

Access to Medicines in Jeopardy: Central America in negotiations with the EU



Overview

The European Union (EU) and Central America (Costa Rica, El Salvador, Guatemala, Honduras, Panama and Nicaragua) have restarted negotiations on a trade agreement between the two regions. Round eight of the negotiations will take place in Brussels from 22 to 26 February 2010.

The agreement will include a chapter on intellectual property (IP) rights, which are highly controversial for public health as they can pose barriers to access to medicines, especially in poor countries like in Central America. The European Commission's public stance on seeking extremely high standards of IP protection poses a threat to the legitimate public health protection measures guaranteed to developing countries in the international Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).

IP Rights: TRIPS, Bilateral Agreements and Public Health

The TRIPS Agreement, concluded in 1994 at the World Trade Organization, contains strong IP regulation, which has posed difficulties for public health policies related to access to medicines in many developing countries. However, this multilateral agreement does recognise public health needs and allows certain policy space for developing countries to protect public health (through the so-called 'TRIPS *flexibilities*'). Bilateral trade agreements negotiated by the US and the EU frequently counteract these flexibilities and set higher standards of IP protection, ignoring the progress made in multilateral forums. These TRIPS *plus* standards consolidate and extend monopolies for brand name pharmaceuticals, enabling companies to maintain prohibitively high prices and damaging public health standards in developing countries.

Background

Overreaching IP regulations restrict and delay competition from generic medicines, thereby sustaining high medicines prices as the prices of generics are, on average, a third of branded medicines.

In theory, provisions on Policy Coherenceⁱ contained in EU treaties should oblige the European Commission (EC) to uphold the EU Member States' commitment to support development and avoid regulations that run counter to that commitment. Yet, pursuing high IP standards remains a consistent part of the EC's trade policy and the EU can be expected to demand the most stringent IP measures possible in this agreement.ⁱⁱ

The EU Trade Agreement with Peru & Colombia

The IP chapter has now been closed in this trade agreement and the most controversial provisions (on the extension of patents and data exclusivity) were removed after impact studies showed that they would have a detrimental effect on access to medicines in these countries.

POLICY BRIEF

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Problematic IP provisions foreseen in the European proposal for a trade agreement with the Central American region

Extension of Patents

Supplementary Protection Certificates- The EU proposal foresees additional protection periods for patented medicines that have filed an application for marketing authorisation. The extension will be equal to the time elapsed between the filing of the application for a patent and the date of the first market authorisation, up to a maximum of 5 years.

The extension of supplementary data protection would represent yet another legal mechanism that delays generic competition, extending the monopoly term for the originator.

Data protection

In practice, data protection prolongs the monopoly period for the product owner. The European proposal exports its strict system for the protection of medicines data, which can extend the exclusivity that the patent holding company enjoys for up to 11 years. Currently, CAFTA (Central America Free Trade Agreement) countries grant 5 years of data protection (due to the implementation of the US Free Trade Agreement). The extension of the data protection period would further delay generic competition, as generic manufacturers need access to these test data to be able to register their products. A recent study (see section: Impact Studies) has shown that the additional 5 year protection period has already caused considerable damage to access to medicines in Guatemala.

Enforcement

Provisions on enforcementⁱⁱⁱ represent a main priority of the EC and are a cause for concern as they potentially undermine generic competition.

The European proposals for enhanced border measures would pose a serious threat to the legitimate trade of generic medicines for the Central American countries. In the much-publicised recent cases of customs authorities in EU Member States seizing generic medicines in transit, it is clear that even more restrictive border measures could be devastating for access to medicines in the region.

Technology transfer

The EU does not tend to make commitments on technology transfer in terms of i) guaranteeing access to innovative products, ii) fostering technological development in the developing countries or iii) prioritising the higher social good, such as human health and technology dissemination.^{iv}

General Provisions of the IP Chapter

The general provisions should include references to:

- The 2001 Doha Declaration on the TRIPS Agreement and Public Health *in the Preamble*
- World Health Assembly resolution 61.21 on a Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property.
- The EU Economic Partnership Agreement phrase: *“Nothing in this Agreement shall be construed as to impair the capacity of the Parties to promote Access to Medicines”*

These references provide important policy space for the interpretation of the articles from a public health perspective.

Standing by EU Commitments to Public Health and Access to Medicines

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

The EC 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.

Doha Declaration

The 2001 Doha Declaration signed by WTO Members reaffirmed the importance of upholding TRIPS flexibilities to protect public health:

“We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.”

Though the EC is a signatory of the 2001 Doha Declaration, the EC 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 EP resolution of July 12, 2007 on the TRIPS Agreement and access to medicines (P6_TA(2007)0353), urges the EC not to demand TRIPS *plus* provisions in bilateral agreements.

Impact Studies

An FTA signed between the US and Guatemala, Honduras, Nicaragua, El Salvador, Costa Rica and Dominican Republic (CAFTA) has already led to significant delays in generic competition in Guatemala for medicines needed to treat major causes of morbidity and mortality, including diabetes, heart disease, pneumonia and HIV and AIDS. This led to increases in medicines prices ranging from 2 to 58 times the cost of the generic equivalent. The TRIPS *plus* measures led to a delay in generic competition in the Guatemalan market.^v

Prospective impact studies in Peru & Colombia

Findings from prospective impact studies^{vi} on similar EU negotiations with Peru and Colombia indicate there is reason for concern.^{vii} The findings on the EU ‘Extension of patents’ proposals forecasted a dramatic increase in medicines’ spending in Peru and Colombia due to a lack of generic competition, resulting in an increase in spending of 250 million dollars in Peru. In addition, the extension of protection of trial data (data exclusivity) from 5 to 11 years would trigger an increase in medicines’ spending of 217 million dollars in Colombia and 136 million dollars in Peru by 2025. As ever, the main victims of the rising cost of healthcare are the poorest families and those without healthcare insurance. The provisions on data exclusivity and data protection have now fortunately been removed from the IP chapter but can be expected to have similar impacts in the countries of Central America.

Conclusion

An EU proposal with TRIPS *plus* measures, listed above, will hinder access to medicines in Central America. The inclusion of TRIPS *plus*, is inconsistent with recommendations by the European Parliament and with prior EC commitments in other multilateral fora, such as the WHA and Doha, and the commitments of all the EU Member States in international human rights treaties such as the International Covenant on Economic, Social and Cultural Rights.

Recommendations

- The EC should not seek TRIPS *plus* provisions in IP chapter, especially not patent extension and data protection provisions
- The EC should not seek IP enforcement provisions beyond those in TRIPS
- The EC should ensure there is an adequate balance between the interests of the IP rights holders and the public good.

For more information on the EU Trade Agenda & Access to Medicines campaign, please contact Sophie Bloemen, HAI Europe: sophie@haiweb.org

ⁱ Treaty on the European Union; Title I, Article 3, Treaty establishing the European Community; Title XX, Article 177

ⁱⁱ Oxfam International/ Health Action International (HAI) Europe. *Trading Away Access to Medicines: How the European Union's trade agenda has taken a wrong turn*. October 2009.

<http://www.haiweb.org/20102009/OxfamHAIReportTradingAwayAccessToMedicines.pdf>

ⁱⁱⁱ In this regard, the EC exports the contents of the European Directive 2004/48/EC and European Customs Regulation 1383/2003.

^{iv} Xavier Seuba; *The Protection of Health in the New Association Agreement between the CAN and the EU in the light of Intellectual Property Rights*. January 2009.

<http://www.haiweb.org/23032009/18%20Mar%202009%20Policy%20Paper%20EU-CAN%20Association%20Agreement%20FINAL.pdf>

^v Centre for Policy Analysis on Trade and Health, 2009

^{vi} IFARMA. *Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru*. October 2009.

[http://www.haiweb.org/11112009/ReportIFARMAImpactStudyPeru\(EN\).pdf](http://www.haiweb.org/11112009/ReportIFARMAImpactStudyPeru(EN).pdf)

^{vii} www.iprsonline.org/ictsd/Dialogues/2007-05-27/Documents/IPR%20IMPACT%20MODEL.ppt