European Union & Andean Community Trade Agreements, Intellectual Property & Public Health

19 September 2011

POLICY BRIEF

Overview

The first round of negotiations toward an Association Agreement (AA) between the European Union (EU) and the Andean Community (CAN) (Bolivia, Colombia, Ecuador, and Peru) was held in September 2007. The AA was to include three pillars: one on political interaction, one on cooperation programmes (also referred to as political dialogue), and one on trade. However, what began as an AA that sought to promote regional integration in the CAN, fractured into bilateral trade agreements involving just two of the four CAN countries: Colombia and Peru. The EU now refers to it as a multi-party agreement.

Civil society organisations in the Andean countries feared that the intellectual property (IP) Chapter in the trade agreement would include IP standards that would negatively affect public health. Higher IP standards would further restrict and delay competition from generic medicines for these countries, as IP protection grants companies a monopoly. Generic medicines play a vital role in raising public health standards through their effect on prices, allowing for affordability. The IP Chapter turned out to be one of the most controversial and difficult sections of the negotiations, not in the least because of the concerns regarding its impact on access to medicines and the presence of a substantial Colombian generic pharmaceutical sector.

In response to a request from local civil society, a coalition of Andean and European NGOs was established, together forming the CAN-EU Alliance for Access to Medicines. This Alliance not only monitored negotiations and carried out advocacy activities, but also offered technical input on the impact of proposed IP provisions on public health and access to medicines.

Now that negotiations have been concluded and implementation is pending, this paper aims to provide an overview of the initial EU demands, the issues that arose during negotiations, and the final outcomes of the negotiations. It also briefly assesses the IP Chapter of the final text and its likely impact on access to medicines in Colombia and Peru.

A Chronology of the EU-Andean Community Trade Agreements is available at: http://haieurope.org/wp-content/uploads/2012/01/Chronology-The-EU-Andean-Community-Trade-Agreement-Access-to-Medicines.pdf

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The Andean Community, the Break Up and Intellectual Property

CAN has its own IP regime referred to as 'Decision 486', defining IP regulations for its four members.[1] The decision came into effect on 1 December 2000. The Free Trade Agreements (FTA) that Peru and Colombia had recently signed with the USA included specific IP provisions, most controversially on data exclusivity (DE), traditional knowledge and biodiversity, which affected 'Decision 486'. In September 2008, negotiations with the EU halted due to a deepening split regarding IP between Bolivia/Ecuador on one side and Colombia/Peru on the other. The disagreement centred on 'Decision 486' and the changes that had to be made to this regime due to the acceptance of certain IP provisions by Peru and Colombia in their FTAs with the USA which were finalised in 2007.[2] On 13 August 2008, Ecuador joined Peru and Colombia in accepting changes to 'Decision 486', while Bolivia abandoned the negotiations with the EU.

Prior to Bolivia leaving the table, the EU was considering two speed negotiations, taking different paces with, on the one hand, Ecuador and Bolivia and, on the other, Peru and Colombia. However, following Bolivia's departure, the EU effectively turned to bilateral negotiations solely focusing on trade leaving the two other pillars on cooperation and political interaction aside as they were now no longer dealing with a regional block but with separate nations. Ecuador was to leave the EU negotiations later (2009) in part due to concerns around IP. Negotiations between Peru, Colombia and the EU were finalised in March 2010. Ecuador is looking at restarting negotiations with the EU, but has indicated that is has no intention of making any significant concessions on IP.

The European Union's proposals – problematic provisions and the Final Text

With regard to the EU's trade strategy, the European proposal to the CAN was unprecedented in many ways. This was the first time it was putting forward certain very ambitious proposals towards developing countries, including its extensive Chapter on IP Enforcement. As the negotiations proceeded, the text of the agreement became more considerate of public health as the EU had to give up many demands. Here, an overview is given of the most important provisions impacting Access to Medicines, as contained in the proposal put forward by the EU in January 2009, as well as the Final Text of the agreements between the EU and Peru and Colombia.

For the initial EU proposal 2007 see: http://haieurope.org/wp-content/uploads/2011/07/Nov-2007-Initial-EU-proposal-to-CAN.pdf

For the 2009 proposal see: http://haieurope.org/wp-content/uploads/2011/07/Jan-2009-EU-proposal-to-Colombia-Peru.pdf

[1]Communidad Andina. Decision 486 Common Intellectual Property Regime. http://www.comunidadandina.org/ingles/normativa/D486e.htm

[2]For an overview of the IP provisions negotiated in the the US FTAs with Colombia and Peru see: Ruben D. Espinoza Carillo. *Propiedad Intelectual y Medicamentos. Analysis de los Decretos Legislativos de Il Implementacion del TLC Peru-EE.UU*. RedGE y AIS Peru. 2009.

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For the Final Text 2010 see: http://haieurope.org/wp-content/uploads/2011/07/Final-text-EU_Colombia_Peru-March-2010.pdf

General Provision of the Intellectual Property Chapter

EU proposal 2009	**Final Text**
(Section 1) Art.1,2 The General Provisions and the objectives of the EU's initial proposal centred almost exclusively on the interests of the IP rights holders and were brief in comparison to those set out in the TRIPS Agreement, with little regard for the public interest. Furthermore, the reference to the Doha Declaration[3] was placed in the article on patents (*Art. 9*), restricting it to this domain of IP.	*(Section 1) Art.1,2,3* The article on **Nature and Scope of the Obligations** now includes: -The Parties recognise the need to maintain a balance between the rights of IP holders and the interest of the public, particularly in education, culture, research, public health, food security, environment, access to information and technology transfer. The **General Principles** now include references to and confirmations of: -The 2001 Doha Declaration on the TRIPS Agreement and Public Health; -WHA 2008 61.21 Resolution on the Global Strategy and Plan of Action on IP, Public Health and Innovation; -The possibility for each Party to make use of the exceptions and flexibilities permitted by the multilateral IP agreements; particularly when adopting measures necessary to protect public health, to guarantee access to medicines and nutrition. -"In accordance with the TRIPS agreement, no provision of this Title will prevent a Party from adopting the measures necessary to prevent the abuse of IP rights by right holders or the resort to practices which unreasonably restrain

[3]Doha Declaration: Trips flexibilities are health safeguards in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), to improve access to medicines. Debate on the interpretation and scope of the flexibilities culminated in the adoption of the Doha Declaration on the TRIPS agreement and Public Health, reconfirming the policy space for WTO members to protect and prioritize public health over IP rights. www.wto.org

	trade or adversely affect the international transfer of technology.''

These references provide important policy space for the interpretation of the articles from a public interest and health perspective. However, trade agreements, to a large extent, still mostly 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."

Supplementary Protection Certificates (SPCs) or Patent Extensions

SPCs are additional protection periods granted to manufacturers for patented medicines for which an application for marketing authorisation has been filed. The rationale for these SPCs is that they allow for a compensation for 'delays' in the marketing authorisation process. They however also delay generic and go beyond the international requirements agreed to in the TRIPS agreement.

EU proposal 2009	**Final Text**
Art.9.3 Halfway throughout the negotiation process the EU proposed prolonged protection periods for patented medicines that have filed an application for marketing authorisation. The extension would 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 five years.	*(Section 5- 3)* The final text does not contain the SPCs or patent extensions as Colombia and Peru did not accept this obligation. However, patent extension may potentially apply by virtue of the agreement with the USA that Peru and Colombia have. Yet, for the USA FTA the language of the Protocol amending the text is constructed in terms of "may" be.[4]

Data Exclusivity

DE prevents competitors from obtaining marketing authorisation, by prohibiting a generic supplier from having access to efficacy & safety data submitted by an originator medicine's manufacturer, when trying to register a generic product. The alternative would be for generic manufacturers to repeat clinical trials of medicines to prove their safety and efficacy. However, as the safety and clinical validity of the medicine being tested is already established, having patients undergo these experiments would be in conflict with medical ethics and international human rights law.[5] The

[4]The US closed negotiations on the FTAs in June 2006, but the US Congress developed a protocol for amendment in June 2007, which included changes to provisions on IP, due to concerns regarding Access to Medicines. http://www.sice.oas.org/Trade/PER_USA/Other_related_docs/Protocol_s.pdf

[5] Seuba X. *La protección de la salud ante la regulación internacional de los productos farmacéuticos* Madrid: Marcial Pons. 2010. p. 191.

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provisions on DE overlap with and complement patent protection and may extend beyond it. Furthermore, DE will apply to all medicines, regardless if they are patented or not. This creates a very strong kind of monopoly, which is 'TRIPS-plus', as TRIPS does not require WTO member states to integrate DE into its national laws.[6]

EU proposal 2009	**Final Text**
Art.10 DE proposals were also made by the EU halfway through the negotiations. This proposal entailed the introduction of EU standards on test data protection, which provides for 10 or 11 years of DE. In practice, DE prolongs the monopoly period for the product owner and the extension of the DE period would further delay generic competition, as generic manufacturers need access to these test data to be able to register their products. At the time of the proposal, Peru and Colombia had already agreed to five years of DE in their FTA with the USA. Ecuador, which was still part of the negotiations at this time, had no such agreement granting DE.	*(Section 6 – 1&2)* An agreement on DE was reached at a later stage of the negotiation process than was the case for an agreement on SPCs, underlining that the latter does not appear to be as much of a priority as DE. The final text holds the DE formula for up to five years, leaving the regime for Peru and Colombia unchanged as both countries had previously agreed to such conditions in their FTA with the USA. One remaining controversial issue regarded the definition of pharmaceutical products to include biological products. This is now different for Peru and Colombia, as Colombia grants DE for biotechnological products while Peru has agreed to protect such data as if they were trade secrets in the absence of other legislation.[7]

IP Enforcement

Provisions on enforcement were a main focus of the IP Chapter, reflecting the clear priority of the EU to export their own legal regime on enforcement.[6] Enforcement provisions are controversial as they can lead to significant costs, and a deterrence in generic competition.

EU Proposal 2009	**Final Text**
Art. 13-30	

[6] TRIPS does not require DE. Art. 39 only requires that countries protect data from unfair commercial uses. The USA and EU are exporting their DE rules by means of bilateral FTAs.

[7] For Colombia and the EU, this protection will include data protection of biological and biotechnology products. For Peru, the protection of undisclosed information of such products shall be granted against disclosure and the practice that are contrary to honest commercial practices, in accordance with Art. 39.2 of the TRIPS Agreement, in absence of specific legislation regarding thereof (see section 5 on data protection in the final text, footnote 10).

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The European proposal on the Enforcement of IP rights transformed the responsibilities originally laid out in TRIPS regarding enforcement. From stipulating only the outcomes of such provisions, thereby providing room for manoeuvre according to national law, here, the EU proposals sought to control the entire architecture of IP enforcement in minute detail. The cost of implementing such measures would present a huge burden for the governments of Peru and Colombia. Moreover, such intractable enforcement measures could potentially deter legitimate trade in low-cost generic medicines. The Chapter sought to export the Enforcement Directive (2004), but generally without the public-interest balancing provisions provided for in this directive.[8]

The Enforcement Chapter contained provisions which presented limitations to compulsory licensing and parallel imports, endangered free transit of generic medicines and criminalised patent infringements.

The initial 2007 European proposal *(Art. 26)* contained a provision criminalising patent infringements by expanding criminal sanctions to all IP rights.[9] This, in fact, went beyond the EU Community Law, and had been rejected quite explicitly by several EU Member States in the context of the talks on the IPRED2 proposal.[10]

(Sections 9,10,&11)

Some aspects of the EU proposal on enforcement were negotiated out of the text. Those particularly important for public health include:

-Criminalisation of patent infringements (the scope of criminal sanctions was limited to counterfeiting and piracy, as in the EU regulation).

-Border measures for patent infringement.

-Colombia and Peru were able to provide safeguards and checks and balances for the provisions above, either referring explicitly to TRIPS (Art. 44.2 with regard to injunctions), or to the appropriateness within domestic law. Furthermore, many of the provisions have been changed from 'the parties will'' to "the parties may''.

Hence, Peru and Colombia were able to insert many let out clauses referring to national or international legislation. Yet, the EU was successful in exporting the adoption of the EU style enforcement with regards to civil enforcement.[12]

[8]Seuba X. *Checks and balances in the intellectual property enforcement field: reconstructing EU trade agreements*. 2011.

[9]Seuba X. *Health Protection in the European and Andean Association Agreement*. HAI Paper Series. 2009. p.14. http://www.haiweb.org/03052009/18%20Mar%202009%20Executive%20summary%20&%20Conclusions%20EU-CAN%20Association%20Agreement%20FINAL.pdf

[10]Proposed Directive 2005/0127(COD), IPRED2, directive on criminal measures aimed at ensuring the enforcement of IP rights, aimed to supplement Directive 2004/48/EC of 29 April 2004 on the enforcement of IP rights (Civil enforcement).

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The proposal demanded rigorous border measures – including controls on patents of medicines in transit. These provisions would allow customs to check for IP infringement in the country of transit, disregarding trade principles such as freedom of transit and the territoriality of IP rights. Such provisions had previously led to the seizures of legitimate generic medicines aimed for developing countries which were in transit in the Netherlands and in Germany in 2008 and 2009. The proposal also carried a provision on injunctions. Once a judicial decision is taken and an infringement is found, an injunction prohibiting the continuation of the infringing activity can be ordered. Hence, injunctions are intended to stop the infringing act and to forbid its re-occurrence in the future, restoring the market exclusivity for the right holder. In the case of infringement, judicial authorities may issue an injunction against the infringer to prohibit the continuation of the infringement. In all cases this possibility is subject to national legislation, and will be implemented "only if appropriate".[11] The EU proposal also carried provisions on the right of information, on evidence, on measures to preserve evidence, damages and corrective measures. In almost all of the cases the corresponding safeguards for consumers of IP rights holding goods and competitors were not proposed.	

[12] Seuba 2011

[11] Injunctions have been found to be abused in the European context to deter generic competition, presenting European health budgets and patients with unnecessary high costs during the time of the regained market exclusivity and resulting monopoly or high prices. *Final Report pharmaceutical sector inquiry* DG Competition 2009. http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

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Technology transfer

Technology transfer is important for developing countries to gain know-how and access to technology yet the EU has been hesitant to commit to it in a meaningful way. The final text contains an elaborate article on technology transfer, the value of which it is, however, hard to judge.

EU proposal 2009	**Final text**
Art.3 The EU initially made no commitments on technology transfer[13] 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. The initial proposal contained one short article comprised of two points, one of which stipulated that "The Parties shall ensure that the legitimate interests of the IP right holders are protected.''	*Chapter 5* The final text contains an elaborate article on technology transfer, with many provisions that would be beneficial to the Andean knowledge base, industry and scientific community. For example, the following provision: "5. The European Community shall facilitate and promote the use of incentives granted to institutions and enterprises in its territory for the transfer of technology to institutions and enterprises from Colombia and from Peru in order to enable Colombia and Peru to establish a viable technological base.'' Nonetheless, it is hard to see where the EU has actually made hard commitments and the question now is how the EU intends to implement these commitments. There remains, however, policy space to pressure the EU on this.

[13] Footnote 14 in text: For greater clarity, transfer of technology includes access to and use of technology as well as the process of generation of technology.

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Impact Studies

The CAN-EU Alliance undertook impact studies in Peru, Colombia and Ecuador on the potential effect of the proposals by the EU on DE and SPCs.

The analysis of the impact is based on the Intellectual Property Rights Impact Assessment (IPRIA) model outlined by the *Guide to estimating the impact on access to medicines due to changes in intellectual property rights*, developed jointly by the World Health Organisation (WHO) and the Pan-American Health Organisation (PAHO), the International Institute for Trade and Sustainable Development (ICTSD) and the World Bank Institute, building on work by IFARMA and HAI Latin America.[14]

The studies indicated that the expected impact on health would be substantial, and predicted a dramatic increase in medicines' spending in all countries due to a lack of generic competition.

It was estimated that the introduction of the two measures on DE and SPCs would lead to an increase in Peru's total pharmaceutical expenditure of 459 million USD in 2025 and a cumulative increase in expenditure of 1267 million USD (at present value, PV) for the same year. This represents the amount required to maintain the current consumption level. A decrease in consumption would be expected, as a result from an 11% increase in the number of active pharmaceutical ingredients (API) protected by the newly introduced measures, which in turn would lead to a 26% medicines price increase.[15]

In Colombia, findings suggested that introducing the two measures on DE and SPCs would lead to an increase of 756 million USD in total pharmaceutical expenditure in 2025, and, at the same time, result in a decrease in consumption of 10%. The consumption decrease would be caused by an 8% increase in the number of IPR protected products, which in turn would produce a 16% price increase.[16]

These impact studies, which were regularly quoted during the negotiations, also underline that stringent IP enforcement measures, including controversial border measures, would potentially lead to a further decline in the trade in generic medicines, which could negatively affect access to treatment. Non-quantified costs and a concomitant chilling effect over generic competition could be inferred from the stringent enforcement framework taken as a whole, due to the shift in balance

[14] http://web.ifarma.org
http://www.aislac.org

[15] IFARMA. *Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru*. November 2009. http://www.haiweb.org/11112009/11Nov2009ReportIFARMAImpactStudyPeru%28EN%29.pdf

[16] IFARMA. *Impact of the EU-Andean Trade Agreement on Access to Medicines in Columbia*. June 2009. http://www.haiweb.org/04102010/29_Mar_2010_Report_IFARMA_Impact_Study_Colombia_EN_.pdf

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between the rights of right holders and those of generic competitors, and provisions benefiting the public interest.[17]

Implementation Effects

The agreement, currently undergoing ratification and implementation, is moving forward at a slow pace due to the political process on the European side. It is still possible to implement the agreement in a way which ensures a greater balance between the protection of rights holders and the public interest, in order to protect public health. However, this opportunity remains in the hands of the governments involved.

Once implemented the following effects could be expected:

- In general, the agreement will promote the position of the IP right holder[18] in Colombia and Peru. Depending on how both countries implement the provisions, one can expect to see a chilling effect on the trade of generic medicines as a consequence of the enforcement provisions that did go through.

- With regards to the Enforcement provision, the Peruvian and Colombian governments will see their expenditure rise in order to implement the measures to protect the private rights of multinational companies. These new costs include, amongst others, the training of judges and customs officials, representing opportunity costs for the public budget of these countries.

- The DE provision on biotechnology for Peru might have a significant effect on this country. Unlike Colombia, Peru previously never held DE requirements on biotechnological products. As an increasing amount of new medicines will be biotechnology based, DE on biotechnological products will be a major issue in the near future. Depending on the actual implementation of this provision by the Peruvian government, there could be a significant impact on health through the extension of market exclusivity on new products.

[17] Idem

[18] In this case referring to originator pharmaceutical companies.

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