

Free Trade Agreements between Colombia/Ecuador/Perú - European Union

Main threats of the European agenda for access to medicines and health in the Andean countries

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This document aims to outline, from an ethical and human point of view, some important issues related to the potential impact on access to medicines and health in the Andean countries as a result of the European agenda in these free trade agreements (FTAs).

Our analysis is based upon the explicit aspirations of the European Union (EU) regarding intellectual property (IP), contained in its proposal to the Andean countries (30 January 2009). Some sources have indicated that the topic of Utility Models² will most likely be included in the near future by the EU in its proposal. We believe it will reflect the terms in the EU agreement with CARIFORUM³, not only because it is the most recent EU agreement with developing countries (2007), but also because for the first time it includes an extensive and detailed chapter on IP, anticipating the content of future treaties.

Main concerns

The following are the main concerns about the European agenda for access to medicines and health in the Andean countries:

- 1. Objectives of the IP Chapter**
- 2. Period extension of pharmaceutical patents**
- 3. Patents of Utility Models**
- 4. Test Data Protection**

Our aim is that the European Parliament, in accordance with their commitment to abide by and implement the Doha Declaration⁴ and WHA Resolution 61.21⁵, will take the necessary steps to prevent these threats from becoming a reality in the final text of the FTAs.

In the following paragraphs we will briefly discuss each of these topics. For those who are interested in reading further on these subjects and others such as the enforcement of IPR, we recommend the paper written by Professor Xavier Seuba, quoted in the footnotes.⁶

¹ General Director of Misión Salud: NGO dedicated to the defence of the right to access medicines and Public Health, whose headquarters are in Bogotá, Colombia.

Coordinator of the Alliance CAN-UE: Alliance of organizations of European and Andean civil society, interested in the defence of the right to access medicines and public health, within the framework of the Agreements of the Association between the European Union and the Andean countries.

² A utility model is the mechanical modification of an object to produce a technical effect that allows for better use. For example, it is clear that the purpose of a knife is to "cut". If someone adds to this knife something that makes it "cut better", this is called a utility model. Some of the Andean negotiators believe that the EU will add a section on Utility Models to the proposals on IP.

³ Agreement of Economic Association with the CARIFORUM countries, 2007.

⁴ Declaration on the TRIPS Agreement and Public Health, adopted by the Ministerial Conference of WTO on 14th November 2001.

⁵ World Health Assembly (WHA), Resolution 61.21 of Mayo 2008, Global Strategy and Plan of Action in Public Health, Innovation and Intellectual Property.

1. Objectives of the IP Chapter

When two governments sit down to talk about IP and health, they do not do it to protect the rights of society or to look for new and balanced formulas between rights and obligations, but to create formulas to strengthen IP for the exclusive benefit of right holders.

Unfortunately, the EU's IP proposal for the Andean countries is not an exception. According to Article 1, the objectives of the IP chapter are to facilitate the production and marketing of "innovative products", and reach an adequate and effective level of protection for Intellectual Property (IP). It is evident that this framework benefits just one of the parties of IP: the right holder, pushing aside the other two stakeholders: the consumer and the community. In contrast, the TRIPS Agreement recognises the protection of IP on measures "conducive to social and economic welfare, and to a balance of rights and obligations" (Art. 7) and authorises the States to "prevent the abuse of intellectual property rights by right holders" (Art. 8.2).

As noted in Professor Seuba's paper, the content of the articles that establish the objectives of an international treaty is no small matter, as it shapes the interpretation of the provisions. This is very important for implementation, since discrepancies may arise. In the case of the TRIPS Agreement, the objectives added to this document have clarified many ambiguous provisions in favour of Public Health. Under Article 1 of the European proposal, the ambiguity favours the so called "innovative products" - which are rarely truly innovative - and IP protection at the expense of generic medicines, which are an essential instrument in solving the problem of access to medicines.

Our recommendation for the EU negotiators is to accept the replacement of the objectives set forth in their proposal, for those in the proposal about IP, presented by Colombia and Perú in February 2009, which match with the principles of the TRIPS Agreement.

2. Period extension for pharmaceutical patents

The proposal presented by the EU to the Andean countries contains a commitment by the Parties to extend the term of pharmaceutical patents; moving it from the date of the application request to the date of marketing authorisation for the final product, minus 5 years.

This change is not about resolving delays in the process of commercial authorisation, but about extending the real period of protection, regardless of delays- whether caused by the applicant or not.

This formula of extreme protection is drawn from the Certificate of Complementary Protection⁷, active in the EU since 1992.

Neither the TRIPS Agreement nor the CAN Decision 486 consider period extensions for patents. Moreover, though the FTAs signed by Colombia and Perú with United States fix compensation for unreasonable delays in the issue of a patent, they exclude pharmaceutical patents. They entitle, though not as a requirement, compensation for delays in the procedure

⁶X. Seuba Hernández, *Health Protection in the New Association Agreement between the Andean Community (and some of its members) and the European Community in Light of Its Provisions Concerning Intellectual Property and Recent Experiences*, Amsterdam: Health Action International, January 2009.

⁷ The Certificate of Complementary Protection is regulated under the 1768/92 EEC Regulation of the European Council, dated 18th June 1992.

of approval for commercial patents. Consequently, the European proposal is not only TRIPS plus and CAN plus; but it even goes beyond the impositions of the highly-criticised Bush administration on Colombia and Perú. This is not consistent with the assurance from the European Council to the European Parliament that they would not demand any new standards from the Andean countries.

The patents extension has no economic justification since the investment in R&D is repaid during the first two or three years of commercialisation.

Surprisingly, while internal European regulations limit the extension to a maximum of 5 years and the period of exclusive rights (patent + certificate) to 15 years, the European proposal for the CAN FTA states no limit. This means that the EU is demanding far more from its Andean associates than is allowed for within its own region, which seems both unfair and unreasonable.

If the European proposal is approved in the FTA it would take even longer for generics to enter the market, with possible delays of 20 years or more, with consequences for the price. In the case of HIV-AIDS, these delays would deprive patients of the benefit of reduced prices for ARVs, between 72% in Brazil to 98% in South Africa, for a longer time. Meanwhile, patients are waiting, suffering and even dying.

It is the European Parliament's responsibility to ensure that the FTAs obey the current status quo for the Andean countries, which does not include extensions for pharmaceutical patents.

3. Patents of Utility Models

The other great threat of the European agenda is not in its proposal to the Andean countries, but in a figure that the EU has started to use in recently negotiated commercial agreements like the CARIFORUM, namely the patents of utility models.⁸

Traditionally, these patents which last 10 years, have been granted only to mechanic innovations on products, and have been specifically forbidden for procedures and materials not protected by invention patent.⁹

In this context, there is no need to worry about the EU incorporating these types of patents to its proposal for the Andean countries. The problem would be if they do it in the same way as for CARIFORUM, which extends the application of these patents: *"The EC Party and the Signatory CARIFORUM States may provide protection for any products or processes in any fields of technology, provided they are new, involve some degree of non-clarity and are capable of industrial application"*.¹⁰

There is a concealed interest behind this figure: that of extending the patentable range of pharmaceutical products for the benefit of the pharmaceutical multinationals. If approved in the treaty with the Andean countries, this would open the door to patents for second therapeutic uses and for the trivial development of known molecules, among others; this is

⁸ A utility model is the mechanical modification of an object to produce a technical effect that allows for better use. For example, it is clear that the purpose of a knife is to "cut". If someone adds to this knife something that makes it "cut better", this is called a utility model.

⁹ Decision CAN 486 of 2000, art. 82

¹⁰ CARIFORUM and EU Partnership Agreement. Art. 148. A.1.

because many of these innovations are likely to fulfil the requirement of “*some degree of non-obviousness*”, making them worthy of monopolist protection.

This would have dramatic consequences for health and the sustainability of health systems in the Andean countries, due to rising numbers of protected active principles, causing a greater delay in the supply of cheap generic medicines, an increase in health expenditure and a loss of access to medicines and other sanitary products.

Due to the pressure from the international pharmaceutical industry, this figure may be brought to the negotiation table at the last minute, to force approval by political means. We hope that the EP will not allow this to happen.

4. Test Data Protection

The European proposal suggests taking the European standard for Data Protection, which is “8+2+1”:

- **8** years of Data exclusivity right, during which no commercial applications can be based on this Data.
- **2** additional years of market exclusivity right, during which a third party must present its own Data to obtain a marketing license.
- **1** additional year of market exclusivity right, in case new product reference indications are registered during the first 8 years.

Of all the threats contained in the European agenda for the FTA, this is the one with greater impact over the fundamental right to health, given the capacity of extending the spectrum of protected medicines. Their generics could not be commercialized before 10 or 11 years, from the marketing authorization date of the original product

As in the case of patents extension, the European formula for Data Protection is TRIPS plus, CAN plus, and -believe it or not- USA plus, since the treaties with USA foresee an exclusive protection of 5 years, which means half of the time of the European formula.

According to calculations made in 2006 based on a methodology designed by the PAHO-WHO,¹¹ setting up Data exclusivity in Colombia for 5 years would mean that the active ingredients with monopoly, which at study date represented 4% of the market, would become 43% in 2010 and 54% in 2020. As a consequence, the generic medicines would lose half of their participation in the market, resulting in a loss of access to medicines. Therefore, it is obvious that the introduction of the “8+2+1” formula will cause a worse sanitary effect.

Our recommendation for the FTA is to respect the current standards in each Andean country: in Ecuador the TRIP Agreement standard, in Colombia the standard of Colombian Decree 2085 (exclusivity for 5 years) and in Perú the FTA with the United States standard (exclusivity for 5 years). Otherwise the EU will be held responsible for any damage caused by this treaty to Public Health in the Andean countries.

¹¹Health-IFARMA Mission, The Intellectual Property in the FTA with the United States: impacts on the pharmaceutical expense and the access to medicines in Colombia, October de 2006 (www.misionsalud.org).

Economic and sanitary impact

If the above mentioned provisions are included in the FTA, they would greatly harm the health systems in the Andean region. It would in effect strengthen the monopoly of expensive medicines and limit the provision of cheaper generics.

We must take into account that in the Andean region generic medicines cost an average of 75% less than the originator brand products and in some cases, even 35 times cheaper.¹² This, added to the good quality of the products, has resulted in generics nowadays supplying 67% of the pharmaceutical market in units.¹³ Therefore, any action that blocks them out of the market or delays their inclusion will definitely result in a loss of access.

The CAN-EU¹⁴ alliance is currently measuring the possible economic and public health effects of the provisions mentioned in this document, based on a model of impact evaluations endorsed by an international consortium comprising of the World Health Organization, the United Nations Development Program, the World Bank Institute, the Inter-American Development Bank, HAI Global and the International Centre for Trade and Sustainable Development. The results of these evaluations will be shared with the European Parliament.

Studies done in Colombia during the negotiations of the FTA with the United States and based on the same model¹⁵, came to the conclusion that giving way to all the initial aspirations of the United States about IP (which were similar to the current European proposals, with the exception of data protection and the period extension for pharmaceutical patents, in which the European Agenda is more severe), will have the following impacts:

- An increase of the active ingredients protected with a patent or with data protection, from 4% to the 30% of the market.
- 46% growth in the medicines price index.
- A rise of US\$1.000 millions per year in health expenditure. This figure is equal to 40% of the national pharmaceutical market.
- Without enough money to absorb these increases, more than 5 million Colombians could lose access to their essential medicines.
- In the case of HIV/AIDS, this would affect 12,000 patients per year, who would see their life expectancy reduced by between 5.3 and 9.9 years.

In Bolivia, Ecuador and Perú there would be similar effects, taking into account the size of the population and the pharmaceutical market.

¹² In the case of the Phenytoin for example, active ingredient used for Head Trauma treatment, in 2004 the difference in prices in Colombia was, COL \$737 the generic v/s COL\$26.151 the international brand product; this means 35 times more. Other examples referring to high frequency or high importance illnesses for Public Health can be found in "Study on Intellectual Property in the Colombian Pharmaceutical Sector" Annex 3, June 2005 FEDESARROLLO.

¹³ In Colombia, the generic medicines represent a 65% in units of the Commercial market and the 80% of the Institutional market (Source for the commercial market: IMS). The situation for Perú is similar.

¹⁴ Alliance of the organized civil society of Europe, with the Andean countries. This network is coordinated in the EU by HAI Europe and in the Andean region by Fundación Misión Salud (misionosalud@yahoo.com).

¹⁵ IFARMA Foundation, The Intellectual Property in the FTA: impacts on the pharmaceutical expense and the access to medicines in Colombia, October de 2006. It can be found with no cost, in the files of Misión Salud: misionosalud@yahoo.com

If we consider the European proposal on patents and data protection to be more severe than those evaluated in this paper, we must conclude that an FTA built on such proposals, would be disastrous for the health of the Andean people.

In this scenario, the FTA could turn into an instrument of pain and loss of human lives. We do not think this is what European citizens and the European Parliament want for the Andean countries.

WHA Resolution 61.21

Last May the World Health Assembly adopted resolution 61.21, the Global Strategy and Plan of Action on Innovation, Public Health and Intellectual Property, surely the “most important world document about intellectual property and public health since the Doha Declaration”.¹⁶

I want to stress that this resolution was approved by general consent, which means that all Members of the WTO, including the European Union and the Andean countries, are obliged to respect it and implement it.

It is also important to bear in mind that the Strategy results from serious consideration by the WHO after five years of research and deliberations¹⁷: The current model of incentives for innovation, based on patents and the perspective of high monopoly prices, is unsuitable for developing countries, which represent the 80% of the worldwide population, because it does not yield medicines for their diseases¹⁸ because of unattractive market potential, and because the treatments for rich country¹⁹ diseases are not affordable.

Consequently, the Global Strategy states two objectives: to encourage research and development of medicines and other products needed to solve health problems in poor countries, and to improve their access to these new products as well as to the ones already on the market.

In short, to improve the capacity of innovation of developed countries towards the urgent pharmaceutical needs of developing countries, to identify incentives for the inventors without patents or high monopoly prices, and to assure the contribution of all countries to the achievement of this goal.

From this perspective, the governments of Colombia and Perú have included in their proposal on IP, a provision in which “The Parties recognize the importance of promoting the implementation and full use of Resolution WHA 61.21...” (Art.1.2)

We leave it in the hands of the EU mission to guarantee the inclusion of this commitment in the FTA.

¹⁶ IP Watch, article about World Strategy, 30.05.2008. By William New.

¹⁷ The Intellectual Property Rights, Innovation and Public Health Commission (CIPIH), created by the World Health Organization 5 years ago, the Intergovernmental Working Group for Public Health, Innovation and Intellectual Property (IGWG Group), created by the World Health Organization in 2006, and three writing groups made up by the IGWG Group. Countries members of the WHO, experts and Institutions participated in the previous mentioned groups.

¹⁸Diseases, known as “neglected illnesses” like malaria, tuberculosis, leishmaniasis, Chagas, dengue and leprosy etc.

¹⁹ Diabetes, cancer, cardiovascular disease, etc.

Final Consideration

In the Andean region, more than half of the population does not have enough access to medicines, either because they do not belong to any health system,²⁰ or because they cannot afford the products that the system provides. Sadly, the average expense in medicine per capita in this region is only half the expense in medicine per cow in Europe.²¹

This problem would get worse if the European expectations, mentioned in this document, were included in the FTA.

The EU cannot be blind to this reality. As President Obama said about the U.S., it cannot stand with indifference “to suffering outside its borders; nor can it consume the world's resources without regard to its effect.... Its power does not entitle it to do as it pleases”.²² The EU must refrain from forcing Andean countries to accept provisions that strengthen the pharmaceutical monopoly, that affect the availability of inexpensive generics which are the only feasible solution for the great majority of the population and therefore, restrict even more the access to these essential goods.

As representatives of the Andean civil society at this meeting, we raise our voice so that in the negotiations of the FTA, equity is assured and common welfare proclaimed as a basic principle. The goal must be an agreement in which Europe and the Andean region can share not only the promotion of commercial interchange, but the construction of a fair social relationship. “We all deserve the opportunity to reach real happiness.”²³

Because of its connection with health and life, access to medicines, is a fundamental right for all inhabitants of this planet. Health is non-negotiable.

²⁰ In Latin America, in 20 countries where there is health insurance, it only covers an average of 45% of the population.

²¹ Federico Tobar, “Déficit de Salud en América Latina”, Tribuna 2006. Clarin.com.

²² Inauguration speech. President Barack Obama 20.01.2009.

²³ Inauguration speech. President Barack Obama 20.01.2009.

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The rising intellectual property enforcement standards in international agreements promoted by the EC

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Xavier Seuba

When analysing the potential problems that a new text on intellectual property (IP) may cause to the protection of public health it is worth recalling that the present framework, the TRIPS Agreement, was adopted just few years ago. The TRIPS Agreement is a treaty that aggravated access to medicines problems in developing countries, problems that have not yet been resolved and that will continue to manifest in the coming years. In fact, the TRIPS implied a fundamental change as far the international regulation of IP is concerned. A change that was very important even in developed countries. At the beginning of the nineties, European Community countries such as Spain, and other OECD economies such as Norway and Iceland, were not fulfilling all the conditions that some years later, in 1995, were set forth and made mandatory in the TRIPS Agreement for all WTO Member countries, most of them developing countries.

Let's introduce a very real example of what the TRIPS Agreement means. In Spain, because of some of the agreements concluded when Spain joined the European Community in 1986, there are up to 15 blockbuster pharmaceutical products whose patents are in dispute. Innovative companies claim that the TRIPS Agreement has retroactive effects, and, consequently, patent product protection should be granted to those products. As you may guess, generic companies and public health advocates claim the opposite. At stake are almost 3000 million euro per year, money that, as you may also guess, is publicly funded.

This is only a small example of the dramatic changes that the TRIPS Agreement implied. Multiply cases like this in relation to very diverse subjects and topics set forth in the TRIPS, considering that these consequences apply not only to public health but also to agriculture, industrial development and, among others, culture. Bearing that in mind, consider the implications of the same scenario applied to developing countries...

Although the TRIPS Agreement caused international controversy, and despite the fact that it has not yet been entirely implemented, the continuous raising of IP standards has not stopped there. In practice, the TRIPS Agreement is the milestone that opened the door to new initiatives that invariably sought to increase IP standards. The proposal of the European Community to the Andean Community regarding intellectual property in the new association agreement continues this trend. A trend that has become so exaggerated that, in fact, the European proposal includes standards even above the existing ones in the European Community.

The part of the European Proposal to the Andean Community of States devoted to enforcement of IP rights is particularly helpful for showing the contradictory trends emanating from different European policies and the exacerbation of intellectual property rights holders

protection. This is not by chance, but it was already anticipated –among other measures- in 2004, in the *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*.

First of all, the European proposed articles regarding enforcement are to be added to the existing relevant regulations in the TRIPS Agreement, which in 1995 were already considered very demanding when compared to the previous international legal framework. The European proposal sets forth eighteen new articles -out of 31 contained therein- exclusively devoted to enforcing IP holders rights.

In its proposal to the Andean Community, the EC has basically exported its own standards regarding IP enforcement, namely the European Directive 2004/48/EC and the European Regulation 1383/2003, standards which, on certain matters, have also been raised.

For example:

Criminal sanctions- The TRIPS Agreement was already novel -internationally speaking- when introducing criminal sanctions for infringements of certain IP rights. However, it limited those sanctions to cases of copyright piracy and trademark counterfeiting. The TRIPS agreement also allowed to exclude, among the criminal sanctions, imprisonment.

By contrast, the European proposal to the Andean Community makes the punishment of all intellectual property rights infringements mandatory through, among other sanctions, imprisonment. But what it is more striking is that these very standards have been explicitly rejected domestically by European countries and also by the European Parliament. You may recall the controversy that surrounded the adoption of the proposed Directive IPRED2 on criminal measures aimed at ensuring the enforcement of intellectual property rights. This obviously raises questions about surpassing the European Parliament to achieve a previously rejected outcome through the conclusion of international agreements.

A second example may be found in relation to border measures. Compared to the TRIPS, the European proposal to the Andean Community increases the activities and also the intellectual property rights for which custom authorities must suspend the release of goods. The TRIPS only made it obliged states to allow the right holder to lodge an application to customs authorities to suspend the release of imported counterfeit trademark or pirated copyright goods into free circulation. By contrast, the European proposal to the Andean Community –and other concluded agreements- enables the right holder to block the importation, exportation, re-exportation, entry or exit of goods suspected of infringing any intellectual property rights in the customs territory. This represents a dramatic broadening of the required measures, and grants a tremendous power to title holders, who will be able to block rival goods alleging a supposed infringement of an IP right. The recent Dutch custom authorities Losartan case illustrates this point quite well. In conformity with procedures set out in the European Regulation 1383/2003, which empowers the EU member states' customs authorities to detain goods in transit on suspicion of an infringement of intellectual property rights, a shipment of the afore-mentioned active ingredient was blocked and sent back to India after a claim was made by the patent holder.

The part of the European proposal devoted to the enforcement of IP rights is a quite complex and tricky one. The underlying goal, however, is to strengthen IP holders position. In contrast

with the TRIPS Agreement and other relevant documents agreed by the European Community and its Member States, such as the *WIPO Development Agenda* and *WHO Strategy and Plan of Action on Public health, innovation and IP*, the European proposal disregards flexibility and exports to developing countries the most advanced European IP enforcement regulations. If adopted, this will produce a rise in the budget allocated to intellectual property rights protection, something which is expressly excluded in the TRIPS Agreement, and which is particularly problematic when considering the financial and development situation of the affected countries.