Original Article

The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries

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ABSTRACT The availability of affordable generic medicines has been critical to expanding access to treatment for HIV/AIDS and other diseases in developing countries. In recent years, access to generics has come under threat by the global enforcement of minimum standards

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for intellectual property protection as determined by the World Trade Organization, together with additional policy measures promoted by the European Commission and others. Data exclusivity, border control measures, counterfeit legislation, the undermining of judicial process and patent term extensions all threaten to limit the ability of developing countries to access affordable medicines. The potential harm caused by these policies is magnified by the fact that the global economic crisis is resulting in shortfalls of donor funding to fight HIV/AIDS and other infectious diseases.

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INTRODUCTION

The AIDS crisis has highlighted the critical importance of generic medicines to provide access to essential medicines. Ten years ago, the cost of antiretroviral medication to treat HIV/AIDS was over US$10 000 per patient per year, and policy makers and academics argued that treating AIDS in resource-limited settings was not cost-effective.[1,2] Price decreases from generic competition and a fixed-dose combination only available from generic manufacturers were key factors to allow worldwide treatment expansion in developing countries: today those same medicines are available for under $100 per patient per year, and over five million people have been started on antiretroviral treatment.[3,4]

Generic manufacturing has in recent years been restricted by the global enforcement of minimum standards for protection of intellectual property (IP) as set by the World Trade Organizations Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[5] In addition, there have been various efforts by industrialized countries and multinational pharmaceutical companies to seek higher intellectual property protection than provided by the TRIPS Agreement.[6]

In this article we provide an overview of the negative impact of the European Commission's (EC) customs regulation on access to affordable medicines for developing countries and the EC's attempt to obtain increased monopoly protection and IP enforcement through an EU-India Free-Trade Agreement (FTA) and the Anti-Counterfeit Trade Agreement (ACTA). At the time of writing, negotiations on the former agreement were well advanced[7] and expected to be finalized in the early months of 2011. The finalized text of ACTA was released in December 2010, and ratification in participating countries able to proceed from 2011 onwards.[8]

PREVENTING THE FLOW OF GENERIC MEDICINES FROM PRODUCER TO PATIENT: THE DETENTIONS

Since 2008, there have been multiple cases of legitimate generic medicines being detained on the basis of EC customs regulations. In December 2008, 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. The drug is neither patented in India nor Brazil, but the customs seizures were carried out on the basis that the drugs were under patent in the country of transit (the Netherlands). The shipment was eventually returned to India. According to the Brazilian government, 300 000 patients in Brazil were awaiting treatment with the detained medicines.

The full extent of the problem became clear in April 2009, when the Dutch government revealed 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 disease, HIV/AIDS, dementia and schizophrenia.

In some instances, detentions have resulted in the blocking of medicine supplies purchased by funds from other EU countries. 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 (United Kingdom, France) and these actions are undermining the EU's contribution to help provide AIDS treatment in affected countries.

Other countries have taken similar steps. In 2009, the German authorities seized a shipment of generic amoxicillin at Frankfurt airport on the misguided assumption of trademark infringement of GlaxoSmithKline's brand Amoxil.

Customs officials justify these detentions as they are authorized under EC Customs regulations that allow intellectual property rights holders to petition customs officials to act 'when goods are suspected of infringing an intellectual property right' even if they are in transit and not destined for the European market.[9]

Given its geographical position and transportation infrastructure, the EU is an important transit hub for the international trade in medicines. However, the continued threat of detentions of legitimate generic medicine shipments will force generic companies to seek out alternative transport routes that may increase costs and delay supply.

The Indian government has taken this issue to the World Trade Organization (WTO) and has been joined by a number of other countries, including Brazil. India and the EU have held several rounds of consultations. In December 2010, during a European Union–India summit in Brussels, European Trade Commissioner Karel De Gucht announced that the EC will amend its customs regulations and that medicines in transit will no longer be checked except for counterfeiting. As a result, India has suspended, but not withdrawn, its formal complaint at the WTO.[10]

Such a decision by the EC builds on previous statements that it will no longer detain drugs in transit, provided that they do not violate patents in production or destination country.[11] However, the revised EC customs regulations will still cover commercial trademark disputes over similar labelling, which means detentions similar to the German detentions could happen. The EC is seeking that other countries adopt similar rules that would allow border guards similar powers through the FTA and has succeeded in obtaining such provisions in the ACTA.

PREVENTING THE REGISTRATION OF GENERIC MEDICINES: DATA EXCLUSIVITY

According to World Health Organization guidelines and national drug regulatory laws in developing countries, a generic medicine can be registered and marketed once the manufacturer has demonstrated that its drug is equivalent to an existing medicine in terms of chemistry and bioavailability. There is no requirement for the generic company to repeat clinical trials to establish safety and efficacy, as reliance on the original clinical trial data is sufficient for the drug regulatory authority to grant marketing approval.[12] The research-based pharmaceutical industry, however, has on many occasions sought to obtain monopoly rights over clinical trial data through the drug regulatory system, and claimed that the scientific evidence and data are its property that cannot be relied upon by the national drug regulatory authorities in developing countries.[13,14] Since 1987 the EU

has applied 'data exclusivity' legislation that grants period of time (usually up to 10 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. The EC is seeking to convince India to introduce data exclusivity rules as part of the EU-India FTA.

This would mean that if a generic company wanted to market a medicine in India, it would either have to wait until the period of data exclusivity has expired or generate its own clinical trial data to register a medicine. Both of these options imply greater costs and delays. In addition, the requirement to repeat clinical trials for medicines already proven effective has major ethical concerns, 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.

If India accepts data exclusivity, it would serve to undermine the public health flexibilities in India's patent law. It would provide a patent-like monopoly to medicines deemed to not fulfil the strict patentability criteria in India. In addition, were data exclusivity to apply to an unpatented medicine, it would not be possible as with patents to lift the exclusivity through the use of flexibilities such as pre- or post-grant patent oppositions and compulsory licensing.

The TRIPS Agreement does not require data exclusivity. Article 39.3 of the TRIPS agreement requires data protection against unfair commercial use and against disclosure for new chemical entities. Importantly, the TRIPS Agreement does not prevent the use of clinical trial data by drug regulators themselves to verify the quality, safety and efficacy of medicines including generics. TRIPS further specifically recognizes that disclosure of such data is allowed when it is necessary to protect the public.[15–17]

A study by Health Action International and Oxfam on the effects of data exclusivity in the EU-Andean Free Trade Agreement showed that in Colombia alone the introduction of a 10-year period of test data exclusivity would have led to an increase in expenditure of $340 million on medicines by 2030.[18] The EC has been active in pursuing free trade agreements in Latin America – an FTA signed with Colombia extended data exclusivity to biologics for example. In addition, the EC is currently negotiating an agreement containing similar provisions with Central America.

The case of nevirapine syrup provides an illustration of the impact of data exclusivity. Nevirapine syrup is a medication to treat children who are HIV-positive. The medicine was not granted a patent by the Indian patent office, meaning that generics could immediately begin producing and exporting it to developing countries. 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.

In the latest of letter exchanges between Médecins Sans Frontières and the EC Commissioner, the Commissioner confirmed that the EC continues to ask for data exclusivity and acknowledged its impact on access to medicines by pointing to the possibility of including certain exceptions to data exclusivity for public health needs.[19–22]

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 alleged patent and trademark infringements while also influencing the way in which disputes around patents and civil trademark infringements will be settled in courts.

Table 1: Overview of measures harmful to access to medicines in draft EU-India FTA and finalized ACTA text

	EU-India FTA (draft 23 April 2010)	*ACTA (final text December 2010)*
Data exclusivity	Yes	Undisclosed data covered but a party may exclude his data from certain sections of the ACTA
Border measures that can lead to drug detentions of legitimate generic medicines	Yes. Alleged civil trademark infringement included	Yes. Alleged civil trademark infringement included and applies law of transit country not law of country of importation
Scope of agreement	Patent and civil trademark infringements included	Covers all intellectual property (IP) rights. Civil trademark infringement included in all sections. Patent infringements only explicitly excluded from penal measures; for other sections leaves it optional for signatories to apply to patents (may). Also contains procedure for future amendment/additions
Excessive punishment for IP infringement while failing to sufficiently penalize abuse by rights holders	Yes	Yes

These changes are being driven by two main negotiations: the EU-India FTA, and the ACTA. To date, ACTA has been negotiated by only a few countries (Japan, United States, European Union, Switzerland, Australia, Mexico, Morocco, New Zealand, the Republic of Korea and Singapore), but parties to the negotiations have made it clear that they intend to put pressure on other countries to sign up to this non-negotiated agreement once it is completed.

There are four measures that exist in either the India-EU FTA negotiations or the ACTA, or both, that could have a negative impact of access to affordable medicines. These are outlined in Table 1 and summarized below.

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 providers by seeking to produce an exact copy of a pill (shape and colour), medicine packaging or logo. However, the EC is seeking to introduce a separate category, that of civil trademark disputes, into the EU-India FTA and has obtained these in the ACTA. Civil trademark disputes occur where one company accuses a competitor of having a trademark or packaging that is too similar to its own trademark. This has nothing to do with a deliberate intention to deceive with a fake medicine, but the effect will be that legitimate generic competition/production can challenged as counterfeit.

Border measures

The EC has advocated for a provision that would allow for the detention and seizure of goods based on civil trademark infringement. The EU-India FTA and ACTA would increase the ability of customs officials in different transit points 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.

Undermining the role of the judiciary

When an intellectual property-holding pharmaceutical company decides that a generic company is producing a medicine in

violation of its intellectual property rights, it can ask for a court injunction that will require the generic company to stop making the medicine. Many countries make distinctions with respect to essential medicines. 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 in one such proceeding that in the case of pharmaceutical products, courts have to ensure there is no violation of the Indian Constitution's guarantee to the right to life.[23] This safeguard is recognized in the TRIPS Agreement – which recognizes, 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.[24] But provisions in the ACTA and EU-India FTA seek to increase the grant of injunctions at an early stage of an infringement challenge and, in some cases, call for the destruction of infringing goods even before a court has decided if the claim is valid. In practical terms, this could mean effective and safe medicines are stopped from being produced or are destroyed in order to protect company profits.

Excessive punishment for intellectual property infringement

The EC has advocated for provisions in the FTAs it is negotiating and obtained provision in ACTA that require high penalties for alleged infringers – including injunctions, damages and criminal sanctions. Generic suppliers or public health authorities inadvertently infringing a patent may face bankruptcy. ACTA will 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; and NGOs such as MSF who provide treatment. This could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines.

ACTA and FTA enforcement provisions can be easily abused by permitting seizure and destruction of medicines without notification of the owner, without providing the owner the opportunity to respond or mandating judicial oversight.

CONCLUSIONS

Despite the European Communities' stated commitment to access to affordable medicines, the EC is promoting a range of policies that go well beyond the requirements of the WTO and threatening access to affordable medicines for developing countries. This is in direct contradiction with previous EC commitments, including the 2001 Doha Declaration, and the WHO-endorsed Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property,[25] as well as the European Council conclusion on global health[26] and the European Parliament Resolution on TRIPS and access to medicines.[27]

The potential harm caused by these policies is magnified by the fact that they are being promoted at a time when the affordability of essential medicines is of acute importance: the global economic crisis has meant that global health initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria are critically underfunded, and major donors are pushing to handover responsibility of financing HIV/AIDS programmes to national governments. This conflict has been highlighted by people living with HIV/AIDS who have pointed out that the EC is effectively undermining its own efforts to realize of the Millennium Development Goals.[28]

In addition, such EC initiatives not only affect access to generics, but serve to consolidate the predominance of patent-protected monopolies as the main way to incentivize and finance medical research and development. This in turn weakens the

prospect of alternative innovation models or business strategies, including proposals such as prize funds that de-link the cost of R&D from the price of products.

Other industrialized countries are pursuing similar TRIPS-PLUS policies that threaten access to medicines. Switzerland is seeking similar provisions as the EC through a European Free Trade Association-India FTA and the US government continues to threaten trade sanctions against countries the United States considers to be inadequately protecting intellectual property, singling out, among others, Thailand, Brazil and India this year.[29]

The EC policies are being opposed by civil society groups. In early October, EC negotiators arriving in New Delhi were met with HIV-positive groups protesting against the impact of such a deal on access to medicines. Similar demonstrations have taken place in Bangkok, Jakarta, Kathmandu, Nairobi and Brussels. The EC's negotiating position during the now-finalized Anti-Counterfeiting Trade Agreement is also coming under fire in the European Parliament for its impact on health.

The EU policies are also facing opposition in certain developed countries, where the EU is seeking further protections from competition for its pharmaceutical companies. The EU is currently negotiating an economic and trade agreement with Canada, which contains similar demands. These include extra rights of appeal when a claim for patent infringement has been rejected; extensions to the existing period of data exclusivity in Canada, including for off-patent medicines; and border measures that allow detention for goods in transit based on allegations of patent and trademark infringement. Trade unions and civil society groups have raised concerns that the effect of all of these demands that delay the entry of generic companies would be to drive up drug prices and costs for Canada's health-care system and individual consumers.[30]

India is a particular concern, as it is a key supplier of generic medicines to developing countries. A recent study 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 per cent of these came from India.[31] Similarly, 80 per cent of the 160 000 people living with HIV/AIDS supported by MSF medical programmes are receiving Indian generic antiretrovirals. It appears that India's position in the FTA negotiations is trying to prevent impact on generic medicines, but the country is under intense international pressure with direct lobbying of the Prime Minister's Office by multi-national companies, the demands of the EC in FTA negotiations and the pressure created by the US government, its special 301 process and lobbying, and it remains to be seen what final text will be agreed between the parties.

The EC can still change its position and drop provisions that could be harmful to access to medicines. In particular, the EC should revise its customs regulation to exclude not only patent but also civil trademark infringement as a reason to detain health technologies in transit, to drop the controversial provisions in its FTA, particularly the imposition of data exclusivity, border measures that include civil trademark disputes, and excessively broad enforcement measures. Given that the finalized ACTA text continues to contain provisions that will inhibit trade in legitimate generics, the EC and other parties should revoke their current intention to pressure developing countries to join the agreement.

REFERENCES AND NOTES

1. Creese, A., Floyd, K., Alban, A. and Guinness, L. (2002) Cost-effectiveness of HIV/AIDS interventions in Africa: A systematic review of the evidence. *Lancet* 11,359(9318): 1635–1643.
2. Marseille, E., Hofmann, P.B. and Kahn, J.G. (2002) HIV prevention before HAART in sub-Saharan Africa. *Lancet* 25,359(9320): 1851–1856.
3. Médecins Sans Frontières. (2010) Untangling the web of antiretroviral price reductions, 13th edn. http://utw.msfaccess.org, accessed 1 November 2010.

4. WHO, UNAIDS, UNICEF. (2010) Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector. Progress report 2010, http://www.who.int/hiv/pub/2010progressreport/report/en/index.html, accessed 1 November 2010.
5. 't Hoen, E. (2009) *The Global Politics of Pharmaceutical Monopoly Power. Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, http://www.msfaccess.org/main/access-patents/the-global-politics-of-pharmaceutical-monopoly-power-by-ellen-t-hoen/. Amsterdam: AMB Publishers, accessed 1 November 2010.
6. 't Hoen, E. (2002) TRIPS, pharmaceutical patents and access to essential medicines: A long way from Seattle to Doha. *Chicago Journal of International Law* 3(1): 27–48.
7. IPR Chapter of India-EU Broad-based Trade and Investment Agreement, 23 April 2010, preliminary consultation draft, http://www.ip-watch.org/weblog/2010/09/03/lack-of-transparency-in-eu-india-fta-talks-spurs-requests-for-halt/, accessed 1 November 2010.
8. Anti-Counterfeiting Trade Agreement Final Text, 3 December 2010, http://trade.ec.europa.eu/doclib/docs/2010/december/tradoc_147079.pdf, accessed 30 December 2010.
9. EC regulation No. 1383/2003.
10. Tailor, L.(2010) EU pledge to India over generics seizures. *Pharma Times*, 14 December, http://www.pharmatimes.com/Article/10-12-14/EU_pledge_to_India_over_generics_seizures.aspx, accessed 30 December 2010.
11. Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010, http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf, accessed 1 November 2010.
12. World Health Organization. (2004) Multisource (generic) pharmaceutical products: Guidelines on registration requirements to establish interchangeability. Geneva, http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_093Rev4_final.pdf, accessed 1 November 2010.
13. Abbott, F. and Dukes, G. (2009) *Global Pharmaceutical Policy. Ensuring Medicines for Tomorrow's World*. Cheltenham, UK: Edward Elgar Publishing.
14. International Federation of Pharmaceutical Manufacturers Associations. (2000) Encouragement of new clinical drug development: The role of data exclusivity. Geneva, http://www.ifpma.org/documents/NR643/DataExclusivity_2000.pdf, accessed 1 November 2010.
15. Correa, C. (2002) Protection of data submitted for the registration of pharmaceuticals: Implementing the Standards of the TRIPS Agreement. South Centre, http://www.southcentre.org/index.php?option=com_content&view=article&id=68%3A protection-of-data-submitted-for-the-registration-of-pharmaceuticals-implementing-the-standards-of-the-trips-agreement&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en, accessed 1 November 2010.
16. Commission on Intellectual Property Rights, Innovation and Public Health. (2006) Public health, innovation and intellectual property rights: Report of the Commission on intellectual property rights, innovation and public health. WHO, Geneva, http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, accessed 1 November 2010.
17. Timmermans, K. (2007) Monopolizing clinical trial data: Implications and trends. *PLoS Med* 4(2): e2, http://www.plosmedicine.org/article/info%3Adoi%F10.1371%2Fjournal.pmed.0040002.
18. Oxfam and Health Action International. (October 2009) Trading away access to medicines. How the European Union's trade agenda has taken a wrong turn, http://www.oxfam.org/sites/www.oxfam.org/files/bp-trading-away-access-to-medicines.pdf.
19. MSF Letter to EC Trade Commissioner on EU-India FTA, 6 April 2010, http://www.msfaccess.org/fileadmin/user_upload/medinnov_accesspatents/MSF%20letter%20to%20Trade%20Commissioner%20April%202010.pdf, accessed 1 November 2010.
20. Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010, http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf, accessed 1 November 2010.
21. MSF Letter to EC Trade Commissioner on EU-India FTA, 8 November 2010, http://www.msfaccess.org/fileadmin/user_upload/medinnov_accesspatents/2%20-%20MSF%20open%20letter%20to%20Commissioner%20de%20Gucht%20Nov%202010%20FINAL_01.pdf.
22. Letter by EC Commissioner Karel de Gucht to MSF, 7 December 2010, http://trade.ec.europa.eu/doclib/docs/2010/december/tradoc_147167.pdf.
23. *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.
24. TRIPS Art. 44.
25. Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property. World Health Assembly Resolution 61.21, http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, accessed 29 December 2010.
26. Council of the European Union. (2010) Council conclusions on the EU role in Global Health. 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010, http://onetec.be/global_health/doc/Council%20Conclusions%20Global%20Health%20May%202010.pdf, accessed 30 December 2010.
27. European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and access to medicines, http://www.europarl.europa.eu/sides/getDoc

.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN, accessed 30 December 2010.

28. Asia Pacific Network of People Living with HIV/AIDS (APN+). People living with HIV call out EU hypocrisy on MDGs as it pushes FTAs, http://www.bilaterals.org/spip.php?article18216, accessed 1 November 2010.
29. Médécins Sans Frontiérs. (2010) MSF Statement regarding the 2010 special 301 review. 3 March 2010, http://www.msfaccess.org/main/access-patents/msf-s-statement-regarding-the-2010-special-301-review/, accessed 1 November 2010.
30. The National Union of Public and General Employees (NUPGE) statement regarding the Canada-European Union Comprehensive Economic and Trade Agreement (CETA). 25 October 2010, http://nupge.ca/content/3681/nupge-concerned-big-pharma-trying-sway-ceta-negotiations-attempt-fatten-profits, accessed 1 December 2010.
31. Waning, B., Diedrichsen, E. and Moon, S. (2010) A lifeline to treatment: The role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *Journal of the International AIDS Society* 13: 35, doi:10.1186/1758-2652-13-35, http://www.jiasociety.org/content/13/1/35, accessed 1 November 2010.