

# Protecting Access to Medicines: The India and Mercosur trade agreements

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## Overview

All eyes are on the European Union (EU)-India trade agreement, and the repercussions it will have on access to medicines, not only in India but also in the many developing countries that rely on Indian-produced generic medicines. At the same time, the EU is also negotiating agreements with the Mercosur countries (Argentina, Brazil, Paraguay, Uruguay and Venezuela). The next round of negotiations takes place from 2 - 6 May, in Asuncion, Paraguay.

The EU's position on intellectual property (IP) in previous trade agreements suggests that we can expect similarly stringent IP standards that affect the right to health. How Indian negotiators react to the EU's push for new heights of IP will certainly have an impact on other EU trade negotiations. Therefore, India's resistance to EU demands is crucial for the protection of health and development globally. Negotiations do not take place in a vacuum; both India and Mercosur must stand firm to halt the momentum of the EU's IP creep.

Health Action International (HAI) Europe works closely with civil society in Mercosur countries through the *Global-Latin American and Caribbean Alliance for Access to medicines*, and there is widespread concern that health budgets and access to medicines in the region will come under further strain as a result of the agreement.

## The Link: IP and Access to Medicines

Overreaching IP protection and enforcement restricts and delays legitimate competition from generic manufacturers, thereby sustaining market monopolies, high monopoly prices, and significantly affecting access to affordable treatment.

MARKET  
MONOPOLIES  
=  
HIGH PRICES  
=  
POOR ACCESS

A number of public health NGOs, the European Parliament, UNAIDS, the UN Development Programme, the UK Commission on Intellectual Property Rights and Development Policy, respected international IP academics, and even the World Health Organization (WHO) all recognise the link between IP provisions that disproportionately favour rights-holders, and poor access to medicines. EU trade negotiators cannot credibly deny the harmful effects of its IP policies on public health.

### **Intellectual Property: TRIPS, Bilateral Agreements and Public Health**

The Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS), concluded in 1994 at the World Trade Organization, contains strong IP protection, which has posed difficulties for public health policies related to access to medicines in many developing countries. However, this agreement did allow some policy space for countries to protect public health (through the so-called 'TRIPS flexibilities'). But, bilateral trade agreements negotiated by the EU frequently undermine these flexibilities and set higher levels of IP protection, ignoring this policy space. These TRIPS *plus* standards entrench and expand the monopolies of brand name pharmaceuticals, hindering competition from generic medicines.

POLICY BRIEF

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When the EU negotiates trade agreements with countries that have large poor populations, the EU Commission negotiators have an obligation to respect both the letter and the spirit of the commitments entered into by the EU Member States.

### ***TRIPS flexibilities and access to HIV/AIDS treatment: The Case of Brazil***

Brazil, one of the members of Mercosur, has an extensive HIV/AIDS treatment programme, guaranteeing universal free access to antiretroviral drugs (ARVs) to its citizens. It produces generic versions of ARVs and has used the TRIPS flexibilities to sustain its treatment programme in the past. Brazil also produces ARVs for export and plays an essential role in generic competition. This role of generic producer and treatment supplier should in no way be curtailed by a trade agreement with the EU.

## **EU Policy Incoherence**

In theory, provisions on Policy Coherence contained in EU treaties oblige the EU Commission to uphold Member States' commitments on health and development. Yet, the Commission's very public pursuit of new heights of IP protection and hard-hitting enforcement measures<sup>i</sup> remains a consistent part of EU trade policy. This pursuit poses a real threat to the public health flexibilities guaranteed in the TRIPS Agreement.

An EU proposal to the Mercosur countries that features TRIPS *plus* measures will hinder access to medicines and is inconsistent with (i) recommendations by the European Parliament, (ii) long-standing EU commitments in other multilateral fora, and (iii) the commitments that bind all EU Member States in international human rights treaties such as the International Covenant on Economic, Social and Cultural Rights, iv) recent commitments in the EU Global Health Council Conclusions.

## **The EU's IP Ambitions & Access to medicines**

### ***Data exclusivity: How many times should companies be paid for research and development?***

Patents, and the accompanying exclusivity period, were intended to be a reward for successful research and development (R&D). But companies are seeking additional rewards for data gathered during the R&D process in the form of data exclusivity provisions that, in effect, prolong their monopoly period. Data exclusivity provisions in the US-Jordan free trade agreement resulted in a lack of generic competition for 79% of medicines that entered the Jordanian market since 2001;<sup>ii</sup> posing a real threat to medicines' affordability and access.

WHO, and more recently UNITAID,<sup>iii</sup> have argued that data exclusivity has a negative effect on access to medicines and should be avoided. Yet, despite this, the EU continues to push for this provision in agreements with countries that have large poor populations. Those in favour of data exclusivity provisions argue that the data *protection* foreseen in TRIPS,<sup>iv</sup> has somehow now been transformed into an *obligation* for data *exclusivity*. However, WHO South-East Asia Regional Office affirms that "the Article does not make any reference whatsoever to exclusivity or exclusive rights".<sup>v</sup>

### ***Data exclusivity: The Case of India***

The case of India is especially relevant due to India's role as the 'Pharmacy of the developing world'. Data exclusivity in this agreement would also have compromised access to affordable medicines in the many countries that rely on access to Indian-produced generics.

### *General enforcement measures: TRIPS-plus burdens on developing countries*

Provisions on enforcement are often a central feature of the IP chapter, reflecting its status as a priority EU strategy.<sup>vi</sup> Extra enforcement provisions on IP that go beyond TRIPS delay and deter generic competition, complicating the use of the TRIPS flexibilities of public health safeguards. It is especially hard for the Commission to justify proposals that would require countries with large poor populations to increase spending to support the enforcement of private intellectual property rights instead of allocating resources to other public priorities.

– *Border measures: Even if it's broken, don't fix it*

Customs regulation 1383/2003 was cited as the cause of the much-publicised seizures of generic medicines, which became public in 2009.<sup>vii</sup> After being brought to the World Trade Organization's Dispute Settlement system by India and Brazil, the EU then committed to reviewing the regulation to ensure that trade in generic medicines would not be hampered. That was in 2010. To date, there has been no news or follow-up on the regulation review.<sup>viii</sup>

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### *Supplementary Protection Certificates (SPCs): Extending the monopoly period*

SPCs extend the effective patent period further than what is set out in the TRIPS Agreement by 'compensating' rights-holders with additional years of protection to off-set time between the patent filing and the market authorisation. Prospective impact studies<sup>ix</sup> by the Global-Latin American and Caribbean Alliance for Access to medicines on SPC proposals during the EU's negotiations with the Andean region show that there are good reasons to be concerned. The forecast for the 'extension of patents' proposals revealed a dramatic increase in medicines' spending in Peru and Colombia due to the lack of generic competition in the market. In order to maintain current access levels, an increase in spending of 250 million USD was predicted.

## Key Conclusions

The EU takes a simplistic view of IP based on the assumption that the more stringent the IP protection, the better. It fails to consider the adverse effects of high levels of IP protection on technology transfer, innovation, development, and public health for emerging and developing countries.<sup>x</sup>

By seeking to export these assumptions through over-reaching IP provisions in bilateral trade agreements, the EU threatens the ability of emerging and developing countries to make use of established flexibilities that have important socioeconomic benefits, including public health. IP protection and ever tighter restrictions on access to knowledge and information can, in fact, weaken innovation, as well as severely limiting the ability of poorer countries to develop new technologies and industries, such as pharmaceuticals, which would ultimately contribute to a more sustainable access to medicines.

The EU must consider the broader context and effects of its IP demands, not only for public health, but also for socioeconomic development. Putting up more monopoly barriers will only sustain the *status quo* of inequity in health and development that exists between citizens in developed, emerging, and developing countries.

## END NOTES

- <sup>i</sup> [European Union Directive on the enforcement of intellectual property rights](#), and [ACTA \(Anti-counterfeiting Trade Agreement\)](#)
- <sup>ii</sup> Oxfam, (2007): [All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines](#)
- <sup>iii</sup> 3 March 2011. [UNITAID concerned over future of medicines access after EU-India FTA](#), and [WHO Briefing Note: Data Exclusivity and Other TRIPS plus Measures \(2006\)](#)
- <sup>iv</sup> TRIPS Article 39.3 specifies the protection of “such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public”, which would, of course, encompasses the role of drug regulatory authorities reviewing safety and efficacy data.
- <sup>v</sup> [World Health Organization Briefing Note: Data Exclusivity and Other TRIPS plus Measures \(2006\)](#)
- <sup>vi</sup> [European Union Strategy for the Enforcement of Intellectual Property Rights in Third Countries. 2004.](#)
- <sup>vii</sup> [World Trade Organization. 2 March 2010. News Item. Intellectual Property. In depth: TRIPS and health: 2. Generics detained in transit in the EU.](#)
- <sup>viii</sup> [Directorate-General Taxation & Customs, European Commission. Review of customs legislation on enforcement of intellectual property rights](#)
- <sup>ix</sup> IFARMA. [Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru](#). November 2009. HAI Europe.
- <sup>x</sup> Nunn et al. AIDS Treatment In Brazil: Impacts and Challenges. 2009. Health Affairs, Volume 28, Number 4. [http://www.hsph.harvard.edu/pihhr/files/homepage/recent\\_publications/BrazilHealthAffairs.pdf](http://www.hsph.harvard.edu/pihhr/files/homepage/recent_publications/BrazilHealthAffairs.pdf)

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## EU Commitments to Public Health, Development and Access to Medicines

### *Doha Declaration*

The 2001 Doha Declaration on TRIPS and public health signed by WTO Members reaffirmed that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”. Though the EU is party to the 2001 Doha Declaration, the Commission proposals fail to adhere to the spirit of the text and, in fact, establish several barriers to public health protection measures mandated by the Declaration.

### *European Parliament Resolution*

The European Parliament resolution of July 12, 2007 on the TRIPS Agreement and access to medicines (P6\_TA(2007)0353), urges the European Commission not to demand TRIPS *plus* provisions in bilateral agreements.

### *Global Strategy & Plan of Action on Public Health, Innovation and Intellectual Property (GSPA)*

The EU is committed to the GSPA, adopted by the World Health Assembly in May 2008. The GSPA enshrines the principle of placing public health protection over commercial interests, and devotes considerable attention to the impact of IP rights on public health, singling out the practice of overreaching IP protection clauses in bilateral trade agreements. Yet, the EU trade policy on IP has shown little consideration for this commitment thus far.

### *EU Policy Coherence for Development*

Article 178 of the EC Treaty reads:

“The Community shall take account of the [development] objectives referred to in Article 177 in the policies that it implements which are likely to affect developing countries.”  
(177 being development cooperation principles)

Article 208 of the Lisbon Treaty states the primary objective of the Union development cooperation policy to be,

“the reduction and, in the long term, the eradication of poverty. The Union shall take account of the objectives of development cooperation in the policies that it implements which are likely to affect developing countries.”

### *EU Global Health Council Conclusions<sup>i</sup>*

Article 16 (a) of the May 2010 Council Conclusions reads, the EU should:

“support third countries, in particular LDCs, in the effective implementation of flexibilities for the protection of public health provided for in TRIPs agreements, in order to promote access to medicines for all, and ensure that EU bilateral trade agreements are fully supportive of this objective”