

# ACCESS TO MEDICINES AT RISK ACROSS THE GLOBE: What to Watch Out For in Free Trade Agreements with the United States



**MSF BRIEFING NOTE**

One by one, countries are trading away their people's health in "free trade" agreements with the United States. These countries are being pushed to accept extremely restrictive intellectual property provisions that could put an end to competition from generic medicine producers and to countries' ability to make use of existing safeguards against patent abuse.

By deliberately restricting the availability of low-cost medicines, these agreements will have a direct impact on the health of people in developing countries.

The purpose of this paper is to point out what to look out for in these free trade agreements, to explain what the United States is seeking and show what the impact will be. Médecins Sans Frontières hopes to advocate that countries do not agree to any measures in trade agreements which restrict peoples' access to essential medicines. Intellectual property should be kept out of these agreements.

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After being forced to compromise in multilateral negotiations, the United States has turned its attention to regional and bilateral free trade agreements (FTAs) that will affect every region of the world. These bilateral and regional agreements are attracting little public attention, are often highly technical in nature, and are

being negotiated in secret, despite repeated requests from civil society to open them to public debate.

The United States' goal in such negotiations reflects the wishes of the group of industry representatives advising the US Trade Representative, which has

said: “The negotiation of an individual [Free Trade Agreement] provides the opportunity to deal with specific intellectual property concerns that US industry may have in the particular negotiating partner. Our goal in the negotiation of an FTA is to set a new baseline for all future FTAs.”<sup>1</sup>

The United States is seeking to secure, or has already secured, the inclusion of several particularly harmful intellectual property provisions in its regional and bilateral trade agreements. These include:

- rules which will turn national drug regulatory authorities into effective “enforcers” of patents on medicines;
- new obstacles related to pharmaceutical test data, which will delay the registration of generic medicines (“data exclusivity”);

- extensions of the life span of patents, which will further delay generic competition;
- measures which will allow known substances to be patented all over again for each “new use”; and
- restrictions which will limit countries’ abilities to use compulsory licenses as legal tools to ensure access to low-cost medicines.

Some or all of these provisions appear in concluded agreements such as the Central American Free Trade Agreement<sup>2</sup> (CAFTA), the US-Singapore Free Trade Agreement, the US-Chile Free Trade Agreement, the US-Morocco Free Trade Agreement and other agreements which have already been signed<sup>3</sup>. The provisions explained below are likely to reappear in trade agreements being negotiated with Thailand, Panama, the Andean countries (Bolivia, Colombia, Ecuador and Peru) and the countries of the Southern African Custom Union<sup>4</sup> (SACU).

## Patents and Drug Registration: Turning Drug Regulatory Authorities into Patent Police

The US has devised a new role for national drug regulatory authorities through negotiating provisions that require these NDRAs to act as “enforcers” of drug patents. They would be prevented from registering a generic version of a drug that is under patent in the country unless the patent holder gives consent – even if the generic has been proved to be of quality, safe and effective. Linking a drug’s registration (also known as its “marketing approval”) to its patent status is an underhanded way of preventing generic competition.

■ **At present:** A drug’s patent status and its registration status are two separate things. In principle, two different bodies look after the two

different areas of competency: patent offices assess whether a drug is innovative and novel enough to be patented, and NDRAs assess whether a drug is of quality, safe and effective enough to be used by the population they are responsible for.

When assessing whether a generic drug should be registered, a NDRA pays no attention to whether or not a patent may be infringed, as this is simply not their job – just as it is not the job of the patent office to assess the quality, safety and efficacy of a drug. It is up to the patent owner itself to sue an infringer before a court – a practice which ensures that the validity of a patent can be publicly questioned and held up to scrutiny before it is enforced.

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## TRIPS and Public Health: Derailing the Doha Declaration

The right of countries to protect public health is enshrined in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (or "TRIPS"), and was reinforced at the 4th WTO ministerial meeting in Doha, Qatar, in November 2001 in an historic declaration – the Ministerial Declaration on TRIPS and Public Health – which became known as the "Doha Declaration".

The Doha Declaration placed the protection of public health above the protection of private commercial interests, and in particular, confirmed the right of countries to use safeguards, such as compulsory licences, to overcome patents when necessary in order to protect public health and promote access to medicines for all.

However, the pharmaceutical industry in wealthy countries has refused to accept the primacy of health over commercial interests, as reconfirmed in the Doha Declaration. Under pressure from industry, wealthy countries, and the United States in particular, have been using bilateral and regional trade agreements to negotiate provisions which go beyond the WTO's TRIPS Agreement ("TRIPS-plus"), which undermine the Doha Declaration and which restrict, if not eliminate, the flexibilities and safeguards it reaffirmed.

■ **What the US wants:** The United States is seeking provisions that would prevent NDRA from registering a generic version of a drug that is under patent. Under these conditions, registration would not be granted to a generic manufacturer before the patent expires. If a drug is not registered, it cannot be legally used in a country.

■ **Likely impact:** These provisions amount to an outright ban on generic versions of patented medicines, by preventing their registration if there is a patent in force. The NDRA becomes the enforcer of a company's private patent rights.

This is of considerable advantage to the patent holder. Rather than the company having to sue through the courts to enforce its patent, the job is done behind the scenes and without publicity by the NDRA.

It is also more likely that patents that have been awarded improperly will be wrongfully enforced. The NDRA will be obliged to enforce a patent monopoly, even though it does not have the power of a court to judge whether a patent has been properly awarded or not.<sup>5</sup>

Further, the linking of patent status and drug registration could undermine the possible use of compulsory licences. A company given authority to produce a generic drug under compulsory license (ie. without the patent holder's consent) still needs to register that drug with the NDRA. But if the NDRA is not allowed to register generics until the patent expires, the compulsory license is effectively useless.

■ **Example:** 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 has learnt that the grounds for this refusal were that the NDRA had 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 blocking generic drugs on false patent grounds would become commonplace.

■ **TRIPS compatibility:** Nowhere in the WTO's Agreement on Trade-Related Intellectual Property Rights (or TRIPS Agreement) is there any reference to an obligation to link patent protection and drug registration. On the contrary, the preamble recognises that intellectual property rights are "private rights" – meaning that it is up to patent holders to enforce their rights, *not* NDRA.

■ **Sample Text:** *US-Chile Free Trade Agreement, Art. 17.10.2(c):*  
*With respect to pharmaceutical products that are subject to a patent, each Party shall:*

*(c) not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner.<sup>6</sup>*

## Data Exclusivity: Blocking competition to non-patented drugs

Even when a drug is not under patent, “data exclusivity” will create a new patent-like monopoly by blocking the registration of generic medicines. Data exclusivity prevents a national drug regulatory authority from using data provided by an originator company to authorise the use of an equivalent generic version of the same drug, thereby providing a *de facto* monopoly for the original manufacturer.

■ **At present:** To register a medicine with a NDRA, an applicant has to show that its medicine is safe, effective and of quality. It is the first applicant who must show clinical trial data to prove the drug’s safety and efficacy.

When generic manufacturers seek registration (or “marketing approval”) of generic versions of medicines, they only have to show that the drugs are of quality and therapeutically equivalent to the original version – in other words, they function the same way as the original medicine. The generic company does not have to submit new safety and efficacy data.

The NDRA can rely on the safety and efficacy data submitted by the originator producer to register the generic medicine. Under these conditions, the introduction of generics to the market is accelerated and facilitated.

■ **What the US wants:** The US is seeking to establish or expand “exclusive rights” over

pharmaceutical test data provided by originator companies to prevent an NDRA from using that data to register a therapeutically equivalent generic version of the drug. The exclusivity would last for a given period from the time the originator drug is first registered in the country (the US is usually seeking a period of five years). During this period, if another company wants to register a generic version of the drug, it would have to generate and submit its own test data.

Further, the US is even seeking in some agreements what could be described as “data exclusivity-plus”: if the original manufacturer has not registered the drug in the country, then the data exclusivity period would start running from the date of approval in the other country (ie. usually the United States).

If accepted, “data exclusivity” provisions apply regardless of whether a drug is patented or not.

■ **Likely impact:** These provisions will keep generic versions of drugs that have already been registered out of a country during the period of data exclusivity (ie. five years). The requirement for a company to generate its own test data will likely discourage generic manufacturers from seeking registration for their drugs. It may even make it impossible, especially for domestic firms in developing countries, given the costs of test data and low margins of generic production.

Photo: © Roger Job



The main effect of this provision will be on drugs which are not under patent, as the generic manufacturer will still be unable to use the originator's test data to obtain registration. In such an instance, data exclusivity acts as a *de facto* patent, preventing competition.

This impact is heightened if the data exclusivity applies from the date of approval in the US – as it means that a brand-name originator drug does not even have to be registered (and thus available) in the country for generic competitors to be blocked from entry. This could lead to a complete lack of availability of essential medicines (either generic *or* originator versions) if originator companies decide for whatever reason not to market a drug in a given country.

The requirement to re-test a drug already proven to be safe and effective is medically unethical, because it forces a number of patients to take part in clinical trials which are not necessary, and requires some to take placebos in order to compare outcomes with the actual drug and therefore forego a proven treatment. It will also increase the cost of the generic medicine.

Further, data exclusivity could effectively block compulsory licenses. Even if a company is given authority to produce a generic drug under a compulsory license, it still needs to register the drug with the NDRA. Data exclusivity would prevent such registration for the period of exclusivity, and thereby prevent the use of a compulsory license during that time.

■ **Example:** Suppose an essential drug is patented and registered in the US, but has not been patented in Honduras for one reason or another. There is therefore no patent barrier, and any generic manufacturer would be free to seek registration in the country. But if the originator company registers the drug in Honduras in 2004, the NDRA would not be able to use the original test data as the basis for registration – and would therefore not be able to allow a generic version onto the market before 2009.

Further, in the case of “data exclusivity plus”, even if the originator company was not interested in registering the product in Honduras, the generic manufacturers would still be effectively prevented from entering the Honduran market for five years from the date of the drug's US registration. Patients in Honduras would, in this situation, have no access to the drug – neither a generic, nor even the brand-name version.

*“I want to see my son grow, I want to see him go to school, I want to see him at his first communion, dance with him when he turns 18. These infants, they don't know what they have [HIV/AIDS], they have the right to keep living, they want to live.”*

Veronica, 30-year-old MSF patient from Lima, Peru, whose husband and son are also living with HIV/AIDS. All three are receiving antiretroviral treatment from MSF. Peru is presently negotiating a free trade agreement with other Andean countries and the United States.

■ **TRIPS compatibility:** Nowhere does TRIPS state that countries should provide *exclusive* rights to the originator of the data for a *given* period. Rather, TRIPS simply refers generally to the need to protect “undisclosed test or other data” from “unfair commercial use” and “disclosure” (Art. 39.3), without answering the question of how such protection should occur. The language in the TRIPS Agreement makes it clear that countries can determine what constitutes “unfair” and that there are multiple approaches that countries can take to satisfy this mandate. Indeed, during negotiations on the TRIPS Agreement, prior to 1994, negotiators rejected the option to include stronger “data exclusivity” provisions in the TRIPS Agreement, as originally proposed by the United States.

■ **Sample Text:** *US-Singapore Free Trade Agreement, Article 16.8:*

1. *If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical... product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product ...*

2. *If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of an approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for at least five years from the date of approval for a pharmaceutical product ... in the territory of the Party or in the other country, whichever is later.<sup>7</sup>*



## Extending Patent Life: Even Longer Monopolies

There is no more straight-forward way to extend a company's monopoly over a drug than to extend the life of the drug's patent – but the impact on patients' access to that drug could be dire.

■ **At present:** Patents on drugs in most countries last for 20 years from the date of filing. The originator company usually applies for a patent at the stage of basic research, well before the company even applies for drug registration. The process of drug registration usually takes two-three years. The process of patent granting can also take two-three years.

■ **What the US wants:** The United States is seeking to “compensate” drug companies for any “unreasonable” time a national drug regulatory authority takes to examine an application for registration, or a patent office takes to examine a patent application. The life of the patent would be extended by the length of “unreasonable” time the authority takes to approve the respective applications.

■ **Likely impact:** The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition. There would be considerable questions over what is considered “reasonable”, especially given the resource constraints on NDRAs and patent offices in developing countries.

■ **TRIPS compatibility:** Nowhere in the TRIPS Agreement is any reference made to an obligation to extend patent life to “compensate” for “unreasonable” delays in granting registration or patent approval. Indeed, countries rejected such proposals when originally negotiating the TRIPS Agreement.

■ **Sample Text:** *Central American Free Trade Agreement, Art. 15.9:*

*6. Each party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later...*

*Central American Free Trade Agreement, Art. 15.10:*

*2. With respect to any pharmaceutical product that is subject to a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.<sup>8</sup>*

## “New Use”: New ways to restrict access to medicines

Patents eventually run out – but not if companies are provided opportunities to perpetually renew their monopolies. One way to do so is through “new use” patents – where known substances can be patented all over again.

■ **At present:** Under the TRIPS Agreement, countries have an obligation to grant patents on pharmaceutical products and processes. But they have no obligation to grant patents on new uses of existing substances. Some countries (such as the Andean countries) have expressly excluded new use from their patent laws. Others reject this class of patent because they do not consider it “novel” or “new” – it’s the same product, but now we know more about it.

■ **What the US wants:** The United States wants to negotiate provisions which would allow companies to apply for a new patent for each demonstrable “new use” of a product. This would allow for patent protection to be greatly extended – for each new therapeutic use of a known compound, a company would be granted yet another 20-year monopoly.

■ **Likely impact:** “New use” is a way to prolong the monopoly companies enjoy through their patents on medicines. A new use of a known product for a killer disease could be found and monopolized. This means that companies will be able to charge artificially high prices for double (or more) the length of time they have already been granted for the same product.

Indeed, this practice can contribute to pharmaceutical companies’ deliberate strategy, well-known in developed countries, of prolonging (or “evergreening”) their monopolies. Patent holders could also use “new use” patents to harass competitors by arguing patent violation.

*“The situation for access to medicines in Guatemala is awful, it is terrible. Regarding HIV/AIDS, there are approximately 1500 people receiving antiretroviral treatment in Guatemala at present, MSF is treating almost one-third of them.*

*We buy quality generics. If there is any compromise on the possibility of buying such generics, then it will become almost impossible to treat HIV/AIDS patients in Guatemala. If only originator ‘brand-name’ drugs are available to treat HIV/AIDS, virtually no patients will receive treatment.”*

Luis Villa, MSF head of mission in Guatemala, which signed the Central American Free Trade Agreement with the United States in Dec 2003.

*“Thailand is beginning to scale-up the numbers of HIV/AIDS patients it treats with ARVs, and has a strong generic industry capable of producing these drugs. But what I’m afraid of, if this country signs an agreement with the United States and if it tightens up on patents, is that Thailand will no longer be able to produce low-cost drugs. If that happens, Thais with HIV are facing disaster, maybe not immediately, but certainly in the future.”*

Paul Cawthorne, MSF head of mission in Thailand, which is soon to commence negotiations on a free trade agreement with the United States.

“New use” patents can in no way be considered to be rewards for new invention, as nothing new has actually been invented. It is not uncommon for scientists and doctors to discover that an existing treatment can be used for a different disease. For instance, AZT was invented in the 1960s as an anti-cancer drug, and in the 1980s, it was discovered that AZT could also be used against AIDS.

■ **Example:** AZT’s 20-year patent (as an antiretroviral) is about to expire in 2005. Suppose scientists discovered that AZT could also be used against another killer disease. If the Andean countries agree to “new use” patents in the coming FTA negotiations with the US, they would need to change their legislation and abandon their current pro-public health policy. As a result, they wouldn’t be able to benefit straight away from AZT generic prices for this disease but would have to wait another 20 years.

■ **TRIPS compatibility:** The TRIPS Agreement gives no guidance in the matter of “new use” patents as it only requires WTO Members to grant patents for products and processes, thereby leaving Members free to determine their own approach. Although TRIPS does not specify any exception to new uses for known substances, TRIPS does not require the grant of such patents either. As a general rule for developing countries, the fewer patents granted on medicines, the better, so that generic versions can be used without delay.

■ **Sample Text:** *US-Morocco Free Trade Agreement, Art. 15.9.2:*

*In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals.*

## Compulsory Licences: Safeguards Under Threat

The United States is seeking to restrict the scope of “compulsory licences”, a key legal means governments have to ensure access to low-cost versions of patented medicines.

■ **At present:** A compulsory license allows the production or importation of a generic medicine without the consent of the patent holder who, nevertheless, receives adequate compensation.

Compulsory licences may be issued by governments for various reasons, including, but not limited to, addressing public health or other types of emergencies. Compulsory licences are considered a standard feature of effective intellectual property rights legislation.

■ **What the US wants:** The US is seeking dramatic limitations on the circumstances under which compulsory licences on pharmaceuticals may be issued. Proposals include limiting compulsory licences to declared “national emergencies” or other situations of extreme urgency, the redress of practices determined to be “anti-competitive” and use in the public sector only.

As noted earlier, the US has also sought less direct ways to restrict compulsory licences. “Data exclusivity” and creating a patent enforcement role for NDRA could both undermine compulsory licences – by restricting generic medicines through the drug registration system, rather than through the patent system.

■ **Likely impact:** Compulsory licences are a legal instrument to overcome patent barriers. Restrictions on them would mean that countries would no longer be able to exercise their inherent right to issue a compulsory license to remedy high prices<sup>9</sup> that restrict access to medicines and to foster competition in the private sector to increase access to essential medicines.

Governments would still be able to issue compulsory licences for public non-commercial use, and in emergencies, but the option to use such licences to promote private sector competition would be closed.

This will have an especially dire impact after 2005, when the TRIPS Agreement specifies that all countries that are Members of the WTO (except least developed countries) must provide patents for pharmaceutical products and processes. For drugs patented after this date, generic production during the life of the patent will rely entirely upon

compulsory licences, meaning that flexible conditions for granting compulsory licenses must be in place in order to allow countries the ability to speed the supply of affordable generic medicines in both the public and private sector.

■ **Example:** In South Africa, the private sector is the major provider of medicines. Presently, the antibiotic azithromycin sells on the private market in South Africa for US\$18.42 per 500mg tablet. Generic versions of the drug already exist – for example, in western Africa, MSF uses versions costing only US\$0.20 per 250mg capsule or US\$0.40 for 500mg. Suppose South Africa agreed to restrictions on compulsory licences in the Southern African Customs Union agreement with the US. This would mean that no generic manufacturer of azithromycin could receive a compulsory license to market a more affordable version of the drug in the private sector. Patients would still be required to pay the more expensive price (or do without the drug).

■ **TRIPS compatibility:** Compulsory licences are explicitly permitted under the TRIPS Agreement. The TRIPS Agreement includes no restrictions on the conditions for their use. The Doha Declaration on TRIPS and Public Health, adopted by all WTO Members in 2001, confirmed that countries have “the freedom to determine the grounds upon which such licences are granted”.<sup>10</sup> Indeed, negotiators explicitly rejected attempts to restrict the terms of compulsory licences during the initial drafting of the TRIPS Agreement.

*“It has been a long battle to bring prices down, to get ARVs produced locally here and to bring about the government’s u-turn on antiretroviral treatment. This was all achieved because of the availability of generic medicines. With this free trade agreement, we’re afraid now that it could be back to square one, that all our efforts could be destroyed if it closes the gates for generic competition.”*

Eric Goemaere, MSF head of mission in South Africa, which is part of the Southern African Customs Union, presently in negotiations on a free trade agreement between the United States.

■ **Sample text:** *US-Singapore Free Trade Agreement, Art. 16.7.6:*

*Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:*

*(a) to remedy a practice determined after judicial or administrative process to be anticompetitive under the competition laws of the Party;*

*(b) in the case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that:*

*(i) such use is limited to use by the government or third parties authorized by the government;*

*(ii) the patent owner is provided with reasonable and entire compensation for such use and manufacture; and*

*(iii) the Party shall not require the patent owner to transfer undisclosed information or technical “know how” related to a patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph.*

*Where a Party’s law allows for such use pursuant to subparagraphs (a) and (b), the Party shall respect the provisions of Article 31 of the TRIPS Agreement.”*

## Conclusion: Keep Intellectual Property Rights Out of Trade Agreements

**MSF wants to send a warning to countries negotiating trade agreements with the United States: the devil is in the details.**

Within the details of these agreements are provisions that will dramatically reduce the ability of countries to provide low-cost quality medicines for their citizens.

In several cases, these trade agreements introduce provisions which go way beyond the WTO TRIPS Agreement and which indeed countries had rejected during negotiations on that agreement. These provisions also contradict the spirit of the 2001 Doha Declaration on TRIPS and Public Health by placing commercial interests before public health. Having not achieved its aims in the WTO, the US is trying again in these bilateral and regional agreements.

These provisions will extend the exclusive marketing position pharmaceutical firms have in the medicines market. They will undermine the capacity to lower prices, by restricting the entry of generic competitors. And they will turn national drug regulatory authorities, whose job is to ensure the safety, quality and efficacy of medicines, into enforcers of the private property rights of corporations.

MSF urges governments to exclude intellectual property provisions from bilateral and regional trade agreements altogether – the TRIPS Agreement is already more than enough. Health should not be under negotiation in these talks.

This is the only way to ensure that governments can uphold their right – and obligation – to protect public health and guarantee access to essential medicines for their people.

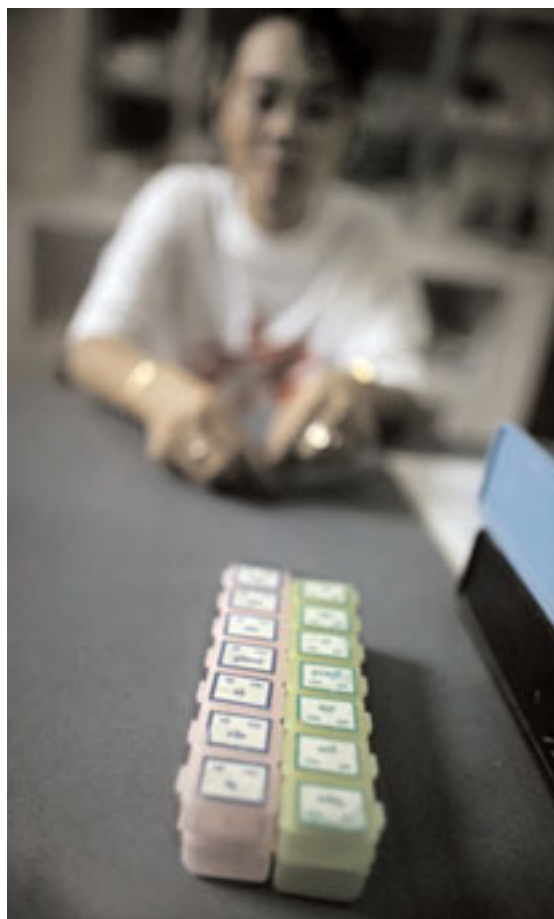


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## Countries signing agreements with the US





<sup>1</sup> "The US-Central American Free Trade Agreement: The Intellectual Property Provisions", Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3)

<http://www.ustr.gov/new/fta/Cafta/advisor/ifac03.pdf>

<sup>2</sup> CAFTA originally included Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua, but the Dominican Republic agreed in March 2004 to sign on to CAFTA as well.

<sup>3</sup> NAFTA (US, Canada, Mexico) as well as several bilateral investment agreements with the US.

<sup>4</sup> SACU includes Botswana, Lesotho, Namibia, South Africa and Swaziland.

<sup>5</sup> NDRAs could also enforce patents in other ways which could threaten public health: for example, a patent on a salt or a polymorph of a given product may also be used to block registration even if the active ingredient is off-patent.

<sup>6</sup> There are similar clauses in the US-Singapore Free Trade Agreement (Art. 16.8.4(c)),

US-Morocco Free Trade Agreement (Art. 15.10.4.(a)) and in the Central American Free Trade Agreement (Art. 15.10.3(a)).

<sup>7</sup> There are similar clauses in the Central American Free Trade Agreement (Art. 15.10.1(a)), US-Morocco Free Trade Agreement (Art. 15.10.1) and the US-Chile Free Trade Agreement (Art. 17.10.1).

<sup>8</sup> There are similar clauses in the US-Morocco Free Trade Agreement (Art. 15.9.7, Art. 15.10.3).

<sup>9</sup> Unless under mechanisms to prevent anti-competitive behaviour, mechanisms which are weak or non-existent in most developing countries.

<sup>10</sup> Paragraph 5.(b) of the Declaration says that "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

<sup>11</sup> There are similar clauses in the US-Jordan Free Trade Agreement (Art. 20).



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**MSF is an international medical humanitarian organisation providing assistance through over 500 medical relief programs in 80 countries worldwide. MSF was awarded the 1999 Nobel Peace Prize.**



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