



Intellectual Property,  
Bilateral Agreements and Sustainable Development:

# INTELLECTUAL PROPERTY IN THE US-PERU TRADE PROMOTION AGREEMENT

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**ABOUT THE INTELLECTUAL PROPERTY, BILATERAL AGREEMENTS AND SUSTAINABLE  
DEVELOPMENT SERIES**

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Catherine T. MacArthur Foundation and the Rockefeller Foundation.**

As part of the feasibility study, CIEL commissioned four papers to provide guidance on the landscape of procedural and substantive challenges posed by bilateral and regional intellectual property negotiations. The four papers are:

**“Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation,” by Pedro Roffe.** This paper examines the development of strategies for developing country officials, civil society organizations, and other stakeholders with respect to the implementation of intellectual property provisions in bilateral and regional free trade agreements. In particular, the paper aims to raise awareness of the continuing pressure for higher intellectual property protection during the implementation and annual review of bilateral trade agreements, as well as to outline the opportunities created by the diverse options for implementation to “claw back” policy space.

**“Intellectual Property, Bilateral Agreements and Sustainable Development: A Strategy Note,” by Ellen ‘t Hoen.** This paper examines strategic considerations for developing country officials, civil society groups, and other stakeholders with respect to upcoming challenges and opportunities in the negotiation of intellectual property provisions in bilateral and regional free trade agreements. In particular, the paper uses the example of the access to medicines issue to provide tangible and realistic recommendations for the next steps that could be taken by civil society groups working on bilateral and regional intellectual property and sustainable development issues.

**“Intellectual Property, Bilateral Agreements and Sustainable Development: Intellectual Property in the US-Peru Trade Promotion Agreement,” by Luis Alonso García.** This paper was written under the auspices of the Sociedad Peruana de Derecho Ambiental (SPDA). It examines a specific free trade agreement, the US-Peru Trade Promotion Agreement, as an example of the challenges and opportunities presented by such negotiations. The paper aims to provide lessons for developing countries and civil society organizations to consider in their future work.

**“Intellectual Property, Bilateral Agreements and Sustainable Development: US Trade Policy-making in Intellectual Property,” by Robert Weissman.** This paper presents an analysis aimed at providing developing country officials, civil society groups, and other stakeholders with critical information as to challenges and opportunities in the U.S. trade policy-making process as it relates to intellectual property discussions in bilateral and regional free trade agreements. The paper provides a clear and comprehensive overview of this process, touching upon the key institutions and players and providing concrete possibilities and suggestions to increase the influence of developing countries, civil society groups, and other relevant stakeholders in bilateral intellectual property discussions.

The analyses and findings of the papers form the inputs to CIEL’s **Framework for Future Action in Bilateral and Regional Trade Agreements**, which recommends specific methodologies and priority areas for civil society work in the bilateral and regional arena.

## ABOUT THE CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (CIEL)

CIEL is a non-profit organization that uses international law, institutions, and processes to protect the environment, promote human health, and create a just and sustainable world. Through our offices in Europe (Geneva) and North America (Washington D.C. and Berkeley, California), we provide advice and support to partners in civil society, government and intergovernmental organizations.

CIEL's Intellectual Property and Sustainable Development Project works with non-governmental organizations and developing country governments to include sustainable development concerns in current multilateral and bilateral rules on intellectual property.

## ABOUT THE AUTHOR

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## ACRONYMS

<b>CAN</b>	Andean Community
<b>CENI</b>	Centro para Negociaciones Internacionales (Center for International Negotiations)
<b>FTA</b>	Free Trade Agreement
<b>FTAA</b>	Free Trade Area of the Americas
<b>INDECOPI</b>	Instituto Nacional de Defensa de la Competencia y la Propiedad Intelectual (National Institute for the Defense of Competition and Intellectual Property)
<b>MERCOSUR</b>	South American Common Market
<b>MINCETUR</b>	Ministerio de Comercio Exterior y Turismo (Ministry of Commerce and Tourism)
<b>NAFTA</b>	North American Free Trade Agreement
<b>PCT</b>	Patent Cooperation Treaty
<b>TPA</b>	Trade Promotion Authority
<b>TRIPS</b>	Trade-Related Aspects of Intellectual Property Rights

## I. INTRODUCTION: NEW DIRECTIONS IN LATIN AMERICAN ECONOMIC INTEGRATION

Efforts at Latin American economic integration are not new. Various initiatives have been promoted in the region seeking economic development and political and social integration: for example, the Andean Community (CAN), Caribbean Community (CARICOM), and the South American Common Market (MERCOSUR). However, the number of voices questioning the results of these initiatives over time is increasing, as it has become evident that countries that make up these integration blocs are neither less poor nor necessarily more developed.

Efforts towards integration have not managed to establish conditions for effective and efficient “take-off” and have not been able to ensure that broader problems in the region, such as economic, social and institutional poverty, are confronted and ultimately solved.<sup>1</sup> Therefore, the proponents of these integration processes are seeking to redefine their objectives and, in most cases, have moved from ideas, which privileged internal markets and supported national industries, to “open regionalism” approaches whose objectives include opening borders, promoting trade among members without increasing external barriers, and developing negotiating capacities with third parties for accessing new markets.<sup>2</sup>

This new approach based on the search for new and bigger markets has resulted in the proliferation of free trade agreements that seek to promote international trade, and at the same time establish instruments to introduce structural and institutional reforms. In this context, because of the North American Free Trade Agreement (NAFTA) experience and the paralyzed Free Trade Area of the Americas (FTAA) process, various Latin American countries are busy concluding trade agreements with the United States, the world’s largest market.<sup>3</sup>

Peru and its Andean partners, Colombia and Ecuador, jointly started negotiations for a Free Trade Agreement (FTA) with the United States in May 2004. Venezuela and Bolivia, also members of the Andean Community block, stayed out of the process. The U.S. Congress ratified the US-Peru FTA agreement in December 2007, but the intervening period saw many shifts and developments, influenced by changes in negotiating partners, changes in U.S. politics, and the increased participation of civil society.

The main justification for Peru and the Andean countries to develop a trade agreement with the United States was to guarantee preferential and permanent access for their export products to its markets. This would be achieved by making the preferences in the Andean Trade Promotion and Drug Eradication Act (ATPDEA) binding and permanent.<sup>4</sup>

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<sup>1</sup> According to Murillo, “Poverty has remained at the same level during the past 20 years (around 35.3% of the total Latin American population has incomes under the poverty line). Unemployment went from 5.7% at the beginning of the 90’s to 8.5% towards the end.” C. Murillo. BRIDGES. Vol. V No. 5. September - December 2004.

<sup>2</sup> C. Murillo. BRIDGES. Vol. V No. 5. September - December 2004.

<sup>3</sup> U.S.-Chile Free Trade Agreement; Central American and the Dominican Republic Free Trade Agreement (DR-CAFTA); U.S.-Colombia Free Trade Agreement; U.S.-Ecuador Free Trade Agreement; and U.S. Peru Free Trade Agreement.

<sup>4</sup> The Andean Trade Promotion and Drug Eradication Act (ATPDEA), previously known as the Andean Trade Preference Act (ATPA), was signed into law by President George W. Bush on August 6<sup>th</sup> 2002. This law establishes a unilateral tariff preference regime granted by the United States to Bolivia, Colombia, Ecuador and Peru. The

Such preferences have meant a significant advantage in exports to the United States. These preferences compensate for serious limitations in the competitiveness of products from the Andean region due to factors such as lack of transportation infrastructure, high labor costs, bureaucratic obstacles, and limited access to credit.<sup>5</sup>

However, there were, and continue to be, significant concerns expressed by civil society as well as other economic actors that the concessions that would have to be made to maintain the preferences would have a damaging effect on sensitive economic sectors and would limit Peru's ability to deliver on public policy objectives such as public health and education. The US-Peru FTA process saw an unprecedented involvement in intellectual property (IP) issues from civil society groups and local pharmaceutical companies. The actions of these actors presented challenges for negotiators and may have had a profound effect on the approach of the U.S. Congress to the agreement.

This paper examines the path that has led to the conclusion of the agreement and analyzes, from the perspective of one of the negotiators, the discourse surrounding the intellectual property provisions as it evolved in Peru. The experience of Peru may suggest some important lessons for any such future negotiations in other regions. The next section outlines the role of intellectual property in the Andean Pact negotiations that preceded the US-Peru FTA process. Section III analyzes the rationale and consequences of Peru's decision to pursue a separate negotiation, while Section IV examines the role and influence of non-governmental actors on the negotiations. Section V outlines the content of the final provisions in the US-Peru FTA.

## **II. INTELLECTUAL PROPERTY IN THE US - ANDEAN FTA**

Among the various issues in the FTA negotiations,<sup>6</sup> intellectual property was one of the most important and, therefore, has received considerable attention from the public and private sector.

Since intellectual property has become embedded within the structure of international trade, mainly as a result of the Uruguay Round, trade agreements now include provisions on intellectual property which, under the objective of "harmonization," generally seek to raise the standards of intellectual property protection beyond that contemplated in international agreements such as the World Trade Organization's (WTO) Agreement on Trade-Related

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purpose was to renew ATPA benefits, which expired on August 6, 2001, and extend trade preferences to cover certain previously excluded products such as apparel, until December 31, 2006. This unilateral concession aimed to promote exports from the Andean region by establishing a preferential market capable of generating sources for alternative employment and support the fight against illegal growth of coca plants and drug trafficking. [www.mincetur.gob.pe](http://www.mincetur.gob.pe).

<sup>5</sup> Morón, E. *Tratado de Libre Comercio con los EEUU: una oportunidad para crecer sostenidamente*. Instituto Peruano de Economía. Centro de Investigación de la Universidad del Pacífico, Lima, 2005.

<sup>6</sup> The FTA negotiations considered a wide range of topics apart from intellectual property. They addressed the following issues: market access for goods (tariff and non-tariff barriers), safeguards and rules of origin, technical barriers, sanitary and phytosanitary measures, and mechanisms of trade defense. Negotiations on trade in services (telecommunications, financial, professional, construction, software, among others), electronic trade, governmental procurement, reciprocal promotion and protection of investments, compliance with labor and environmental norms and application of dispute settlement mechanisms have also been incorporated.

Aspects of Intellectual Property Rights (TRIPS). This usually happens in line with the interests of countries with a comparative advantage in technology production.

Under this scenario and in light of trade agreements signed by the United States during the last few years, there is an evident interest by the U.S. government in establishing a new legal framework on intellectual property (with TRIPS – plus features). The United States has used bilateral trade negotiations to influence intellectual property reform at the regional or national levels, which has been problematic for coherence with multilateral negotiations. This approach was apparent in the proposals of the United States in the FTA negotiations with Andean countries.

However, an important aspect in the Andean FTA negotiation was the “block position,” initially taken by the three countries involved—Colombia, Ecuador and Peru—based on the Andean Community legal system, with common norms and supranational institutions.

Unlike negotiations followed by Chile, Panama and Central American countries, it was useful for Peru, Colombia and Ecuador to have in place a regional intellectual property institutional framework, which operates based on a common policy and legal regime and institutions, which have a long-standing tradition in the development of solid jurisprudence.<sup>7</sup>

Likewise, considering the background of recent agreements by the United States in Latin America, joint participation of the three countries made it possible to engage in difficult and complex negotiations, despite limited margins for flexibility.

Upon conclusion of the round of negotiations in Washington, DC during November 2005, final agreements were made regarding the majority of sections in the chapter on intellectual property, mainly in the area of copyright and copyright-related rights, compliance, trademarks, promotion of innovation and technological development. Issues left pending were those where “red lines” had been placed or which were linked to sensitive aspects for Andean countries and whose evolution depended on the flexibilities expressed by the United States.

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<sup>7</sup> Intellectual property in Andean countries has developed under common rules provided for by various legal instruments (in force in each Andean Community Member State), which prevail over national norms in the case of conflicts between regional and national legislation. These include:

- Decision 486: Common Regime on Industrial Property.
- Decision 351: Common Regime on Copyright and Neighbouring Rights.
- Decision 345: Common Regime on the Protection of the Rights of Breeders of New Plant Varieties.
- Decision 391: Common Regime on Access to Genetic Resources.

### III. PERU AND THE DECISION TO PURSUE AN INDIVIDUAL NEGOTIATION

The U.S. position - considered by many as inflexible – resulted in a deadlocked negotiation process. Quite evidently, this was because the interests of Andean countries were not reflected in the chapter on intellectual property. As a result, there were limited efforts to move forward in the discussions, as also reflected in other chapters of the FTA.

Under these circumstances, and after evaluating the political and technical implications, Peru decided to continue the negotiation process independently, with a view to finalizing the FTA as expeditiously as possible. Once the technical phase was terminated it was time for political decisions to accelerate a final agreement on the FTA text. On December 7, 2005, after intense negotiations, Peru announced that a definitive agreement between Peru and the United States was concluded; it was finally signed by both countries in April 2006.

The Intellectual Property Chapter included the preliminary agreements reached in conjunction with Colombia and Ecuador, which represented a considerable percentage of the total issues in the Chapter. In regard to the most sensitive issues, parameters were established for future regulation in order to protect Peru's interests, and to ensure an adequate balance in the exercise of rights and the preservation of the legal framework. For instance, efforts were made to prevent patents on second uses of pharmaceuticals.<sup>8</sup> Language was crafted to ensure that protection of confidential, undisclosed information would not imply an extension of patent rights and protection periods.

The FTA is an instrument which will determine changes in the national intellectual property scenario, and its regulatory and institutional aspects alike. With regards to ongoing negotiations by Colombia and Ecuador, some analysts indicated that the FTA with Peru could imply a straightjacket for these countries in their negotiation process with the United States.<sup>9</sup>

This concern was not necessarily valid. After negotiating for a year and a half, a period in which national technicians made all their best efforts to safeguard the interests of the parties, options for movement in the negotiation table were reduced, even before Peru decided to continue negotiations individually. Rather, protection mechanisms obtained by Peru for sensitive issues, and which the three Andean countries share, may in fact have been opportunities to improve the negotiating position of Colombia and Ecuador. In any case, Colombia concluded separate negotiations in February 2006, with provisions that reflected similar provisions to those of the Peru FTA. Ecuador withdrew from further negotiations in November 2006.

These concerns were, however, overtaken by changes in the U.S. political landscape. The Congressional election campaign that took place in mid-2006 ensured the delay in consideration of the Peru FTA, as the Republican-dominated Congress was wary of approving a trade agreement in an atmosphere in which their hold on both houses of Congress was threatened. The November 2006 election resulted in a Democratic sweep of both houses and ushered in a new dynamic in Congress that was to prove favorable to the concerns of Peru in its FTA. This time

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<sup>8</sup> Second use patents are an unusual and controversial form of patent that allows a new patent to be granted for a new or secondary use of an already known drug.

<sup>9</sup> See Bridges. [www.ictsd.org](http://www.ictsd.org). January 26, 2006.

period also encompasses the expiration of the U.S. Trade Promotion Authority in June 2007, which had given the U.S. president expanded negotiating powers. It also required the extension of ATPDEA preferences to February 2008 while further negotiations were carried out to meet the demands of the new Congress.

U.S. civil society groups as well as Democratic Party activists demanded further renegotiation of the several FTAs (Peru, Colombia and Panama) to include labor and environmental provisions, and they also addressed public health and access to medicines issues related to patents. In May 2007, the Democratic Congress agreed to re-negotiate provisions with the Bush administration with the consequence that some intellectual property provisions would be altered.<sup>10</sup> The changes provided more flexibilities for Peru on intellectual property-related public health measures than had been the case with the previous chapter. Few changes were made on copyright and other provisions.

These new amendments were presented to Peru and were ratified by Peru's Congress on June 28, 2007.

#### **IV. ACTORS BEYOND THE NEGOTIATING TABLE**

During the negotiation process, public opinion was divided between those in favor of a trade agreement with the United States, considering it beneficial for the country, and those radically opposed to any type of agreement which would impose higher levels of protection for intellectual property rights. Intellectual property was one of the areas that brought many actors to the table, from other government ministries to companies to civil society actors.

Given the significance of the FTA negotiation and its importance for Peru, the Ministry of Commerce and Tourism (MINCETUR) made efforts to convene a wide range of public and private sector institutions to participate in different levels and phases of the negotiation process.

At the start of the negotiations, a total of 131 institutions were accredited, which included twenty-three Regional Governments, twelve Ministries, twenty-two public organs, forty management unions, eleven universities and postgraduate schools, three work unions, five professional academies, five research centers, five associations, and five foundations.<sup>11</sup>

The participation of public institutions focused on technical support for the different thematic tables of the negotiation, under the responsibility of leaders and coordinators. Twenty-nine public entities directly participated in the process, contributing 150 professionals and technical people during the negotiations.

The active and direct participation of officials of the Ministry of Health<sup>12</sup> should be noted in relation to the intellectual property negotiable table. Participation of officials of entities

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<sup>10</sup> For a side by side comparison of old and new provisions see <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/peru2article16sidebysideoldand6-07.pdf>

<sup>11</sup> See, [www.mincetur.gob.pe](http://www.mincetur.gob.pe).

<sup>12</sup> Dr. Pilar Mazzetti, Minister of Health of Peru, participated in the last two rounds of the negotiation, together with the Head of the Table on Intellectual Property.

responsible for administering different systems, directly or indirectly involving elements of intellectual property should also be highlighted.<sup>13</sup>

In this regard, the Ministry of Health, given the relevance of issues under negotiation, sought to safeguard access to medicines and ensure flexibilities in the face of public health problems. In this sense, the Minister of the sector claimed that, “... *as long as trade agreements block access to medicines through provisions such as patents and other restrictions, there will be serious difficulties for people to access these medicines.*”

The Ministry of Health identified a series of provisions that, if applied, could have a significant negative impact on access to medicines for a large sector of the population through restricting the use of flexibilities established in TRIPS, limiting the entry of generic medicines into the market and affecting conditions of competitiveness.<sup>14</sup>

The National Institute for the Defense of Competition and Intellectual Property (INDECOPI) prepared a study to identify the main national interests regarding intellectual property and related issues, and established a framework or referential guide in order to define a national negotiating position. INDECOPI determined that Peru’s position in this area should be based on a cost-benefit analysis of the potential impacts the negotiation terms could have on the national economy and integral development of Peruvian society.<sup>15</sup>

Subsequently, INDECOPI prepared a series of impact studies<sup>16</sup> on more specific issues, oriented towards establishing the effects from exchanging knowledge with the rest of the world, effects on the economy of families, and impacts of the FTA in the trademark system and potential impact on the pharmaceutical market.

Precisely due to the importance of the pharmaceutical market, this sector has received the most attention, as evidenced by studies undertaken on the implementation of a regime for the protection of test data. In addition to the work carried out by INDECOPI, the Ministry of Health,<sup>17</sup> and a private company, Apoyo Consultoría,<sup>18</sup> also prepared studies, although their conclusions did not agree.

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<sup>13</sup> SENASA (agricultural sanitary authority), DIGEMID (sanitary authority for human health), INRENA (natural resource authority), INIEA (agriculture authority), INDECOPI (intellectual property agency), SUNAT (customs authority), CONAM (environmental authority).

<sup>14</sup> See Position of the Ministry of Health regarding intellectual property rights on matters related to medicines. 2004. [www.minsa.gob.pe](http://www.minsa.gob.pe).

<sup>15</sup> See Peru: Los Intereses Nacionales en Propiedad Intelectual y los Tratados de Libre Comercio: Marco Referencial, March 2005. [www.indecopi.gob.pe](http://www.indecopi.gob.pe).

<sup>16</sup> See [www.indecopi.gob.pe](http://www.indecopi.gob.pe).

- Impact of Intellectual Property Rights on family expenses in the framework of the FTA. May, 2005.
- The Balance of Knowledge and Intellectual Property in Trade. May, 2000.
- Analysis of the economic impact of a regime for the protection of test data in the pharmaceutical sector in Peru. May, 2005.
- Impact from Peru adhering to the Protocol related to the Madrid Agreement Concerning the International Registration of Marks and the Trademark Law Treaty. June 2005.

<sup>17</sup> Study: Evaluation of the potential effects from the access to pharmaceuticals of the FTA being negotiated with United States.

A study prepared by Centro de Investigación de la Universidad del Pacífico,<sup>19</sup> requested by the Instituto Peruano de Economía (IPE), concluded that signing the FTA with the United States, and thus allowing the protection of test data as requested by the United States, would not have a major impact on pharmaceutical product prices presently being commercialized in Peruvian markets. The study analyzed and compared the three mentioned studies, pointing out that methodologically, the studies by Apoyo and INDECOPI were “robust,” while the study undertaken by the Ministry of Health, was based on assumptions which were far from the reality of Peru and, therefore, produced results which were technically questionable. At the time, the Ministry of Health insisted, through the media, that although each of the three studies were based on different methodologies, they all concluded that there would be an increase in the prices of pharmaceutical products (medicines). Actors from the private sector, such as NGOs, universities, companies and experts, were continuously convened by those in charge of the negotiation process, although their participation and contribution in the field of intellectual property was limited.

Most participatory activities were driven by the Center for International Negotiations (CENI) and, in particular, through coordination undertaken by the Chamber of Commerce of Lima (CCL). This enabled the participation of sectors of the national pharmaceutical industry, represented by Asociación de Industrias Farmacéuticas de Origen y Capital Nacional (ADIFAN) – the grouping of national pharmaceutical companies.

ADIFAN was critical of the FTA negotiation process, in particular, the intellectual property issues, based on their interests as a commercial management union. The position of ADIFAN<sup>20</sup> in regards to the Intellectual Property Chapter was essentially the following:

- a. The issue of intellectual property should be withdrawn from FTA negotiations. Intellectual property has no link to trade.
- b. Patents should not be granted on diagnostic, therapeutic and surgical procedures.
- c. Patents should not be granted on second uses, new uses or different uses of the same product.
- d. The right to exercise an action to annul a patent at any time while in force should not be renounced.
- e. The 20-year period of a patent should not be extended, exhausting the terms used in the process to apply for a patent or sanitary register.

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<sup>18</sup> Study: Impact of the FTA negotiations with US on matters related to intellectual property in the markets of pharmaceuticals and pesticides. Apoyo Consultoría, 2005.

<sup>19</sup> Study: Technical Opinion concerning existing studies on the analysis from the impact of protecting test data in pharmaceutical markets in Peru. Instituto Peruano de Economía, 2005.

<sup>20</sup> Yzaga, M. President of ADIFAN. Position of ADIFAN with regard to the Chapter on Intellectual Property of the FTA with US. PERU EXPORTA Magazine. July 2005.

- f. Protection should not be granted to undisclosed information through exclusivity terms.
- g. Declarations of the sanitary authority should not be submitted to decisions of the intellectual property authority.
- h. Granting mandatory licenses should not be prevented.
- i. Parallel imports should not be prevented.
- j. Mandatory adherence to the Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT) should not be accepted.

Likewise, the Foro de la Sociedad Civil en Salud (ForoSalud) was also an important actor in this process with a critical view towards the FTA negotiation. ForoSalud is a non-profit public interest association and civil society forum interested in the field of public health, promoting debate, diagnostics, socialization of studies and experiences, elaboration of proposals and collective construction of consensus and discussions with regard to the problems of health in Peru, within a wide-range of pluralism and associative autonomy.<sup>21</sup> The position of ForoSalud throughout the FTA negotiation was based on the following aspects:<sup>22</sup>

- a. Opposition to all mechanisms which would expand the exclusivity of production and sale of pharmaceuticals beyond the 20 years recognized by Andean and Peruvian Law.
- b. The protection and exclusive use of test data for “at least 5 years” would possibly increase the period of exclusivity of pharmaceuticals, and could also be used as a pseudo patent for known drugs, as the concept of new chemical entity has not been defined.
- a. Delay in the entry of generic drugs would favor the monopoly of transnational pharmaceutical companies, mainly affecting patients with limited economic resources suffering from tuberculosis, HIV, diabetes, arterial hypertension, cancer and other diseases.
- d. A demand to respect national sovereignty and health policies.

ADIFAN and ForoSalud were key actors and critics of the FTA process, particularly in the field of intellectual property. However, their proposals were generally regarded as reflecting a political agenda and interest, which reduced their relevance and influence in the overall debate.

Limited participation by the university and corresponding academic sectors, as well as other actors of civil society was regrettable. Apart from some notable exceptions there was considerable apathy.

## **V. DIFFICULT PROVISIONS IN THE US-PERU FTA: THE FINAL OUTCOME**

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<sup>21</sup> See <http://www.forosalud.org.pe>.

<sup>22</sup> Public statement, December 15<sup>th</sup> 2005.

The initial Intellectual Property Chapter that Peru concluded with the United States was composed of fourteen articles, two annexes and an Understanding.<sup>23</sup> Each section regulated different modalities of intellectual property. The final version, approved by the U.S. Congress in November 2007, remains much the same, except for some changes regarding test data exclusivity for pharmaceuticals. A side by side comparison, carried out by the Center for Policy Analysis on Trade and Health (CPATH,) can be found at:

<http://www.cpath.org/sitebuildercontent/sitebuilderfiles/peru2article16sidebysideoldand6-07.pdf>.

During the negotiation process, Peru sought to defend its key positions and interests regarding: preserving the existing regulatory system, including the Andean Community common regulations; guaranteeing adequate access to pharmaceuticals; freedom to apply exceptions to patentability; flexibilities in the light of public health concerns; and recognition and respect of rights over genetic resources and traditional knowledge.

The following were arguably the most critical issues that drew special attention from a wide range of sectors, including at the national and international levels.

### **V.1 Harmonization of Standards of IP Protection**

Following the tendency of other FTAs signed by the United States, a push was made towards legislative harmonization based on adherence to international intellectual property instruments.

In their bilateral commercial agreements with other countries, the United States and the European Union generally require accession to a series of international conventions. The obligation reinforces the trend towards international harmonization of protection standards. Bilateralism contributes to the promotion of standards supported by industrialized countries in a way that would make it more difficult to achieve in multilateral negotiations.<sup>24</sup>

Three different types of obligations arise in relation to the adhesion or ratification of international intellectual property treaties: commitments to adhere to a treaty by the time the FTA comes into force, commitment to adhere to treaties after a certain transition period, and best endeavor clauses.

First, obligations refer to four international treaties of which Peru is not a Member State or party. Those treaties to which Peru has committed to adhere or ratify when the FTA enters into force include:

- *The Convention on the Distribution of Signals for Satellite Broadcast Transmission (1974)*
- *The WIPO Copyright Treaty (1996)*
- *The WIPO Treaty on Performances and Phonograms (1996)*
- *The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and Regulations (1977), amended in (1980).*

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<sup>23</sup> [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Peru\\_TPA/Final\\_Texts/asset\\_upload\\_file392\\_9546.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file392_9546.pdf)

<sup>24</sup> Correa, C. Dialogue on Intellectual Property and Sustainable Development, ICTSD-UNCTAD, CEIDIE, SPDA. Buenos Aires, 2004.

Of particular importance for Peru (in the context of biodiversity and biotechnology related patents) is the Budapest Treaty. The main feature of the Budapest Treaty is that for purposes of disclosure of an invention requiring microorganisms and subject to a patent procedure, the deposit of the microorganisms must be with a recognized “international depositary authority” (scientific institution, typically a culture collection capable of storing microorganisms). The Treaty provides that the deposit of the microorganism with any “international depositary authority” suffices for the purposes of patent procedure before the national patent offices of all the contracting States and before any regional patent office (if such a regional office declares that it recognizes the effects of the Treaty).<sup>25</sup>

It is worth mentioning that the subject matter of the Budapest Treaty is not a new issue to the Andean Community patent system and therefore, to Peru. In this regard, Article 29 of Decision 486 (on a Common Regime on Industrial Property) determines that when an invention refers to a product or a process involving biological material and the invention cannot be described and carried out by a person skilled in the art, the application must be accompanied by a deposit of this material. This provision validates deposits with an international authority recognized under the Budapest Treaty or any other institution acknowledged by the competent national office as appropriate for this purpose.

The second type of obligations refers to adherence to, or ratification of, three treaties of considerable importance for Peru in light of the effects of such instruments in the administration of industrial property in Peru and on Andean Community legislation.

The obligation is deferred to January 1, 2008, or the date the FTA enters into force, whichever is latest. The following are the international conventions to which Peru has agreed to adhere:

- *Patent Cooperation Treaty (PCT) (1970), according to its revision and amendment (1979)*

The Patent Cooperation Treaty (PCT) provides a unified procedure for filing patent applications to protect inventions internationally, through filing of an “international” application. Such applications may be filed by nationals or residents of a Contracting State. Generally, they may be filed before the national patent office of the Contracting State of the applicant’s nationality or residence, or before the WIPO International Office in Geneva.<sup>26</sup>

It is important to mention that of the five countries of the Andean Community, Peru, Bolivia and Venezuela are not parties to the PCT to date. Colombia and Ecuador have been parties since 2001.<sup>27</sup>

In Peru, discussions over whether or not to adhere to the PCT have been taking place since 1999, when INDECOPI undertook a series of public consultations and concluded that adherence to PCT would be beneficial for the country. However, in March 2003, INDECOPI prepared a new

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<sup>25</sup> <http://www.wipo.int>.

<sup>26</sup> <http://www.wipo.int>.

<sup>27</sup> Colombia, in force since February 28, 2001. Ecuador, in force since May 7, 2001.

document where its initial position was radically changed to highlighting the inconvenience of the PCT. This new argument was based on the fact that the number of inventions generated in Peru (and by Peruvians) is very low, making it impossible to claim there is an interest by national inventors to register their inventions in third countries in contrast with foreign inventors interests, who benefit from a simplification in the registering process and therefore the granting of protection of their rights in Member States. This has led to the conclusion that Peru's interests are best served by only *committing* to adhere to the PCT in a reasonable time frame of 5 years.<sup>28</sup> However, the agreement requires Peru to accede to the PCT by January 1, 2008.

- *Trademark Law Treaty (TLT) (1994)*

The Trademark Law Treaty (TLT) is an international instrument seeking to simplify the use of national and international systems to register marks, through provisions which simplify and harmonize the registration and protection procedures.

The majority of TLT provisions relate to procedures to register marks, which can be divided into three main phases: 1) request for registration; 2) modifications after registration; and 3) renovation. Norms applicable for each phase are established to ensure that national offices understand what they may or may not require from an applicant or holder.<sup>29</sup>

A problem which arises from committing to adhere to the TLT implies adopting some provisions of a procedural nature and incorporating them into national legislation, which may contravene the Decision 486 of the Andean Community regarding marks. This may be the case of multi-class registration, as well as provisions on procedures to actually register marks. Nevertheless, Peru has now committed to ratification.

- *International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention)*

According to the TRIPS Agreement (Article 27.3.b), protection of new plant varieties may be granted through patents or through an efficient *sui generis* system.

Peru and countries of the Andean Community adopted a *sui generis* system in 1993. Decision 345 on a Common Regimen on the Protection of the Rights of Breeders of New Plant Varieties<sup>30</sup> establishes the legal framework on intellectual protection for innovation in the area of plant breeding. Colombia and Ecuador are also part of the 1978 Act of the International Convention for the Protection of New Varieties of Plants (UPOV) Convention.

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<sup>28</sup> INDECOPI. National interests in Intellectual Property and the Free Trade Agreements: Referential framework. Lima, 2003.

<sup>29</sup> <http://www.wipo.int>.

<sup>30</sup> Decision 345 governs the protection of new varieties of plants, providing *sui generis* protection by combining provisions of the UPOV Convention in Acts of 1978 and 1991. Peru regulated Decision 345 through Supreme Decree No. 008-96-ITINCI. Since its application to the year 2005, only 11 breeder's certificates have been granted.

Although the legal regime established by Decision 345 contains, in essence, the necessary elements for adequate intellectual property protection,<sup>31</sup> the United States has pressed Peru to adhere to UPOV 1991 as a means to strengthen intellectual protection in this field.

Implementation of the UPOV regime in Peru would not imply a limitation for Peru to apply provisions in Decisions 391 and 486, which seek to prevent the granting of rights based on access to and use of biological and genetic materials obtained illegally. Decision 391 addresses access to genetic resources whilst Decision 486 includes provisions which seek defensive protection and requires applicants to demonstrate the legal origin of genetic materials and associated traditional knowledge.

Finally, the third type of commitment, which is typically found in other FTAs signed with the United States, implies a standard phrasing of an obligation.<sup>32</sup> In the case of the FTA with Peru, this entails an obligation to make “*all reasonable efforts*” to ratify or adhere to three international treaties, namely:

- *Patent Law Treaty (2000)*
- *Hague Agreement on International Deposit of Designs (1999)*
- *Protocol regarding the Madrid Agreement Concerning the International Registration of Marks (1989)*

This type of obligation is a best endeavor clause that does not actually require committing to the agreement in question. This enables a country to take as long a period of time as it deems necessary while it carries out preparations for accession.

## **V.2 Patentable Subject Matter**

As one of the major flexibilities, the TRIPS Agreement contains several areas of subject matter which may be excluded from patentability.

Article 27.2 of TRIPS establishes that “*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*”

Article 27.3 (a) provides for exclusion of patentability for inventions related to diagnostic, therapeutic and surgical methods. In accordance with Article 27.3(b) of TRIPS, related to the protection of biotechnological inventions, the FTA also expressly establishes the possibility to exclude patentability of animals (Article 16.9.2).

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<sup>31</sup> See document: UPOV/DATA/BEI/04/1. June 2004.

<sup>32</sup> FTA - Chile: “Reasonable efforts”; FTA-Australia: “Improved efforts;” CAFTA-DR: “All reasonable efforts;” FTA-Bahrain: “Improved efforts.”

However, in regards to the patentability of plants, the FTA established that parties not granting patent protection to plants, shall carry out “all reasonable efforts” to grant such protection, provided the requirements of novelty, inventive level and industrial application are met.

As explained previously, this formulation, also included in the Central American Free Trade Agreement (CAFTA) does not determine *per se*, a direct obligation for Peru to grant patents over plants. However, for normative coexistence, provisions of Article 20 in Decision 486, establishing that “plants, animals and essentially biological processes, which are not non biological or microbiological processes, for the production of plants or animals shall not be patentable” should also be taken into account.

During the negotiations, another issue of interest for the United States that was ultimately withdrawn from the Intellectual Property Chapter was the requirement to make patents available for “new uses or methods of using a known product.” Although the Chapter does not have a text obliging a party to oppose the granting of a patent for uses and methods of use, the final agreement derived from final negotiations reflected the firm position expressed by Peruvian delegates confirming that there was no obligation to disallow the exclusion of new uses from patentability.

### **V.3 Criteria for Patentability: Industrial Application.**

Article 16.9.1 of the Intellectual Property Chapter provides that patents be granted for an invention, either of a product or procedure, in all fields of technology, when it is new, involves an inventive step, and is susceptible of industrial application. The article also adds that a Party may consider the expressions, “inventive step” and “susceptible to industrial application,” as synonyms of “non obvious” and “useful,” respectively.

Article 16.9.11 also establishes that the claimed subject matter is industrially applicable only if it possesses specific, substantial and credible utility.

This provision generated a series of questions with regards to possibilities of producing “flexibilities” in the content of patent applications, mainly biotechnological developments. It also generated concern with respect to the possibility of allowing the patenting of uses.

On this point, Peru sought to maintain the interpretation of industrial application as expressed in Article 19 of Decision 486.<sup>33</sup> This interpretation applied by patent offices of the Andean Community is maintained. To ensure this specific interpretation, a footnote was included on page 16 whereby it is understood that Article 16.9.11 of the Chapter shall be applicable without prejudice to novelty, inventive step, and industrial application as patentability conditions determined in Article 16.9.1 and others, including consideration of exclusions of patentability previously mentioned.

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<sup>33</sup> Article 19, Decision 486: *An invention shall be regarded as industrially applicable when its subject matter may be produced or used in any type of industry; industry being understood as that involving any productive activity, including services.*

Under certain circumstances, inventions that do not comply with the requirement of utility may be rejected. This would occur when the invention can be carried out or used in any type of industry, but does not demonstrate any practical or useful application. There is a clear difference between the requirement of industrial application and the requirement of use as to inventions that may be used only in a personal manner, although in certain countries, the public benefit of the invention is taken into account.<sup>34</sup>

#### **V.4 Public Health Considerations**

In the initial Intellectual Property Chapter, Peru attempted to ensure several public health related flexibilities. In accordance with the Doha Declaration, which reaffirms the right of countries to adopt the necessary measures to protect public health and exercise their freedom to grant compulsory licenses whenever they consider it necessary, provided they are compatible with TRIPS, Peru initially obtained an important concession from the United States as part of a Side Letter. This Side Letter established that obligations under the Chapter shall not affect the capacity of Peru to adopt necessary measures to protect public health.

In this context, there was recognition that the Intellectual Property Chapter did not prevent the effective use of the TRIPS Solution on Public Health in accordance with the Declaration on Public Health of the TRIPS General Council of August 30, 2003 on the implementation of paragraph six of the Doha Declaration related to TRIPS and public health. The concern arising from the possibility of a test data regime restricting or preventing the freedom to apply for compulsory licenses was clarified through a communication directed to Peru in which the United States confirmed that the test data regime of the Chapter is subject to the Declaration on TRIPS and Public Health.

The amendments, required by the new Democratic-controlled U.S. Congress, made some changes addressing public health, moving closer to addressing the concerns of Peru, although not completely. The elements of the Side Letter, especially those of the Doha Declaration on Public Health were now included in the body of the text, as Article 16.10.2.e and 16.13. The areas affected were test data protection, linkage between patent protection and regulatory approval, and extension of patent terms.

##### *V.4.1 Protection of Test Data*

In relation to test data, the final version of the FTA maintains the previous Chapter's establishment of a regime through which safety and efficiency information required for approving the commercialization of a new pharmaceutical or agricultural chemical product is granted protection for an exclusive period. This prevents generic companies from relying on such information if they wish to gain marketing approval for bioequivalent drugs. The exclusivity period for pharmaceuticals is 5 years, including approval by reference, that is, when evidence is used from a previous commercialization approval in another territory.

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<sup>34</sup> Document WIPO: SCP/9/5. March 2003.

The new changes now apply exclusivity only to “new chemical entities” not simply improvements on existing drugs. They also limit it to information that required considerable effort, removing the risk of inclusion of information already in the public domain.

The agreement maintains the flexibility that Peru may rely on information which may have been generated for a prior approval for commercialization from the North American sanitary authority. This would be the basis for the approval for commercialization in Peru and the date would run from the date of prior approval in the United States.

#### *V.4.2 Patent Term Extension*

The initial Chapter required mandatory term extensions for delays in granting patents. Such mandatory provisions were also eliminated in the new version.

#### *V.4.3 Linkage*

Finally, Parties agreed to remove any linkage of patent protection to regulatory approval. The authority responsible for the approval for commercialization would not be required to make any determinations about patent validity or the existence of patent protection in its decisions. This differs from the requirement in the initial Intellectual Property Chapter that a system within the approval process to commercialize should be implemented to prevent authorizations being granted on products with a patent in force, unless it is with the consent of the holder.

### **V.5 Biodiversity Linked to Intellectual Property**

Under the framework of the FTA, establishing linkages between regulations on access to genetic resources and traditional knowledge and the patent system has been particularly complicated.<sup>35</sup> Requests and proposals by Peru were coherent with the position the country took in different national and international forums.<sup>36</sup> These proposals included:

- a. establishing international obligations to ensure that, as part of the process to assess patent applications, the disclosure of geographical and legal provenance of genetic resources and traditional knowledge directly or indirectly incorporated in an invention was required;
- b. establishing sanctions for non compliance with this requirement; and
- c. establishing obligations, principles or recommendations to allow improvements in and more rigorous systems to search relevant information (to genetic resources and traditional knowledge) to assess novelty and inventive step.

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<sup>35</sup> Andean countries have nearly 25% of global biological diversity and are developing actions towards obtaining the conservation and sustainable use of their components, that is, Andean societies perceive their biodiversity as a real comparative advantage that should be valued in its economic dimension, for which the appointment of concrete property rights are required. Consejo Nacional del Ambiente. CONAM. Lima, 2005.

<sup>36</sup> See document OMC:IP/C/W/2, June 2005.

With these considerations in mind, different proposals were presented by Peru, together with Colombia and Ecuador, as well as a final proposal from Peru.

Finally, through a Side Letter – again, as an integral part of the FTA - the United States took explicit notice of some of the interests of Peru, as a first and important step within the proposed protection scheme.<sup>37</sup> However, the United States did not explicitly assume any obligations to achieve the goals that Peru sought.

Nevertheless, the United States recognized for the first time in a bilateral agreement the importance of traditional knowledge and biodiversity, as well as their potential economic, cultural and social contribution.

It also recognized their importance regarding:

- obtaining informed consent for access genetic resources from the relevant authority before the access take place;
- equitably distributing the benefits that derive from the use of traditional knowledge and genetic resources; and
- promoting the quality of examination of patents to ensure they satisfy patentability conditions.

The United States also acknowledged that access to genetic resources and traditional knowledge, as well as the equitable distribution of benefits that may derive from these resources and knowledge may be adequately assisted through contracts which reflect mutually agreed terms between user and providers.<sup>38</sup> This reflected the position that the United States has taken in international fora, such as the WTO and WIPO.

Finally, the initial foundations were set to establish exchange of information mechanisms, aimed at assisting the work of patent application examiners on patents that may be based on traditional knowledge and genetic resources of interest mainly for Peru. Such mechanisms may be publicly accessible databases with the relevant information, as well as resources to address the relevant examination authority in writing on the state of the art, which may be related to patentability.

## **VI. CONCLUSION**

The FTA that Peru negotiated with the United States has undergone significant changes from its beginning as a regional negotiation to a bilateral negotiation, to a re-negotiation with the U.S. Democratic-controlled Congress. In this regard, the role that Peruvian civil society played in

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<sup>37</sup> “The sole reference to biodiversity and traditional knowledge of indigenous peoples in the FTA is already an achievement in itself, especially considering with whom the negotiations have been taking place and the position of United States on these issues through the last few years.” Manuel Ruiz, *Diario Correo*. Lima. February 11<sup>th</sup> 2006.

<sup>38</sup> “In rigor, contracts arise in the way the Convention on Biological Diversity has been developing. Around the world without exception, contracts are mechanisms incorporated in all norms which regulate access to biodiversity and its components.” M. Ruiz. *Ibid.* at 35

influencing domestic Peruvian decisions on the nature and scope of intellectual provisions does not seem to have been significant. However civil society will likely play an important part in the implementation of the intellectual property provisions. In any such involvement, civil society will have to bring to bear, strong technical information and analysis to support its goals so as to not repeat the difficulties encountered in convincing negotiators of the value of their positions.

This is in contrast to the apparent success of U.S. civil society organizations in convincing the U.S. Congress to seek concessions from the U.S. negotiators that were of benefit to Peru. However, it may be that their success was built on the initial civil society participation encouraged by the Peruvian government. This created a legitimate group who could represent the public interest of Peru and on which U.S. civil society groups could rely on for information and support regarding Peruvian popular opinion and concerns. This suggests alternative methods for negotiators working with the United States to put pressure on their U.S. counterparts. This depends on a watchful and supportive U.S. Congress, which may not always be the case, where FTAs are involved. Peru has been fortunate to negotiate its agreement during a time of favorable trends in U.S. domestic policy.

The standards that Peru has finally reached in its agreement with the United States are closer to the goals first aimed at by the Peruvian negotiators. The Peruvian government was justifiably proud of what it had achieved in the initial version of the IP Chapter, given the greater negotiating power of the United States and the pressure to maintain trade preferences. Nevertheless, there was significant dissatisfaction within Peru regarding the initial IP chapter. The new version of the Intellectual Property Chapter, while an improvement, may not necessarily reflect any specific action by the government of Peru. These changes were essentially produced without significant input from the Peruvian government. This suggests that future negotiators should consider that there may be significant domestic interest groups in the United States who may share their goals and who can play a crucial part, before the negotiation or signing of an agreement, in putting forward their case.

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