



# Health Protection in the European and Andean Association Agreement

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

Xavier Seuba Hernández<sup>1</sup>

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# Foreword

This report is at the heart of a campaign that emerged from a need for direct action from civil society groups in both Europe and Latin America to intervene in the negotiations for the Association Agreement between the European Union and the countries of the Andean Region.

While written in the context of these negotiations, the report will undoubtedly stand alone as a reference document on EU Trade Policy in relation to Intellectual Property Rights and Access to Medicines in general.

The groundwork for restrictive IP policies towards developing countries was laid by the US Free Trade Agreements, demonstrating the commercial power and influence of lobbies such as the pharmaceutical industry. Now, all eyes should be on Europe, as the centre of activity on IP in trade has shifted to the old continent. It is of major importance to guarantee that both within and beyond Europe commercial interests do not take precedence over public health needs and that access to essential rights, such as healthcare and essential medicines, prevails.

This paper provides a remarkably in-depth analysis of the IP provisions contained in the Association Agreement and their negative implications for Access to Medicines in the Andean Region. Improving Access to Essential Medicines in developing countries is at the core of Health Action International's mission and we are therefore very grateful to the author, Dr Xavier Seuba, for contributing his expertise and time.

We hope this document will serve as a useful tool to mobilise other NGOs and civil society groups in the public health field around the world. The report will equip them with the information they need to actively participate in this technical debate and amplify the voice of the public health perspective. This will ensure that future policies do not further contribute to entrenching big pharma monopolies and delaying competition, but rather to meeting real public health needs.

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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.



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# I. Agreement Relevance and State of the Negotiations

The desire to increase trade volume between the Andean Community (CAN)<sup>2</sup> and the European Union (EU)<sup>3</sup> is the chief factor driving negotiations for a new framework that will direct relations between the two regional blocs. Nonetheless, negotiations for adopting an “association agreement” encompass three pillars, also called “dialogues”, which, in principle, are inter-related: cooperation, political dialogue, and trade. As is expected, the bulk of the discussions are focused on the “trade dialogue”.

From the perspective of CAN Member States, negotiation is essential, given that the EU is the region’s second largest trading partner and its largest investor. Moreover, the volume of trade between the CAN and the EU has been significantly increasing since the 1980s: 73% between 1980 and 2004<sup>4</sup> and annual percentages have, since then, been close to 20%.<sup>5</sup> Trade between the CAN and the EU in 2007 was \$19.811 million, an increase of 17% from 2006.<sup>6</sup> Nevertheless, Andean countries are well aware that the journey has just begun since the CAN sits in twenty-ninth position on the EU’s list of trading partners.

Between 17 and 21 September 2007, the first round of negotiations for adopting an association agreement between the CAN and the EU were held in the city of Bogota, Colombia. During those meetings, the new agreement’s principles, objectives, and scope were touched upon, and fourteen negotiating groups were formed, members of which met to discuss trade and aspects related to it. Responsibility for intellectual property fell to Subgroup 11, and it took no time at all for that arena to run into conflict. From the start, Bolivia took the position that it would not assume any new obligations in several different areas, one being intellectual property rights, to which the EU responded that decisions on potential commitments had to be adopted as a result of negotiations in each sector.<sup>7</sup>

The second round of negotiations took place in Brussels from 10 to 14 December 2007, where the fourteen subgroups met again. In contrast with the first and third rounds, neither party supplied official information on what was negotiated. Yet, certain documents from the negotiation tables did leak, and

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<sup>2</sup> Peru, Colombia, Ecuador, and Bolivia (Venezuela left the CAN in 2006).

<sup>3</sup> Austria, Belgium, Bulgaria, Cypress, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Rumania, Slovakia, Slovenia, Spain, Sweden, and the UK.

<sup>4</sup> European Commission – DG Trade, *Andean Community of Nations, Trade relations between the EU and the Andean Community*, [http://ec.europa.eu/trade/issues/bilateral/regions/andean/index\\_en.htm](http://ec.europa.eu/trade/issues/bilateral/regions/andean/index_en.htm) (10/2008).

<sup>5</sup> Andean Community General Secretariat, *Comunidad Andina – Unión Europea (27): Comercio exterior de bienes – Principales características*, SG/de 210, May 20<sup>th</sup>, 2008, 8.46.63

<sup>6</sup> “La CAN decide intentar una nueva negociación con la UE”, *El Comercio*, October 19<sup>th</sup>, 2008,

<sup>7</sup> Other areas were: services, investment, movement of capital, and public procurement. See European Commission, “*Start of the Negotiation of an Association Agreement between the EU and the Andean Community (CAN – Joint report of the meeting of the working group of negotiations on trade in the framework of the first round of negotiations CAN - EU, 27 September 2007, at* [http://trade.ec.europa.eu/doclib/cfm/doclib\\_section.cfm?sec=156&lev=2&order=date](http://trade.ec.europa.eu/doclib/cfm/doclib_section.cfm?sec=156&lev=2&order=date) (10/2008)

one was of particular interest for this study: the European proposal for Subgroup 11 on intellectual property, which will be the object of analysis in due course.<sup>8</sup>

The third round of negotiations took place in Quito, Ecuador from 21 to 25 April 2008, with noteworthy advances supposedly being made during these meetings, and participants even projected that negotiations would conclude sometime in the second half of 2009.<sup>9</sup> The parties, beyond communicating how well discussions were going, gave no greater detail on what had been agreed to. As for Subgroup 11, reports were that it had “advanced” on the task at hand and that a mini round of negotiations had been proposed for June 2008 in Brussels, which would predate the fourth round of negotiations set for July 2008 in Brussels. It was during the third round that the CAN undertook to send the EU, as soon as possible, its proposed text on intellectual property.<sup>10</sup>

However, despite the existence of a CAN – EU joint report, the third round of negotiations was when people began to doubt, seriously, the real possibility that the two trade blocs would reach an agreement. Bolivia had taken a position on topics like investment, services, and intellectual property that was diametrically opposed to that of Peru and Colombia, and Ecuador’s undecided position demonstrated that there were profound discrepancies among the CAN Member States. Once the third round had concluded, Colombia’s chief negotiator expressed his misgivings about the proceedings, and he remarked that bloc negotiation between the CAN and the EU was not viable.<sup>11</sup> As a result, an agreement began to materialise between the EU, Peru, and Colombia with the possibility of including Ecuador.

The controversy surrounding modifications to Decision 486, regarding the intellectual property regime in the CAN, is certainly connected to the problems in negotiations between the blocs and also to the progression toward bilateral agreements. In June 2008, Peru adopted a packet of legislative modifications to its intellectual property regime in order to adapt its laws to provisions laid out in the recently ratified US – Peru FTA. Some of the promoted amendments and, in particular, those set forth in Legislative Decree 1075, ran counter to Andean Community law, which brought about a huge controversy before and after its passage. This controversy took on a regional scope and disturbed relationships among the Andean countries, especially those between Peru and Bolivia. The CAN finally approved Decision 689 by a majority vote in August 2008, and this after one round of voting in which Bolivia was able to block the needed consensus. The decision legalised Peruvian amendments by offering the possibility to the other countries of “further developing and deepening” provisions laid out in Decision 486 that were affected by the US – Peru FTA.<sup>12</sup> At the same time, in relation to discrepancies that brought about the summoning of the Andean Council of Presidents Summit in Guayaquil on 14 October 2008, Bolivia’s president, Evo Morales, said that: “For the Bolivian

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<sup>8</sup> *Subgroup 11: Intellectual Property*. Document: CAN-UE/SGPI/dt/004, dated November 27<sup>th</sup>, 2007.

<sup>9</sup> So deduced, for example, from the Andean Community press release: “Concluye III Ronda de Negociación CAN-UE con evidencia de asimetrías”, April 25<sup>th</sup>, 2008, [www.comunidadandina.org/prensa/articulos/efe25-4-08.htm](http://www.comunidadandina.org/prensa/articulos/efe25-4-08.htm) (10/2008).

<sup>10</sup> *Informe conjunto de la Reunión del Grupo de Comercio en el marco de la Tercera Ronda de Negociaciones CAN-UE*, [www.comunidadandina.org/documentos/actas/CAN-UEronda3.htm](http://www.comunidadandina.org/documentos/actas/CAN-UEronda3.htm) (10/2008).

<sup>11</sup> “Avances en las negociaciones entre CA, la CAN y la UE”, *Puentes*, vol. 9, n°2, 2008, <http://ictsd.net/i/news/12506> (10/2008).

<sup>12</sup> To consult the decision, go to [http://www.senapi.gov.bo/Modif\\_486.pdf](http://www.senapi.gov.bo/Modif_486.pdf) (10/2008).



government, life is something sacred and cannot be patented. Nature, plants, and animals cannot be owned... life is something sacred, therefore we cannot negotiate it with the European Union.”<sup>13</sup>

Between August and October of 2008, high ranking officials in the Andean nations, especially those in Peru and Colombia, were constantly making statements and issuing press releases saying that negotiations with the EU should continue and that in the event that Ecuador and Bolivia were unwilling to continue, they would negotiate their own treaty with the EU. Yet, there was still one formal obstacle to overcome related to the European Commission’s negotiation mandate, which is for negotiations with the CAN regional bloc and not its individual member states. As a consequence, Colombia and Peru requested that “trade dialogue” negotiations continue for each individual country and the other dialogues be maintained with the other CAN countries.<sup>14</sup> Yet, one should not overestimate the effects of the EU’s mandate. In other cases where parties forming a regional bloc were unable to reach an agreement, as in the example of the ACP countries, the EU entered into “provisional” agreements with individual nations willing to do so, with the expectation that subsequent agreements with the remaining countries would be reached. There are also other options, like the Peruvian and Colombian proposal or one that would fulfil a regional dimension if Ecuador is brought on board. Besides, it seems clear that the EU is willing to examine alternatives to reaching an agreement before November 2009, when its mandate runs out, or even to change the EC’s negotiation mandate, as stated by President Barroso.<sup>15</sup>

With this as the backdrop, the Andean Community presidents held their summit on 14 October 2008. It was a short three hour meeting in which the presidents (with the exception of Colombia’s president, Alvaro Uribe, who sent the Under Secretary of Foreign Trade in his place) recognised the difficulties the CAN was experiencing and agreed to ask the EU for a meeting in order to express their desire to reach an association agreement in which trade would include different levels of commitment. Presidents Correa and Morales (Ecuador and Bolivia, respectively) pointed out that this differentiation is especially necessary on the topics of intellectual property, public procurement, services, and tariff elimination.<sup>16</sup> In any case, the position of Ecuador and Bolivia is not as consistent as is usually presented. In the face of Bolivia’s outright rejection of negotiating certain terms, Ecuador maintains a more indecisive position, and its Under Secretary of Foreign Trade stated that “Ecuador will seek out a bilateral agreement or one that includes Peru and Colombia. For us, leaving the negotiation table is not in our best interest.”<sup>17</sup>

The political shifting should not make one lose sight of the ultimate goal, which is reaching an agreement that is economically attractive for both parties and stimulates the development of the Andean nations. Given the current situation of the CAN, it would be no exaggeration to say it has much more to gain from an agreement with the EU as an integrated regional bloc than if each of its

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<sup>13</sup> “Comunidad Andina irá a Cumbre Presidencial en medio de fuertes diferencias”, *ABI*, 14/10/2008, [www.abi.bo.index.php?i=noticias\\_texto\\_paleta&j=20081014224239&k=\(10/2008\)](http://www.abi.bo.index.php?i=noticias_texto_paleta&j=20081014224239&k=(10/2008)).

<sup>14</sup> “Comunidad Andina irá a Cumbre Presidencial en medio de fuertes diferencias”, *Puentes*, vol. 9, n° 4, 2008.

<sup>15</sup> “La CAN decide intentar una nueva negociación con la UE”, op. cit.

<sup>16</sup> “CAN pedirá a la UE reunión a fines de octubre para destrabar negociación”, *ABI*, 14/10/2008, [www.abi.bo](http://www.abi.bo) (10/2008); “Evo: Se salvó unidad de la CAN, pero de mantener diferencias la crisis continuará”, op. cit.; “La CAN decide intentar una nueva negociación con la UE”, op. cit. Not to mention, the regime for protection foreign investments is especially tricky for countries like Bolivia.

<sup>17</sup> Cfr. “La UE debe ser más flexible en dos temas”, *El Comercio*, 21/2/2008.

member states were treated separately. On one hand, it is much more interesting and beneficial for the CAN to offer the EU, during the course of the negotiations, a potentially larger market than just four, small ones. This interest would place the CAN in a stronger negotiating position. On the other hand, it is likely that relations between an economic giant like the EU and the comparatively small Andean economies would result in a deficit for the latter if Andean trade integration does not also proceed.

## II. European Community's New Intellectual Property Policy for Third Countries

Protecting intellectual property is of the utmost importance to the EC. In 2000, within the framework of the Lisbon Strategy,<sup>18</sup> the EU stated its willingness to become the most competitive and dynamic knowledge economy in the world by 2010. Recently, this priority has also been inserted into the EU's planned foreign activities. As such, the Director General of the EC's Directorate-General for Enterprise & Industry stated in December 2006 that "a substantial improvement in the international enforcement of intellectual property rights" was one of the three priorities of the EU's intellectual property rights policy and that the EU had to focus on ensuring enforcement of the World Trade Organization's (WTO) TRIPS Agreement.<sup>19</sup>

Attainment of this goal has been pursued through different actions and policies, with the most significant ones being bilateral pressure, determined action in the midst of international forums on intellectual property protection, and conclusions of new international treaties. As for the last one, the EU is negotiating a new generation of international treaties containing a wide range of content through its economic partnership (EPAs), association and cooperation, and free trade agreements. Each of these places great weight on intellectual property, frequently through promoting commitments beyond what is laid out in the TRIPS Agreement.

The EU's competence to harmonise intellectual property legislation among its Member States and to create an internal market is defined by articles 95 and 295 of the Treaty on European Union. Moreover, its competence to negotiate international agreements on intellectual property was set forth by the Court of Justice of the European Communities through its affirmation that "the Community and its Member States are jointly competent to conclude TRIPS."<sup>20</sup> Afterwards, in 2001, the Treaty of Nice amended certain articles, among them being n°133 of the Treaty of Rome, that outlined the Commission's competence to negotiate agreements with respect to the commercial aspects of intellectual property, and it can also negotiate agreements on the non-commercial aspects of the same

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<sup>18</sup> Promoted by the European Council in March 2000 and stressed during following European Councils, particularly the 2002 edition in Barcelona during which the Council proposed increasing investment in R&D until it reaches 3% of the GDP, at least two thirds of which must come from the private sector.

<sup>19</sup> *Cfr.* "Propiedad Intelectual: ¿Cómo debería actuar la UE en los próximos cinco años?", *IPR Helpdesk Bulletin*, n°3 0, November/ December 2006, p. 1. Its practical consequences can be consulted at: [http://ec.europa.eu/trade/issues/sectoral/intell\\_property/index\\_en.htm](http://ec.europa.eu/trade/issues/sectoral/intell_property/index_en.htm) (3/2008).

<sup>20</sup> Opinion of the Court of 15 November 1994. - Competence of the Community to conclude international agreements concerning services and the protection of intellectual property - Article 228 (6) of the EC Treaty. - Opinion 1/94 European Court reports 1994 Page I-05267.

if the Council unanimously agrees to it on a proposal from the Commission and after consulting the European Parliament.

Traditionally, the Community practice of negotiating economic agreements has been one of getting commitments for adhering to or for adopting multilateral treaties that protect intellectual property. Nonetheless, some of the new EU treaties are in direct contrast to this position when they incorporate specific chapters with substantive content on protecting intellectual property.<sup>21</sup> Likewise, intellectual property is one of the EU's priorities in several of the negotiations already underway.<sup>22</sup> One of the foundations for this change is found in the Strategy for the Enforcement of Intellectual Property Rights in Third Countries adopted in 2004 and, as is clearly stated in its unequivocal title, it aims to strengthen enforcement of intellectual property rights globally.<sup>23</sup>

Some of the more prominent goals of the Strategy for the Enforcement of Intellectual Property Rights in Third Countries are:

1. The desire of the EU to begin consultations with trade partners for launching an initiative in the Council for TRIPS due to the insufficient enforcement of agreement provisions
2. To assure constant supervision for TRIPS Agreement enforcement
3. To review intellectual property policy in EU-ratified free trade agreements
4. To bring up the question of enforcement of intellectual property rights on a more frequent basis in committees set up to monitor bilateral agreements
5. To gather data from EU delegations in different countries and from Member States' embassies on enforcement of intellectual property rights

### **III. The Special Relevance Granted to Intellectual Property Rights Enforcement**

Enforcing the TRIPS Agreement substantive obligations as well as conferred rights through different international channels has been on the increase since its adoption. At present, several initiatives are underway that attempt to guarantee, in different fields, certain levels of enforcement.<sup>24</sup> One of the most interesting among them is the push for new international treaties with provisions that interpret

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<sup>21</sup> On contents and general guidelines of agreements entered into by the EU and the change alluded to in the sentence; See M. Santa Cruz, *Intellectual Property Provisions in European Union Trade Agreements and implications for developing countries*, Geneva: ICTSD, 2007.

<sup>22</sup> See below, point IV.

<sup>23</sup> European Commission, *Strategy for the enforcement of intellectual property rights in third countries*, 10 November 2004, [http://trade.ec.europa.eu/doclib/docs/2004/november/tradoc\\_120025.pdf](http://trade.ec.europa.eu/doclib/docs/2004/november/tradoc_120025.pdf) (10/2008).

<sup>24</sup> For a detailed study on the range of existing initiatives, see C. Correa, *The new offensive for the enforcement of intellectual property rights and the interests of developing countries*, Geneva: ICTSD, 2008.

and increase already existing TRIPS obligations in different fields. As for intellectual property rights enforcement and exercise, the chief driver of these types of provisions is the EU.<sup>25</sup>

When analysed, the EC's proposal on intellectual property to the CAN shows enforcement of intellectual property rights as one of the Union's priorities, a priority which was declared in 2004 in the abovementioned Strategy for the Enforcement of Intellectual Property Rights in Third Countries that identified "strengthening the enforcement of intellectual property rights" as one of its actions to be carried out. Likewise, the TRIPS Agreement dedicates Part III to enforcement of intellectual property rights and therein declares that, on one hand, "this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general," and, on the other hand, "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."<sup>26</sup>

The EC's position on enforcement of intellectual property rights in third countries begins with the outward projection of secondary community law.<sup>27</sup> In particular, Directive 2004/48 on the enforcement of intellectual property rights<sup>28</sup> and Council Regulation (EC) 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.<sup>29</sup> Provisions of both texts – on occasion clearly TRIPS Plus and TRIPS Extra – are being written into agreements that the EU is planning on entering into. Take, for example, article 13 of the proposed economic partnership agreement between the EU and the ECOWAS African regional bloc in which article 3 of Directive 2004/48 has been introduced, word for word; this is a situation that will also be seen in the analysis of the European proposal to the CAN.

Together with the transference of its internal policies on intellectual property to third countries, the EC is also pressuring countries with which it intends on concluding association agreements, a practice that, while not quite reaching the extremes of US Trade Act Section 301, does indicate a more belligerent attitude on the part of the EU when it comes to intellectual property. The pressure takes the form of, for example, identifying and classifying different categories of countries that supposedly do not do everything in their power to keep intellectual property rights from being infringed.<sup>30</sup> The

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<sup>25</sup> See X. Seuba Hernandez, "La nueva política de la Comunidad Europea sobre propiedad intelectual en terceros Estados", *Revista Aranzadi Unión Europea*, vol. 35, n° 6, 2008, pp. 5-11.

<sup>26</sup> Article 41.5 of the TRIPS Agreement

<sup>27</sup> As stated by the European Commission itself in its *Strategy for the enforcement of intellectual property rights in third countries*, op. cit., p. 2.

<sup>28</sup> DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights, (Official Journal of the European Union L 157 of 30 April 2004).

<sup>29</sup> This should also be viewed with Commission Regulation (EC) n° 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights (Official Journal of the European Union 328/16).

<sup>30</sup> The first report on this topic was adopted in 2006: See European Commission, *Survey on Enforcement of Intellectual Property Rights in Third Countries*, [http://europa.eu.int/comm/trade/issues/sectoral/intell\\_property/survey\\_en.htm](http://europa.eu.int/comm/trade/issues/sectoral/intell_property/survey_en.htm). (3/2008). Among the countries analyzed were: Argentina, Australia, Azerbaijan, Bangladesh, Brazil, Chile, China, Costa Rica, Croatia, Georgia,

resulting list, adopted for the first time in 2006, is being updated, with the term for right-holding companies to charge countries that, in their judgment, are not doing enough to guarantee enforcement of intellectual property rights having terminated in May 2008.<sup>31</sup> While the EU affirms its intention is not to create a “black list” of infringing countries but to identify those that need “greater cooperation”, this initiative is clearly modelled on the lists written up from the US Trade Act Section 301.<sup>32</sup>

That the EC’s interest in protecting intellectual property rights has increased is also borne out in its internal management and in its action within international organisations. In terms of its own work, the EU is augmenting human resources allocated to supervising enforcement of intellectual property rights in third countries with specialists who are dedicated exclusively to this matter in key cities, the likes of Bangkok, Beijing, and Moscow.<sup>33</sup> What is more, the EC has introduced and pushed the issue of enforcing intellectual property rights within the WTO, namely the Council for TRIPS, in spite of the fact that it is not clear whether this issue falls within its jurisdiction.<sup>34</sup>

Lastly, enforcement is also a priority area for cooperation between the EC and nations that share similar interests, in particular the United States, Japan, and countries belonging to the European Free Trade Association (EFTA). This is the same field in which the United States and the EC created the Working Group on Intellectual Property and, in 2006, approved the Action Strategy for the Enforcement of Intellectual Property Rights, which is not limited to bilateral cooperation but commits the Europeans and Americans to adopting actions that guarantee enforcement of intellectual property in third countries.<sup>35</sup> The EU is cooperating on the same matter with Japan, and together issued the Japan – EU Joint Initiative for the Enforcement of Intellectual Property Rights in Asia in 2003.<sup>36</sup> One of the most recent and controversial enforcement initiatives set out by developed countries is the negotiation between the EU, United States, Switzerland, Australia, Japan, Canada, South Korea, Mexico, and New Zealand for adopting ACTA in order to deal with counterfeiting.<sup>37</sup>

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India, Indonesia, Japan, Kazakhstan, South Korea, Morocco, Pakistan, Paraguay, Peru, Russia, Thailand, Turkey, Ukraine, Uruguay, Venezuela, and Vietnam.

<sup>31</sup> See European Commission, *Annex II. Questionnaire for right holders / associations*, [http://trade.ec.europa.eu/doclib/docs/2008/april/tradoc\\_138533.doc](http://trade.ec.europa.eu/doclib/docs/2008/april/tradoc_138533.doc) (10/2008).

<sup>32</sup> In virtue of Section 301 and in accordance with the rating they deserve, countries designated by the US may have their trade preferences withdrawn or even have development aid channeled through USAID suspended. In a two pronged strategy, these lists pressure nations to enforce certain interpretations of intellectual property rights while, at the same time, these same nations are offered free trade agreements that contain TRIPS Plus provisions, thus allowing them to put their basic products onto Western markets.

<sup>33</sup> W. New, “EU Seeks Stronger IP Enforcement At Every Level”, *IP Watch*, 30 July 2007.

<sup>34</sup> See *Joint Communication from the EC, US, Japan and Switzerland to the TRIPS Council on IPR Enforcement*, 16/10/2006, [http://trade.ec.europa.eu/doclib/docs/2006/october/tradoc\\_130863.pdf](http://trade.ec.europa.eu/doclib/docs/2006/october/tradoc_130863.pdf) (3/2008)

<sup>35</sup> Action Strategy for the Enforcement of Intellectual Property Rights, [http://trade.ec.europa.eu/doclib/docs/2006/june/tradoc\\_129013.pdf](http://trade.ec.europa.eu/doclib/docs/2006/june/tradoc_129013.pdf).

<sup>36</sup> European Commission, *Strategy for the enforcement...*, op. cit., p. 6.

<sup>37</sup> Anti-Counterfeiting Trade Agreement (ACTA).

# IV. Recent Experiences

## 1. Objectives and types of agreements

The goals the EU pursues when negotiating agreements with other regional blocs and countries may help explain the adopted treaty model and the respective provisions on intellectual property. Agreements between the EU and its trade partners conform to different patterns:

1. In some cases, adopting a convention is a step the other party must take before entering the European Union.
2. In other cases, the agreement is an alternative to entrance.
3. Still others, it promotes a certain integration of neighbouring countries, albeit non-European.
4. There are others in which it is about free trade agreements.
5. Lastly, there are cases that establish a *sui generis* framework with former European colonies.

The EU has concluded and is negotiating numerous agreements that have as one of their objectives the intention of broadening the liberalisation of international commerce. 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.<sup>38</sup> Agreements already in force or in the negotiation stage are bilateral and with regional blocs. Among the agreements signed with regional blocs, the most recent ones are those between the EU and the ACP countries, and many of these are provisional in nature. Besides the negotiations with the CAN, the EU is currently hammering out other agreements with regional blocs, such as MERCOSUR and ASEAN, although, in both cases, the contents are more diffuse when compared with those of the ACP and the CAN.

To date, the majority of the agreements in force feature similar content and structure on intellectual property. With the exception of treaties concluded with candidates for entrance to the Union, the particularities of intellectual property centre on geographic indications and the enforcement of rights. However, it should be pointed out that there are many agreements presently under negotiation, and while the value of information leaked from them is relative, it seems to indicate that the current uniformity of the EC's agreements may give way to greater diversity. This diversity will depend upon factors such as the degree of development and industrialisation of the countries, the existence of sufficient unity within the regional bloc, and whether they offer the EC interesting and imaginative proposals.

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<sup>38</sup> European Commission – DG Trade, *Overview of bilateral negotiations involving trade agreements, State of play 18/9/2007*, [http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc\\_118238.pdf](http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_118238.pdf) (3/2008).

## 2. Bilateral agreements

As for bilateral agreements, the EC's current negotiations with large trade powers, such as South Korea, India, and Russia, have incorporated intellectual property protection. The South Korean case is perhaps the least significant for developing countries since it is part of the select group of Organisation for Economic Co-operation and Development (OECD) industrialised countries<sup>39</sup> and therefore, shares the EC goals in numerous aspects, not least those of intellectual property rights. The EC and South Korea concluded the seventh round of negotiations in May 2008 for a free trade agreement, and all things point to its signature happening very soon. What is not among the pending issues is intellectual property, on which the two parties had, for all practical purposes, reached a full agreement during the sixth round of negotiations. The only factors left to settle are the limits of the regime's geographic indications. Further ahead, there will be a discussion of the fact that all things concerning controversial and sensitive public health issues, such as data protection, seem to have been concluded in accordance with European standards.<sup>40</sup>

The 2005 approved India – EU Strategic Partnership Joint Action Plan is one of the main guidelines for Euro-India relations.<sup>41</sup> At the Marseille summit in September 2008, the EU and India identified enforcement of intellectual property rights as one of the “new activities” for complementing the joint action plan.<sup>42</sup> It needs to be stressed, however, that matters of enforcement were already included in the 2005 joint action plan, and these contained specific references to customs and the “implementation and enforcement” of intellectual property rights.<sup>43</sup> During the same meeting, the parties agreed that it was important to conclude, as quickly as possible, a bilateral treaty on trade and investment.<sup>44</sup> In fact, negotiations for adopting this trade agreement began in June 2007 and are particularly important for both parties since trade between them has doubled and investments have risen tenfold in the past five years.<sup>45</sup> For India, the EC is its main trading partner, while India is number nine on the list of the EC's chief partners.<sup>46</sup>

From the outset of the EU – India free trade agreement negotiations, it was clear that special attention would be placed upon intellectual property protection<sup>47</sup> and that this would move beyond what had

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<sup>39</sup> European Commission, *EU and Korean negotiators make progress in sixth round of FTA negotiations*, 1/2/2008, [http://trade.ec.europa.eu/doclib/docs/2008/february/tradoc\\_137701.pdf](http://trade.ec.europa.eu/doclib/docs/2008/february/tradoc_137701.pdf) (3/2008). Read with more detail other documents on the same European Commission web page, “Mandelson: ambitious EU-Korea FTA a priority for 2008”, 13/12/2007, “EU and Korea complete 7<sup>th</sup> Round of FTA negotiations”, 15/5/2008.

<sup>40</sup> See below D. Cronin, “South Korea Urged to strengthen IP in EU Trade Talks”.

<sup>41</sup> *The India – EU Strategic Partnership Joint Action Plan*, 2005. To view it, go to [http://commerce.nic.int/trade/international\\_ta.asp?id=2&trade=i](http://commerce.nic.int/trade/international_ta.asp?id=2&trade=i) (10/2008).

<sup>42</sup> “EU-India Summit Marseille, 29 September 2008. Global Partners for global challenges: The UE-India Joint Action Plan”, [.http://meaindia.nic.in/speech/2008/09/29ss02.htm](http://meaindia.nic.in/speech/2008/09/29ss02.htm).

<sup>43</sup> *The India – EU Strategic Partnership Joint Action Plan*, 2005, pp. 18 and 21, respectively. Go to [http://commerce.nic.int/trade/international\\_ta.asp?id=2&trade=i](http://commerce.nic.int/trade/international_ta.asp?id=2&trade=i) (10/2008)

<sup>44</sup> *EU-India Joint Press Communique*, Mareseille, 29 September 2008.

<sup>45</sup> “EU-India Summit Marseille, 29 September 2008. Global Partners for global challenges : The UE-India Joint Action Plan”, <http://meaindia.nic.in/speech/2008/09/29ss02.htm>

<sup>46</sup> European Commission, *EU-India trade in facts and figures*, <http://ec.europa.eu/doclib/html/140777.htm> (10/2008).

<sup>47</sup> European Commission, *India*, [http://ec.europa.eu/trade/issues/bilateral/countries/india/index\\_en.htm](http://ec.europa.eu/trade/issues/bilateral/countries/india/index_en.htm) (3/2008).

been laid out by WTO agreements in areas of “mutual interest”.<sup>48</sup> Despite the fact that, for the moment, there is little information about the potential agreement’s content, intellectual property does indeed figure in the negotiation agenda, and it seems clear that the agreement will at least set out provisions concerning enforcement and geographic indications.<sup>49</sup> As to that, the EU – India High Level Group, which organised the latest European – Indian summit, reported that any potential bilateral trade agreement would include provisions covering intellectual property for moving towards “effectively protecting and enforcing intellectual property rights.”<sup>50</sup> As a consequence, reports on potential benefits of a trade agreement between India and the EU that the latter has requested, are recommending this inclusion.<sup>51</sup> These reports criticise the possibility of Indian law allowing objections to the granting of a patent in order to assure the patents quality,<sup>52</sup> as well as what is called “inappropriate patentability criteria”, which are aimed at preventing the “evergreening” of patents.<sup>53</sup> It still remains to be seen how far shared EU and Indian interests on the matter of copyrights or software protection may determine what the latter will give up when it comes to questions of patentability criteria and procedures for guaranteeing the quality of patents.

Lastly, it should be noted that intellectual property protection is also an important part of the negotiation agenda between the EU and Russia, which began in 2005, for establishing a common economic space. During the “dialogues”, the parties have put much stress on matters related to intellectual property and of particular emphasis are those related to enforcing international obligations.<sup>54</sup>

### 3. Regional agreements

While officially speaking, only the details of those agreements the EU has concluded with the ACP countries are known, it has become public that intellectual property protection is one of the central negotiation topics with MERCOSUR<sup>55</sup> and with ASEAN.<sup>56</sup> It appears that negotiations with the latter

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<sup>48</sup> “EU and India hold bilateral discussions on new trade and investment agreement”, 28/6/2007.

<sup>49</sup> “India-EU trade talks to resume ahead of Paris summit”, *Economic Times*, 7/9/2008.

<sup>50</sup> *Report of the EU-India High Level Trade Group to the EU-India Summit*, 13th October 2006, p. 9. <http://trade.ec.europa.eu/doclib/html/130306.htm> (10/2008).

<sup>51</sup> CARIS, *Qualitative analysis of a potential Free Trade Agreement between the European union and India, Executive Summary*, 2007, pp. 2 y 8. <http://trade.ec.europa.eu/doclib/html/135112.htm> (10/2008). The consultant (*Qualitative analysis of a potential Free Trade Agreement between the European Union and India, Annex 3: Regulatory Issues*, p. 97) directly cited that guaranteeing enforcement of intellectual property obligations was a priority in this setting.

<sup>52</sup> It is a surprising criticism because it figures, as well, in the European Patent Convention, whose accession is an essential requirement for becoming part of the EU. To read the respective criticism, go to CARIS, *Qualitative analysis of a potential Free Trade Agreement between the European Union and India, Annex 3: Regulatory Issues*, p. 97. In any case, the chapter on intellectual property from the report drafted by CARIS is quite deficient. See, for example, p. 98 concerning compulsory licensing.

<sup>53</sup> CARIS, *Qualitative analysis of a potential Free Trade Agreement between the European Union and India, Annex 4: Implementation Issues*, 2007, p. 68.

<sup>54</sup> European Commission, *Russia*, [http://ec.europa.eu/trade/issues/bilateral/countries/russia/index\\_en.htm](http://ec.europa.eu/trade/issues/bilateral/countries/russia/index_en.htm) (3/2008)

<sup>55</sup> See European Commission, *Mercosur*, [http://ec.europa.eu/trade/issues/bilateral/regions/mercosur/index\\_en.htm](http://ec.europa.eu/trade/issues/bilateral/regions/mercosur/index_en.htm) (3/2008).

<sup>56</sup> See European Commission – DG Trade, *TREATI – Work Programme and Progress Report*, Brussels, December 2007, [http://trade.ec.europa.eu/doclib/docs/2007/december/tradoc\\_137414.pdf](http://trade.ec.europa.eu/doclib/docs/2007/december/tradoc_137414.pdf) (2/2008).



bloc will continue for a while longer and those negotiations could be of immediate interest to the CAN, given that both are experiencing a fragmentation of their respective groups.<sup>57</sup> Even though negotiations with ASEAN were an attempt at deepening Southeast Asian regional integration, as they are with CAN, the EU has stated its intention to continue negotiating the matter of economics with individual countries that would prefer to conclude an agreement much sooner. The significant differences in the level of economic development between ASEAN Member States plus certain countries' political situations (Burma, in particular) are increasing the possibility that the EU will enter into trade agreements only with the most developed ASEAN countries.<sup>58</sup> This possibility, together with disintegration of the regions of ACP countries should raise a red flag to anyone stating that an agreement between the EU and certain members of the CAN is not possible.

The ACP countries' experience, and especially that of CARIFORUM, could be relevant for the Andean case. The framework that governs relations between the EU and ACP countries is the Cotonou Agreement, and its Article 36 is the declaration of the parties' shared will to conclude economic partnership agreements,<sup>59</sup> with the condition that the ACP countries should be grouped in regional blocs.<sup>60</sup> The goals of these agreements are to promote economic development and to line up trade relations between the EU and a large number of its former colonies with WTO law.<sup>61</sup> Realising the second objective would have required concluding economic partnership agreements before December 2007, at which time the WTO waiver that permits preferential trade relations between the EU and ACP countries expired.

At the end of 2007, the EU concluded an EPA with CARIFORUM<sup>62</sup> as well as a score of provisional EPA's with many other ACP countries.<sup>63</sup> Some forty other ACP countries preferred not to conclude agreements,<sup>64</sup> which is why their trade regime with the EU is under a certain degree of legal insecurity.<sup>65</sup> Whatever the case, negotiations between the EU and the twenty signatory countries have

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<sup>57</sup> In October 2008, the EU and ASEAN held their sixth meeting. Nevertheless, the ASEAN Secretary General pretty much discarded the possibility of concluding an agreement in two years. See "Two years target for FTA conclusion with EU very ambitious, says ASEAN Sec-Gen", *Bernama*, 8/8/2008.

<sup>58</sup> *Mandelson sees multi-speed regional pact as key to EU - ASEAN negotiation*, 7/5/2008, <http://trade.ec.europa.eu/doclib/html/138798/htm> (10/2008); "EU plans two-track approach for FTA", *Bangkok Post*, 15/9/2008;

<sup>59</sup> Cotonou Agreement, article 36, [http://ec.europa.eu/development/icenter/repository/agr01\\_en.pdf](http://ec.europa.eu/development/icenter/repository/agr01_en.pdf) (2/2008).

<sup>60</sup> Cotonou Agreement, article 37, n° 5.

<sup>61</sup> However, given agreement contents, it is rather difficult to pin down where development ends and where the mere commercial aspects begin.

<sup>62</sup> Groups together fifteen ACP Caribbean countries: Antigua and Barbuda, the Bahamas, Barbados, Belize, Dominica, the Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St Kitts & Nevis, Saint Lucia, Saint Vincent and the Grenadines, Surinam, Trinidad and Tobago

<sup>63</sup> Cameroon, Burundi, Kenya, Rwanda, Tanzania, Uganda, Comoros, Madagascar, Mauricio, Seychelles, Zimbabwe, Fiji, Papua New Guinea, Botswana, Lesotho, Namibia, Swaziland, Ivory Coast, and Ghana.

<sup>64</sup> Benin, Burkina Faso, Cape Verde, Gambia, Guinea, Guinea Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leona, Togo, Angola, Cook Islands, Kiribati, Marshall Islands, Micronesia, Nauru, Niue, Palau, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu, Djibouti, Eritrea, Ethiopia, Malawi, Sudan, Zambia, Central African Republic, Democratic Republic of Congo, Chad, Equatorial Guinea, Gabon, Republic of the Congo, and São Tomé and Príncipe.

<sup>65</sup> The fact is the waiver allowing preferential relations between the EU and ACP countries expired on December 31<sup>st</sup>, 2007. As a result, it could lead to objection being raised by other WTO Member States and/ or result in brusque interruption in commercial relations.

continued into 2008 and will continue into 2009. Their objective is to conclude the planned comprehensive economic partnership agreements, topics and agendas of which have been set in provisional agreements.<sup>66</sup> For now, negotiations and interim agreements have focused on liberalising the trade of goods, chiefly from the EU to the ACP countries.<sup>67</sup>

It should be noted that the process that began with the signing of the Cotonou Agreement has failed in reaching its stated objective of promoting regional integration, a circumstance that also appears to be occurring with the CAN.<sup>68</sup> The *a priori* agreements that should have been concluded with six large regions have turned into a myriad of provisional agreements between the EU and individual ACP countries. Some of the reasons that explain this failure are internal discrepancies between countries from the regions, the lack of technical resources in different ACP regions,<sup>69</sup> and the rushed negotiations, always under the looming shadow of the termination of the WTO waiver and the economic dependence that several ACP countries have on the EU.

The provisional agreements now in force expressly anticipate intellectual property protection to be a matter for discussion during the second phase of negotiations.<sup>70</sup> In spite of opposition from several ACP nations to the inclusion of substantive obligations on intellectual property,<sup>71</sup> and though updating the EU and ACP country trade relations vis-à-vis the WTO regime does not precisely require obligations on intellectual property protection<sup>72</sup> further than what is called for in the TRIPS Agreement,<sup>73</sup> the EU still insists on the importance of its inclusion.<sup>74</sup> In fact, intellectual property is a field that was deeply explored in the CARIFORM agreement, and the section concerning it is very detailed and is certainly the harbinger of the EU's soon to be negotiated agreements. When analyzing the European proposal to the CAN, cross-reference will be made to de EU-CARIFORUM Agreement.

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<sup>66</sup> Among the topics are competence, services trade, intellectual property, and investment.

<sup>67</sup> For the opposite case and with respect to a rather large gamut of products, these are now practically liberalised. It has been made public that the concessions granted by the countries that have concluded these agreements with the EU are much greater than what the WTO regime requires. South Centre, *EPA Negotiations: State of Play and Strategic Considerations for the Way Forward* February 2008, SC/AN/TDP/EPA/13, p. 3.

<sup>68</sup> *Ibid.*

<sup>69</sup> *Ibid.*

<sup>70</sup> See, for example, article 26 of the EU – Ghana EPA or article 26 of the EU – Ivory Coast EPA.

<sup>71</sup> For instance, SADC members made it clear in their negotiation proposal that any obligatory agreement in the field of intellectual property had to be excluded and references in the EPA had to be limited to matters of technical cooperation. SADC, “A Framework for the EPA Negotiations between SADC and the EU”. For a more general overview, see ECOSOC (Economic Commission for Africa) – African Union Commission, *Economic Partnership Agreements Negotiations: A Comparative Assessment of the Interim Agreements*, E/ECA/COE/27/12a – AU/CAMEF/EXP/12a(III), 7 of March 2008, p. 8.

<sup>72</sup> C. Correa *et al.*, “EU in danger of breaking its promises to the poor”, *Financial Times*, 24/5/2007.

<sup>73</sup> Article 46 of the Cotonou Agreement alludes to intellectual property protection and refers, in general terms, to adherence to the TRIPS Agreement and international agreements dedicated to protecting intellectual property referred in the TRIPS Agreement. Nowhere, however, does article 46 urge for the adoption of new intellectual property protection standards or for the adoption of additional measures for adhering to treaties that allude to them, which is why the EC's affirmation is unfounded. In our opinion, the maximum article 46 of the Cotonou Agreement could allow for is the inclusion of provisions in economic partnership agreements through which countries that are not signatories of the previously mentioned agreements would commit to comply with them. In this sense, see. S. F. Musungu, *An analysis of the EC Non-Paper on the objectives and Possible Elements of an IP Section in the EC-Pacific EPA*, Geneva: ICTSD, 2007, pp. 13-15 y 30.

<sup>74</sup> The EC states that protecting intellectual property is an essential element an EPA development dimension and its inclusion has also been set forth in article 46 of the Cotonou Agreement.

As will be demonstrated further ahead, some of the provisions set forth in the CARIFORUM Agreement are more advantageous than the ones in the European proposal to the CAN, if developing nations interests are taken into account. Nevertheless, in general terms, the European proposal to the CAN and the CARIFORUM agreement coincide, particularly when it comes to enforcing intellectual property rights and geographic indications.

## V. European Community Proposal to the Andean Community

In order to analyse the relationship between public health and the EU's policy on intellectual property for third countries, one can appeal to documents Subgroup 11 has used as the basis of the EU – CAN negotiations that have leaked from its meetings. On a more concrete level, there is the European proposal submitted on 27 November 2007.<sup>75</sup> Since it is an eleven month old document from the second negotiating round, its value is limited to a glimpse of what the EU's aspirations are.

When focusing this study on public health, several matters of the EU proposal that are especially onerous but unconnected to the question at hand will be left out or be mentioned as tangents, such as geographic indications, a field of particular interest to the Europeans throughout all their negotiations. In contrast, the following analysis will focus on five specific issues concerning the European proposal:

1. General provisions
2. The article on patents
3. The provision dealing with test data protection
4. Provisions dealing with enforcement of intellectual property rights
5. Cooperation

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<sup>75</sup> CAN-UE/SGPI/dt/004 document, *op. cit.*

# 1. General Provisions

## 1.1 Objectives

European Proposal: Article 1.	TRIPS Agreement: Preamble, Articles 7 & 8
<p>The objectives of this chapter are to:</p> <ul style="list-style-type: none"> <li>(a) facilitate the production and commercialization of innovative and creative products between the parties; and,</li> <li>(b) achieve an adequate and effective level of protection and enforcement of intellectual property rights.</li> </ul>	<p>(Preamble) “to reduce distortions and impediments to international trade”</p> <p>(Preamble) “to promote effective and adequate protection”</p> <p>(Preamble) “that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”</p> <p>(Preamble) “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”</p> <p>(Article 7: Objectives) The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.</p> <p>(Article 8: Principles) 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement.</p> <p>2. Appropriate measures, provided that they are consistent with the provisions of this agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.</p>

Contents of articles related to objectives of an international treaty are not a minor issue. They can be useful for interpreting treaty provisions, something especially important if discrepancies in their enforcement exist, and they likewise make it possible to understand the treaty in a general manner. Objectives found in the European proposal are notably different from those laid out in the TRIPS Agreement. The former makes reference exclusively to “facilitating the production and commercialization of innovative and creative products...” and to protecting and enforcing intellectual property rights. Compared to the delicate balance reached by the TRIPS Agreement, these are certainly terse in nature. In addition, the EC proposal would be found lacking in comparison with other

EU agreements that have come into force recently, which do refer to objectives and principles listed in the TRIPS Agreement.<sup>76</sup>

The objectives and principles of the TRIPS Agreement have allowed the clarification of several ambiguous provisions to favour public health. Furthermore, interpreting the TRIPS Agreement requires an examination of its Preamble and provisions,<sup>77</sup> and if any ambiguities were to be found, then those could be solved by resorting to articles 7 and 8, where the objectives and principles are laid out. The importance of preambles in WTO agreements has been stressed by the Appellate Body.<sup>78</sup> The TRIPS preamble reflects a balance of obligations and rights, with particular concern for the relationship between the agreement's objectives and purposes.<sup>79</sup> The opening statement outlines the objective that motivated Members to adopt the TRIPS Agreement: "to reduce distortions and impediments to international trade" to take "into account the need to promote effective and adequate protection of intellectual property rights." In this way, the TRIPS Agreement is linked to the objectives of the WTO, i.e. reducing trade impediments and discrimination so as to promote economic development and to improve standards of living.<sup>80</sup> Because overprotection of intellectual property inhibits trade liberalisation,<sup>81</sup> the preamble warns against the use of intellectual property as an obstacle to legitimate trade.<sup>82</sup>

The need to encourage "adequate" protection of intellectual property rights is also in the TRIPS preamble.<sup>83</sup> The word "adequate" means in general terms that which is "appropriate to conditions, circumstances, or object"<sup>84</sup> and not the highest protection possible. Thus, "adequate protection" is that which is appropriate for the international trade regime to operate<sup>85</sup> and for the objectives set forth in TRIPS Agreement article 7 to be realised. Additionally, the preamble emphasises the intrinsic flexibility of the TRIPS Agreement and urges parties to "take into account differences in national legal systems" when it comes to protecting intellectual property rights. This elevated flexibility reaches to the level of "maximum flexibility" regarding least developed countries<sup>86</sup> and is confirmed in article 1.1

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<sup>76</sup> Take, for example, article 139.2 of the economic partnership agreement between the CARIFORUM States and the European Community and its Member States.

<sup>77</sup> The TRIPS Agreement has neither annexes nor agreements relating to the treaty which were made between all the parties in connection with the conclusion of the treaty. Likewise, it has no instruments which were made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

<sup>78</sup> In the matter of the United States – Shrimp, the Appellate Body underscored the importance of the GATT – 94 preamble for integrating environmental protection into the regime for trade liberalisation. See *Estados Unidos - Prohibición de las importaciones de determinados camarones y productos del camarón*, (*Estados Unidos-Camarones*), WT/DS58/AB/R, 12/10/998, pars. 12, 17, 129 y 130.

<sup>79</sup> For a more critical vision of the preamble, see C. M. Correa, *Trade Related Aspects of Intellectual Property Rights*, Oxford: Oxford University Press, 2007, pp. 1-18.

<sup>80</sup> First paragraph of the preamble through which the WTO was created.

<sup>81</sup> S. Frankel, "WTO Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property", *Virginia Journal of International Law*, vol. 46, Winter 2006, p. 375.

<sup>82</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, New York: Cambridge University Press, 2005, p. 10.

<sup>83</sup> Subparagraph b) of the second paragraph of the preamble.

<sup>84</sup> As per the Royal Spanish Academy Dictionary.

<sup>85</sup> UNCTAD-ICTSD, op. cit., 2005, p. 11.

<sup>86</sup> Sixth paragraph.

when it provides that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

The preamble confirms the instrumental nature of intellectual property rights when it acknowledges “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives,” and these objectives are especially important in the TRIPS Agreement in such a manner that they are explicitly described in articles 7 and 8, which lay out agreement objectives and principles,<sup>87</sup> that is, the guiding principles for interpreting and applying TRIPS provisions and for evaluating the adequacy and effectiveness of national intellectual property law.<sup>88</sup>

Article 7 of the TRIPS Agreement states that protecting intellectual property must meet different objectives: promoting technological innovation and transferring and disseminating technology, doing this to the mutual advantage of producers and users, and contributing to social and economic welfare and to a balance of rights and obligations. These are the TRIPS Agreement objectives, which encase it in the instrumental viewpoint of intellectual property and recognise the traditional balance between right holders and users that is sought after by intellectual property law,<sup>89</sup> the consideration of which is transferred to the multilateral level.<sup>90</sup> Following these objectives, article 8 sets forth agreement principles and states that members can adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development.<sup>91</sup>

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<sup>87</sup> These are not the only articles that define the TRIPS Agreement objectives and principles. As is stated in the Canada – Patent Protection of Pharmaceutical Products case, “Both the goals and the limitations stated in Articles 7.1 and 8 must obviously be borne in mind when doing so (referring to the examination of restrictive conditions in article 30) as well as those other provisions of the TRIPS Agreement which indicate its object and purposes.” Grupo Especial, *Canadá- Protección mediante patente de los productos farmacéuticos*, WT/DS114/R, 17/3/2000, par. 7.26.

<sup>88</sup> A. A. Yusuff, “TRIPS: Background, Principles and General Provisions”, C. M. Correa, A. A. Yusuff (Eds.), *Intellectual Property and International Trade: The TRIPS Agreement*, London-The Hague-Boston: Kluwer Law International, 1998, p. 12.

<sup>89</sup> A. A. Yusuff, “TRIPS: Background, Principles and General Provisions”, op. cit., p. 12.

<sup>90</sup> UNCTAD-ICTSD, op. cit., p. 119.

<sup>91</sup> The possible need for adopting measures to react to intellectual property rights abuses is also recognised, including but not limited to competition law.

## 1.2 Nature and scope of the obligations

European Proposal: Article 2	TRIPS Agreement: Article 1
<p>1. The parties shall ensure an adequate and effective implementation of the international treaties dealing with intellectual property to which they are parties and of the Agreement on Trade-related Aspects of Intellectual Property (hereinafter called TRIPS Agreement). The provisions of this chapter shall complement and specify the rights and obligations between the parties under the TRIPS Agreement and other international treaties in the field of intellectual property.</p>	<p>1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this agreement, provided that such protection does not contravene the provisions of this agreement. Members shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice.</p>
<p>2. For the purpose of this agreement, intellectual property rights embody copyright, including copyright in computer programs and in databases, <i>sui generis</i> rights for non-original databases, and neighbouring rights, rights related to patents, trademarks, trade names, designs, layout-designs (topographies) of integrated circuits; geographical indications, including Designation of Origin and Indications of Source, plant varieties, protection of undisclosed information, and the protection against unfair competition as referred to in Article 10bis of the Paris Convention for the Protection of Industrial Property (Stockholm Act of 1967)</p>	<p>2. For the purposes of this agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.</p>
	<p>3. Members shall accord the treatment provided for in this agreement to the nationals of other members.<sup>92</sup> In respect of the relevant intellectual property right, the nationals of other members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.<sup>93</sup> Any member availing themselves of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").</p>

<sup>92</sup> When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

<sup>93</sup> In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

Differences between article 2.1 of the EU proposal and article 1.1 of the TRIPS Agreement are relevant. Firstly, where the TRIPS Agreement states that “members shall give effect to the provisions of this Agreement,” the European proposal sets forth that “the parties shall ensure an adequate and effective implementation of the international treaties dealing with intellectual property,” to which they are parties. What “adequate and effective” protection is can be argued, but as for now, the EU proposal does not recognise the freedom to determine “the appropriate method of implementing the provisions of this agreement within their own legal system and practice” as laid out in the TRIPS Agreement and that was part of the EU – CARIFORUM agreement already in force.<sup>94</sup> This provision is important for providing flexibility to the intellectual property provisions and for adapting them to the legal tradition and national reality. Freedom to determine the adequate method for applying provisions in the context of a country’s own legal system along with the provision of article 41.5 of the TRIPS Agreement, which also recognises enforcement flexibility, make up the framework for legislative incorporation and application of TRIPS obligations. This flexible framework is not acknowledged in the European proposal.

Article 2.1 of the EU proposal brings up, at a minimum, two questions. First, stating that “the parties shall ensure an adequate and effective implementation of the international treaties dealing with intellectual property to which they are parties” could be construed as veiled reinforcing of the application of TRIPS Plus and TRIPS Extra provisions that have been incorporated into free trade agreements entered into with the United States by some of the CAN members. The question at hand is not about strengthening the rights of American patent holders, something that is definitely not necessary, but it does touch upon the possible extension to European patent holders. This comment may appear rather exacting, but when placing it in relation to certain interpretations of clauses regarding most favoured nation treatment and national treatment set out in the TRIPS Agreement, it may be harnessed to extend TRIPS Plus and TRIPS Extra provisions to European intellectual property right holders.<sup>95</sup>

The second question is derived from the statement, “provisions of this chapter shall complement and specify the rights and obligations of the parties under the TRIPS Agreement and other international treaties dealing with intellectual property.” The TRIPS Agreement is a multilateral treaty, the result of a complex negotiation process, which is why one party should not be able to impose its own interpretation of the treaty that alters the balance therein created, thereby affecting the other parties’ rights. While the European proposal makes allusions to “the rights and obligations of the parties”, meaning the EU and the CAN, as those that will be affected by the “conclusion” that is being formulated, it should be understood that, for example, in virtue of the obligation of a national treatment in the TRIPS Agreement, the abundant provisions on enforcement that “complement and specify” the TRIPS Agreement could also be applied to intellectual property right holders, protected within the Andean countries, who are neither European nor from the CAN. In this way and unless there is the unlikely assumption that differentiated systems of enforcement exist, then they are imposing a certain interpretation of the TRIPS Agreement onto national intellectual property right holders from TRIPS member states that had no part in its formulating. In any case, this extreme must be put in the context of observations about national and most favoured nation treatments, mentioned

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<sup>94</sup> Article 139.4

<sup>95</sup> *Vid. infra.*



further ahead in this report, which are, in the TRIPS Agreement, exclusively extended to rights and matters the agreement specifically deals with.

Article 2.2 follows the European trend of including categories of intellectual property rights that do not appear in the TRIPS Agreement along with others that have generated a discussion concerning their nature as standalone categories of intellectual property. Exemplifying the former is the inclusion of “*sui generis* rights for non-original databases” as an intellectual property right, an arguable category and unknown in most countries.<sup>96</sup> For the latter, it is exemplified through introducing “plant varieties” as a standalone intellectual property right. In its chapter on patents, the TRIPS Agreement makes exclusive reference to plant varieties, stating that members “shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.” Protecting life forms, such as plant varieties, through property, i.e. through patents, a *sui generis* system, or a combination of the two, is especially worrisome to Bolivia and it raised ideological and specific cultural principles to reject any type of protection.

In contrast with what the EU offered to eastern and southern African nations and in the agreement with CARIFORUM,<sup>97</sup> this proposal does not mention specific forms of protection for traditional knowledge or raise the Convention on Biological Diversity. Omitting the latter overlooks issues like the obligation to reveal the origin of genetic resources, prior informed consent, and fair distribution of benefits. Such omissions are extremely glaring in the Andean case, given that the region is known for sheltering great wealth in both fields (cultural and natural). It must be highlighted that there is the potential for the relationship between the Convention on Biological Diversity and medicines that could be invented through advances in biotechnology. A recent and still very controversial case is the one concerning avian flu virus sample that Asian countries have submitted (or refused to do so) for use in manufacturing a vaccine. These countries have stated that, in accordance with the Convention on Biological Diversity, they should share in the benefits gotten from the genetic materials they provide. These benefits should at least allow them equitable access to the medicines that pharmaceutical companies develop;<sup>98</sup> something that is called into question by the recent patents on compounds derived from these samples awarded to the North American National Institutes of Health and Centers for Disease Control.

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<sup>96</sup> In fact, this form of protection exclusively exists in the EU on account of Directive 96/9/EC, but economically developed countries like the US have outright rejected it. See J. Hughes, “Political Economies of Harmonization: Database Protection and Information Patents”, *Cardozo Law School, Public Law Research Paper* n°47, 2002. An emblematic case in this field is the US Supreme Court Feist decision, See US Supreme Court, 27 March 1991, *A.M.I.* 1991.

<sup>97</sup> Read, for example, article 150.3 of the Economic Partnership Agreement between the CARIFORUM States and the European Community and its Member States.

<sup>98</sup> See, M. Khor, S. Shashikant, “Winners and losers in the sharing of avian flu viruses”, [www.twinside.org.sg/title2//intellectual\\_property/info.service/twn.ipr.info.050705.htm](http://www.twinside.org.sg/title2//intellectual_property/info.service/twn.ipr.info.050705.htm) (10/2008).

### 1.3 Most favoured nation treatment

European Proposal: Article 2 bis	TRIPS Agreement: Article 4
<p><i>* The European proposal states that in further proposals it will specify this article.</i></p>	<p>With regard to the protection of intellectual property, any advantage, favor, privilege, or immunity granted by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members. Exempted from this obligation are any advantage, favor, privilege, or immunity accorded by a member:</p> <ul style="list-style-type: none"> <li>a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;</li> <li>b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;</li> <li>c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;</li> <li>d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.</li> </ul>

Most favoured nation treatment brings with it complex and interesting questions. TRIPS Plus and TRIPS Extra provisions written into the European proposal, together with other like provisions accepted by certain CAN Member States in their FTA's with the United States, force one to wonder what the degree of connection is between the two. In other words, can other TRIPS Member States demand what the CAN members agreed upon with the US and the EU? If this were the case, then intellectual property rights holders would benefit substantially from the complementarity. The United States has managed to increase intellectual property rights standards in fundamentally substantive fields, while the EU is doing so in the area of enforcement. As a result, certain considerations regarding most favoured nation treatment and national treatment have to be raised.

Applying the two cardinal principles of the multilateral trade system, i.e. most favoured nation treatment and national treatment, may have particularly harmonising effects on intellectual property protection. From the perspective of the WIPO, most favoured nation treatment in the field of intellectual property did not appear to make much sense. The explanation is straightforward: conventions WIPO administers envisage the national treatment principle, and it can hardly be conceived that foreign right holders would be given greater protection than nationals. However, as a consequence of pressure from the United States during the 1980s, some countries began to concede

greater protection to foreign rights holders than to their own national ones, which, in turn, benefited the incorporation of the most favoured nation principle treatment into the TRIPS Agreement.<sup>99</sup>

By virtue of the most favoured nation treatment, any “advantage, favour, privilege, or immunity” related to intellectual property protection granted to nationals of *any* country is thereby extended to *all* WTO Member States. What is relevant to pharmaceutical patents is that this principle is not applied to advantages, favours, privileges, or immunities provided in agreements: 1) related to intellectual property rights that entered into force before 1995, 2) notified to the Council for TRIPS, and 3) that do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.<sup>100</sup> In principle, this exclusion has opened the door to the application of the most favoured nation treatment regarding TRIPS Plus provisions contained in treaties that entered into force after 1995,<sup>101</sup> and these later agreements “must be considered potential connecting factors for applying the most favoured nation clause.”<sup>102</sup> This way, the EU and the US can, for all intents and purposes, enjoy what the other has managed to obtain in the respective agreements with TRIPS Plus provisions.

Nevertheless, observations concerning the effects of the most favoured nation clause in the TRIPS Agreement must be raised. Firstly, what is the meaning of “advantage, favour, privilege, or immunity”? As the TRIPS Agreement allows for priority protection of public health, it would seem logical to comprehend them not as provisions aimed at increasing TRIPS obligations, but rather as those that offer greater flexibility and, therefore, protect public health.<sup>103</sup> If it is taken that there is room for flexibility in the TRIPS Agreement, then expanding that to the rest of the members could not be seen as breaking the minimum standards set forth in the Agreement itself, which is why it is legal for nations that understand it is an advantage or immunity to claim the flexibility be extended to them as well. Besides, given the protectionism inherent in intellectual property, this interpretation can be understood as the most appropriate for the context of trade liberalisation in which the TRIPS Agreement is set.

A second important observation concerns the scope of the term “intellectual property” in the TRIPS Agreement. Article 1.2 states that “the term ‘intellectual property’ refers to all categories of intellectual

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<sup>99</sup> UNCTAD- ICTSD, *op. cit.*, p. 63. The panel that ruled upon the matter “European Communities - Trademarks and Geographical Indications” confirmed that applying this principle in the field of intellectual property is explained when a country concedes lesser protection to local national holders of intellectual property rights than to foreign national holders. See Grupo Especial, *Comunidades Europeas - Medidas relacionadas con la protección de las marcas de fábrica o de comercio y las indicaciones geográficas en el caso de los productos agrícolas y los productos alimenticios*, (CE - Marcas e Indicaciones Geográficas), WT/DS174/R, 15/3/2005, par 7.702.

<sup>100</sup> Art. 4.d). Exceptions to GATT article XXIV here are thus reduced since neither customs unions nor free trade areas created after WTO agreements entered into force will be exempt from applying the principle of most favoured nation treatment.

<sup>101</sup> E. Galán Corona, “El Acuerdo ADPIC (TRIPS) y la protección de la información confidencial”, Grupo Español de la AIPPI, *Los Acuerdos ADPIC (TRIPS), TLT y Protocolo del Arreglo de Madrid y su incidencia en la legislación española*, Barcelona: Grupo Español de la AIPPI, 1998, p. 93.

<sup>102</sup> La Evolución del los ADPIC: hacia un sistema multilateral flexible”, Remiche, B., Kors, J., (Comp.), *Propiedad Intelectual y Tecnología*, Buenos Aires: La Ley-Facultad de Derecho de la UBA, 2006, p. 16.

<sup>103</sup> X. Seuba Hernández, “La interpretación del Acuerdo sobre los ADPIC a la luz de la protección de la salud pública”, X. Seuba Hernández (Coord.), *Salud Pública y Patentes Farmacéuticas. Cuestiones de Política, Economía y Derecho*, Barcelona: Bosch Editor, 2008.

property that are the subject of Sections 1 through 7 of Part II,” of which patents is one.<sup>104</sup> Different provisions in treaties that increase the protection afforded intellectual property are now no longer called TRIPS Plus but TRIPS Extra, i.e. “new parameters of protection that govern and arrange previously unaddressed matters in the TRIPS Agreement.”<sup>105</sup> In this sense and with regards to the relationship between TRIPS Extra provisions and the most favoured nation and national treatment clauses, the TRIPS Agreement limits the effects of those clauses to “intellectual property rights specifically addressed in this Agreement.”<sup>106</sup> The reference to “rights” is an important one since, on one hand, the Appellate Body has made it clear that rights, like those derived from *sui generis* protection, which are required in article 27.3. b), be included among those specifically addressed by the Agreement, even though they are not mentioned in the section heading,<sup>107</sup> and, on the other hand, because it excludes unstated forms of protection, which is relevant to the pharmaceutical field, for instance, in terms of protecting test data for determined periods of time that different free trade agreements incorporate<sup>108</sup> and whose protection other nations may not appeal to due to the most favoured nation and national treatments.<sup>109</sup>

The most recently concluded EC agreements, which are especially strong on enforcement, pose another interesting question. The footnote attached to article 3 of the TRIPS Agreement states that “For the purposes of Articles 3 and 4 [national treatment and most favoured nation treatment], “protection” shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.” This footnote opens the door to at least two interpretations:

1) National and most favoured nation treatments can only be cited for *i*) matters affecting the availability, acquisition, scope, maintenance, and enforcement expressly set forth in the Agreement and *ii*) matters affecting the use of intellectual property rights specifically addressed in this Agreement.

2) Conferred rights –intellectual property categories- expressly set forth in the TRIPS Agreement are the determining criteria. If enforcement, use, acquisition, and other cited matters are directed towards rights contained in the TRIPS Agreement, then these will be affected by national treatment and most favoured nation treatment clauses.

In practical terms and if the EC’s proposal to the CAN were to stand, the first interpretation would imply that, given that the TRIPS does not allude to the application of border measures to goods in transit nor to the exports control of products allegedly infringing IPR, non European holders of

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<sup>104</sup> In all, there are Copyright and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout-Designs (Topographies) of Integrated Circuits, and Protection of Undisclosed Information.

<sup>105</sup> J. Kors, “La evolución del Acuerdo sobre los ADPIC: Hacia un multilateralismo flexible”, B. Remiche, J. Kors, (Comp.), *Propiedad Intelectual y Tecnología*, Buenos Aires: La Ley-Facultad de Derecho de la UBA, 2006, p. 33.

<sup>106</sup> See foot note n°3 of the TRIPS Agreement, article 3.

<sup>107</sup> *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R, 6/8/2001, par. 335.

<sup>108</sup> C. M. Correa, *Trade Related Aspects ...*, op. cit., pp. 31-35, 67; See also J. Drexler, op. cit., p. 13.

<sup>109</sup> In keeping with Correa, agreement scope reaches to those matters covered by protection in TRIPS Sections 1 – 7, other conventions concerning intellectual property members have pledged to adhere to, and the rights specifically cited in the TRIPS Agreement and treaties referred to.

intellectual property rights could make no claim for this. In contrast, if the second interpretation were used, then all IPR title holders would always be covered by the measures as the affected right is among the “intellectual property rights specifically addressed in this Agreement”.

These observations appear to be legal and conceptually valid though arguable in their extreme cases. However, practically speaking, asymmetries do exist that would impede developing nations from choosing any of the described alternatives. First, several free trade agreements containing TRIPS Plus and TRIPS Extra provisions countries have signed with the United States have stipulated that, before these could enter into force, the other party had to amend its national law in ways the US deemed necessary.<sup>110</sup> Secondly, an aspect closely related to that point is the fact that the US has stressed its free trade agreements are not self-executing treaties and do not impact internal legislation.<sup>111</sup> What is left, then, is a scene in which developing nations, desiring to gain the expected benefits from a free trade agreement, abandon several possible interpretations and adopt, instead, the one bearing the US stamp of approval, without extracting the same commitments in return.

Lastly, countries that have pledged to adopt TRIPS Plus and Extra provisions amend their national law, whether it is for the other party to comply with their obligations or as a provision of the treaty itself. When this occurs, such changes do not usually differentiate between local and foreign nationals and even less when it comes to those from other countries. On account of current legislative practices regarding domestic incorporation of TRIPS Plus and Extra provisions, it would therefore seem that European right holders do indeed benefit from agreements with the United States and vice versa. One proposal that could overcome these difficulties would be the incorporation of a provision in amended national intellectual property law that reads like this: “provisions in this law will apply in accordance with those on most favoured nation treatment and national treatment laid out in the TRIPS Agreement.”

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<sup>110</sup> For further reading, consult P. Roffe, *Intellectual Property, Bilateral Agreements, and Sustainable Development: The Challenges of Implementation*, CIEL, 2007, p. 9.

<sup>111</sup> *Ibid.*, p. 10

## 1.4 Technology transfer

European Proposal: Article 3	TRIPS Agreement: Articles 7, 8, and 66.2
<p>1. The parties agree to exchange views and information on their domestic and international practices and policies affecting transfer of technology. This shall, in particular, include measures to facilitate information flows, business partnerships, licensing, and subcontracting deals on a voluntary basis. Particular attention shall be paid to the conditions necessary to create an adequate enabling environment for technology transfer in the host countries, including issues such as the relevant legal framework and development of human capital.</p>	<p>(Article 7) “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology.”</p>
<p>2. The parties shall assure that the legitimate interests of the intellectual property right holders are protected.</p>	<p>(Article 8) “Appropriate measures (...) may be needed to prevent (...) the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”</p>
	<p>(Article 66.2) Developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country members in order to enable them to create a sound and viable technological base.</p>

The European proposal contains no relevant novelties regarding technology transfer. Like the TRIPS Agreement, the EC proposal has not incorporated precise or advantageous obligations for developing nations, and it even bypasses making reference to incentives the TRIPS Agreement demands be granted to enterprises that transfer technology to least developed countries.<sup>112</sup> Perhaps what stands out the most is the redundancy with which the Europeans have dressed up the proposal, in at least two respects. Number one, it is odd that a proposal for adopting a specific legal framework lays out that information exchange (which is what the EC has reduced the transference of technology to) has “the relevant legal framework” as one of its target topics. And number two, it is also surprising that this proposal for establishing a legal framework for protecting intellectual property and related to technology transfer provides “the parties shall assure protection of the legitimate interests of the holders of intellectual property rights.” Yet, given the fact that an international treaty does not normally incorporate words without specific purpose, this last reference could be a veiled threat against using one of the chief mechanisms for transferring technology: compulsory licenses. The likelihood that this is the case is strengthened by the fact that the EC proposed provision on technology transfer alludes to the voluntariness of licensing and subcontracting deals.

In any case, the contrast between the weakness of the provisions on technology transfer and the rest of the provisions in the European proposal should come as no surprise: it was also true for the TRIPS Agreement. There, article 7 lays out that intellectual property protection must contribute to transferring and disseminating technology, while article 8 provides for adopting measures to prevent

<sup>112</sup> This last reference is certainly unnecessary – none of the CAN Member States is on the list of least developed countries.

practices that adversely affect the transfer of technology. Likewise, TRIPS article 66 sets out that developed countries will provide incentives to enterprises and institutions for encouraging technology transfer to least-developed countries. Nonetheless, after thirteen years of the TRIPS Agreement adoption, and while WTO Members have incorporated obligations dealing with intellectual property protection into their national legislation, it begs the question whether a similar zeal for implementing obligations regarding technology transfer has existed. The answer is clear: the practical repercussions of this part of the TRIPS Agreement are insignificant.<sup>113</sup> For articles 7 and 8, their broad nature has caused them to be overlooked when examining whether or not the TRIPS Agreement is fulfilling its obligations and principles. On the other hand, article 66 establishes an obligation that is unclear, and, besides that, favours a reduced group of nations (least developed), which can hardly take advantage of technology transfer.<sup>114</sup> In short, the TRIPS Agreement does not practically address matters of technology transfer, confining its language to general statements<sup>115</sup> and their results to reports developed countries send to the WTO Working Group on Trade and Transfer of Technology.

It should again be noted that when comparing the EU – CARIFORUM EPA to the proposal offered to the CAN, the latter lags behind on the matter of technology transfer. As such, article 142 of the EU – CARIFORUM EPA requires the parties to control possible abuses by intellectual property right holders which could impede the granting of licenses and which amount to “an abuse of intellectual property rights” or “an abuse of obvious information asymmetries in the negotiation of licenses.” Similarly, the same article commits the EU to “facilitating and promoting” the use of incentives for transferring technology, a provision missing from the proposal to the CAN.<sup>116</sup>

The lack of provisions regarding technology transfer in the European proposal can be mitigated, at least in the field of health, by appealing to the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, a document unanimously adopted in 2008 by the World Health Assembly and therefore, all EU Member States. Among those references to technology transfer in this text,<sup>117</sup> it is point 34 that offers the precision missing from the current EU proposal:

“The actions to be taken in relation to this element are as follows:

- 4.1)** promoting transfer of technology and the production of health products in developing countries
  - a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries;

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<sup>113</sup> Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública, *Salud Pública, Innovación y Propiedad Intelectual*, Ginebra: OMS, 2006, p. 153.

<sup>114</sup> Stating that “...is well intentioned but it is not likely on its own merits to achieve significant increases in ITT.” K. E. Maskus, “Using the International Trading System to Foster Technological Transfer for Economic Development”, *Michigan State Law Review*, vol. 219, 2005, p. 235.

<sup>115</sup> K. E. Maskus, *Encouraging International Technology Transfer*, Geneva: UNCTAD-ICTSD, 2004, pp. 1, 7.

<sup>116</sup> Consult article 142.2 and 142.3 of the EU – CARIFORUM EPA.

<sup>117</sup> See, as a minimum, points 9, 14, 19, 33, and 34.

- b) promote transfer of technology and production of health products in developing countries through investment and capacity building;
  - c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate.
- 4.2)** supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development:
- a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry;
  - b) facilitate local and regional networks for collaboration on research and development and transfer of technology;
  - c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights;
  - d) promote the necessary training to increase absorptive capacity for technology transfer.
- 4.3)** developing possible new mechanisms to promote transfer of and access to key health-related technologies:
- a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices;
  - b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.”

### 1.5 Exhaustion of rights

European Proposal: Article 4	TRIPS Agreement: Article 6
The parties shall be free to establish their own regime for exhaustion of intellectual property rights, subject to the provisions of the TRIPS Agreement.	For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights

The European proposal echoes TRIPS Agreement provisions, which basically leave it up to the members to determine when rights will be exhausted. The holder of an intellectual property right



exhausts that right when he introduces the product into the market or gives consent for a licensee to do so. Exhaustion is a vitally important limitation to intellectual property rights since it keeps the right holder from controlling alternative use or resale of the product. While the doctrine of exhaustion has traditionally been adapted to the territorial nature of intellectual property and limited to the national arena, economic liberalisation, trade interdependency as well as the evolution of case law in fields like the “specific object” of intellectual property and the distinction between “existence” and “exercise” of those rights has given rise to the broadening of regional and international exhaustion of rights.

The doctrine of international exhaustion of rights backs parallel importation, a useful tool for controlling the cost of pharmaceutical products.<sup>118</sup> However, it is not an easy way to lower the cost of pharmaceutical products. Though in principle the exhaustion of rights opens great possibilities when parallel importation is part of the equation, it could also become a deterrent to pharmaceutical investments in countries that have adopted the doctrine and provoke manufacturers to move towards a single global price for their products, which would most likely be set at a price that the market can bear in the wealthier countries.<sup>119</sup> This is the danger that all regimes incorporating parallel importation of pharmaceutical products must weigh. By contrast, allegations from pharmaceutical companies that parallel importation promotes the existence of substandard products, constitutes fraud and only benefits importers and not consumers, must be ruled out.<sup>120</sup> Additionally, the argument against exhausting intellectual property rights presupposes the admission that the principles upon which the multilateral trading system is based are only beneficial for consumers in wealthy nations since they would be the only ones to get products at more competitive prices than in a protectionist regime, an argument not shared by either the countries where these consumers live nor the WTO.

As for the multilateral trade regime and intellectual property protection, the main, pre-TRIPS concern was to guarantee that national measures for protecting intellectual property did not erect obstacles to legitimate trade.<sup>121</sup> When the parties understood the WTO regime was going to harmonise intellectual property standards, they pointed out the dubious admissibility of the principle of national exhaustion on the grounds that it restricted trade and its discriminating effects,<sup>122</sup> which is why they insisted the

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<sup>118</sup> Vid. WHO, *Trade and public health. Statement of the World Health Organization at the Third WTO Ministerial Conference*, Seattle, 1999, p. 2.

<sup>119</sup> G. Velasquez, P. Boulet, “Globalización y acceso a los medicamentos. Implicaciones del Acuerdo de la OMC sobre los ADPIC”, OMS, *Globalización y acceso a los medicamentos. Perspectivas sobre el Acuerdo ADPIC/OMC*, Ginebra: OMS, 2ª Ed., 1999, WHO/DAP/98.9, p. 27. Along the same lines, Commission on Intellectual Property Rights, Innovation and Public Health, op. cit., pp. 111-112. Yet, “developing countries have not, in any systematic way, benefited from lower prices as would be expected from a discriminating monopoly. One of the reasons given has been that, in the absence of powerful insurance systems, the industry deems it to be more beneficial to direct their activity towards a reduced group of wealthier consumers, whose demand is very inelastic and enables manufacturers to charge relatively high prices.” J. Rovira Forns, “Comentarios iniciales”, C. Vassallo, M. Sellanes de Romero, *Demanda y Acceso a Medicamentos*, Buenos Aires: Observatorio de Salud, Medicamentos y Sociedad, 2002, p. 10.

<sup>120</sup> Consult IFPMA, *TRIPS, Pharmaceuticals and Developing Countries*, Geneva: IFPMA, 2000, p. 18. There are people who approximate parallel importations with drug trafficking. Read F. H. Miller, “Foreword: Globe-hopping pharmaceuticals”, *American Journal of Law and Medicine*, n° 32, 2006, p. 155.

<sup>121</sup> A. A. Yusuf, A. Moncayo von Hase, “Intellectual Property Protection and International Trade”, *World Competition: Law and Economics Review*, vol. 16, n°1, 1992, p. 115.

<sup>122</sup> *Ibid.*, pp. 127-128.

principle of international exhaustion of rights be incorporated.<sup>123</sup> Nevertheless, given the differences of position on the issue, the TRIPS Agreement was drafted with the commitment of not taking a uniform position,<sup>124</sup> letting each country choose the doctrine of exhaustion it deemed most appropriate,<sup>125</sup> and it excluded disagreements rooted in the principle of exhaustion from the WTO dispute settlement system. This solution was also adopted in later multilateral agreements<sup>126</sup> (though not in other more recent bilateral and regional agreements) and endorsed by the Doha Declaration since it provides each member with the freedom to choose the regime for the principle of exhaustion that deems most appropriate.<sup>127</sup>

In an attempt to obtain the same benefits that are sought after in the European context, i.e. profiting from the competition and the subsequent optimisation of offer and price, countries and regions with integration organisations have adopted or legitimised the doctrine of international exhaustion of rights. One of the most important regional integration organisations is the CAN, with its “Common Intellectual Property Regime”, whose provisions on intellectual property rights exhaustion<sup>128</sup> remain unaffected by recent passage of Decision 689<sup>129</sup> and furthermore recognise international exhaustion. Similarly, not only have developing nations adopted the principle of international exhaustion of rights, but some developed ones have as well. Japan, the UK, Australia, New Zealand, and Switzerland<sup>130</sup> have adopted it in relation to copyrighted and, occasionally, patented materials. However, for the United States, even though it has accepted the principle of international exhaustion, christening it “first sale doctrine”, it has excluded pharmaceutical products from its application.<sup>131</sup> Among developing countries, there are as many countries that explicitly follow the principle of international exhaustion of

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<sup>123</sup> *Ibid.*, p. 129.

<sup>124</sup> Read V. Chiappetta, “The Desirability of Agreeing to Disagree: the WTO, TRIPS, International IPR Exhaustion, and a Few Other Things”, *Michigan Journal of International Law*, vol. 21, n°3, pp. 333-392.

<sup>125</sup> This regulation reveals “the lack of consensus among states and the desire to keep open a wide area in which to maneuver in.” A. María Ávila, J. A. Castillo Urrutia, M. A. Díaz Mier, *Regulación del Comercio Internacional tras la Ronda Uruguay*, Madrid: Tecnos, 1994, p. 194.

<sup>126</sup> Such is the case with the WIPO Copyright Treaty of 1996 (article 6: “Nothing in this Treaty shall affect the freedom of Contracting Parties to determine the conditions, if any, under which the exhaustion of the right (...) applies after the first sale or other transfer of ownership of the original or a copy of the work with the authorization of the author”) and with the WIPO Performances and Phonograms Treaty of 1996 (article 8.2: “Nothing in this Treaty shall affect the freedom of Contracting Parties to determine the conditions, if any, under which the exhaustion of the right (...) applies after the first sale or other transfer of ownership of the original or a copy of the fixed performance with the authorization of the performer.”).

<sup>127</sup> Sub paragraph 5 d). This was deduced from article 6 of the TRIPS Agreement, but attempts by the United States to argue the opposite provided grounds for including this sub paragraph.

<sup>128</sup> That provides a patent holder will not hinder importation of patented products that are available in another country with his consent or that of another person authorized by him or that has been granted a license to do so. Article 54 of Decision 486 of 2000 replaces article 35 a) and c) of Decision 344 of 1993 that also incorporated the doctrine of international exhaustion except for the aspect that it did not demand product having been commercialized with the patent holder’s authorization.

<sup>129</sup> Decision 689, Updating of Certain Articles of Decision 486 - Common Intellectual Property Regime – to permit the development and deepening of Intellectual Property Rights through Member State’s Internal Legislation. *op. cit.*

<sup>130</sup> UNCTAD-ICTSD, *op. cit.*, p. 110-111; C. Correa, *Propiedad Intelectual y Salud Pública*, Buenos Aires: La Ley, 2006, pp. 141-142.

<sup>131</sup> 21 USC 381(d).

rights as there are that do not,<sup>132</sup> and countries that have attempted to implement it are under remarkable pressure.<sup>133</sup> Nonetheless, though this doctrine may not be in a country's legislation, one should not suppose that it is not applicable there since it could be set forth through case law. In any case, for the purpose of legal certainty, it is important that the principle of international exhaustion have a specific place in legislation.<sup>134</sup> That incorporation should furthermore state rights are exhausted when a product has been legally placed in the market, thereby granting greater amplitude.<sup>135</sup>

One positive aspect of the EC proposal to the Andean Community is that, for the time being, there are no references like the existing ones in EC proposed trade agreements to other developing nations that would weaken parallel importation. For instance, during the negotiations with CARIFORUM and ECOWAS, negotiators insisted taking into account losses experienced by innovative enterprises from the entrance of cheaper pharmaceutical products when it came time to decide on the doctrine of exhaustion. In several EC agreement proposals to African countries, it has been urged to take into consideration pharmaceutical companies' donation programs before adopting an international exhaustion regime. This is rather paradoxical given that choosing one exhaustion principle or another is a medium and long term drug policy, whereas donations are specific short term actions (and frequently not as beneficial as they are said to be).<sup>136</sup> Nevertheless, it is possible that the regime of parallel importations may face obstacles (at least in the future) on account of other provisions in the EC proposed agreement, something that will be described when analysing border measures.<sup>137</sup>

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<sup>132</sup> S. F. Musungu, C. Oh, *The use of flexibilities in TRIPS by developing countries. Can they promote access to medicines?* Geneva: South Centre-WHO, 2006, p. 49. View Table 5 of Annex II.

<sup>133</sup> Maybe the most well known case is that of South Africa. Responding to the HIV/ AIDS pandemic, South Africa passed the *Medicines and Related Substances Control Act* in 1997 in which article 15 c) lays out the doctrine of international exhaustion of rights. Object of this particular act was to reduce the cost of and to increase access to antiretroviral medications. However, this act was countered on two fronts: internally, via the private sector, represented by a coalition of thirty-nine pharmaceutical companies, and internationally, via the public sector, represented by the United States. Another controversial example of adoption of the principle of international exhaustion took place in Kenya during its drafting of the 2001 Industrial Property Law. While certain countries and the pharmaceutical industry did apply pressure and managed, initially, to subject the exercise of international exhaustion to having the authorisation of the patent holder, all references to patent holder authorisation were finally eliminated, thus allowing parallel importation of pharmaceutical products from any country where the product had been legitimately being commercialised. See S. Musungu, C. Oh, *op. cit.*, pp. 50-52.

<sup>134</sup> Examples of these provisions are article 36 c) of the 1995 Argentinean Patent Law (n°24.481) and section 15 c of the South African Medicines and Related Substances Act.

<sup>135</sup> Such is the case with the Argentinean Patent Law, which states that rights are exhausted when the product "has legally been placed in the market of any country." When hanging exhaustion on whether or not a product is legally placed in the market, then products in foreign markets that are objects of compulsory licensing can also be imported. Although compulsory licenses, by definition, are not granted with the consent of the patent holder, the TRIPS Agreement does not, in fact, make reference to the consent of the patent holder. This is the reason why "it does not restrict the possibility of a compulsory license being executed through importing a patented product. C. Correa, *Propiedad intelectual y salud pública*, *op. cit.*, p. 153..

<sup>136</sup> G. Velásquez, "Acceso a medicamentos en perspectiva global: retos, respuestas y derechos", X. Seuba Hernández (Coord.), *op. cit.*, p. 25.

<sup>137</sup> See below, chapter V, 4.7

## 2. Patents

The only article of the EU proposal to the CAN that specifically mentions patents is the ninth. On one hand, this provision broadens TRIPS commitments by listing parties' obligation to comply with treaties (and their recent amendments) not referred in the TRIPS Agreement and, on the other, makes reference to the relationship between patents and public health.

<b>European Proposal: Article 9</b>
Article 9.1 – International Treaties
The parties shall comply with: <ul style="list-style-type: none"><li>a) Articles 1 through 52 of the Patent Cooperation Treaty (Washington, 1970, last modified in 2001)</li><li>b) Articles 1 through 15 of the del Patent Law Treaty (Geneva, 2000)</li><li>c) Articles 2 through 9 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977, amended in 1980)</li></ul>

The first paragraph of article 9 states the parties “shall comply with” several articles from the Patent Cooperation Treaty, the Patent Law Treaty, and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The TRIPS Agreement makes no mention of any of these three treaties, which, generally speaking, introduce new rights and mechanisms favouring intellectual property right holders. As a consequence, the EU proposal has become a tool for the implementation of the WIPO Patent Agenda.

In the context of the WIPO Patent Agenda, announced in August 2001, significant advances are being made towards higher protection standards. This agenda revolves around the ratification of the Patent Law Treaty, which aims at harmonising formal requirements for applying, obtaining, and maintaining patents (i.e. required data, application form and content, simplifying possible requirements, and, in short, strengthening applicant's position so as to avoid application rejection due to formal reasons), and on the reform and ratification of the Patent Cooperation Treaty, the purpose of which is to coordinate international searches and preliminary searches and to establish time periods for requesting patent protection. Also under negotiation is the Substantive Patent Law Treaty, whose object is to create a uniform law on patentability requirements, a particularly worrisome matter given the singular importance of flexibility when it comes to patentability.

One issue that could turn out to be important is the meaning of “comply with”. Does that mean parties must ratify said treaties? Or, just comply with them in their jurisdictions? Normally, countries sign and ratify international treaties because they gain some type of benefit from them, yet the fact of merely “complying with” a treaty without, consequently, being a party to it makes little sense. What is more, references to certain treaties, like the Patent Cooperation Treaty, beg the obvious question of how a country accedes to it if it is not party to it.<sup>138</sup> In this specific case, the treaty creates no substantive rights; it just establishes a cooperation process among the treaty members' intellectual property

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<sup>138</sup> M. Santa Cruz, op. cit., p. 27.

offices. If this is the goal of the EC, then its proposal should most definitely state something about the ratification of the Patent Cooperation Treaty and not just simply refer to its “compliance”.

#### European Proposal: Article 9.2 – Patents and public health

1. The parties recognize the importance of the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Ministerial Conference of the World Trade Organization. In interpreting and implementing the rights and obligations under this article, the parties shall ensure consistency with this Declaration.
2. The parties shall contribute to the implementation and respect the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as well as the protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.

Seemingly, one positive element is the reference to the relationship between public health and intellectual property, which appeals to the Doha Declaration and the mechanism designed to deal with the situation of countries with limited or no production capacity. Since this reference must be interpreted in “good faith”, according to international treaties interpretation rules, it is worth pointing out two problems with its objective of protecting public health. First, it exclusively cites patents and, second, it approves the “Protocol amending the TRIPS Agreement” and forces the other party to accept it.

The fact that a reference is made to the relationship between “patents” and public health and not, in contrast, to that of intellectual property rights and public health could be important. One possible interpretation is that, as opposed to the Doha Declaration, which discusses the relationship between “the TRIPS Agreement and public health”, when the EU proposal states in article 9.2 that “the parties will guarantee that the interpretation and implementation of the rights and obligations assumed under this article are consistent with said Declaration (Doha)”, it limits the Doha Declaration to patents (which is the only issue article 9 addresses). This precludes the application of a pro public health interpretation to several related articles and figures. Moreover, this does not appear to be a mere drafting problem because the EU – CARIFORUM EPA also restricts the pro public health interpretation to patents.<sup>139</sup> In this context, a pro public health interpretation is important for matters of exhaustion of rights, data protection, technology transfer, enforcement, and also provisions that frame the overall interpretation. If the proposal’s reference to the Doha Declaration remains as it now stands, it could limit the scope of the Doha Declaration to patents, while it was originally conceived to cut across the entire TRIPS Agreement (the pro health interpretation). A good reference to improve the EC text would be point n° 36 5.2 of the WTO’s *Global strategy and plan of action on public health, innovation, and intellectual property*.<sup>140</sup>

<sup>139</sup> See article 147.2, titled “Patents and Public Health”.

<sup>140</sup> Which, along with other Doha references, provides and demands to “a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognised by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003; b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without

Moreover, the EU proposal obliges “the implementation and enforcement of the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.” This is a very important provision because none of the CAN Member States had, as of October 2008, ratified the TRIPS Agreement amendment which incorporates the Decision of 30 August 2003. To put this EU provision adequately into context, some of the circumstances that could have led the Andean countries not to ratify the amending protocol need to be outlined.

The sixth paragraph of the Doha Declaration called upon the Council for TRIPS to find an expeditious solution to the problem facing countries lacking manufacturing capacity. To these countries, the reaffirmation of the flexibilities through the confirmation of the legality of compulsory licensing is of little use as it stands. While the Council had been charged to solve the issue before the end of 2002 and did arrive at an agreement in December that same year, the United States blocked that decision.<sup>141</sup> Negotiations continued into 2003 up to a few days before the beginning of the Ministerial Conference held in Cancun, at which time the Council reached an agreement, included in the WTO General Council Decision of 30 August 2003.<sup>142</sup> In spite of the fact that it was presented as a solution to the latest obstacle erected within the WTO to access to pharmaceutical products,<sup>143</sup> the Decision did, in fact, create a highly impractical system, as the criticism and subsequent events have demonstrated.

The applicability of the Decision is looked at sceptically by developing nations, academics, and NGOs, all of which agree that “the problems with this system are basically procedural.”<sup>144</sup> Some have stated that the Decision set out a complicated and unattractive regime, both for countries and pharmaceutical product manufacturers,<sup>145</sup> and the latter will hardly be interested in producing under its regime.<sup>146</sup> Firstly, it states that one can only use the mechanism to protect public health, so commercial purposes have now been excluded. The result is that it places in opposition two inseparable aspects to lowering medicines prices. The most affordable medicines are those that several companies manufacture, which, as such, pursue commercial ends and compete amongst each other. As the Decision imposes a correlation among a disease, an importer, a license, an exporter, and a company, it limits the number of stakeholders in the market, fragmenting it into unattractive sub-markets for generic manufacturers. As well as disregarding that competition leads to lower prices, the Decision

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prejudice to the sovereign rights of Member States; c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognised by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003.”

<sup>141</sup> It was the so-called “Motta Text”. The United States wanted the agreement to specify i) which countries would benefit from the system, ii) diseases the system would encompass, iii) a clause stating countries could exclude themselves from the system, and iv) limit use to emergency situations. To find out about the WTO president’s reaction to that and the desire to set a limit on diseases. OMC, *Supachai lamenta la falta de acuerdo en relación a las cuestiones de salud y desarrollo*, comunicado de prensa PRESS/329, 20/12/2002..

<sup>142</sup> Decision of the General Council of 30 August 2003, “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, IP/C/W/405.

<sup>143</sup> WTO, *Decision removes final patent obstacle to cheap drug imports*, WTO Doc Press/350/Rev.1 2003.

<sup>144</sup> D. Vaver, S. Basheer, “El consumo de pastillas patentadas: Europa y una dosis de TRIPS durante una década”, B. Rémiche, J. Kors, (Comp.), op. cit., p. 106.

<sup>145</sup> K. Timmermans, “Ensuring Access to Medicines in 2005 and Beyond”, P. Roffe, G. Tansey, D. Vivas-Eugui (Eds.), *Negotiating Health. Intellectual Property and Access to Medicines*, London: Earthscan, 2006, p. 45.

<sup>146</sup> X. Seuba Hernandez, *Medicaments, els beneficis de la salut*, Barcelona: ANUE, 2005, p. 28.

ignores the fact that it is companies that produce pharmaceutical products and they will not do so unless they can make a profit.<sup>147</sup>

Secondly, several operational requirements are inadequate. In this sense, the extra labelling and medicine control add a substantial amount to the cost of a product that must be maintained very close to the marginal cost to remain competitive and affordable.<sup>148</sup> Moreover, in the statement issued by the President of the General Council, when citing certain practices pharmaceutical companies engage in, he equates the system with donations and special discounts, while, to be operational, there must be a system based on competition and not on charity. As well, it is difficult to prove that one country does not have manufacturing capacity, which brings up other issues, like whether this is about technical incapacity, economic incapacity, or both. And then there is the matter of whether this is about total incapacity or is it sufficient to compare a country to others to prove that local production had limited viability. Additionally, it is unclear if this lack of capability has to affect the entire pharmaceutical sector or is it enough that one specific pharmaceutical product is affected.<sup>149</sup>

On the other hand, besides placing an important administrative burden on the Council for TRIPS regarding contract notifications, quantities and beneficiaries, the purpose of sending possible controversies to the Council for TRIPS is unclear. Developing countries fear it is another means to pressure countries that choose to use this system. As to that, the nature of the procedure before the Council for TRIPS is also unclear. The United States insists that for the process to be valid, it requires authorisation from the Council for TRIPS, while developing countries say the procedure implies nothing more than simple a notification.<sup>150</sup> In the same way, another aspect that can be criticised is limiting the exemption of national consumption in member states of regional blocs where more than half the integration members are on the list of least developed countries. For example, this requirement excludes the most active organisation of African regional integration, which groups together countries with the greatest prevalence of HIV, namely the Southern African Development Community, because only five of its eleven members are on that list.<sup>151</sup> Consequences of this lowering of market potential for compulsory licensing are significant, given that potential manufacturers will only be interested in assuming the costs of producing a pharmaceutical product if the market is attractive enough.

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<sup>147</sup> As foreseen by Correa, “overcoming legal obstacles to exporting would not make much sense if there are no firms interested in supplying needed, low cost pharmaceutical products.” C. Correa, *Repercussions of the Declaration ...*, op. cit., p. 34. Along the same lines, B. K. Baker, “Arthritic flexibilities for accessing medicines: Analysis of WTO action regarding paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, *Indiana International and Comparative Law Review*, vol. 14, 2003-2004, pp. 613-7; A. McBeth, “When nobody comes to the party: why have no states used the WTO scheme for compulsory licensing of essential medicines?”, *New Zealand Yearbook of International Law*, vol. 3, 2006, p. 95.

<sup>148</sup> The Philippines and other countries rejected an obligatory safeguarding system to avoid re-exportation since it deemed the administrative and economic costs would make the system impractical for developing countries. Go to [www.perspectivaciudadana.com/0212221/salud01.html](http://www.perspectivaciudadana.com/0212221/salud01.html) (11/2003).

<sup>149</sup> X. Seuba Hernández, “Patentes farmacéuticas y derecho a la salud, la armonización posible”, *Revista Europea de Derechos Fundamentales*, n° 9, 2007, p. 90.

<sup>150</sup> R. Lavagna, “TRIPS Agreement. Options for Latin America”, Main Conference, November 14<sup>th</sup>, 2003, First International Congress on Drug Policies, Buenos Aires (personal notes).

<sup>151</sup> Botswana, Republic of South Africa, Madagascar, Zambia, Lesotho, Namibia, Zimbabwe, Swaziland, Mauricio, Tanzania, and Angola

If the Decision's intention had truly been to set up an attractive regime, the fact that very few countries have ratified the amendment<sup>152</sup> to incorporate this system and the lack of system application contradicts this aim.<sup>153</sup> The bureaucracy and the exceptional nature of the system have impeded its proper functioning as a rapid and agile system. There are also doubts about the inclusion of vaccines and diagnostic equipment<sup>154</sup> and also about the intended special attention to the most AIDS affected countries, because the provision concerning integration areas excludes a substantial part of these countries. And lastly, the lack of ratification of the amendment that incorporates the decision is indicative of how little countries are convinced by the system as a stable legal framework.

In fact, the reference to the Decision of 30 August, 2003 and the TRIPS Protocol of Amendment should be re-evaluated or complemented with something simpler or more imaginative. There is a simple proposal from the Director of the Oxford Intellectual Property Research Center: a system of "licenses of right" through which the request is automatically granted if it satisfies a few minimum requirements. And if injunctions are sought, it would not paralyze the system's operations.<sup>155</sup>

### 3. Data protection

European Proposal: Article 10
Protection of data submitted to obtain a marketing authorization <i>[to be developed at a later date by the EU]</i>

One of the peculiarities in the European proposal is data protection. It is curious that the article concerning one of the most controversial matters in the free trade agreements entered into by numerous developing countries with the United States is devoid of content. Rather than what is provided in the EU – CARIFORUM association agreement, which simply cites article 10 *bis* of the Paris Convention for the Protection of Industrial Property on protection against unfair competition, the European proposal contains a provision that specifically relates to protecting data submitted for marketing authorisations. Similarly, the EU proposal states that provision's contents "shall be developed at a later date by the EU," which opens up the possibility of allowing temporary and exclusive protection of pharmaceutical data submitted to the patent office. Consequently, there are two alternatives; the first is that the EC demands the same treatment afforded in treaties that certain CAN Member States have entered into with the United States (or not demand it, but simply expect to gain it through applying the principle of national treatment). The second entails the EC's continued exportation of its own standards, in particular, Directive 2004/27/EC.

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<sup>152</sup> The amendment must pass with two thirds of the members voting in favor of it. As of May 2008, three years and one term extension, only 40 countries (27 of them being members of the European Community) and the EC itself have ratified it. This means that more than 60 countries are needed to reach the two thirds approval mark.

<sup>153</sup> There has only been one, odd request to use this system: Rwanda in 2007. It was odd because the requested medicine is no longer protected by a patent in India and can be gotten for a better price than what it is being sold at in Canada, the country that apparently was pushing Rwanda to use the system. See E. Anér, *The WTO Decision on Compulsory Licensing*, Stockholm: Kommerskollegium, 2008, p. 30.

<sup>154</sup> Argentina's former Ministry of the Economy expressed his concern that vaccinations were not accounted for in the system. R. Lavagna, *op. cit.*

<sup>155</sup> D. Vaver, S. Basheer, *op. cit.*, p. 106.



Directive 2004/27/EC provides an exclusive protection term of eight years; add to that another two year term for marketing exclusivity, during which time manufacturers of generic medications can submit data to prove product bioequivalence, and one year more for new therapeutic indications for existing products. Hence, a generic product could not be commercialised until ten years had passed after the original product had received its marketing authorisation, or eleven in the event the authorisation holder obtained new therapeutic indications that bring a significant clinical benefit.<sup>156</sup>

In spite of recurring and frequent rumours about what is happening in trade agreement negotiations—the allegation that the EC is pressing for the inclusion of its data protection standards in agreements with developing or transitional countries—right now, relevant association agreements, such as the one Chile entered into with the EC, are rather scant on the matter. Considering the Chilean example, as well as others such as Mexico, Algeria, and Egypt; these list categories of intellectual property that are to be protected, among them being the protection of undisclosed information vis-à-vis unfair competition in accordance with Article 10 *bis* of the Paris Convention for the Protection of Industrial Property.<sup>157</sup>

There are several interpretations of whether or not protection of undisclosed information includes temporary and exclusive protection of test data, as laid out in this article. Article 39 of the TRIPS Agreement applies the concept of “unfair competition” with regard to required protection of confidential data by citing article 10 *bis* of the Paris Convention for the Protection of Industrial Property, which defines it as any act of competition contrary to honest practices in industrial or commercial matters.<sup>158</sup> With a link established between the meaning TRIPS article 39.1 gives to “unfair competition” and the reference in article 39.3 to “unfair commercial use”, protection against unfair competition does not imply granting periods of exclusivity, just the normal operation of the rules of competition.<sup>159</sup> In this regard, it appears to be another means of applying pressure so that developing countries adopt this type of protection, rather than an obligation directed at health authorities to exclude the use of test data for granting marketing authorisations to products that show bioequivalence to the product for which test data was originally submitted; an activity that can in no way be associated with the concept of unfair competition.

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<sup>156</sup> Paragraph 8 of Directive 2004/27/EC

<sup>157</sup> Decision No 2/2001 of the EU-Mexico Joint Council of 27 February 2001 implementing Articles 6, 9, 12(2)(b) and 50 of the Economic Partnership, Political Coordination and Cooperation Agreement (2001/153/EC) 12.3.2001 *Official Journal of the European Communities* L 70/17; Joint Declaration Relating to Article 44 of the Agreement, through which an Association between the European Community and its Member States, of the one part, and the People’s Democratic Republic of Algeria, of the other part, is established, *Official Journal of the European Union*, 265/2, 10.10.2005; Joint Declaration Relating to Article 37 of the Agreement, through which an Association between the European Community and its Member States, of the one part, and the Arab Republic of Egypt, of the other part, is established, [http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc\\_117680.pdf](http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc_117680.pdf), (3/2008).

<sup>158</sup> It furthermore provides examples, like acts of such a nature as to create confusion, false allegations in the course of trade of such a nature as to discredit a competitor, and indications or allegations the use of which in the course of trade is liable to mislead the public.

<sup>159</sup> For an opposing perspective to this interpretation, see E. Galán Corona, “El Acuerdo ADPIC (TRIPS) y la protección de la información confidencial”, Grupo Español de la AIPPI, *Los Acuerdos ADPIC (TRIPS), TLT y Protocolo del Arreglo de Madrid y su incidencia en la legislación española*, Grupo Español de la AIPPI: Barcelona, 1998, pp. 101-102.

There are, most definitely, more demanding precedents, such as in the EC – Ukraine association agreement of 1998, which made it clear that the Ukraine had to offer a level of protection “similar to that existing in the Community”<sup>160</sup> within five years, a case similar to the EC – Turkey association agreement.<sup>161</sup> At the moment, the fact is that neither the EC – CARIFORUM EPA nor the twenty other provisional EPA’s allude to exclusive data protection and concrete terms, although it seems likely these might be included in the agreement between the EC and South Korea.<sup>162</sup>

## 4. Enforcement

The bulk of the provisions found in the EC’s proposal to the CAN are focused on “enforcement of intellectual property rights”, something also found within other treaties it has recently signed. As to that, the EU is trying to export the contents of European Directive 2004/48/EC and of European Regulation 1383/2003, a move that had, in fact, been declared in the Strategy for the Enforcement of Intellectual Property Rights in Third Countries.<sup>163</sup> In reality, the proposal in question moves beyond even community law when it tries to export contents that had been rejected by the Europeans themselves from the not yet approved Directive IPRED2.<sup>164</sup> As well, the Community has pointed out that progress made on enforcement through broadening TRIPS Agreement obligations will subsequently be “carefully supervised and effectively implemented.”<sup>165</sup>

The European proposal transforms provisions in the TRIPS Agreement that are results-oriented and often allow significant room for manoeuvre into others that list in minute detail, not only the results, but also the necessary actions. CAN Member States should be particularly concerned since they are some of the few countries that have expressly passed a law as a regional bloc in which the TRIPS Agreement part III -on enforcement- is, for all practical purposes, incorporated.<sup>166</sup> This is an incorporation that now, only few years later, they will have to modify in order to correspond to European standards or standards that move well beyond what the Europeans set out.

Given the quantity, specificity, and characteristics of the new enforcement requirements, it is necessary for the CAN Member States to evaluate the costs of complying with those requirements or to consider to what extent their capability of “overall enforcement of their legislation” is affected. This is a matter that arose at the time the TRIPS Agreement was approved, and some tables were prepared indicating estimated costs. Those costs reflected the mid 1990’s economic situation and enforcement requirements that are lower than what the European proposal now contains.

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<sup>160</sup> Article 50 of the Partnership and Cooperation Agreement between the European Communities and their Member States, and Ukraine, [http://tradeinfo.cec.eu.int/doclib/docs/2003/october/tradecoc\\_111612.pdf](http://tradeinfo.cec.eu.int/doclib/docs/2003/october/tradecoc_111612.pdf) (3/2008)

<sup>161</sup> Article 32.1 of the Annex to the Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union forces Turkey not only to enforce secondary community law dealing with intellectual property, but also to adopt a level of protection comparable to the EU.

<sup>162</sup> D. Cronin, “South Korea Urged to strengthen IP in EU Trade Talks”, *IP Watch*, 21 November 2007. In fact, South Korea agreed to temporary exclusive test data protection in its FTA with the United States.

<sup>163</sup> European Commission, *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, op. cit., p. 5

<sup>164</sup> See below, footnote 174.

<sup>165</sup> *Ibid.*

<sup>166</sup> See Title XV of Decision 486, titled, “On Actions for Infringement of Rights”

**Figure 1 World Bank Projects**<sup>167</sup>

Country	Project Description	Cost
Brazil 1997-2002	To train staff involved in intellectual property administration – component of a science and technology reform project.	\$4,000,000
Indonesia 1997-2003	To enhance the intellectual property regulatory framework – component of a larger information infrastructure development project.	\$14,700,000
Mexico 1992-1996	To establish an agency to implement industrial property laws – component of a science and technology development project	\$32,100,000

**Figure 2 United Nations Conference on Trade and Development (UNCTAD) cost estimates for reforming industrial property regimes of certain countries**<sup>168</sup>

Country	Reforms	Cost
Bangladesh	To draft new laws; to improve enforcement	\$250,000 initially and \$1,100,000 annually
Chile	To draft new laws; to train staff involved in intellectual property administration	\$718,000 initially and \$837,000 annually
Egypt	To train staff involved in intellectual property administration	\$1,800,000
India	To modernize the patent office	\$5,900,000
Tanzania	To draft new laws; to build capacity for enforcement	\$1,000,000 – \$1,500,000

The following discussion highlights some of the main differences between the EU proposal and the TRIPS Agreement.

<sup>167</sup> J. M. Finger, P. Schuler, “Implementation of Uruguay Round Commitments: the Development Challenge”, *World Bank Development Research Working Paper n° 2215*, Washington D.C.: World Bank, 1999. Cited in UNCTAD-ICTSD, *Intellectual Property Rights: Implications for Development*, Geneva: UNCTAD-ICTSD, 2003, p. 50.

<sup>168</sup> Cited in *Ibid.*

## 4.1 General provisions

European Proposal: Article 13, General Obligations	TRIPS Agreement: Article 41 (the only article under Part III, Section 1, "General Obligations")
<p>1. Both parties reaffirm their commitments under the TRIPS Agreement, and in particular of its part III, and shall provide for complementary measures, procedures, and remedies necessary to ensure the enforcement of the intellectual property rights.<sup>169</sup> Those measures, procedures, and remedies shall be fair and equitable, and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.</p>	<p>1. Members shall ensure that enforcement procedures as specified in this part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.</p>
<p>2. Those measures and remedies shall also be effective, proportionate, and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.</p>	<p>2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.</p>
	<p>3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.</p>
	<p>4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.</p>
	<p>5. It is understood that this part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of members to enforce their law in general. Nothing in this part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.</p>

<sup>169</sup> For the purposes of Articles 13 to 25 the notion of "intellectual property rights" should at least cover the following rights: copyright; rights related to copyright; sui generis right of a database maker; rights of the creator of the topographies of a semi conductor product; trademark rights; design rights; patent rights, including rights derived from supplementary protection certificates; geographical indications; utility model rights; plant variety rights; trade names in so far as these are protected as exclusive rights in the national law concerned.

As it is stated in the EC proposal article 13.1, the intellectual property rights enforcement subsection includes several “complementary measures” to the TRIPS Agreement. It should be recalled that the TRIPS enforcement framework was already controversial due to the precision and exigency of its provisions. In any case, one noteworthy omission is 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”. This provision, which was introduced following a proposal from India,<sup>170</sup> is especially important from the point of view of developing countries’ needs and priorities. In fact, some say the creation of specialised intellectual property courts is one of the causes for the trend in inflating intellectual property protection.<sup>171</sup>

There is a solid foundation upon which CAN Member States can construct a stronger negotiating position on matters dealing with enforcement. Point n° 45 of the WIPO Development Agenda recommends “to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”, in accordance with Article 7 of the TRIPS Agreement”.

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<sup>170</sup> MTN.GNG/NG11/W/40, 3, n° 4(e). Cited in UNCTAD-ICTSD, op. cit., p. 585.

<sup>171</sup> For the US case and the creation of the Federal Circuit Court in 1982, a court specialised in intellectual property cases, See, B. Jaffe, J. Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton: Princeton University press, 2004, p. 10.

## 4.2 Entitled Applicants

European Proposal: Article 14	TRIPS Agreement: Article 42
<p>1. The parties shall recognize as persons entitled to seek application of the measures, procedures and remedies referred to in this Section and in Part III of the TRIPS Agreement of:</p> <ul style="list-style-type: none"> <li>a) the holders of intellectual property rights in accordance with the provisions of the applicable law</li> <li>b) all other persons authorized to use those rights, in particular licensees, insofar as permitted by and in accordance with the provisions of the applicable law</li> <li>c) professional defence bodies which are regularly recognized as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law.</li> </ul>	<p>Members shall make available to right holders<sup>172</sup> civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.</p>
<p>2. The parties may recognize as persons entitled to seek application of the measures, procedures and remedies referred to in this Section and in Part III of the TRIPS Agreement intellectual property collective rights management bodies which are regularly recognized as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law.</p>	

In the TRIPS Agreement, right holders, which also include “federations and associations having legal standing to assert such rights” on the basis of footnote n° 11, are entitled to start procedures in the event their rights have been infringed. The TRIPS Agreement, however, does not include within its entitled applicants third parties legally authorised to exercise a holder’s rights, a matter left up to the nations themselves to decide. The European proposal does away with that decision making power and expands and specifies the legitimacy when it includes among the “entitled applicants” “the holders of intellectual property rights”, “all other persons authorised to use those rights, in particular licensees”, “professional defence bodies”, and, in the event the parties so recognise them, “intellectual property collective rights management bodies.”

It has to be emphasised that article 14 merely discusses the rights of applicants and fails to make any allusion to the rights of interested third parties, in particular to the rights of users of high tech goods. In certain legal systems, including European ones, procedures have been set up so interested third parties can take part in the process for awarding patents, enabling, for instance, prior and *a posteriori* opposition to patent grants deemed undeserving by third parties. Because the section on enforcement may have significant effects on access to products protected by intellectual property rights, pharmaceutical products being part of those, it would be advisable to open up the possibility for consumers to participate in the administration of the enforcement system or to do so through different types of organisations.

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<sup>172</sup> For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

Similarly, another new matter significantly expanding present TRIPS Agreement obligations is found in the actions and measures entitled applicants can request be applied. Entitled applicants may only initiate civil and administrative procedures as per Article 42 of the TRIPS Agreement since it is under the section titled “Civil and Administrative Procedures and Remedies.” Nevertheless, the EU proposal makes reference to the legitimacy of requesting “measures, procedures, and remedies referred to in this Section and in Part III of the TRIPS Agreement.” In terms of the European proposal, the section in question (which the text actually names a sub-section) does not restrict actions to mere civil and administrative procedures but also includes criminal ones. In short, the EU proposal does not simply broaden active legitimation, but also presupposes a qualitative leap in the gravity of the actions and measures that entitled applicants may request, something that will be demonstrated later in the text.<sup>173</sup>

**4.3 Evidence**

<b>European Proposal: Article 15</b>	<b>TRIPS Agreement: Article 43</b>
<p>The parties shall take such measures as are necessary, in the case of an infringement of an intellectual property right committed on a commercial scale, to enable the competent judicial authorities to order, where appropriate and following an application, the communication of banking, financial or commercial documents under the control of the opposing entity, without prejudice to the protection of confidential information.</p>	<p>1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.</p>
	<p>2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.</p>

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<sup>173</sup> See below, section V. 4.6.

<p style="text-align: center;"><b>European Proposal: Article 16</b> <b>Measures for preserving evidence</b></p>	<p style="text-align: center;"><b>TRIPS Agreement: Article 50</b> <b>Provisional Measures</b></p>
<p>The parties shall ensure that, even before the commencement of proceedings on the merits of the case, the competent judicial authorities may, on application by an entity who has presented reasonably available evidence to support his claims that his intellectual property right has been infringed or is about to be infringed, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement, subject to the protection of confidential information. Such measures may include the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents relating thereto. These measures shall be taken when necessary and without the other party being heard, in particular where any delay is likely to cause irreparable harm to the right holder or where there is a demonstrable risk of evidence being destroyed.</p>	<ol style="list-style-type: none"> <li>1. The judicial authorities shall have the authority to order prompt and effective provisional measures:               <ol style="list-style-type: none"> <li>a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;</li> <li>b) to preserve relevant evidence in regard to the alleged infringement.</li> </ol> </li> <li>2. The judicial authorities shall have the authority to adopt provisional measures <i>inaudita altera parte</i> where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.</li> <li>3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.</li> <li>4. Where provisional measures have been adopted <i>inaudita altera parte</i>, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.</li> <li>5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.</li> <li>6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.</li> </ol>



<b>European Proposal: Article 16</b> <b>Measures for preserving evidence</b> <i>continued</i>	<b>TRIPS Agreement: Article 50</b> <b>Provisional Measures</b> <i>continued</i>
	<p>7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.</p> <p>8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this section.</p>

The articles of both texts intend to ensure access to evidence that proves an infringement and that are in the control of the other party. When the EU's provisions on evidence are set side by side with those of the TRIPS Agreement, it is clear the rights of the supposed infringing party are diminished. Perhaps the most glaring example is the reference to adopting measures without first having heard the other party. As it stands, while the reference to preliminary and final determinations judicial authorities can make in cases where a party refuses access to necessary information is subject to "providing the parties an opportunity to be heard", article 16 of the European proposal points out that judicial authorities may adopt "prompt and effective provisional measures to preserve relevant evidence" without the other party being heard. Furthermore, as happens in other enforcement related provisions, what the TRIPS Agreement sets forth as a Member State's obligation to empower its judicial authorities has become an obligation of the state itself ("the parties shall ensure") in the EU proposal. Along the same lines, where the TRIPS Agreement requires evidence be "reasonably available (possesses) and sufficient to support (its) claims" before acting and demanding evidence that is in the possession of the alleged infringing party, the Europeans simply provide for "reasonably available evidence."

#### 4.4 Right to information

European Proposal: Article 17	TRIPS Agreement: Article 47
<p>1. The parties shall ensure that, in the context of proceedings concerning an infringement of an intellectual property right and in response to a justified and proportionate request of the claimant, the competent judicial authorities may order that information on the origin and distribution networks of the goods or services which infringe an intellectual property right be provided by the infringer and/or any other person who:</p> <ul style="list-style-type: none"> <li>a) was found in possession of the infringing goods on a commercial scale;</li> <li>b) was found to be using the infringing services on a commercial scale;</li> <li>c) was found to be providing on a commercial scale services used in infringing activities; or</li> <li>d) was indicated by the person referred to in subparagraph (a), (b) or (c) as being involved in the production, manufacture or distribution of the goods or the provision of the services.</li> </ul>	<p>Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.</p>
<p>2. The information referred to in paragraph 1 shall, as appropriate, comprise:</p> <ul style="list-style-type: none"> <li>a) the names and addresses of the producers, manufacturers, distributors, suppliers and other previous holders of the goods or services, as well as the intended wholesalers and retailers;</li> <li>b) information on the quantities produced, manufactured, delivered, received, or ordered, as well as the price obtained for the goods or services in question.</li> </ul>	
<p>3. Paragraphs 1 and 2 shall apply without prejudice to other statutory provisions which:</p> <ul style="list-style-type: none"> <li>a) grant the right holder rights to receive fuller information;</li> <li>b) govern the use in civil or criminal proceedings of the information communicated pursuant to this article;</li> <li>c) govern responsibility for misuse of the right of information;</li> <li>d) afford an opportunity for refusing to provide information which would force the person referred to in paragraph 1 to admit to his own participation or that of his close relatives in an infringement of an intellectual property right, or;</li> <li>e) govern the protection of confidentiality of information sources or the processing of personal data.</li> </ul>	

The detail introduced by the EU proposal on the matter of information that can be requested during procedures of an intellectual property right infringement is surprising when compared to the TRIPS Agreement. In the first place, the European proposal lacks the provision found in the TRIPS Agreement that allows infringing parties not to inform on third parties or distribution channels if this “would be out of proportion to the seriousness of the infringement.” Secondly, what the TRIPS Agreement assumes to be a power of the state (“Members may provide”) to authorise the “judicial authorities”, the European proposal turns into a right of the claimant since it lays out that information may be ordered turned over in response to “a justified and proportionate request of the claimant.” Furthermore, the TRIPS Agreement states the infringer must be the one to provide the information, whereas the EU proposes 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. And moreover, the only information that can be supplied under the TRIPS Agreement is the identity of the third parties who have participated in the “production and distribution” and of their channels of distribution. In contrast, if the Andean states choose to adopt the European proposal, then they will have to order their judicial authorities to force 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.” After such a statement, the EU proposal goes on to echo the right against self incrimination that all people have (Article 18.3.d).

**4.5 Damages**

European Proposal: Article 22	TRIPS Agreement: Article 45
<p>1. The parties shall ensure that when the judicial authorities set the damages:</p> <p>a) they shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the right holder by the infringement; or</p> <p>b) as an alternative to (a), they may, in appropriate cases, set the damages as a lump sum on the basis of elements such as at least the amount of royalties or fees which would have been due if the infringer had requested authorization to use the intellectual property right in question.</p>	<p>1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.</p>
<p>2. Where the infringer did not knowingly, or with reasonable grounds know, engage in infringing activity, the parties may lay down that the judicial authorities may order the recovery of profits or the payment of damages, which may be pre-established.</p>	<p>2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney’s fees. In appropriate cases, members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.</p>

European Proposal: Article 23- Legal costs	
The parties shall ensure that reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity does not allow this.	

The TRIPS Agreement simply states that compensation must be adequate to compensate damages caused by a wilful or negligent infringer. Defining exactly what “adequate” payment is has been left up to the discretion of Member States, and if they follow a literal interpretation, then they should understand “adequate” to mean that which is “appropriate to conditions, circumstances, or object.”<sup>174</sup> As stated in the TRIPS Agreement, it is for the judiciary to order infringing parties to pay the right holder’s legal fees, and, furthermore, it is the power of the Member States to authorise the judicial authorities to order successful claimant to recover net profits and/or payment of adequate damages even where the infringer did not knowingly engage in the infringing activity. On the contrary, not only in the European proposal must there be “adequate” payment, but this must also encompass “all appropriate aspects”, which at a minimum includes profits made by the infringer and, lost profits and even “moral prejudice” suffered by the right holder. The European proposal even goes as far as permitting a lump sum payment for damages caused. Moreover, while the TRIPS Agreement only provides Member States with the power to authorise the *judicial authorities* to order the infringing party to pay the right holder’s legal expenses, the European proposal demands that *the parties* ensure all legal fees and other expenses incurred by the successful claimant be paid for by the infringer. That way, what was the authority of the courts has now been turned into the responsibility of the state.

#### 4.6 Criminal Sanctions

European Proposal: Article 26	TRIPS Agreement: Article 61
1. Without prejudice to the measures and procedures set out by the other provisions of this agreement, the parties shall take the necessary measures to ensure that any intentional infringement of an intellectual property right on a commercial scale, as well as attempting, aiding or abetting and inciting such infringements, are treated as criminal offences and subject to deterrent sanctions.	Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.

<sup>174</sup> As per the Royal Spanish Academy Dictionary

<b>European Proposal: Article 26</b> <i>continued</i>	
<p>2. For the offences referred to in paragraph 1, the parties shall provide for the following sanctions:</p> <p>a) for natural persons: custodial sentences;</p> <p>b) for natural and legal persons:</p> <p style="padding-left: 20px;">(i) fines;</p> <p style="padding-left: 20px;">(ii) confiscation of the object, instruments, and products stemming from infringements or of goods whose value corresponds to those products.</p>	
<p>3. For the offences referred to in paragraph 1, the parties shall provide that the following penalties are also available in appropriate cases:</p> <p>a) destruction of the goods infringing an intellectual property right;</p> <p>b) total or partial closure, on a permanent or temporary basis, of the establishment used primarily to commit the offence;</p> <p>c) a permanent or temporary ban on engaging in commercial activities;</p> <p>d) placing under judicial supervision;</p> <p>e) judicial winding-up;</p> <p>f) a ban on access to public assistance or subsidies;</p> <p>g) publication of judicial decisions.</p>	

One of the most striking components of the EU proposal is the criminal penalties it sets forth. Like other parts of the proposal, this article is particularly concise and it even details the penalties to be imposed on infringers, something not commonly found in international public law and even less so in trade agreements. Thus, the European proposal requires the parties to establish and apply different levels of punishment for infringements against intellectual property rights, such as imprisonment, fines, confiscation of materials and products, destruction of goods, closure of involved establishments, ban on engaging in commercial activities, judicial winding up, exclusion from public assistance or subsidies, and publication of judicial decisions. In contrast, the TRIPS Agreement specifies imprisonment and monetary fines in just two cases, that of copyright piracy and trademark counterfeiting and, what is more, it leaves open the option of excluding imprisonment in the phrasing “and/ or”.

The EU also demands that its Andean partners accept commitments that European countries have rejected internally within the EC, i.e. most of the provisions in the proposed parallel Directive 2004/48/CE, which does not include criminal sanctions. And, subsequent legal progress made in the

area of EC law has placed special emphasis on excluding patent infringements from any criminalisation.<sup>175</sup>

It is not just European countries that have excluded most intellectual property rights infringements from the legal scope but also economically developed nations like the United States. Not even in international agreements with TRIPS Plus provisions has the United States included obligations in the criminal field such as those proposed by the Europeans.<sup>176</sup> As a matter of fact, a paradoxical phenomenon has recently been observed: while developing nations are adopting criminal provisions for combating large scale infringements of intellectual property rights, at the prompting of developed countries, criminal penalties are still an extreme remedy in those countries pushing for those changes.<sup>177</sup> Regardless, the crux of the matter is whether the European Commission has the authority to negotiate provisions in international treaties dealing with matters that have been utterly rejected by the European Parliament; provisions that will not only place obligations on Andean states, but also on European ones. In addition to the question of competence, it must be considered to what extent the Commission is seeking to introduce standards through its international negotiations that have been unsuccessfully negotiated within the European Community.

The EC's expansion of criminal prosecution in its proposal to include all intellectual property rights violations is a marked differentiation from the TRIPS Agreement. TRIPS Agreement article 61 simply obligates the opening of criminal proceedings for cases of wilful trademark counterfeiting or copyright piracy. In the TRIPS, criminal prosecution in other cases of intellectual property rights infringements is left up to the judgment of the states. If the European proposal were accepted, then it would force criminal prosecution for "any willful infringement of an intellectual property right on a commercial scale." Such prosecution, when it falls within the jurisdiction of criminal law, despite the fact that it is really about private economic rights, would be officially initiated and its costs would then be publicly funded.<sup>178</sup> These are just some of the most problematic issues that arise when patent infringements become matters for criminal law (which, it must be stressed, has been expressly excluded in Europe):

"i) The interpretation of patent claims requires special skills that are generally lacking in criminal courts; ii) Patent infringements under most jurisdictions may be literal or by equivalence; iii) There is a considerable discretion in courts' judgment to establish when an infringement by equivalence has taken place; iv) Often, patents are found invalid or revoked when scrutinised by courts due to a lack of patentability requirements, insufficient disclosure, or other reasons; v) Criminal accusations may be prone to abuse by patent holders as they would intimidate competitors and force them out of the market

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<sup>175</sup> Proposed Directive 2005/0127(COD) on criminal measures aimed at ensuring the enforcement of intellectual property rights, known as IPRED2, was approved by the European Parliament in April 2007 after it had been intensely edited in the matter of criminal conduct. Some of the aspects excluded from criminalisation are patent infringements (article 1) and parallel imports with third countries. In any case, the directive follows the codecision procedure and presently (Oct. 2008) is in the second reading at the Council of the European Union.

<sup>176</sup> For example, the US – Jordan Free Trade Agreement provides that criminal actions shall be initiated "at least in cases of copyright piracy or trademark counterfeiting" (article 26).

<sup>177</sup> On this subject, see L. Harms, *The enforcement of intellectual property rights by means of criminal sanctions: an assessment*, prepared for the WIPO Advisory Committee on Enforcement, WIPO/ACE/4/3, September 7. Cited in C. Correa, *The new offensive for the enforcement...*, op. cit., pp. 24-25 y 53.

<sup>178</sup> See, for example, the footnote on page 78 of C. Correa, *The new offensive for the enforcement...*, op. cit., p. 24 y 58.

even if infringement did not exist; *vi*) The cost of defence in criminal courts may be prohibitive for alleged infringers, particularly SMEs; *vii*) It is virtually impossible for law enforcement officers and border officials to determine, *prima facie* whether any particular product is an infringing product”<sup>179</sup>

As an example, look at the consequences of the following case and substitute the civil and administrative actions and consequences for the corresponding criminal ones, and then extrapolate them to the European proposal. In 1993, a Chilean firm was sued for infringing a patent for processing Fluconazole, an important medicine in the treatment of meningitis, a disease frequently associated with AIDS. The patent holder obtained an injunction to prevent the marketing of the allegedly infringing product. And, though the lawsuit was dismissed a few years later, the price of the drug skyrocketed during that period, and the accused pharmaceutical manufacturer had to pay the court and legal expenses as well as the opportunity cost of not being able to sell the product.<sup>180</sup> Unfortunately, this case is not exceptional.<sup>181</sup>

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<sup>179</sup> C. Correa, *The new offensive for the enforcement...*, op. cit., p. 25.

<sup>180</sup> See footnote on page 209, UNCTAD-ICTSD, op. cit., p. 636.

<sup>181</sup> See C. M. Correa, “Internationalization of the patent system and new technologies”, *Wisconsin International Law Journal*, vol. 20, n°3, 2002, p. 543; C. M. Correa, “Abuso de derechos de patente y efectos sobre la salud pública”, X. Seuba (Coord.), op. cit.

## 4.7 Border measures

European Proposal: Article 28	TRIPS Agreement: Article 51
<p>1. The parties shall, unless otherwise provided for in this section, adopt procedures<sup>182</sup> to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, entry or exit of the customs territory, placement under a suspensive procedure or placement under a free zone or a free warehouse of goods infringing an intellectual property right<sup>183</sup> may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation or the retention of such goods.</p>	<p>Members shall, in conformity with the provisions set out below, adopt procedures<sup>184</sup> to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods<sup>185</sup>, may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.</p>
<p>2. Any rights or duties established under Section IV of the TRIPS Agreement concerning the importer shall be also applicable to the exporter or to the holder of the goods.</p>	

<sup>182</sup> It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder.

<sup>183</sup> For the purposes of this section, "goods infringing an intellectual property right" means:

- (a) "counterfeit goods", namely:
  - (i) goods, including packaging, bearing without authorization a trademark identical to the trademark duly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark holder's rights.
  - (ii) any trademark symbol (logo, label, sticker, brochure, instructions for use or guarantee document), even if presented separately, on the same conditions as the goods referred to in subparagraph (i);
  - (iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in subparagraph (i);
- (b) "pirated goods", namely goods which are or contain copies made without the consent of the holder, or of a person duly authorized by the holder in the country of production, of a copyright or related right or design right, regardless of whether it is registered in national law.
- (c) goods which, according to the law of party in which the application for customs action is made, infringe: (i) a patent; (ii) a plant variety right; (iii) a design; (iv) a geographic indication.

<sup>184</sup> It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

<sup>185</sup> For the purposes of this Agreement:

- a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;
- b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.



The EC is exerting pressure bilaterally, multilaterally, and regionally to broaden border measures as they are laid out in the TRIPS Agreement. For example, the EU submitted a proposal to the Council for TRIPS in 2006 seeking to introduce border measures into council discussions.<sup>186</sup> As a matter of record, it was an action foreseen as far back as 2004 in the Strategy for the Enforcement of Intellectual Property Rights in Third Countries.<sup>187</sup> In their proposal, they claim that the volume of goods intercepted at its external borders had risen 1000% since 1994 and so proposed the need to increase what the TRIPS Agreement article 51 provides. Back then, several developing countries had rejected this plan, but the EC has placed its border measure standards in the international agreements it has concluded.

When compared to the TRIPS Agreement, the EC proposal to the CAN increases the activities for which customs authorities must suspend the release of goods, and increases the number of intellectual property rights infringements that justify the suspension of release into free circulation of IP-protected products. TRIPS Agreement article 51 simply refers to imports of infringing goods, whereas the EC proposal includes cases of “importation, 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.” As in several other aspects of the European proposal, this is an attempt to transplant EC law into international agreements. In this case, the “exported” provision is article 9 of Council Regulation 1383/2003.<sup>188</sup>

The European proposal also expands TRIPS article 51 references to counterfeit trademarks and copyright pirated goods. In this sense, expansion could not be bigger: the EC proposal alludes to the infringement of “an intellectual property right”. This term had already been defined in the proposal, but here it is clarified in light of this article’s specific objectives. So, “intellectual property”, when it comes to adopting border measures in the EC proposal, does not just include trademarks and copyrights, but also patents, “plant varieties” rights, designs and geographic indications. In these cases, the EC has moved further than “may enable” to making it an obligation to adopt measures as they stand in the European proposal.

The fact that the TRIPS Agreement only refers to border measures regarding “counterfeit trademarks” and “pirated copyright goods” did not happen by accident. It was drafted this way because these infringements can easily be recognised by customs officials visually inspecting the merchandise. Nonetheless, broadening border measures can have harmful effects on trade, especially if products are patented. As C. Correa affirms, it is very difficult or out-and-out impossible for customs authorities to make a *prima facie* determination of a patent right infringement.<sup>189</sup> In relation to public health, this obstacle may cause especially serious problems if, for example, customs officials receive a claim

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<sup>186</sup> *Enforcing intellectual property rights: border measures. Communication from the European Commission, IP/C/W/47, 9 June 2006.*

<sup>187</sup> European Commission, *Strategy for the enforcement...*, op. cit., p. 5.

<sup>188</sup> Commission Regulation (EC)1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights (L 328/16).

<sup>189</sup> C. Correa, *The new offensive for the enforcement...*, op. cit., p. 5.

alleging that a certain active pharmaceutical ingredient that has been imported to the country—or is in transit—is infringing a patent on a manufacturing process for that compound.<sup>190</sup>

While this is not the case for CAN Member States anymore, other countries in the midst of concluding similar agreements with the EC should carefully examine the potential effects of a footnote attached to a provision on border measures. The first footnote for this provision states that “it is understood that there shall be no obligation to apply such procedures (border measures) to imports of goods put on the market in another country by or with the consent of the right holder”. This footnote also appears in the TRIPS Agreement, but in TRIPS it only makes reference to trademarks and copyrights. As noted earlier,<sup>191</sup> there are several interpretations of when a right holder exhausts his intellectual property right. For some countries, the right holder exhausts his right and parallel importation become legitimate the first time his product has been placed legally on the market. This position removes the need for the title holder’s consent, for instance in case the product has been compulsory licensed.

The EC proposal’s footnote strengthens a CAN self imposed limitation. Article 54 of Decision 486 of 2000 replaced article 35 a) and c) of Decision 344 of 1993. The 1993 regime incorporated the international exhaustion of rights principle without demanding that products be marketed with the consent of the right holder, a situation that under the 2000 regime has been changed. Presently, the Andean Community regime requires securing the title holder consent –or his voluntary product placement into the market- before parallel importing a product. If the Andean countries accept the EC proposal as it stands, any article 54 of Decision 486 future amendment that might make it agree more with the greater flexibility allowed in the TRIPS Agreement would oblige the Andean states to amend the treaty concluded with the EC if the present European text is accepted.

One last observation illustrates the zeal behind the EC’s attempt at imposing its interpretation of border measures and the problems it may generate for the EC itself. Article 51 of the TRIPS Agreement is under Part III, Section 4, which is titled “Special Requirements Related to Border Measures.” This section title has a footnote that states “where a member has dismantled substantially all controls over movement of goods across its border with another member with which it forms part of a customs union, it shall not be required to apply the provisions of this section at that border.” It is a logical provision given the progress being made on regional integration across the globe, especially in Europe. Nevertheless, there is nothing similar in the EC’s proposal to the CAN. This absence is worrying because it could, in principle, be interpreted as the EC demanding customs controls between countries in regional integration areas be reinstated to stop the circulation of products that are allegedly infringing intellectual property rights. However, given that this same issue could apply in relation to the EC, it raises the –nonsense- question of whether border measures will be reinstated in the European internal market to the extent the EC is demanding from the Andean nations, i.e. to take it literally from the European proposal, go back to “release of goods” between EC Member States.

Perhaps it would be reasonable if the EC understands that demanding this from the CAN is needed for halting the intra-regional trade of goods infringing on intellectual property rights. The latest United States Trade Representative (USTR) report placed the Czech Republic on its watch list as “hundreds of open air market stalls are notorious for selling pirated and counterfeit products.” Other EC-27

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<sup>190</sup> *Ibid.*, p. 33.

<sup>191</sup> See above, section V. 1.5.

countries mentioned in the report, placed on the watch list, and featuring similar comments are: Greece, Hungary, Poland, Romania, Spain, and Italy.<sup>192</sup>

**4.8 Codes of conduct and forensic cooperation**

European Proposal: Article 29
<p>1. The parties shall encourage:</p> <ul style="list-style-type: none"><li>a) the development by trade or professional associations or organizations of codes of conduct aimed at contributing towards the enforcement of the intellectual property rights, particularly by recommending the use on optical discs of a code enabling the identification of the origin of their manufacture</li><li>b) the submission to the competent authorities of the parties of draft codes of conduct and of any evaluations of the application of these codes of conduct</li></ul>
<p>2. Parties shall cooperate in order to identify forensically illegal optical discs which are produced by plants located in the Community of Andean Countries. The competent authorities shall collect and store samples for each production line in a database to which trade or professional associations or organizations shall have access, under the conditions defined by domestic law, to compare samples found on the market. In exchange, these associations or organizations may use, at the request of the competent authority, their international sample database to help that competent authority determine the source of the illegal product that it has reason to believe was produced outside the Community of Andean Countries.</p>

Something the European proposal has added to TRIPS Agreement provisions on this matter is the commitment to encouraging the development of codes of conduct aimed at contributing to the enforcement of intellectual property rights. Even though this provision seems to have been moulded with arenas other than patents in mind, and therefore not very relevant to public health, adopting codes of conduct may also be referred to patents and is an activity that moves beyond any article in the TRIPS Agreement. Similarly, the peculiarity that only one of the parties is identified as the origin of potential activities that infringe intellectual property rights must be pointed out (see article 29.2).

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<sup>192</sup> USTR, *2008 Special 301 Report*, Washington D. C.: Office of the USTR, 2008. Go to [www.ustr.gov/Document\\_Library/Reports\\_Publications/2008/2008\\_Special\\_301\\_Report/Section\\_Index.html](http://www.ustr.gov/Document_Library/Reports_Publications/2008/2008_Special_301_Report/Section_Index.html)

## 5. Cooperation

European Proposal: Article 30	TRIPS Agreement: Article 67
<p>1. The parties agree to cooperate with a view to supporting implementation of the commitments and obligations undertaken under this chapter.</p>	<p>In order to facilitate the implementation of this agreement, developed country members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least-developed country members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.</p>
<p>2. Subject to the provisions of article [X, horizontal art. on assistance/cooperation issues] of this agreement, areas of cooperation include, but are not limited to, the following activities:</p> <ul style="list-style-type: none"> <li>a) exchange of information on the legal framework concerning intellectual property rights and relevant rules of protection and enforcement; exchange of experiences on legislative progress</li> <li>b) exchange of experiences on enforcement of intellectual property rights</li> <li>c) exchange of experiences on central and sub-central enforcement by customs, police, administrative and judiciary bodies; coordination to prevent exports of counterfeit goods, including with other countries</li> <li>d) capacity building; exchange and training of personnel</li> <li>e) promotion and dissemination of information on intellectual property rights in, inter alia, business circles and civil society; public awareness of consumers and right holders.</li> <li>f) enhancement of institutional cooperation, for example between intellectual property offices.</li> </ul>	
<p>3. [Possible inclusion of a dialogue mechanism to be launched at the request of one of the parties]</p>	

The reference to cooperation follows the trend of exploring what the TRIPS Agreement says on the matter. In fact, the European Commission has affirmed that an “enforcement perspective” can be granted to TRIPS article 67.<sup>193</sup> The cooperation that is being advocated is solely for purposes of legally developing provisions for protecting intellectual property rights as well as to enforcing those rights. The fundamental difference is again in the detail of the European proposal since it specifies specific spheres of cooperation, such as customs, law enforcement and the judiciary. Actually, the fact there is a very detailed article on cooperation should come as no surprise since the Europeans

<sup>193</sup> European Commission, *Strategy for the enforcement...*, op. cit., p. 9.

specifically identified Latin America as a priority area in its *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*.<sup>194</sup> Similarly, that strategy also predicted developing countries would argue that more urgent priorities than intellectual property rights enforcement exist. In that regard, the European Commission is stressing the importance of its cooperation and technical assistance programs in order to ensure enforcement.<sup>195</sup> From the point of view of the CAN Member States, provisions concerning cooperation on intellectual property rights administration that meet their needs would logically be more useful.

## 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

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<sup>194</sup> *Ibid.*, p. 10.

<sup>195</sup> *Ibid.*, op. cit., p. 8. More details on EC plans for encouraging enforcement are found in C. Correa, *New offensive for the enforcement...*, op. cit., p. 16.

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.