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Open letter to: Working Group members
AMLAT
C133
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Brussels, 23 April 2009

Subject: Grave concerns about Intellectual Property Rights in the CAN-EU Association Agreement and its impact on Access to Medicines

Dear Sir/Madam,

The third round of negotiations between the European Union and Peru, Colombia and Ecuador will take place in Brussels from 4 to 9 May. On behalf of a wide constituency of non-governmental organisations representing European and Andean civil society, we would like to express our grave concerns with respect to these agreements that will have a negative impact on access to medicines through the inclusion of overreaching Intellectual Property Rights provisions.

The European Commission (EC) failed to demonstrate flexibility when the Andean Community (CAN) countries could not reach a consensus on contentious issues in the initial Association Agreement, such as intellectual property rights. Instead of promoting a pro-development platform by accepting and incorporating progressive proposals by Ecuador and Bolivia, the EC pressured the Andean countries. What started as an Association Agreement between the European Union and the CANⁱ is now proceeding in the form of bilateral agreements. Without a coalition, the CAN countries are more likely to accede to European demands that do not sufficiently take into account the public interest.

A number of the EC's proposed IP provisions create barriers to access to essential medicines. As the main supranational regulation that the CAN possesses is their common regime on IP, the negotiations with the EC on IP could also contribute to further ruptures within the Andean Community regional bloc. This thoroughly undermines the EU's commitment to foster regional integration.

The European proposal contains:

- Overreaching IP regulations that will restrict and delay generic competition and therefore sustain high medicines prices. Generics play a vital role in raising public health standards as their prices are on average only one third of branded medicine;
- An IP chapter that has been exclusively formulated to protect the rights of IP holders. It includes TRIPS *plus*, TRIPS *extra* and EC *extra* provisions and inhibits interpretation from a public interest or health perspective.ⁱⁱ

- IP enforcement standards that go far beyond TRIPS obligations. The standards include the border measures provision on in-transit goods, which has recently been rejected by members of the WTO and the international public health community. The recent cases of Dutch seizures of generic medicines in-transit are a dire warning of things to come if these enforcement provisions are featured in trade agreements with developing countries.
- Provisions on patent law and data exclusivity that will inflate health costs and decrease the ability to pay for medicines for poor people in the Andean region.

Preliminary findings from impact studies¹ show that the extension of the patent period by 5 years in Peru would increase the price of medicines by up to 26%. In Colombia, data exclusivity provisions would increase the annual medicines spending to 217 million dollars (see annex 2).

Aside from the damaging public health consequences, the European position is alarmingly incoherent with other EU policy. The inclusion of TRIPS *plus* provisions are inconsistent with the recommendations handed down by the European Parliament and with prior EC commitments in other multilateral forums, such as the World Health Assembly (WHA)ⁱⁱⁱ, 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.^{iv}

Protecting the European knowledge economy is a legitimate aim. Yet, the current EC approach of imposing overreaching IP standards in trade agreements with developing countries is not acceptable and does not protect or improve the European knowledge economy. There is a profound asymmetry in EC policy towards developing countries: the EC refuses to assume new commitments (for instance to enable technology transfer to developing countries), while simultaneously imposing heavy burdens on developing countries to protect intellectual property at the expense of the public interest and public health. Pursuing overreaching IP standards is a consistent part of the EC's trade policy.^v However, Policy Coherence for Development provisions contained in EU treaties^{vi} should compel the EC to recognise the Member States' commitment to support development and avoid IP regulations that run counter to that commitment.

The signatories of this letter respectfully request that the Council puts pressure on the European Commission to curb its IP demands in these agreements, thereby granting the CAN countries their legitimate flexibilities to protect public health.

Yours sincerely,

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 Oxfam International
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¹ Interim results from 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 for Trade and Sustainable Development (ICTSD). For more info see www.haiweb.org



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ⁱ The CAN is composed of Bolivia, Colombia, Ecuador and Peru.

ⁱⁱ See Annex (fact sheet)

ⁱⁱⁱ WHA Resolution 62.21, Global Strategy on Public Health, Innovation and Intellectual Property, 2008.

^{iv} ICESCR, United Nations GA, 1966.

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

^{vi} Treaty on the European Union; Title I, Article 3, Treaty establishing the European Community; Article 177, 178



ANNEX

Intellectual Property Rights: 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 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 Free trade agreements (FTAs) negotiated by the US and the European Union (EU) are frequently used to set higher standards of IP protection, ignoring progress made in multilateral forums. These *TRIPS plus* and *TRIPS extra* standards that the pharmaceutical industry failed to obtain in multilateral platforms, consolidate and extend monopolies for brand name pharmaceuticals, maintaining high prices and reaping huge revenues for the originator companies.

General Approach/Provisions

The objectives on IP in the agreements' general provisions almost exclusively adopt the position of IP holders. This severely limits any interpretation of the treaties that allows for the protection of public health. Furthermore, the European Commission's (EC) proposals limit the ability of the Andean countries to use certain TRIPS flexibilities. For example, the European proposal avoids the reference to the freedom to establish 'the appropriate method of implementing the provisions of this (TRIPS) Agreement within their own legal system and practice'.

The provisions on enforcement of IP rights are particularly rigorous. The EC's pursuit of extended IP provisions in trade agreements impedes the use of flexibilities designed to protect public health. The EC's actions run counter to previous EU commitments to support these flexibilities in multilateral fora.

Data protection

In practice, data protection prolongs the duration of the monopoly of the product owner. The European proposal exports its strict system for the protection of medicines' data, which can extend the exclusivity of the patent holding company by up to eleven years. If the European proposal succeeds, Andean countries would be obliged to enact legislation ensuring that marketing authorisation data would remain undisclosed to third parties for up to eleven years. In contrast, the implementation of the US FTAs by Peru and Colombia grants 5 years while Ecuador does not currently grant any period of exclusivity. 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.

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.

Enforcement

Provisions on enforcement are a main focus of the chapter on intellectual property.ⁱ The application of the proposed enhanced border measures would create serious constraints. 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 generics, even if the allegations were later proved unfounded.¹

Technology transfer

The EU has made no commitment regarding technology transfer on either guaranteeing access to innovative products, fostering technological development in the CAN countries or prioritising higher social goods, such as public health and technology dissemination.

A lack of coherence on multiple fronts

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

In May 2008, the European Commission committed the EU 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. The GSPA devotes considerable attention to IPRs and their impact on public health, singling out the worrying practice of overreaching IPR protection clauses negotiated in bilateral free trade agreements. In adopting the GSPA, the EU committed to the protection of public health over commercial interests.

Doha Declaration

The 2001 Doha Declaration signed by WTO Members, including the European Union, reaffirmed the importance of upholding TRIPS flexibilities to protect public health. While quoting the Doha Declaration, the EC proposal to the CAN countries fails to fully match the spirit of the text.

Recommendations of the Parliament in its 2006 and 2007 Resolution

The following recommendations featured in resolutions given to the EC by the Parliament yet they seem to have been disregarded in the negotiation process: i) Using negotiating guidelines on development cooperation designed to achieve the Millennium Development Goals, including the protection of public health, ii) ensuring the 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.

And finally, 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.

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

¹ Xavier Seuba, Health Protection in the European and Andean Association Agreement, Health Action International (Europe) and Accion Internacional para la Salud (AIS) Latinoamérica & Caribe Paper series; January 2009. <http://www.haiweb.org/23032009/18%20Mar%202009%20Policy%20Paper%20EU-CAN%20Association%20Agreement%20FINAL.pdf>

CALCULATING THE IMPACT ON PHARMACEUTICAL SPENDING AND ACCESS TO MEDICINES

Preliminary Findings

24 March 2009

The analysis of the impact of intellectual property on Access to Medicines is based on the *'Guide to estimate the impact on access to medicines due to changes in intellectual property rights'*,¹ produced jointly by the World Health Organization and the Pan-American Health Organization (WHO/PAHO). The Guide presents the IPRIA (Intellectual property rights impact assessment) model, which has been applied in numerous settings and countries.² The most recent studies were conducted in partnership with a consortium of organisations including WHO, PAHO, the World Bank Institute and the International Centre for Trade and Sustainable Development (ICTSD), who have been refining the methodology.

The final report on this study will present the impact assessment of the EU's intellectual property provisions with regard to the ongoing negotiations between Colombia, Peru and the European Union. The analysis will focus specifically on the articles relating to patents, protection of data for marketing authorisation, industrial designs and observance. So far, results have been obtained only for the first two of these articles.

The following preliminary results were obtained from an analysis of the private medicine markets in Colombia and Peru, which represent approximately two thirds of the total markets in each country.

1 Patents

The extension of the patent period by 5 years could cause an increase of around 26% in the price of medicines in Peru, resulting in increased spending on medicines. This spending increase would amount to an increase of around 250 million dollars annually by 2025, which is equivalent to the healthcare spending of some 2.7 million citizens in Peru. Without an increase spending, consumption would be affected, shrinking by up to 21%.

2 Protection of Trial Data

The extension of the exclusivity period for trial data on medicines from 5 years, the current figure for Colombia (Decree 2085 of 2002) and Peru (FTA with United States) to 10 years, as proposed by the European Union, would entail an average increase in medicine prices of 11% in Colombia and 14% in Peru. This would compel an increased in medicines' spending amounting to approximately 217 and 136 million dollars per year respectively by 2025. This additional spending is equivalent to the cost of healthcare for 1.2 million people in Colombia and over 1.4 million people in Peru.

¹ ROVIRA, Joan, et al. "Guía para estimar el impacto sobre el acceso a los medicamentos de cambios en los derechos de propiedad intelectual DPI". OPS/OMS. 2005

² Colombia (2005, 2006, 2007), Guatemala (2005), Costa Rica (2005), Bolivia (2006), Costa Rica (2008), Dominican Republic (2008), Uruguay, Argentina, Malaysia and Thailand, (2006)