final section summarises the implications for public health if Brazil is forced to change its policies.

3. Threats to Brazil's medicines policy and AIDS programme

Concerted action on HIV/AIDS by the Brazilian government and grassroots groups has averted a human calamity. In the early 1990s, it looked as though Brazil was heading for an AIDS crisis of devastating proportions. UN forecasts spoke of millions falling victim to the virus. Today, the number of HIV-positive people is estimated at half a million, a figure which is still far too high, but which can be seen as a positive result for policies in place since the mid-1990s. According to government figures, there has been an 80 per cent drop in hospitalisations for AIDS-related diseases, and a 50 per cent drop in mortality rates since 1996. 146,000 hospitalisations have been avoided between 1997 and 1999, saving the health services US$422 million. If one counts in the cost of drugs used to treat opportunistic infections, the savings are nearer to US$500 million. UNAIDS, the UN Secretary General Kofi Annan, and many others have publicly praised these achievements.

To what is Brazil's success in tackling AIDS due? One factor in controlling the epidemic has certainly been the intense effort in education and prevention, much of it carried out by voluntary groups, activists, and NGOs. A UNAIDS study, for example, showed that young people in Brazil were possibly the best-informed about HIV in the world. Another important factor in reducing transmission, morbidity, and death has been the free distribution of ARVs since 1996, including those needed to stop mother-to-child transmission. Currently, the health service provides free ARV treatment to 95,000 people. This is only possible because ten of the twelve drugs needed are not patented in Brazil and can therefore be produced as generics, without paying the royalties or monopoly prices that have to be paid in industrialised countries. Brazil was spending around US$8,000 per patient per year in 1997. By increasing generic production, the annual cost halved by the year 2000, and is now just over US$3,000. Thanks to hard bargaining with the companies, the price will fall further. These figures contrast sharply with the US$10,000 cost per patient in the USA.

Aside from its HIV/AIDS programme, the Brazilian government has also been lauded for its National Drug Policy, launched in 1998. Dr Gro Harlem Brundtland, Director of the World Health Organisation, visiting Brazil last year, spoke warmly about the policy's stress on generic medicines, which she believes '*can make drug markets more competitive and efficient and can contribute to the goals of improved equity, quality and efficiency in health… The current changes occurring in the Brazilian health sector represent an excellent opportunity to promote and benefit from these strategies.*'

Why Brazil can produce generic versions of new drugs, but not for long

Why can Brazil produce or import low-cost generic versions of some of the drugs that are so expensive in rich countries? The answer is simply that Brazil did not adopt pharmaceutical patenting until 1996. It could therefore legally produce equivalents of expensive medicines patented before that date in the industrialised countries, or import them from India, which also did not have patenting on pharmaceutical products. Both countries are now obliged by the WTO TRIPS agreement to have national legislation in place by 2005 which provides patent terms of at least 20 years for all products and processes. The fact that Brazil met this requirement nearly ten years early is testimony to the intensity of US economic and political pressure, including the use of trade sanctions, although it also reflects a weak commitment on the part of the Brazilian government to a more independent economic development strategy.

The WTO TRIPS Agreement

The 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), introduced after sustained lobbying by TNCs, was the most significant extension of patenting rights in the twentieth century. It obliges member states to grant at least 20-year patent protection in all fields of technology, including medicines. This enables already powerful pharmaceutical TNCs to consolidate their market domination on a global scale. Longer patent periods delay the appearance of the low-cost generic equivalents which traditionally supply developing-country needs. Only the expensive, patented version of new medicines will be available. At a time when millions of people are already unable to afford essential medicines, and when public health is threatened by a combination of new diseases and drug-resistant variants of old killers, WTO rules will further reduce access to modern medicines.

TRIPS was just one of the agreements signed at the conclusion of the Uruguay Round of multilateral trade talks. Countries could not opt out of any of the agreements, nor register a reservation on specific clauses – it was an indivisible package. Many developing countries did not fully understand the implications of the TRIPS agreement. Others knew it was not to their advantage, but expected gains from other agreements, such as greater access to rich-country markets for their exports. Regrettably, those expectations have not been met.

The key point, however, is that from 1996 onwards, Brazil has not had the option of local generic production of new drugs for HIV/AIDS or for any other disease. And Brazil would not be distributing free ARVs today if the TRIPS agreement had come into force a few years earlier. Based on US patented prices of $10,000 per patient per year, the annual treatment bill for the Ministry of Health today would be a huge and unaffordable US$950 million. Ideally, Brazil would return to a system of lower patent protection for medicines that would allow earlier generic production, but TRIPS does not permit this. Unless and until TRIPS is reformed, the only way in which Brazil can ensure that new drugs are affordable is by price controls, with compulsory licensing as a bargaining chip and as a last resort. It is precisely this policy that Brazil is pursuing, and it is precisely this policy that the companies are resisting so vigorously.

Hard bargaining on AIDS drugs

One area of tension between the Brazilian government and the transnational drug companies is the pricing of patented ARVs prescribed by the health service, which has led to potential conflict over the patents themselves. Since last year, the Minister of Health, José Serra, has been openly threatening to override patents on two important ARVs - efavirenz (marketed by Merck as Stocrin) and nelfinavir (marketed by Roche as Viracept) - unless the companies further reduce their prices. The issue of price is of vital importance, as payments for the two drugs have been consuming one third of the government budget for ARVs. In the case of efavirenz, the government has also requested a voluntary licence from Merck to enable the State-run Institute of Pharmaceutical Technology, known as Far-Manguinhos, to produce the drug. Far-Manguinhos already manufactures 40 per cent of the locally made ARVs. Brazil also sought price reductions on indinavir, an ARV marketed by Merck as Crixivan. Indinavir is off-patent, but Brazil needs to purchase from Merck to cover shortfalls in local manufacture. Merck can well afford to make concessions on prices. In 2000, its global sales rocketed by 23 per cent to US$40.4 billion, and after-tax profit rose by a very healthy 16 per cent to US$6.8 billion.

On 30 March 2001, the Ministry of Health announced that it had reached agreement with Merck over the new price of indinavir and efavirenz. Prices will fall by 65 per cent and 59 per cent respectively, knocking US$40 million off the total annual bill of US$300 million for ARVs. The Ministry regards this as a victory, and a vindication of its tough negotiating position. The outcome demonstrates the importance for governments of having the last resort of compulsory licensing in their negotiating toolbox. For Merck, the loss of income is unlikely to be a problem - it is equivalent to one thousandth

of its annual earnings. The Ministry warns, nevertheless, that it still has not reached agreement with Roche, to whom it currently pays US$85 million a year for nelfinavir.

A step forward in fairer pricing?

Merck's new prices in Brazil for annual treatment with indinavir and efavirenz are US$1,029 and US$920 per patient. This is about a quarter and a sixth respectively of the US price, though still almost double the cost in sub-Saharan Africa, where prices have fallen in response to public pressure and competition from Indian generics. Merck says its developing-country price policy for ARVs will be based on the UN Human Development Index and the incidence of HIV/AIDS. While the details of this new approach to pricing are still not known, it does mean recognition of the need for more fairness and transparency in pricing, something for which Oxfam and others have been campaigning. A good next step would be to extend such a system to other vital medicines.

Legal threats regarding alleged patent infringement

Despite the agreement on prices, relations between the government and Merck are still tense because of the allegation of patent infringement by Far-Manguinhos, which is responsible for essential medicine production, research and development of pharmaceuticals, and professional training in pharmacology. In March 2001, Merck wrote to Far-Manguinhos warning that the institute had violated its patent rights on its anti-retroviral drug, efavirenz, by importing the raw materials for its manufacture.

Far-Manguinhos says that it imported 20 kilos of the raw material from India for scientific research and technical analysis, and not for sale, and that it is acting within the terms of Brazil's Industrial Property law. It also claims that its actions are TRIPS-compliant, since the provision in Brazilian law on so-called 'early working' is carefully based on a WTO panel ruling that competitors can research and develop versions of patented drugs, provided that they stop short of manufacturing and stockpiling. Merck seems to be ignoring the legality of this provision.

The Ministry of Health has denied any patent infringement and has made clear that Far-Manguinhos will continue testing and other scientific preparation for local production of both the patented ARVs, should this prove necessary or desirable. At the time of writing, it is not clear how Merck will react to this. Far-Manguinhos has also imported the ingredients for nelfinavir for research purposes, but so far Roche has not taken any action. Eventual local production, based on the components imported from India, could happen under a compulsory licence, if the companies fail to co-operate on price and supply, or under a voluntary licence if the companies so agree.

Pulling up the ladder

Dr Eloan Pinheiro, the Director of Far-Manguinhos, believes very strongly that scientific research on pharmaceuticals in developing countries, including evaluating and testing, is and should be allowed by national and international patent law. The patenting system, after all, is supposed to ensure that knowledge is placed in the public domain, provided that it is not commercially exploited. She sees the Merck allegation of patent violation as *'very dangerous'* because, apart from the implications for the cost of medicines in Brazil, it is a broader attack on the capacity of poor countries to develop an independent industrial, scientific, and technological base.

India has been able to produce the raw materials imported by Brazil because it is taking longer than Brazil to introduce pharmaceutical patenting, and has considerable technical capacity. However, it is critical to note that, due to TRIPS, India has already lost the ability to manufacture low-cost equivalents of any new drugs coming onto the market in industrialised countries. Although India has until 2005 to be fully TRIPS-compliant, WTO rules oblige it to offer interim 'market exclusivity' for products with patents filed after 1999. Once India's new patent law is approved, these patents will be

formally granted. This 'exclusivity' amounts to granting a patent because it prevents generic competition. In this way, TRIPS has already deprived many developing countries of a vital source of low-cost medicines. In India itself, it has been estimated that medicine prices will rise at least threefold as a result of TRIPS.

The argument over efavirenz and nelfinavir is just one in a long-running battle between Brazil and the transnational pharmaceutical companies over the price of medicines for treating HIV/AIDS. There were congressional inquiries into pricing in 1998, and in 1999, despite opposition from companies, the National Sanitary Supervision Agency was given greater powers to monitor and control prices. In October 1999, a Presidential decree was issued, governing the grant of compulsory licences in broadly defined situations of national emergency or public interest, provoking strong criticism from William Daley, the US Trade Secretary, during his visit to Brazil a few months later, accompanied by the President of Merck & Co.

Even if the argument over these particular patented medicines is resolved, Brazil's problems are not over. Effective anti-HIV medicines may be developed which have fewer side effects, or which can cope with the drug-resistant strains that may emerge. These treatments will also be patented, and the same battles will occur. The price of patented medicines which are needed to treat other infectious diseases such as tuberculosis, particularly the multi-drug resistant types, will also become a cause of contention.

The threat of a good example

Corporate fears that their commercial interests in Brazil's large pharmaceutical market are under threat are compounded by anxiety about Brazil's example spreading to other countries. Indeed, Brazil has offered to supply other poor countries with advice, technology and ARVs for dealing with HIV/AIDS, and is an international leader on the broader issue of access to medicines. For example, at the 1999 World Health Assembly, despite vehement opposition from the US delegation, Brazil pressed for an active role for the World Health Organisation in monitoring the price of medicines world-wide and in evaluating the impact of WTO patent rules. In June 2001, it will propose to the UN General Assembly special session on HIV/AIDS that developing countries should be able to make or import generic drugs for treating AIDS and opportunistic infections. As President Cardoso said recently in the New York Times, '*Brazil has raised this banner because it is a cause that has to do with the very survival of some countries, especially the poor ones of Africa… This is a political and moral issue, a truly dramatic situation…*'. These actions by Brazil form part of a larger international movement seeking to ensure that vital drugs are affordable to poor people and poor countries. It is this broader context which helps explain why Brazil is now in the firing line for its medicines and patents policies.

4. The WTO case, and drug company pressure on patent laws

The US complaint at the WTO

On 8 January 2001, the USA requested a WTO Dispute Settlement panel to resolve its differences with Brazil over its 1996 Industrial Property Law, opening another chapter in a long saga of US pressure on the country over patenting. It may be no coincidence that this action, which could have been taken at any point in the preceding years, occurred just a few weeks after the Brazilian government froze drug prices for the rest of 2001 at 4.4 per cent above their August 1999 level. Brazilian trade officials are in no doubt that the Ministry of Health's firm stance on prices, backed by its

willingness to issue compulsory licences for local production of patented AIDS drugs, explains why the USA initiated the WTO dispute at this time. The formal request for a panel was made in the last days of the Clinton administration, but there is no reason to believe that President Bush's policy on Brazil will be different to that of his predecessor. Oxfam believes that the US government should withdraw the complaint. If the case continues, the panel should find in favour of Brazil on both legal and public interest grounds

While raising the temperature at the WTO, the USTR has also kept Brazil on the Special 301 'watch list', behind which lies the menace of unilateral trade sanctions. In both cases, the administration is following the lead of PhRMA, which '*strongly supports the (US government) efforts to resolve outstanding TRIPS inconsistencies and welcomes the WTO's February 1, 2001, decision to establish a dispute settlement panel'.* PhRMA exercises remarkable influence in Washington, thanks partly to the huge donations made by pharmaceutical companies to parties and politicians, and to systematic lobbying. It has been estimated that the industry spent US$236 million on lobbying Congress and the executive in the period 1997-1999.

It is important to note that the US government challenge at the WTO does not include Article 71, which allows for compulsory licensing in cases of national emergency or public interest. Nevertheless, as explained later in this paper, this essential safeguard has been criticised by the US government bilaterally and by PhRMA, which claims that the legislation is not TRIPS-compliant.

The legal arguments

The US government claims that Article 68 of Brazil's 1996 Industrial Property Law, effective from May 1997, violates the WTO TRIPS Agreement. This article stipulates that if a patent holder fails to manufacture a patented product in Brazil within three years of patent registration (either in its own factory or by granting a license to a local firm), the government may suspend the patented product's right to 'market exclusivity', and authorise another company to manufacture it. Since the authorisation can be issued without the consent of the patent-holder, it is known as a 'compulsory licence'. In essence, US trade officials are saying this 'local working' requirement discriminates against imported products, while the Brazilians claim that article is intended to deal with 'abuse of rights or economic power' by the patent holder, and is therefore TRIPS-compliant. There is plenty of scope for complex legal arguments over Article 68, because the wording is not clear. Moreover, since it has never been employed, there is no legal precedent to guide interpretation. Nor, importantly, is there any concrete injury that the USA could claim. In addition, since TRIPS is more akin to a constitution than a patent law, it is itself open to widely different interpretations. The two sides have not yet presented their submissions to the Dispute Settlement panel, but the thrust of their legal arguments is clear.

The specific allegation of the US government is that Brazil's 'local working' requirement breaches Articles 27 and 28 of TRIPS and Article III of the General Agreement on Trade and Tariffs (GATT), essentially because it discriminates between locally made and imported products. TRIPS lays down that a country must grant patent protection for qualifying products, irrespective of their place of origin, provided the manufacturer supplies the market with the product. TRIPS considers that exporting to a market is a valid form of supply.

The Brazilian government argues that the local working requirement is TRIPS-compliant, since it is not a blanket, mandatory measure, and may be imposed only when a specific patent-holding company has abused its rights or economic power. TRIPS does indeed allow for patent rights to be overridden in cases of anti-competitive practice, and the US government has itself forced companies to surrender patents in anti-trust actions. Thus some of the discussion in the WTO panel hearings may centre on what constitutes 'abuse'. The Brazilians could argue that setting high prices or refusing to transfer technology and expertise through local production could be considered abuse.

The argument for 'local working'

In this context, it is important to note that a key stated objective of the TRIPS agreement is *'the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.* Although the agreement is silent as to how this will be achieved, it implies the establishment of local manufacturing of the patented product, since this is the principal vehicle for technology transfer. A company in an industrialised country supplying a developing-country market through exports is clearly not transferring its technology to the same degree. It is also worth noting that industrialised countries themselves used local working requirements in the past, in order to promote their own national economic development - something which they now wish to deny the developing world.

Whether or not refusing to set up local production of a patented product is an abuse of economic power, there are strong development grounds for a local working requirement, and overwhelming public-health grounds for such a requirement to be available for pharmaceutical products. In Brazil's case, the net foreign-exchange bill for drugs (imports less exports) has risen to well over US$1 billion, making supply vulnerable to the overall state of the balance of payments. Between 1994 and 1997 alone, drug imports tripled. By encouraging local manufacture and thus greater self-reliance, a developing country enhances its long-term health security. The figures for the cost of ARVs in Brazil clearly illustrate this point: between 1996 and 2000, the price of ARVs produced in Brazil dropped 72.5 per cent, while imported ARVs went down by only 9.6 per cent. It is important to note, too, that the mere *availability* of a local working requirement strengthens the ability of the government to negotiate reductions in the high cost of imported medicines.

Loaded against the poor

The broader negative impact of the TRIPS agreement on access to medicines in developing countries illustrates the way in which intellectual property rules in all economic sectors have been designed to favour the commercial interests of industrialised countries rather than development goals. Many poor countries are concerned that excessive levels of IP protection now required of them will have a damaging overall effect on their economic development, raising the cost of the technology and know-how to which they must have access if they are to compete and grow. For example, there are widespread concerns about the threat to rural livelihoods posed by the extension of patenting in agriculture, which will increase the price of seeds and other inputs. The problems with the TRIPS agreement in turn highlight the way in which world trade rules, policed by the WTO, are loaded against poor people and countries. In Oxfam's view, these rules and institutions are in need of radical reform in order to put development and poverty reduction at their heart.

Parallel imports

The USA also objects to the clause in Article 68 that states that if a patent holder does not manufacture the patented product in-country, the government may allow the import of the patented product from the cheapest source, whatever the wishes of the patent holder (a practice known as 'parallel importing'). Thus if an international drug company *imports* a patented medicine into Brazil at US$2 a dose, the government could authorise the 'parallel import' of an identical medicine from another country where it is priced at US$1.50. If the company manufactures the drug locally, it is protected from parallel importing, and is therefore freer to set the price according to local market conditions. By providing protection from parallel imports, Brazilian law goes beyond the minimum levels of protection established by the TRIPS agreement, but the US government argues that linking this protection to 'local working' is a violation of TRIPS. Brazil argues that the parallel importing provision is also a safeguard, to be used cases of abuse of power.

Oxfam believes that TRIPS should allow developing countries to make prohibition of parallel imports conditional upon in-country manufacture, without having to argue an 'abuse of rights', and that Brazil

should consider revising its legislation to that effect. It may even to be to Brazil's advantage to liberalise parallel imports completely - a measure not precluded by the TRIPS agreement.

Brazil's other line of defence

In its defence submission to the panel, Brazil may also use a more procedural argument, based on the practice of WTO panels to date. Article 68 of Brazil's patent law does not *mandate* TRIPS-inconsistent behaviour by the government, even if it might possibly *permit* it. Brazil can claim that the case is outside the jurisdiction of the WTO unless the government were to *implement* the law in a TRIPS-inconsistent way, which has not happened to date. This argument is indirectly corroborated by the European Commission, which stated in a technical note on the South Africa court case that '*Generally, a WTO panel or the Appellate Body would conclude that a law or regulation is in itself in breach of WTO rules if it mandates WTO-inconsistent behaviour, i.e. leaves no discretionary power to the Government to apply it in a TRIPS-compliant manner. If, on the contrary, there is discretion to implement the regulation in a WTO-consistent manner, a panel or the Appellate Body can only pronounce itself on a particular implementing measure.*'

and counter-claim…

In February 2001, the Brazilian government tabled concerns at the WTO about TRIPS violations in the US Patents Code, and asked for 'consultations' with the US trade authorities, which is the first step before starting a formal dispute. This tit-for-tat action was partially aimed at drawing attention to the fact that many countries have aspects of their legislation that could be challenged as non-compliant, particularly since TRIPS is a set of general principles open to wide interpretation. Brazil believes the US government singled it out for broader political reasons, notably opposition to Brazil's policy of controlling drug prices and of promoting domestic generic drug production as a sustainable way of ensuring access to medicines.

What happens in the WTO Dispute Settlement process?

The US complaint at the WTO will be resolved through the Dispute Settlement mechanism that was set up at the end of the Uruguay Round of multilateral trade negotiations to deal with conflicts over WTO trade agreements. The WTO will shortly name a panel to hear the complaint. The panel's decision will probably be handed down before the end of 2001. If the complaint is upheld, the panel will instruct Brazil on how to amend its law. If Brazil does not do so, the panel can authorise the USA to apply trade sanctions to Brazil's exports, up to a set value. Either party can appeal against a panel decision to an Appellate Body. It is important to note that the final verdict becomes the definitive interpretation of a given WTO rule, and will be applicable in all 140 member states.

Cuba, the Dominican Republic, Honduras, India, and Japan have registered as third parties in this case, which means that they have the right to make submissions and address the panel. The panel itself has the right to seek information and technical advice from any individual body that it deems appropriate. However, it is not normal practice to take evidence or opinions from non-government organisations, nor indeed from other inter-government organisations such as the WHO, even though the subject before the panel often has ramifications well beyond narrow trade issues. Properly, there is growing pressure on the WTO to broaden participation in the process.

Corporate pressure and Special 301

The Pharmaceutical Research and Manufacturers of America (PhRMA), which has the world's ten biggest pharmaceutical companies among its members, has a long list of objections to Brazil's patent regime. PhRMA claims that the situation in Brazil is affecting the 'siting decisions' of member companies, which is a polite way of saying that unless industry gets the changes it wants, it will go elsewhere. Harvey Bale, director of the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), delivered the same message in an interview published in Brazil on 4 April 2001, saying that his members *'will stop investing in Brazil if the country continues questioning intellectual property rights on medicines, or authorises compulsory licences'*. The Ministry of Health was combative in reply, but since even industrialised countries such as Britain seem to submit to this kind of argument, it may be unrealistic to expect Brazil to stand firm.

PhRMA, as well as persuading the US government to act at the WTO, also instigates pursuit of its concerns through US bilateral negotiation with Brazil, and lobbies to keep Brazil on the USTR's Special 301 priority watch list. Apart from the issues presented to the WTO panel, PhRMA objects to the October 1999 Presidential decree on compulsory licensing, which regulates Article 71 of the national patent law. This article, in common with Article 68, enables the Brazilian government to override the market exclusivity conferred by a patent and authorise third-party production of the patented product. Article 71, however, allows for this on grounds of public interest or national emergency, rather than 'abuse of rights', and is not concerned with 'local working' per se. The definition of 'public interest' includes matters important to public health and to social and economic development. This is an extremely important safeguard: without it, the government's ability to negotiate affordable prices with the pharmaceutical industry is severely curtailed, leaving a company freer to charge what it likes for life-saving drugs, or even to refuse to supply a market. Remarkably, PhRMA also claims that the 1999 decision by the government to involve the health authorities in the approval of patents for pharmaceuticals could be a violation of the TRIPS Agreement.

Public health could also be threatened by PhRMA's claim that Brazil is not compliant with the 'data exclusivity' provisions of TRIPS. Data exclusivity refers to the legal restrictions on access to clinical test data presented to regulatory authorities by a patent-holding company seeking approval for a new drug. This obscure but highly significant form of IP keeps competitors out of the market and means that prices stay at monopoly levels for much longer. Competitors have to replicate trials, at great expense, or wait until the 'exclusivity' expires. In some countries, even the authorities cannot use an originator's data to assess an equivalent product made by another company, further delaying the onset of competition. The 'exclusivity' term lasts up to ten years in Europe, and can extend several years *beyond* the product patent. TRIPS requires that national law protects data against unfair *commercial* use by third parties, but the transnational pharmaceutical firms argue that this means the obligatory introduction of European-style provisions everywhere. This interpretation is hotly contested by generic manufacturers. Whichever reading of TRIPS prevails, there is the risk that PhRMA will get its way in Brazil and elsewhere through US bilateral pressure, or through IP provisions in regional agreements such as the Free Trade Area of the Americas.

Two steps to getting a patent law

Step 1: On 11 June 1987, the US Pharmaceutical Manufacturers Association filed a petition with the USTR complaining of Brazil's lack of process and patent protection for pharmaceutical products, claiming it was an unreasonable practice that burdened or restricted US commerce. This request was backed by intensive industry lobby and campaigning.

Step 2: On 23 July 1987, the USTR initiated an investigation and requested consultations with Brazil, which resulted in no resolution. On 21 July 1988, the US President determined Brazil's policy to be indeed unreasonable, and on 20 October he used his Section 301 authority to impose penal tariffs on Brazil's exports to the USA of certain paper products, non-benzenoid drugs, and consumer electronics items.

Result: On 26 June 1990, the government of Brazil announced that it had decided to seek legislation to provide patent protection for pharmaceutical products and the process of their production.

5. Conclusion

If the US government and the pharmaceutical companies get their way, Brazil's ability to provide needed medication to the half-million HIV-positive people in the country, or to provide other essential medicines at affordable prices, will be jeopardised. This will cause considerable human suffering in a country where sixty million people are impoverished.

Brazil, and any other developing country, will be prevented by WTO rules from insisting that patented products be produced locally, a measure which can ensure the development of a domestic pharmaceutical industry, bring down drug prices, and reduce the foreign-exchange costs, thus ensuring more secure and affordable access to medicines. If Brazil is also prevented from allowing parallel imports in cases where there is no local production, the prices of medicines will be higher than need be, with corresponding hardship for patients and their families. With the loss of both these policy options, the Brazilian health ministry would be in a much weaker position to negotiate affordable prices with the big drug companies. If PhRMA succeeds in obtaining the additional policy reforms that it seeks, the control of new medicines will be largely in the hands of a few international drug companies. This would cripple the government's ability to manage its medicines policy for the public good.

Brazil’s successful resistance to pressure from the US government and the pharmaceutical companies, like that of South Africa, would have symbolic and political significance in the broader battle over the rival priorities in global economic management - human development or corporate profit. More immediately, it would influence the fate of hundreds of thousands of people with HIV/AIDS, and a far larger number of impoverished people in desperate need of cheaper medicines.

This briefing was prepared by the Policy Department of Oxfam (Great Britain) for Oxfam International as part of the 'Cut the Cost of Medicines' campaign. It will shortly be available in Portuguese and Spanish. All campaign reports are available on the Oxfam GB website (www.oxfam.org.uk). These include more detailed analyses of the issues concerning access to medicines, particularly in relation to patent rules and corporate social responsibility, as well as Oxfam's coverage of the legal action brought by pharmaceutical companies against South Africa.

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