

The EU-CAN Association Agreement, Access to Medicines in jeopardy!

2 December 2008



Overview

The European Union (EU) and the countries of the Andean Community (CAN) are in the process of negotiating Association Agreements (AA). Three rounds of negotiation *en bloc* have taken place since September 2007 and it now seems the negotiations will proceed bilaterally. The AAs will include sections on political interaction, cooperation and trade. The commercial pillar of the agreements will include a chapter on intellectual property (IP) rights. Intellectual property rules (IPRs) are highly controversial for public health as they pose barriers to access to essential medicines, which can be particularly detrimental in developing countries.

Policy Incoherence

The European Commission's ambitions for the IP chapter are extremely high and at odds with EU commitments on development and public health. Actions countering the commitments made by the European Commission (EC) to the European Parliament and the international community should not be accepted.

Key recommendation

The negotiated text of the EU-CAN treaties should refer to the May 2008 WHA resolution 62.21 on the Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property.

Background

Rigid IP regulations restrict and delay generic competition and, therefore, sustain high medicines prices. Generics play a vital role in raising public health standards through their effect on prices which are, on average, a third of branded medicines. In theory, provisions on Policy Coherenceⁱ contained in EU treaties should oblige the EC to recognise the EU institutions and states' commitment to support development and avoid overly stringent IP regulations that run counter to that commitment. Yet, pursuing high IP standards is 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

IP Rights: TRIPS, Bilateral Agreements and Public Health

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), concluded in 1994 at the WTO, contains strong IP regulation, which has posed difficulties when formulating 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 FTAs negotiated by the US and the EU are frequently used to set higher standards of IP protection, ignoring progress made in multilateral forums. The TRIPS *plus* and TRIPS *extra* standards that the pharmaceutical industry failed to obtain in multilateral platforms, consolidate and extend monopolies for brand name pharmaceuticals, allowing companies to charge high prices and reap huge revenues.

POLICY BRIEF

Overtoom 60/II
1054 HK Amsterdam
The Netherlands
Tel: +31 20 683 3684
Fax: +31 20 685 5002
Email: info@haiweb.org
www.haiweb.org

General Approach/Provisions

The general provisions objectives on IP in the AA almost exclusively adopt the position of IP holders. This severely limits any interpretation of the treaty that allows for the protection of public health. Furthermore, the EC's proposal limits the ability of the CAN countries to use certain TRIPS flexibilities. 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'*.

The provisions on enforcement of IPRs are particularly rigorous. A reference is made to the Doha declaration, but only in the article referring to patents, not to IP in general, omitting important issues such as data protection, technology transfer and, monitoring and enforcement.^{iv} It is difficult to account for the EC's decision to pursue extended IP provisions limiting flexibilities when they have repeatedly committed themselves to allowing for this.

Patents

The article on patents (article 9) extends obligations to comply with international treaties that were not foreseen in the TRIPS Agreement. Also, the proposal obliges the ratification of an amendment of the TRIPS Agreement on compulsory licences,^v cutting off the path to other options even though this one does not work very well. In five years, this mechanism has only been used once (Canada-Rwanda, a very controversial case) and has proved to be a failure as it is not operational.

Data protection

In practice, data protection prolongs the duration of the monopoly of the product owner. As there is no clarity yet on the exact content of this provision in the EC proposal, there is a danger that, based on recent EU treaties, the very high EU standards (TRIPS *extra*) or similarly strict US standards, could be introduced.

Enforcement

Provisions on enforcement are the main focus of the chapter on intellectual property,^{vi} reflecting the main priority of the EC. Not only does the EC go beyond TRIPS, relinquishing the flexibility on enforcement,^{vii} but even *beyond current Community law (EU Plus)*. The EC proposes to extend criminal sanctions to all IP infringements, something that the EU Parliament refused in the well-known IPRED2.

Furthermore, the application of the proposed enhanced border measures would create serious drawbacks in the area of pharmaceutical patents. These problems are not only related to the increased budget allocation to customs activities, but they extend to access to medicines. Third parties would be able to temporarily block the entry of pharmaceutical products by alleging reasons that, even if they are later proven unfounded, would delay the entry of generic competitors into the market.

Technology transfer

The EU has made no commitment regarding technology transfer or i) guaranteeing access to innovative products, ii) fostering technological development in the CAN countries and iii) prioritising the higher social good, such as human health and technology dissemination.^{viii}

A lack of coherence on multiple fronts

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

In May this year, the EC committed itself to the GSPA, adopted by the World Health Assembly. Government delegations were brought together for over two years to revise and apply concepts into a global strategy and plan of action. They recognised that market-driven research and development (R&D) must be supplemented with additional incentives for needs-driven research and development, and that those initiatives need to ensure that these advances are affordable and accessible to developing countries.

The GSPA, devotes considerable attention to IPRs and their impact on public health, singling out the worrying practice of over-reaching IPR protection clauses negotiated in bilateral FTAs. In adopting the GSPA, the EC abided to the protection of public health over commercial interests.

Doha Declaration

The Doha Declaration signed by WTO Members in 2001 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.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

The EC has also committed itself to the Doha Declaration of 2001. While quoting the Doha Declaration, the EC proposal to the CAN fails to meet the spirit of the text and, in fact, the EC’s proposal establishes several barriers for public health protection mandated by the Doha Declaration. It is particularly worrying that the EC is attempting to limit the Doha Declaration to only patents.

Recommendations of the Parliament in its 2006 and 2007 Resolution

The following recommendations feature in resolutions given to the EC by the EP:^{ix}

i) Using negotiating guidelines on development cooperation designed to achieve MDGS, including the protection of public health, ii) ensuring coherence of development policies in line with the principle enshrined in Article 178 of the EC Treaty, iii) granting high priority for greater access to education and health, iv) fostering regional integration by negotiating block by block.

Clearly, these recommendations are in conflict with the EC’s stand on limiting TRIPS flexibilities and the one-sided perspective of IPR holders. Furthermore, the EC is now looking toward bilateral agreements, possibly excluding some of the Andean countries.^x The European Parliament has pointed out the importance of fostering regional integration in the CAN through the AA. Clearly bilateral negotiations would grant the EC greater bargaining power and would likely result in the adoption of more stringent IP provisions.^{xi}

On July 12th, 2007 there was the **European Parliament resolution on the TRIPS Agreement and access to medicines (P6_TA(2007)0353)**, urging the EC not to demand for TRIPS plus provisions in bilateral agreements.

The EP should be aware of how these negotiations are being conducted and, in particular, the process through which IP rights are being upheld, which conflicts with the recommendations given by the EP to the Commission.

Conclusion

The current EC approach to IP in the AA hinders access to essential medicines in the Andean countries, as it includes rigid and far-reaching IP protection standards. 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. The overall emphasis on enforcement of IP rights stands out, with the EC proposing IP protection standards superior to the European ones.

There is a profound asymmetry in EC policy, while it refuses to assume new commitments (for instance with regard to technology transfer), it imposes, in turn, heavy burdens onto developing countries.

The inclusion of TRIPS *plus, extra* and EC *extra* provisions is inconsistent with the mandate handed down by the EP 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 European Parliament should adopt a Resolution on the recommendations below with a view to affirming the EC's commitments to Health and Development.**
- **The negotiated text on IP should be coherent with, and refer to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.**
- **There should be reference made to the Doha Declaration relating to all IP provisions in the text, not only patents.**
- **The proposed text should emphasise that IP enforcement measures should not divert resources away from other priority areas, such as health protection.**



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} A good reference to improve the EC text is point 36.5.2 of the WHO Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property.

^v August 30, 2003 amendment to TRIPS on compulsory licenses.

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

^{vii} The TRIPS Agreement, in article 41.5, states that it “does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.”

^{viii} Xavier Seuba; The Protection of Health in the New Association Agreement between the CAN and the EU in the light of Intellectual Property Rights. 2008

^{ix} P6_TA(2007)0080, <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0080+0+DOC+XML+V0//EN&language=EN>

^x As happened in ACP countries

^{xi} Xavier Sueba