



Executive Summary &  
Conclusions and Recommendations

# Health Protection in the European and Andean Association Agreement

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Paper Series Reference 05-2009/01

NOTE: These excerpts are from the updated version of the publication, *Health Protection in the new Association Agreement between the Andean Community (or some of its members) and the European Community in light of its provisions concerning intellectual property and recent experiences*, originally published in January 2009.

*Published by:*

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from

***Health Protection in the European  
and Andean Association Agreement***

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A HAI Europe/AIS Latinoamérica & Caribe Publication

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# Executive Summary

The European Community (EC) is in the process of negotiating and has already concluded numerous bilateral agreements and agreements with regional blocs that, along with other objectives, aim to continue liberalising trade and strengthening fields of interest for the EC, such as intellectual property. These treaties are called by different names; for example, there are association agreements, economic partnership agreements, partnership and cooperation agreements, and simply free trade agreements. Since September 2007, the Andean Community of Nations (CAN) and the EC have been negotiating an association agreement based on three pillars, or “dialogues”: cooperation, political dialogue, and trade.

By October 2008, three rounds of negotiation had been held and a fourth had been cancelled. During these rounds, the split among the Andean countries has become evident, at both a political level and with regard to the commitments they are willing to make with the EC. Peru and Colombia seem willing to accept the European proposals without raising significant objections in problematic areas such as intellectual property in exchange for a greater opening of the European market. Bolivia is set against making new commitments on intellectual property and other matters, whereas Ecuador is attempting to hold on to the possibility of entering into a trade agreement without accepting the accompanying costly commitments in the EC’s areas of interest. The most likely outcome is the adoption of bilateral agreements and the exclusion of some of the Andean countries. The latter has already occurred in the agreements between the EC and group of African, Caribbean and Pacific (ACP) countries, and it seems probable that it will also be the case in the agreement between the EC and the Association of Southeast Asian Nations (ASEAN) countries.

Sub-group 11 of the EC – CAN negotiations is in charge of matters relating to intellectual property, and this group is also the source of the leak of the European proposal. This proposal holds the line of the EC’s priority protection of intellectual property standards, in particular relating to enforcement, ever since it adopted the *Strategy for the Enforcement of Intellectual Property Rights in Third Countries* in 2004. The EC has identified various channels for encouraging enforcement of certain standards of intellectual property protection, among them being the conclusion of international agreements, bilateral pressure (through expatriate representatives of the Commission, the creation of lists of countries that are supposedly lax about infringements, etc.), actions within multi-lateral organisations (particularly the Council for the Agreement on Trade Related Aspects of Intellectual Property Rights, but also the World Intellectual Property Organization (WIPO), and cooperation with other countries with similar interests (several strategies with Japan and the United States and the Anti-Counterfeiting Trade Agreement (ACTA) initiative).

Looking at the intellectual property issues contained in the European proposal to the CAN from the perspective of protecting public health, special attention should be paid to:

- i) the general provisions
- ii) the article on patents
- iii) the provision dealing with test data protection
- iv) provisions dealing with enforcement of intellectual property rights
- v) cooperation

Within the general provisions are the agreement objectives, which are very narrow when compared to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and almost exclusively adopt the position of the intellectual property right holders. Its narrowness and focus could have negative effects when interpreting treaty provisions that allow for public health protection. As for the objectives, the European proposal to the CAN is not just inferior to the TRIPS Agreement, but also less attentive to consumers' rights and the general societal interests, particularly when compared to what the EC has agreed with other regional integration organisations.

This European association agreement proposal lacks the TRIPS Agreement reference to the freedom of members to "determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice." Instead, it sets a rigid and extremely precise framework for the measures and actions states must adopt and implement regarding intellectual property.

The proposal furthermore intensifies the European trend of including categories of intellectual property rights that are not included in the TRIPS Agreement, along with others on which there is disagreement as to whether they are standalone intellectual property categories. What is more, under the European proposal, life forms must be protected by means of patents, a *sui generis* system, or a combination of both. However, unlike other agreements concluded by the EC, in the proposal to the CAN, no mention is made of the Convention on Biological Diversity. Given the dispute about patenting biological resources, it seems highly necessary to mention the basic principles of this Convention, such as the equitable sharing of benefits, the disclosure of the origin of genetic resources, and prior informed consent. These are all issues that can have a relevant impact on public health and biotechnological products.

The degree of interconnectivity between the TRIPS Plus and TRIPS Extra standards included in the European proposal and other TRIPS Plus and Extra standards accepted by some of the members of the Andean Community in free trade agreements (FTAs) with the United States should be considered. That is to say, it should be clear whether what is agreed upon with the United States and the EC can also be demanded by other TRIPS Members. The nature of the complementary is clear: the United States is increasing substantive standards, while the EC is strengthening enforcement. In this regard, there are diverse positions one could adopt, each one resulting in a different IP regime:

- The TRIPS Plus and TRIPS Extra obligations are not referred to TRIPS Agreement advantages, privileges, favours, and immunities in clauses on national treatment and most favoured nation treatment. Therefore, they cannot be extended beyond American or European intellectual property right holders that benefit from these clauses contained in treaties concluded by their states.
- Only new obligations undertaken on issues relating to intellectual property rights expressly set forth in the TRIPS Agreement can be extended. This interpretation is in keeping with the text of the TRIPS Agreement, particularly footnote 3. Hence, TRIPS Plus provisions would be extended to the European and American holders but not TRIPS Extra provisions.
- The criterion for determining the scope of TRIPS Plus provisions is not only that they be matters related to rights expressly set forth in the TRIPS Agreement, but also those relating to enforcement and exercise of intellectual property rights expressly set forth therein.

- *Given*
  - a) the usual channels of indiscriminate incorporation of treaty obligations which include provisions beyond the TRIPS Agreement,
  - b) and the asymmetries between developed and developing countries vis-à-vis the established obligations and the channels used to interpret their appropriateness and implementation requirements,

the aforementioned remarks may be conceptually valid but lacking in practical effects. When the latter is not duly solved through adequate regulatory measures, this option offers the most demanding results in what concerns the observance of obligations by the States.

In the European proposal, the article on technology transfer is more limited than the already feeble and largely ineffective equivalent articles in the TRIPS Agreement. Moreover, this article is also weak compared to the commitments made by the EC with other states. Within the specific scope of the relationship between technology transfer and public health, the EC recently made a commitment in the WHO to undertake much more interesting and practical activities. The Andean countries have a good text, *The Global Strategy and Plan of Action for Public Health, Innovation, and Intellectual Property*, from which to extract and incorporate provisions that truly seek to promote technology transfer.

With regard to the exhaustion of rights, the European proposal does not modify the system currently in force in the CAN. However, Andean countries should be aware that, if they want to resort to the maximum flexibility allowed by the TRIPS Agreement, i.e. international exhaustion even when the intellectual property right (IPR) holder has not consented to commercialise the product, then the proposed European provisions on border measures could prevent them from doing so. In order not to hinder future amendments to Andean intellectual property legislation that benefit health protection, it would be advisable to modify a footnote in the European proposal and replace the holder's consent reference with another referring to the legality of commercialisation.

In the European proposal to the CAN, only article 9 makes a specific reference to patents. On one hand, this provision expands the commitments contained in the TRIPS Agreement by requiring that the parties comply with international treaties (and modifications) not provided for in the TRIPS Agreement. On the other hand, it discusses the relationship between patents and public health. Yet, the fact that a reference is made to the relationship between "patents" and public health and not, in turn, to the relationship between intellectual property rights and public health is important because it limits the Doha Declaration to patents and precludes the application of a pro public health interpretation to numerous articles and related measures. A good reference to improve the EC text is point 36.5.2 of the WHO *Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property*. Furthermore, the Andean countries must evaluate whether it is prudent to accept the European proposal's obligation to ratify an amendment to the TRIPS Agreement that establishes a failed system of compulsory licensing for exports to countries without production capacity.

The article devoted to a particularly important question – data protection – is still lacking in content. In this regard, there may be two alternatives. The first is that the EC will claim the same measures as those agreed upon in the treaties signed by some CAN members with the United States (or just not claim them but simply expect to get them through the application of national treatment). The second is

that the Community could continue exporting its own standards, particularly Directive 2004/27/EC. For the CAN countries that have not signed free trade agreements with the United States with TRIPS Extra provisions (exclusive, temporary data protection), the standard continues to be from article 10 *bis* of the Paris Convention, namely, the protection of data against unfair competition.

The bulk of the European proposal to the CAN focuses on the enforcement of intellectual property rights, as in other agreements recently signed by the EC. The EC is exporting the contents of European Directive 2004/48/EC and European Regulation 1383/2003. In fact, the proposal in question even goes beyond the EU regulations by attempting to export rejected contents of the Directive IPRED2, which is still pending approval. The European proposal transforms the TRIPS Agreement provisions, which are results-oriented and allow significant room for manoeuvre, into articles that define both results and required actions in great detail.

One noteworthy omission is the reference to article 41.5 of the TRIPS Agreement, which states that “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.” Alternatively, a good general framework for enforcement can be found in Point n° 45 of the WIPO Development Agenda.

The European proposal to the CAN increases the number of entitled applicants that can take action to defend an intellectual property right and includes third parties legally authorised to exercise holders’ rights. Another new matter is actions and measures that entitled applicants can request and that significantly broaden obligations in the TRIPS Agreement. As opposed to the TRIPS Agreement, entitled applicants may file not only civil and administrative actions, but also criminal ones.

When compared to the TRIPS Agreement, the provision regarding preservation of evidence that may be in the possession of an alleged offending party undermines that party’s rights. This is seen in several issues, such as the adoption of measures without the other party being heard, the transformation of what the TRIPS Agreement states is a judicial power into an obligation for the states, and the omission of the TRIPS Agreement reference, which demands that evidence a claimant must provide “be sufficient to support the claims.”

Besides transforming into obligations what in the TRIPS are faculties, the European proposal remarkably expands the information to be provided in proceedings on the infringement of intellectual property rights. The TRIPS Agreement states that the infringer must be the one to provide the information, whereas the EC proposal sets forth that information must be provided by the infringer and any other person who was found in possession of, using, or providing the infringing goods or services on a commercial scale. Moreover, information that can be supplied under the TRIPS Agreement can only be related to the identity of third parties who have participated in the “production and distribution” and to their channels of distribution. In contrast, the European proposal demands that the Andean countries order judicial authorities to require the infringer to report the names and addresses of the producers, manufacturers, distributors, suppliers, and other previous holders of the goods or services, as well as wholesalers and retailers, and also on the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the goods or services in question.

The TRIPS Agreement merely states that the wilful or negligent infringer must pay adequate damages to compensate for the injury the right holder has suffered. Requiring payment of the holder's legal expenses is a power of the courts, and it is a power of the Member States to authorise the courts to grant reparation for benefits and/or damages in the event the infringer did not know he was carrying out unlawful activities. However, according to the European proposal, not only must there be "adequate" compensation, but this compensation must cover "all the relevant aspects", which include, no less than, damages caused to the holder, profits obtained by the infringing party, and even "moral prejudice" he has caused.

One of the most striking aspects of the European proposal relates to criminal remedies advocated in cases of intellectual property right infringement, which surpass not only the TRIPS Agreement, but also European legislation. This is a particularly concise article, which seeks to define and apply imprisonment, monetary fines, confiscation of materials and products, destruction of goods, closure of involved establishments, disqualification, judicial supervision and winding up orders, exclusion from public benefit or aid, and publication of judicial decisions. The EC is urging its Andean partners to accept commitments that European countries and the European Parliament have internally rejected or, in other words, the generalisation of criminal remedies for infringements of intellectual property rights, even in cases of patent infringements. The first matter to be addressed is whether the European Commission has the authority to insist on commitments that the European Parliament expressly rejected within the European Union. One could also question the degree to which the Commission is seeking to introduce measures via international negotiations that it had unsuccessfully negotiated within the European Community. By expanding criminal prosecution to all infringements of intellectual property rights, the European proposal differs considerably from the TRIPS Agreement, which only requires criminal proceedings to take place for cases of wilful trademark counterfeiting or copyright piracy. To make any infringement of intellectual property rights on a commercial scale (a highly debatable term) part of criminal law passes the defence and cost of private economic rights to the state. On the other hand, it also complicates the administration of specific and unique areas (patent law and criminal law), given that the two fields of law are now crossing over into each other and a new instrument is created to intimidate potential competitors.

The EC has been applying pressure bilaterally, multilaterally and regionally to expand the terms set forth in the TRIPS Agreement regarding border measures. In comparison with the TRIPS Agreement, European proposal to the CAN increases activities for which customs authorities must suspend the release of goods and increases the number of intellectual property rights whose alleged infringement would likewise obligate customs officials to suspend the release of suspected goods. With regard to the activities, it is now no longer just a matter of import control but also encompasses exportation, re-exportation, entry or exit of the customs territory, placement under a suspensive procedure or placement under a customs free zone or a customs free warehouse. Moreover, provisions in article 51 of the TRIPS Agreement that only make reference to counterfeit trademarks and copyright piracy are broadened in the European proposal, which adds the infringement of "an intellectual property right" and, in this specific scope, includes not only trademarks and copyrights, but also patents, plant variety rights, designs, and geographical indications. The expansion of border measures could have harmful effects on trade, especially for patent protected products because it is very difficult, if not impossible, for customs authorities to determine, *prima facie*, that a patent has been infringed. It should also be pointed out that there is a potential requirement to reinstate customs checks in areas of regional

integration, where it has been eliminated. And this is true not only for the CAN, but also for the EC, an effect which the latter may not have foreseen.

Two final remarks must be made on issues other than enforcement. The first is the innovative commitment to foster the development of codes of conduct aimed at facilitating enforcement of intellectual property rights. And the second is that 'cooperation' is limited to the legal development of provisions to protect intellectual property rights, as well as practices designed to guarantee IPR enforcement. A more useful alternative in the field of cooperation would be cooperation on forging intellectual property rights administration that would meet the CAN Member States' needs on public health, for instance.

In conclusion, with regard to intellectual property, the European proposal to the CAN barely commits the EC while erecting barriers for the CAN countries. This proposal seems designed exclusively to protect intellectual property right holders, restricting conferred rights in the TRIPS Agreement, and limiting the effects of the Doha Declaration. All in all, it is the emphasis placed on IPR enforcement that stands out, and this zeal has led the European Commission to propose higher standards than those applied to European countries, standards which are, on occasion, contradictory and even debatable in terms of the EC's own legal framework.

## VI. Conclusions and Recommendations

Concluding an association agreement between the EC and the CAN could be attractive for both parties. In strictly economic terms, the CAN still has much ground to make up in the European market, while the EC is on a quest to strengthen three fronts: its position in the sphere of commerce, the legal position of its investors, and the position of intellectual property rights holders. For both the EC and the CAN, an economically integrated Andean region is much more beneficial than one with four segmented national markets. So, disagreements within the CAN only weaken its negotiating position and make the potential trade agreement less attractive to the EC.

The repercussions that a divided CAN could have on a potential trade agreement are speculative at this time, but it would appear reasonable to expect the EC to demand higher standards of intellectual property protection than it would in an agreement with a united CAN. For the time being, these standards are TRIPS Plus, TRIPS Extra, and EC Plus.

One important issue relates to clarifying the effects of TRIPS clauses that define national treatment and most favoured nation treatment. While it is clear that these clauses break the *pacta tertiis* principle and extend what has been laid out in subsequent agreements to national holders of intellectual property rights of WTO countries that are not participants in such agreements, the subject of what exactly is extended is debatable. The CAN countries should take a joint position on the extended “advantages, privileges, favors, and immunities” as well as on issues like the non-application of these clauses in areas such as the exclusive and temporary protection of test data. In addition, an in depth study must be conducted into the possible exclusion of national treatment and most favoured nation treatment of the provisions regarding enforcement and implementation that are not specifically defined in the TRIPS Agreement. In any case, the CAN Member States would do well to consider the multiplying potential these clauses have with respect to the beneficiaries of concessions they make on intellectual property, or at least their potential as a source of pressure and disputes.

Another general though significant matter is the relationship between the TRIPS Agreement and the potential association agreement between the CAN and the EC. On the subject of intellectual property, the European proposal asserts that it “interprets and complements” the TRIPS Agreement. However, there are plenty of important matters it has left out, and these have nothing to do with the, as yet, unwritten articles on most favoured nation treatment and data protection, but rather are omissions in objectives, compulsory licensing, patentability requirements, exceptions to holders’ rights, and other important subjects from the perspective of public health (and industrial and innovation policies). In this sense, to remove any ambiguity that could lead to restrictive interpretations on these subjects, it must be emphasised that, pursuant to article 30.4.a of the Vienna Convention on the Law of Treaties, all terms of the former treaty—i.e. the TRIPS Agreement—that have not been repealed, or are incompatible with the latter treaty, shall remain in force. Therefore, for those countries that have not relinquished the measures for weighing the protection of intellectual property against the higher social good (also known as the “TRIPS flexibilities”) through other channels, the flexibilities remain valid. These measures, along with others, such as article 40 of the TRIPS Agreement, which refers to the control of anti-competitive practices in contractual licenses, should facilitate access to pharmaceutical products if there is a political will to do so.

While not necessary in strictly legal terms, it would be wise to introduce a provision in the body of articles that reminds the parties of their obligations by virtue of other international agreements. This could be a *chapeau* article that mentions international commitments made in the areas of labour, the environment, and human rights. In this last respect, specifically for issues related to pharmaceutical service, it would be appropriate to mention article 12 of the International Covenant on Economic, Social, and Cultural Rights, a treaty to which both the EC and the CAN Member States are party. By virtue of this article, states have undertaken to respect, protect, and comply with the right to health in the pharmaceutical sphere and to allow other states to do the same with respect to the individuals who are under their jurisdiction.

There are several aspects of the European proposal where considerable improvements could be made. One such improvement would be a more comprehensive draft of the objectives and principles that inspire and govern the agreement, which is important for the purposes of interpreting the provisions it contains. In this regard, merely emphasising TRIPS Agreement provisions or reintroducing terms from other recent agreements between the EC and developing countries would suffice. Issues that should be stated as objectives in the intellectual property section of the association agreement are:

- i) guaranteeing access to innovative products
- ii) promoting the transfer of technology
- iii) fostering technological development in CAN Member countries, and
- iv) prioritising protection of higher public goods, such as human health.

In addition, it is also important that the text does not restrict the reference to the Doha Declaration to article 9 regarding patents, but rather that it be extended to all intellectual property rights, as provided for in the Doha Declaration. Likewise, the Andean countries should rethink their commitment to sign an agreement (the protocol amending article 31 of the TRIPS Agreement) that contains a text (the Decision of 30 August 2003) that is rarely put into practice and is at the moment barely viable. Furthermore, it would be advisable to include a reference to the Convention on Biological Diversity, which the EC has agreed to include in other recent treaties, and to clarify whether the Andean countries will be expected to ratify the treaties they have undertaken to apply.

Given the current characteristics of the EC proposal to the CAN, the association agreement appears open to incorporating provisions on temporary and exclusive protection of test data that has been submitted for pharmaceutical product registration. If they accept, CAN Member countries would become the first developing countries to give in to this European request and would, as a result, hinder both access to and development of pharmaceutical products. For the latter, this would occur because it would become necessary to repeat dangerous, unnecessary trials on human beings, and for the former, because the temporary and exclusive data protection would hinder the entry of generic medications into the market, even after the patent protection period had expired.

The articles on enforcement constitute a substantial portion of the proposal, reflecting or expanding the contents of the secondary European law. The proposal provisions correspond, fundamentally, with the articles contained in other relevant and recently concluded agreements. Overall, accepting the European proposal as it is means relinquishing the flexibility on enforcement expressly recognised in the TRIPS Agreement. Furthermore, it is questionable whether developing countries should apply their resources to implementing enforcement standards for intellectual property rights that are even stricter

than those in the TRIPS Agreement, whose chapters on intellectual property rights enforcement and exercise were surprising just a few years ago.

Also on the subject of enforcement but in relation to more specific matters, the European proposal moves beyond current Community law. Such is the case, for example, of criminal remedies for all commercial-scale infringers of any intellectual property rights, not just trademark and copyright rights, as laid out in the TRIPS Agreement. Responsibility is also expanded to include intermediaries, and then there is the remarkable aspect to consider of the consequences for the police and judicial systems of implementing what is required on information that infringers are forced to divulge. A similar situation can be seen with border measures, which are nothing more than the Community's regime, without a doubt costly and proven to be difficult to implement. As noted previously, the application of the proposed border measures creates serious drawbacks in the area of pharmaceutical patents, drawbacks not just limited to increased budgets for customs checks, but also expanded to encompass access to medicines by permitting the, at least temporary, blockage of medicines following allegations that, even if they are later proven unfounded, will delay the entry of competitors into the market.

One option available to the CAN Member States is to seek expert advice from independent international organisations. If Thailand resorted to Resolution WHA60.30 to request a WHO mission to advise it on the use of the so-called TRIPS flexibilities, then the CAN, as a bloc or the member countries individually, can use the *Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property* (WHA61.21), point 36.5.2, which authorises the WHO to provide technical support on the use of the TRIPS flexibilities, which logically includes support for the evaluation of treaty proposals that limit such flexibilities.

The CAN must conduct studies on the economic impact and public health consequences of incorporating TRIPS Plus and Extra and EC Plus provisions that are contained in the European proposal. Impact studies must consider such relatively new issues as the economic cost of customs measures and police and judicial measures prescribed in the European proposal, as well as not so new issues for some of the CAN members like data protection and the extension of the patent protection terms. These latter issues will certainly depend on the interpretation of the national treatment and most favoured nation treatment principles as well as of the specific regional and national legislative incorporation of the agreed provisions. However, bear in mind that it is highly unlikely the EC will accept a degree of protection for its holders that is lower than that granted to United States.

The CAN Member States should likewise keep in mind the less than relative effect of attached side letters and other additional agreements that could be concluded for the purpose of reaching an international agreement. These types of documents have become frequent in free trade agreements signed with the United States, and their effect is more political than legal (offering a more or less graceful way out of sensitive areas in which concessions have been made). In effect, article 31.2 of the Vienna Convention on the Law of Treaties states that both preambles and agreements in connection with the conclusion of the treaty are part of the context in which the treaty should be interpreted. However, one should only resort to interpretation when the treaty text is unclear, that is, the *in claris non fit interpretatio* rule shall prevail, and therefore states that conclude clear agreements with specific provisions cannot cite accompanying rules aimed at interpretation. In any case, if one wishes to risk exploring this possibility, then he should cite these two principles: good faith and *pacta sunt servanda*, plus the assumption of minimum obligations.

Finally, one last issue is the profound asymmetry with regard to intellectual property in the European proposal. In practical terms, the EC makes hardly any commitments while some of the demands it proposes to developing countries (such as removing third-party opposition to patent grants, applying border measures even in integrated areas, and imposing the criminalisation of patent infringements) are questions the EC considers as appropriate within Europe but not abroad (channels for third party opposition to patent grants), does not consider (reinstating intra-Community customs release), or has dismissed in its own context (making patent violations a criminal offence). EC policy is thus erratic, but two characteristics are clear: its refusal to make new commitments (even with regard to the transfer of technology), and the imposition of severe burdens on developing countries.