EUROPE! Hands Off Our Medicine

Millions of people in developing countries rely on affordable generic medicines produced in countries like India to stay alive. But the European Commission is pushing aggressive policies that will severely restrict people's access to these life-saving medicines. The attack is taking a number of different forms – free trade agreements, international treaties, customs regulations. If Europe succeeds, millions of people across the developing world could see their source of affordable medicines dry up, as generic companies will no longer have the space to produce or sell them.

"Europe! Hands Off Our Medicine" is Médecins Sans Frontières' campaign to push Europe to back down.

"We depend on access to affordable generic medicines like those produced in India to treat all kinds of diseases. We buy 80% of our AIDS medicines from India - medicines that keep 160,000 people alive today," said Dr. Unni Karunakara, President of MSF's International Council. "On their behalf, we cannot remain silent as Europe works to close the door on every aspect of drug supply – the production of a generic medicine, its registration, and its transportation to patients in other parts of the world. So today we are launching a campaign demanding 'Europe! HANDS OFF our medicine."

"What the Europeans are doing is effectively snatching the medicines out of our hands," said Dr. Marius Müller, MSF's Medical Coordinator in Kenya. "Because generic medicines are more affordable, we have been able to put more and more patients on AIDS medicines. This has meant a lot of hope for our patients who can work again, who can bring up their children again. But if Europe has its way and shuts off this source, we risk killing the success of what has been achieved here in the last five years."

I – BACKGROUND: Patents, generics, and access to medicines

India: The 'pharmacy of the developing world'

When a drug company holds a patent on a medicine, it can prevent other companies from producing or selling the drug in a country for the duration of the patent's term, usually 20 years. This allows the company to charge high prices in countries where it holds patents, because there are no competitors in the market, and drugs remain unaffordable for longer. Competition among multiple producers is the tried and tested way to bring the price of medicines down – it's what helped pushed the cost of AIDS treatment down by more than 99% from US$10,000 per patient per year in 2000 to under $70 per patient per year today.[1]

Until recently, India did not grant patents on medicines, so local companies could forge ahead and produce identical quality drugs to the original product, but at heavily reduced prices. As a result, these generic drugs manufactured in India are among the most affordable in the world. By producing and exporting cheaper generic versions of drugs that were patented in other countries, India became a key source of affordable essential medicines, such as antiretroviral medicines to treat HIV/AIDS. India is in effect the 'pharmacy of the developing world.'

[1] See Médecins Sans Frontières' analysis of access to AIDS medicines, *Untangling the Web of ARV prices*, available at: http://utw.msfaccess.org/background/aids_progress_under_siege

More than 80% of the medicines MSF uses to treat its more than 160,000 patients on AIDS treatment come from generic producers in India. A study[2] published in September 2010 in the *Journal of the International AIDS Society* reviewed 17,000 donor-funded purchases of AIDS medicines made by 115 low- and middle-income countries between 2003 and 2008, and found that more than 80% of these came from India. The proportion of AIDS medicines produced by Indian manufacturers is even higher – up to 90% - with certain important medical needs such as paediatric medicines to treat HIV in children.

Accessing affordable medicines from India is a lifeline for all developing countries – but this situation is now under attack, and the European Commission is playing a leading role in these attacks.

The treatment time bomb

As a World Trade Organization member, India has to comply with the trade rules set by the WTO. These rules include minimal levels of intellectual property (IP) protection such as patents and trademarks. The central agreement is the Agreement on Trade-related Aspects of Intellectual Property, or TRIPS, which obliges WTO countries to grant patents on technological products, including pharmaceuticals. To comply with TRIPS, India changed its patent law in 2005 and started to grant patents on medicines. As a result, if patents are granted in the country, Indian generic manufacturers will not be able to produce cheaper generic versions of these medicines, which will have an impact not only in India, but also on other countries that rely on importing generic medicines from India in order to treat their populations.

HIV/AIDS is a life-long disease and people require access to newer medicine combinations when side effects or drug resistance develops over time. Some of the newer AIDS medicines such as raltegravir and etravirine have already been patented in India, blocking the generic competition that led to the deep price drops with the first generation of AIDS drugs. With growing numbers of people in urgent need of treatment, this is effectively a treatment time bomb waiting to explode.

Access to medicines will therefore increasingly depend on the use of what are known as 'TRIPS flexibilities' – legal measures enshrined in countries' laws to promote access to more affordable medicines. For example, when India's Parliament was designing its patent law, it ensured that a certain amount of safeguards were included to limit abusive patenting practices by pharmaceutical companies. Another TRIPS flexibility is allows governments to overcome patents when they stand in the way of access to medicines is the issue of a compulsory licence which authorises a third party to produce, import or export a drug, despite the patent. Thailand for example issued a compulsory licence on a patented AIDS medicine in 2006, as the original product was too expensive, opening the way for domestic production of the drug.

But the effectiveness of these types of flexibilities is now threatened by the EC.

2 – The European Commission's multiple attacks on access to medicines

The attacks of the EC on access to medicines are taking multiple forms – customs regulations that block trade in generic drugs, bilateral free trade agreements, and the international anti-counterfeiting trade agreement or ACTA.

In pursuing these trade policies, the EC is acting in violation of its previous commitments. In 2001, all WTO countries – including European Union member states - signed the Doha Declaration, which

[2] http://www.jiasociety.org/content/13/1/35

states "that the [TRIPS] 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." This Declaration allows countries to take measures to protect public health. The EC repeatedly says it's acting in accordance with the Doha Declaration – but at the same time pursues aggressive policies that threaten to shut down access to affordable medicines across the world.

Customs regulations and the detention of generic medicines

European governments have hindered the flow of legitimate generic medicines by detaining shipments of drugs destined for patients in developing countries as these medicines were transiting through the EU. The EU took these steps on the basis of EC customs regulations that concern violations of patents or trademarks.

Cynically, the EC has tried to justify these detentions on the grounds of public safety, stating that these rules are needed to combat fake medicines. While fake medicines are indeed a public health threat, these rules have in fact been used to hamper the transit, storage and export of legitimate generic medicines for people living in developing countries. These detentions can lead to significant delays in the delivery of medicines, or even stock outs, for patients who in many cases rely on these drugs to stay alive.

Free trade agreements

Through bilateral trade agreements, the EC is seeking to get countries to agree to higher standards of intellectual property (IP) protection and enforcement than even the TRIPS agreement requires. EC trade negotiators remain staunchly in favour of expanding the IP system and the rights and benefits of IP holders at the expense of access to medicines for millions of people in developing countries.

In addition, these trade policies undermine the EU and member states' own efforts to increase access to medicines to people living in developing countries, as they purchase key medicines for people living with HIV/AIDS from India via bilateral or multilateral financing mechanisms.

The EC is currently negotiating such free trade agreements (FTAs) with several developing countries, including India, Brazil, Thailand and the Philippines. Of these, the most concerning is the one being negotiated with India, given the developing world's dependence on the country's generic manufacturing capacity. Negotiations for a bilateral trade agreement between the European Commission and India are now entering their final round and are set to conclude in late 2010. The FTA is expected to be completed in time for the India-EU Summit in December 2010.

Earlier this year, MSF raised concerns with EC Trade Commissioner Karel De Gucht and urged the EC not to push for measures in the EU-India FTA that will affect access to affordable medicines in developing countries. The EC responded by stating that certain provisions – such as patent term extensions which prolong the life of a patent and keep drugs unaffordable for longer - will not be included in the FTA. Later versions of the text seem to confirm this point. The EC also stressed that while they will continue to pursue other provisions, these will not hinder access to affordable generics. But contrary to the EC's claims, these measures will have a significant negative impact on access to medicines. MSF cannot afford to stay silent as the EC seeks to close off access to affordable medicines in the developing world.

The secret treaty – ACTA

Rich countries, including those in the EU, have been using a secret treaty to aggressively champion heightened intellectual property enforcement measures that will have a detrimental impact on access to medicines. The anti-counterfeiting trade agreement (ACTA) negotiations are reportedly

nearing finalisation after more than two years.[3] Early non-official indications are that the EC has not succeeded in imposing many of its problematic clauses it was pursuing, but the vast majority of these provisions are the same ones the EC is seeking to get India to agree to in the FTA. In other words, the EC is now effectively trying to push terms on a developing country that may have been deemed too intrusive or onerous for rich countries negotiating ACTA.

Most developing countries are not part of this negotiation, but the EC and others have made it clear that they intend to put pressure on these countries to sign up to this non-negotiated agreement once it is completed. The danger of ACTA becoming the new global standards is therefore very real.

The potential consequences for access to medicines are considerable – the positions taken by the EC could ultimately limit considerably the manufacture, distribution and availability of affordable generic medicines across the developing world.

While there have been attempts to justify ACTA as a way to deal with the hazard of fake medicines, ACTA has nothing to do with improving the quality of medicines used in developing countries at all. Its purpose is to protect private commercial interests, such as those of pharmaceutical companies. In fact, because ACTA jeopardizes access to low-cost, quality generic medicines, it may lead to a shortage of affordable medicines, which itself usually leads to increased illegal trade in spurious and fake medicines.

This treaty aims to create a global enforcement regime for intellectual property rights. This is in direct challenge to the fact that patent and trademark rights are not global and differ from country to country. Developing countries have the right to design their intellectual property laws in a way that takes their public health needs into account – India's patent law, for example, restricts abusive patenting in an effort to balance the need to protect intellectual property with the need to protect public health. But ACTA would heighten intellectual property standards across the board.

The European Commission has been aggressively pushing the agenda at these negotiations, targeting intellectual property in the area of pharmaceuticals. It takes the worst of the EC rules, such as the customs regulations and those it seeks to impose in India via the FTA, and attempts to transform this into a global agreement.

ACTA does not include protections for patients, or safeguards to prevent abuse. ACTA would limit competition, thus increasing the cost of medicines, because of its deterrents for generic manufacturing and export. But very little in ACTA recognizes the need to protect the public.

3 - How the EC's actions are harming access to medicines

1. By preventing the flow of generic medicines from producer to patient: the detentions
Since 2008, there have been multiple incidents of legitimate generic medicines being detained on the basis of EC customs regulations:

- Dutch customs authorities detained a shipment of an active pharmaceutical ingredient (losartan potassium) necessary to make a generic medicine to treat high blood pressure. The medicine was transiting from its producers in India to Brazil via the Netherlands in December 2008. The drug is neither patented in India nor Brazil, but the customs raids were carried out nonetheless, on the basis that the drugs were under patent in the country of transit – the

[3] Official negotiations for ACTA began in June 2008. Key negotiating parties are from developed countries and currently include Japan, the US, the EC, Switzerland, Canada, Australia, Mexico, Morocco, New Zealand, South Korea, and Singapore.

Netherlands. The shipment was eventually returned to India, and according to the Brazilian government, 300,000 patients in Brazil were awaiting treatment with the detained medicines.

- In November 2008, a shipment of an AIDS medicines purchased by UNITAID for use in Nigeria was seized in transit through the Netherlands. UNITAID is an initiative funded in part by EU governments (UK, France) and these actions are undermining the EU's contribution to help provide AIDS treatment in affected countries.
- The Dutch government further revealed in April 2009 that customs authorities had conducted 17 seizures in 2008 of medicines bound for Brazil, Peru, Colombia, Ecuador, Mexico, Portugal, Spain and Nigeria. The drugs were for the treatment of diseases such as cardiac ailments, AIDS, dementia and schizophrenia.
- In 2009, generic antibiotics were seized at the Frankfurt airport by German authorities on the misguided assumption of trademark infringement.

Customs officials justify these detentions as they are authorised under EC regulations that allow intellectual property rights holders to petition customs officials to act "when goods are suspected of infringing an intellectual property right".[4]

Given its geographical position and transportation infrastructure, the EU is an important transit hub for the international trade in medicines. However, continued detentions of legitimate generic medicine shipments will force generic companies to seek out alternative transport routes that may increase costs substantially. This could in turn hamper the supply of generic medicines to developing countries, as well as to humanitarian organisations such as MSF.

MSF's own medicine procurement activities may be affected by the EU customs authorities' use of the EC Customs Regulations 2003. MSF often transits and stores drugs in Europe in readiness for a rapid response to humanitarian crises as well as to ensure regular supply to its projects. Any question mark over the legality of this process could seriously impair our ability to provide humanitarian medical aid in developing countries.

The Indian government has since decided to take this dispute to the World Trade Organization and has been joined by a number of other countries, including Brazil. To date, India and the EU have held two rounds of consultations in Geneva, the latest of which in September 2010 failed to resolve the dispute. India and Brazil are expected to press ahead with a request for the establishment of a WTO dispute settlement panel.

While the EC now states it will no longer detain drugs in transit if they do not violate patents in production or destination country, this remains to be seen, and the EC customs regulations remain in place, unchanged. In addition, the EC is now seeking through the EU-India FTA and ACTA to encourage other countries to adopt similar rules that would allow border guards these kinds of powers.

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[4] EC regulation No. 1383/2003

ACTA has not limited the text to wilful infringement so all trademark disputes are covered, which is a direct threat for access to medicines. ACTA also applies the law of the transit country rather than the importing country where the laws could be different.

Border measures for both patents and trademarks remain in the EU-India FTA.

2. By preventing the registration of generic medicines: data exclusivity

Today, a generic medicine can be registered and put on the market in a country provided the manufacturer shows that its drug is equivalent to an existing medicine in terms of its chemistry and bio-availability (the amount of a drug that is actually absorbed into a patient's bloodstream). There is no requirement for the generic company to conduct lengthy clinical trials to establish that it is safe and effective – relying on the original clinical trial data is sufficient for the drug regulatory authority to grant marketing approval.

But the EC now wants this situation to change in India, and is seeking through the FTA to convince the country to introduce so-called 'data exclusivity,' which refers to a period of time (usually five to nine years) during which a country's drug regulatory authority is prohibited from relying on existing clinical trial data in order to register a generic medicine.

This would mean that if a generic company wanted to market a medicine in India, it would have two options: either to wait until the period of data exclusivity has expired, which means drugs will stay unaffordable for longer, or generate its own clinical trial data to register a medicine, which would impose huge costs. Given that the generic manufacturing model relies on low profit margins, the second option is unlikely to be viable. Additionally, repeating clinical trials for medicines already proven effective is not ethical, as it means denying treatment known to be safe and effective from some patients (the control group), solely for the purpose of proving something that is already known. Therefore, data exclusivity would have the practical effect of generic companies simply abandoning their ambition to market more affordable medicines, essentially shutting off the tap of affordable medicines from India.

The TRIPS agreement does not require data exclusivity, it only refers to data protection. This is very different and does not mean that countries have to stop using data for marketing approval.

What the European Commission is asking for therefore goes far beyond the practice in other countries. In seeking to go beyond what the TRIPS agreement requires, **the EC is ignoring the negative impact on public health with the sole purpose of pursuing its own pharmaceutical industry's interests: shutting down competition from developing country manufacturers**. A study by Health Action International on the effects of data exclusivity in the EU-Andean free trade agreement showed that the effect on Colombia alone of the introduction of a ten-year period of test data exclusivity would lead to an increase in expenditure of US$340 million on medicines by 2030.[5]

If accepted by India, data exclusivity provisions will apply to all drugs – regardless of whether they are patented or not, essentially creating a new patent-like monopoly by blocking the registration of generic medicines. Competition would be stifled even on older drugs which are not under patent and on new drugs which have been found not to merit patent protection.

The case of nevirapine syrup provides an illustration of the impact of data exclusivity. This medication designed to treat AIDS in children was not granted a patent by the Indian patent office, meaning that generics could immediately begin producing it and exporting it all over the developing

[5] Oxfam and Health Action International – October 2009 – Trading away access to medicines. How the European Union's trade agenda has taken a wrong turn.

world. Had data exclusivity been in place in India, those waiting for the medicine in developing countries would have had to wait a number of extra years, until the expiry of the data exclusivity, before medicines could be produced and exported.

Additionally, data exclusivity could effectively block compulsory licences, one of the crucial public health safeguards in the TRIPS agreement. Even if the Indian government decided that a compulsory licence were necessary and authorised a company to produce a generic version of a patented drug under a compulsory license, the company would still need to register the drug with India's drug regulatory authority in order to market it in India or export it to the rest of the developing world. Data exclusivity here would essentially block one of the lifelines that developing countries have come to rely on.

3. By preventing the production of generic medicines: intellectual property enforcement

The intellectual property enforcement agenda driven by the EC promotes new standards that will require increased surveillance of goods and more intrusive police powers for government officials, without adequate safeguards to protect public health. It aims to substantially increase the penalties for people alleged to have infringed patents and trademarks. It is also an attempt to govern the way the disputes around patents and civil trademark infringements will be managed by the courts. If India signs up to these clauses, the Indian judiciary will have its hands tied and will no longer be able to balance IP rights with the right to health of patients.

Enforcement provisions exist in either the India-EU FTA negotiations or ACTA, or both, and include the following range of measures:

a. Border Measures

The EC has advocated for a provision that would allow for the detention and seizure of goods that infringe a patent and civil trademark. This means the "Dutch seizures" that delayed the transfer of legitimate generic medicines to developing countries could be repeated over and over again. The EU-India FTA and ACTA would increase the ability of customs officials to seize goods, including for goods in transit from one developing country to another. If accepted and implemented, this will increase border searches and interfere with cross-border transit of legitimate generic medicines.

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Border measures for both patents and trademarks remain in the EU-India FTA however.

b. Patent and civil trademark disputes

The definition of 'counterfeit' according to the TRIPS Agreement is targeted at a wilful trademark counterfeiting on a commercial scale. Wilful trademark counterfeiting is a form of fraud in which there is deliberate intention to exactly copy the branding of a product. In the case of medicines,

this means a deliberate intention to deceive patients and treatment providers by seeking to produce an exact copy of a pill (shape & colour), medicine packaging or logo.

Yet the EC is seeking to introduce a completely separate category, that of civil trademark disputes, into the EU-India FTA and ACTA. Civil trademark disputes occur where one company accuses a competitor of having a trademark or packaging too similar to its own trademark. This has nothing to do with a deliberate intention to deceive with a fake medicine, and must be distinguished from the fight against counterfeit medicines. Civil trademark disputes will likely remain a common occurrence in the pharmaceutical field as companies will often choose brand names for medicines that sound inevitably similar, in that they are derived from the drug's international non-proprietary name (INN).

Yet the EC is seeking to blur this distinction, by including patent infringements and civil trademark infringement disputes in the definition of counterfeits for the purpose of targeting legitimate generic competition/production. There is no place for patents or civil trademark infringement in a genuine anti-counterfeiting treaty.

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Newly-released ACTA text is not finalised for this section, as the U.S. is trying to limit the scope of this provision to 'wilful trademark' infringements, against the wishes of the EC, which is pushing for the more hard-line measures described above.

Although there will not be another round of formal negotiations, this issue is due to be resolved by informal e-mail discussions. This is likely to be finalised very quickly. However, the ACTA text will have to go before the European Parliament, so it is important that pressure is maintained to try to amend the remaining problematic clauses.

The question of patent and trademark disputes remains a threat in the EU-India FTA.

c. Undermining the role of the judiciary in protecting the right to health

When a patent-owning pharmaceutical company decides that a generic company is producing a medicine in violation of its patent rights, it can ask a court for an order, known as an injunction, requiring the generic company to stop making the medicine.

Many countries however place the right to health and access to medicines above private intellectual property rights. For example courts in India distinguish the case of life-saving drugs from other cases of intellectual property rights infringement where injunctions are routinely granted. The Delhi High Court observed that in the case of pharmaceutical products, courts have to tread with care and ensure there is no violation of the Indian Constitution's guarantee to the right to life.[6]

This flexibility is recognized in the TRIPS Agreement – which recognises for example that a court may oblige the company that is infringing the patent to pay compensation to the patent-owner, rather than having to cease production or distribution of the medicines.[7] But ACTA, like the FTA, would require injunctions even at the early stage of an infringement challenge – and in some

[6] F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Limited, I.A 642/2008 IN CS (OS) 89/2008, Delhi High Court, Order dated 19 March 2008

[7] TRIPS Art. 44.

cases calls for the destruction of infringing goods. In practical terms, this could mean effective and safe medicines are stopped from being produced or are destroyed in order to protect company profits.

The EU-India FTA and ACTA not only undermine judicial discretion to prioritize the right to health, and also adds to the burdens of generic manufacturers and distributors.

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Newly-released ACTA text has been changed to allow some judicial discretion if national laws allow it. But it is not yet clear if this is wide enough to allow sufficient discretion in all cases. Importantly this section still applies to patents, although the US is trying to limit to wilful trademarks. The EC is pushing for both patents and trademarks to be included.

Although there will not be another round of formal negotiations, this issue is due to be resolved by informal e-mail discussions. This is likely to be finalised very quickly. However, the ACTA text will have to go before the European Parliament, so it is important that pressure is maintained to try to amend the remaining problematic clauses.

The role of the judiciary remains under threat in the EU-India FTA.

d. Excessive punishment for intellectual property infringement
ACTA requires high penalties for alleged infringers – including injunctions, damages, and criminal sanctions. Generic suppliers or public health authorities inadvertently infringing a patent may therefore face bankruptcy or even criminal proceedings. This goes beyond what is required under TRIPS, which does not require countries to provide for criminal sanctions in case of patent infringement and in the case of trademarks limits criminal procedures to wilful trademark counterfeiting. It also goes beyond the EC's own laws which do not apply criminal sanctions to patent infringements, as it was recognised that these are such complex cases that they require civil judicial review. But if EC has its way in ACTA negotiations, criminal sanctions will be applied across the board.

The punishment is excessive and acts as a deterrent to the production and sale of generic medicines.

ACTA would also put third parties at risk of severe penalties for an alleged infringement. This could implicate, for example, suppliers of active pharmaceutical ingredients used for producing generic medicines; distributors and retailers who stock generic medicines; NGOs who provide treatment. This could act as a massive deterrent to anyone involved in the production, sale and distribution of affordable generic medicines.

STOP PRESS:
Newly-released ACTA text has limited criminal sections to wilful trademark infringements and does not apply them to patent infringements. This is welcome. But inadvertent infringement of patents or trademarks will still attract large civil damages and third parties are still at risk of civil damages.

However, the ACTA text will have to go before the European Parliament, so it is important that pressure is maintained to try to amend the remaining problematic clauses.

4. By preventing the production of generic medicines: Investment provisions that include intellectual property

In recent years, 'investment rules', provisions that govern the way foreign investment can be done and is protected in a country, have increasingly been adopted as part of bilateral trade agreements. The investment chapter of the draft text of the EU-India free trade agreement is no exception. In the draft, the definition of investment is extended to include intellectual property. The purpose of such a move is to allow foreign investors to take a government to court over disputes concerning intellectual property.

If accepted by India, multinational drug companies would then have the right to sue the Indian government in a bid to stop the government from taking actions like compulsory licensing, or setting price controls or regulations. This means that a government's authorisation of a compulsory licence, although it is perfectly legal under the international trade rules as set out by the TRIPS Agreement, would attract potential claims of expropriation against the government.

A clear example of how companies can use a bilateral investment treaty to challenge government decisions related to public health on grounds of IP infringement exists. In February 2010, Philip Morris filed a case against Uruguay under a Switzerland - Uruguay Bilateral Investment Treaty in order to challenge Uruguay's decision to increase the size of warning labels on cigarette packets. Philip Morris argues that these measures infringe on their trademarks and hamper their competitiveness in the Uruguayan market.[8]

It is critical to remove intellectual property from the definition of investment so that public health measures such as a compulsory licence or the refusal to provide data exclusivity, cannot be linked to either the definition of 'investment' or be the subject of legal challenges by companies.

5. By preventing the production of generic medicines: Patent term extensions

There is no more straightforward way to extend a company's monopoly on a drug than to extend the life of the drug's patent. At present, patents on drugs in most countries last for 20 years from the date of filing. Through the EU-India FTA, the EC wants the life of the patent to be extended by the length of time the drug regulatory authority takes to examine an application for registration, or a patent office takes to examine a patent application. (This extension would be limited to a maximum of 5 years) 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 competitors. In the case of the EU-India FTA, the EC has already stated publicly that it will likely drop that demand. However, it is still not definite that they will follow through.

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Against the background of continued problems of millions lacking access to medicines because of high drug prices, falling donor commitments to health, and the real danger of not meeting the Millennium Development Goals, the EC's focus on intellectual property enforcement is hypocritical and immoral. It will deepen global health inequity, and exacerbate the problems that millions of people, in MSF projects and beyond, face in accessing to life-saving medicines.

[8] http://www.bilaterals.org/spip.php?article16921