

Protecting Access to Medicines in EU Trade Agreements: The Andean Region

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Overview

The European Union (EU) and the countries of the Andean Community (CAN) are in the process of negotiating bilateral trade agreements. What began as an association agreement that promoted regional integration has fractured into bilateral trade agreements that include only three of the four CAN countries: Colombia, Ecuador and Peru. The third round of negotiations is taking place from 4 to 9 May in Brussels.

The agreements include a chapter on intellectual property (IP) rights, which are highly controversial for public health as they can pose barriers to access to essential medicines. 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 also recognises 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* and TRIPS *extra* 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.ⁱⁱ Objectives in these negotiations can be summarised in the achievement of the "the highest existing standard of IP in the world".ⁱⁱⁱ

Policy Incoherence

The EC's ambitions for the IP chapters are at odds with EU commitments on development and public health. Actions that contradict the commitments made by the EC to the European Parliament and the international community should not be accepted.

POLICY BRIEF

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Problematic IP provisions in the European proposal

General Provisions of the IP Chapter

Raising awareness on the potential negative impacts of the EU proposal has produced some success. The general provisions now include references to:

- The 2001 Doha Declaration on the TRIPS Agreement and Public Health
- WHA 61.21 (in brackets)
- EPA statement: Nothing in this Agreement shall be construed as to impair the capacity of the Parties to promote Access to Medicines' (in brackets)

These references provide important policy space for the interpretation of the articles from a public health perspective. However, the objectives on IP in the trade agreements still almost exclusively adopt the position of IP rights holders. For example, the European proposal avoids the TRIPS reference to the freedom to establish *'the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'*.

Patents

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 represents yet another legal mechanism that delays generic competition.

In addition, the article on patents (article 9) extends obligations to comply with international treaties that were not foreseen in the TRIPS Agreement and obliges the countries to ratify an amendment of the TRIPS Agreement on compulsory licences,^{iv} cutting off the path to other flexibilities. Though, the compulsory licences mechanism has itself been problematic; in five years it has been used only once in the controversial Canada-Rwanda case and it did not prove to be operational.^v

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 eleven years. This while currently, Peru and Colombia both grant 5 years (Implementation of the US FTA) and Ecuador does not grant any. 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.

Enforcement

Provisions on enforcement are the main focus of the chapter on intellectual property^{vi} and represent the main priority of the EC. Though criminal penalties have been successfully negotiated out of the text by the Andean country negotiators, there are still causes for concern.

The European proposals for enhanced border measures would pose a serious threat to the legitimate trade of generic medicines for the CAN countries. In the much-publicised recent cases of the Dutch Customs Authorities seizing generic medicines in transit, it is clear that even more restrictive border measures could be devastating for access to medicines in the Andean region.

Technology transfer

The EU has made no commitments on technology transfer in terms of i) guaranteeing access to innovative products, ii) fostering technological development in the Andean countries or iii) prioritising the higher social good, such as human health and technology dissemination.^{vii}

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 protection of public health 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 Commission's negotiators have shown little consideration for this commitment in the negotiation rounds 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 to the Andean countries fail to meet the spirit of the text and, in fact, establish several barriers to public health protection measures mandated by the Declaration.

Impact Studies

Preliminary findings from studies^{viii} indicate there is reason for concern. The impact studies are based on the WHO (World Health Organization) and PAHO (Pan American Health Organization) methodology: *The Guide to estimate the impact on access to medicines due to changes in intellectual property rights*^{ix}. The preliminary findings on the EU 'Extension of patents' proposals forecast a dramatic increase in medicines' spending in Peru due to a lack of generic competition, resulting in an increase in spending of 250 million dollars. 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.

Conclusion

The current EC proposal to the Andean countries will hinder access to essential medicines in these countries. The text on IP seems conceived exclusively to protect the rights of IP holders, restrict TRIPS flexibilities, and limit the effects of the Doha declaration. In particular, the overall emphasis on enforcement of IP rights stands out.

There is a profound asymmetry in the EC's strategy. The EC refuses to assume new commitments, for instance on technology transfer, whilst simultaneously imposing heavy burdens onto developing countries.

The inclusion of TRIPS *plus, extra* and EC *extra* provisions is inconsistent 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

- Restore the balance between the interests of IP rights holders and the public good
- Do not seek enforcement provisions beyond those in TRIPS
- Remove TRIPS *plus* data extension and data protection provisions
- Reflect on implications for the CAN when imposing a strong IP regime while Bolivia is out of the negotiations

For more information on the campaign to protect Access to Medicines in the EU-Andean Trade Agreements, please contact Sophie Bloemen, Projects Officer, HAI Europe

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

ⁱⁱ Strategy for Enforcement of Intellectual Property Rights in Third Countries. EC, DG TRADE.

ⁱⁱⁱ Chief of the European negotiating team mentioned at the beginning of the negotiations in 2007, the goal was the establishment of the highest existing standards of IP in the world (source: IFARMA).

^{iv} August 30, 2003 amendment to TRIPS on compulsory licenses.

^v <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1373>

^{vi} In this regard, the EC exports the contents of the European Directive 2004/48/EC and the European Regulation 1383/2003.

^{vii} 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>

^{viii} The impact studies conducted by researchers at IFARMA are expected to be completed in June. The methodology was developed by a consortium of organisations including WHO, PAHO, the World Bank Institute and the International Centre Trade and Sustainable Development (ICTSD). For more info see www.haiweb.org

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



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