

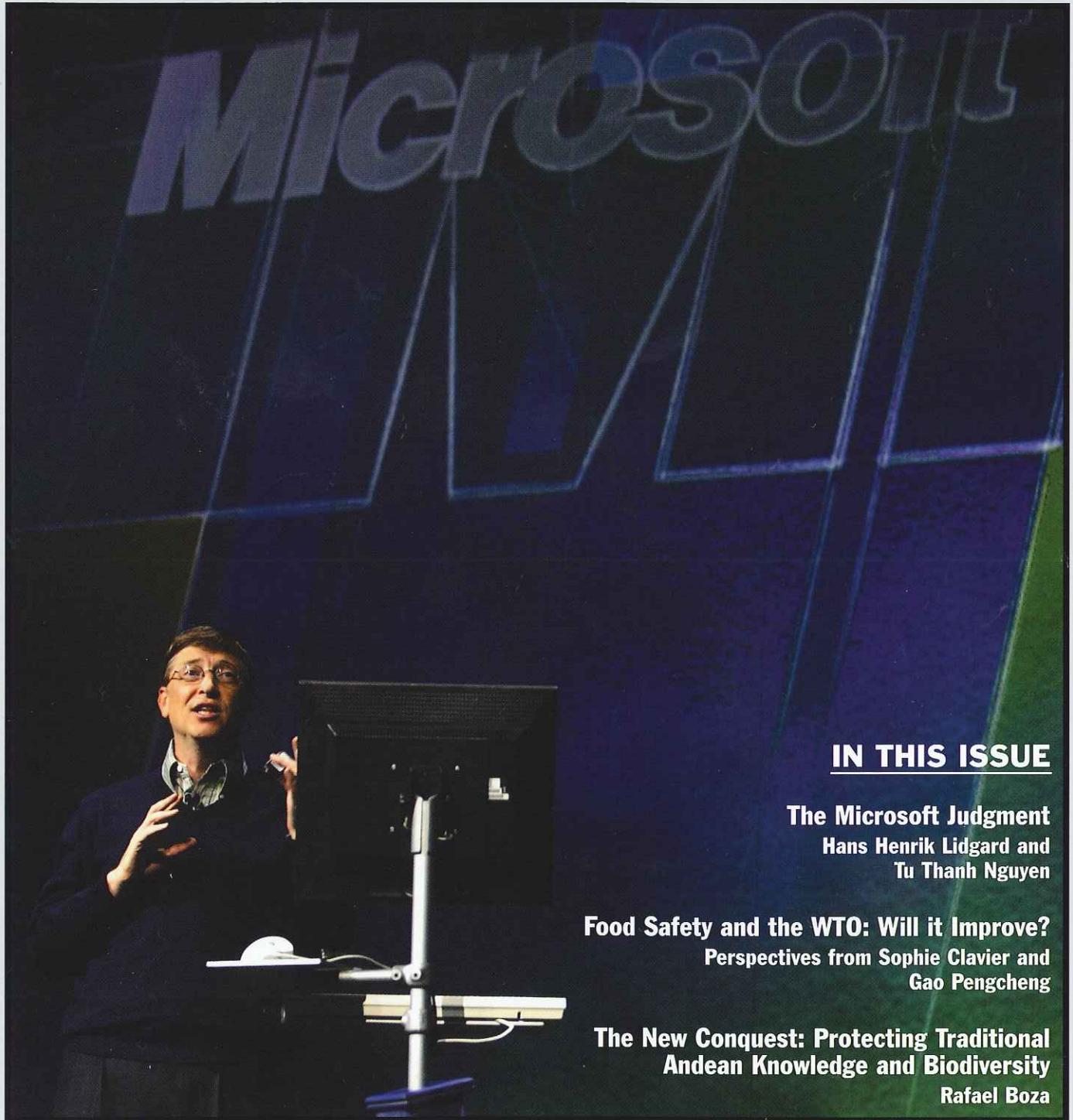
# CURRENTS

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## IN THIS ISSUE

### **The Microsoft Judgment**

Hans Henrik Lidgard and  
Tu Thanh Nguyen

### **Food Safety and the WTO: Will it Improve?**

Perspectives from Sophie Clavier and  
Gao Pengcheng

### **The New Conquest: Protecting Traditional Andean Knowledge and Biodiversity**

Rafael Boza

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## CONTENTS

- 3** FOOD FIGHT AT THE WTO: CAN THE PRECAUTIONARY PRINCIPLE RECONCILE LIBERALIZATION AND PUBLIC FEAR?  
*Sophie M. Clavier*
- 13** CHINA, THE U.S., AND FOOD SAFETY UNDER THE WTO REGIME  
*Gao Pengcheng*
- 31** APEC: WHAT FUTURE COURSE OF ACTION SHOULD IT PURSUE?  
*Eric M. Pedersen*
- 41** THE CFI MICROSOFT JUDGMENT AND TRIPS COMPETITION FLEXIBILITIES  
*Tu Thanh Nguyen and Hans Henrik Lidgard*
- 52** PATENT RIGHTS IN COMMERCIAL AGREEMENTS RECENTLY ENTERED BY THE U.S.A. WITH NATIONS OF THE SOUTH  
*Horacio Rangel-Ortiz*
- 62** FUTURE INTERNATIONAL TRADE ISSUES: IS BRAZIL THE SOLUTION TO WORLD ENERGY SHORTAGES THROUGH ETHANOL TRADE?  
*Joe A. Flores*
- 76** CHESTER JAMES TAYLOR 2007 WRITING AWARD WINNER: PROTECTING ANDEAN TRADITIONAL KNOWLEDGE AND BIODIVERSITY PERSPECTIVES UNDER THE U.S.-PERU TRADE PROMOTION AGREEMENT  
*Rafael T. Boza*
- 94** TERRORISM AND TRADE: MUCH ADO ABOUT NOTHING  
*Colin S. Sherrod*



## LETTER FROM THE EDITOR

Dear Readers:

The 2007-2008 Editorial Board and Members of *Currents* are pleased to present the Summer 2008 issue. This is an extremely special issue to the Editorial Board and members because this is the first time *Currents International Trade Law Journal* has ever published three issues within one school year. This accomplishment would not have been possible without the dedication of all those involved with the publication of this issue and the previous two issues.

Both domestically and internationally, food safety is of great concern; thus making it an appropriate topic to start off the first two articles in this issue. Professor Sophie M. Clavier's article begins the Summer 2008 issue with a proposed application of the Precautionary Principle on the continued conflict between the United States and the European Union in the WTO relating to genetically modified foods and synthetic hormones in meat. Continuing on the topic of food safety, Pengcheng Gao's article brings forth the issues and concerns caused by Melamine when it was discovered last year in pet food, and how this impacts China's food safety export measures.

Articles that follow include a wide range of interesting topics, including an examination of the past, present and possible future actions of the Asian Pacific Economic Cooperation (APEC); the consequences of the CFI Microsoft judgment and its relation and impact to the TRIPS Agreement; the effect of recent trade agreements between the U.S. and South American nations on patent rights; and the use of Ethanol as an alternative energy resource in the future and Brazil's role in facilitating the trade of Ethanol.

This issue concludes with two student pieces. The first of the two pieces is the article written by Rafael Boza, who is this year's winner of the Taylor Writing Competition, for his article on the protection of traditional knowledge and biodiversity under the U.S.-Peru Trade Promotion Agreement. The Editorial Board of *Currents* has also selected Colin Sherrod's piece on the consequence on trade by terrorism. Congratulations to both students for getting their pieces published in this issue!

Again, I would like to offer my sincere appreciation to the authors for publishing their work with *Currents*, Associate Dean Elizabeth Dennis and Professor Cherie O. Taylor for their guidance, and Joshua Starnes' dedication and assistance. I would also like to express my heartfelt gratitude to this year's Editorial Board and members. Without the team effort of everyone involved in this issue, publishing a third issue of *Currents* this year would not have been achievable. Thanks again for everyone's hard work and endless hours on making this issue possible.



Angela Ban  
Editor-in-Chief

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Please direct inquiries and correspondence to:  
Editorial Board  
*CURRENTS*  
South Texas College of Law  
1303 San Jacinto Street, Suite 217  
Houston, Texas 77002-7006  
E-mail: currents@stcl.edu

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# CHESTER JAMES TAYLOR 2007 AWARD WINNER: PROTECTING ANDEAN TRADITIONAL KNOWLEDGE AND BIODIVERSITY UNDER THE U.S.-PERU TRADE PROMOTION AGREEMENT

RAFAEL T. BOZA\*

## I. INTRODUCTION

“Peru is a beggar sitting on a bench of gold.”<sup>1</sup> I may have heard it a million times, my grandparents, my teachers, my professors repeated that same phrase many times trying to explain why a country so rich in natural resources was one of the poorest in the world.

Much of Peru’s “gold” is not actual metal but biodiversity –plants and animals; an enormous natural diversity that has been exploited in a sustainable manner for centuries, even before the Incas ruled in South America and before the Spaniards conquered the continent. Those ancient civilizations learned how to use nature to their benefit, i.e. how to use plant extracts or animal by-products to feed the hungry, cure illness, tone the body and free the soul. This knowledge was transmitted from generation to generation, as a tradition, in an uninterrupted chain for centuries until today.

Some international organizations, such as the World Intellectual Property Organization (hereinafter WIPO), have attempted to define traditional knowledge, however, it is an elusive concept. This fact has been clearly expressed by a WIPO publication, which

presented the following question: “Can the astonishing diversity of indigenous and local intellectual traditions and cultural heritage be bundled together into one single definition, without losing the diversity that is its lifeblood?”<sup>2</sup> The most likely answer to that question would be no.

Nevertheless, some kind of definition is needed. WIPO uses the phrase traditional knowledge to refer to:

“tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields [which] have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. [These] could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge.”<sup>3</sup>

Yet, it was not until relatively recent, about the last 40 years, that the economic importance of traditional knowledge became evident.<sup>4</sup> For generations indigenous peoples from all over the world had practiced the art of creating new varieties of plants and they used their extracts.<sup>5</sup> However, efforts like the International Union for the Protection of

New Varieties of Plants (hereinafter UPOV)<sup>6</sup> of 1961 or the United Nations Food and Agriculture Organization – FAO International Undertaking on Plant Genetic Resources (1983),<sup>7</sup> and the FAO recognition of farmers’ rights<sup>8</sup> created an environment where the economic value of plants was increased and that, in turn, caused an increased commercial interest in the pool of knowledge acquired by local communities over centuries.

Companies took advantage of the opportunity and started doing “Bio-prospecting” in less developed countries.<sup>9</sup> These activities resulted in the appropriation of some of that knowledge without giving anything in return to the peoples who created or acquired it.<sup>10</sup> Soon after, the term “Biopiracy” was coined to describe the unlawful appropriation or use of traditional knowledge.<sup>11</sup>

All this created awareness of a problem and gave rise to a protectionist movement among third world countries, which tried to obtain international recognition to the value of traditional knowledge, while they created new national legal tools and mechanisms to protect it.<sup>12</sup>

In this context, a number of international forums were created to address the issue. The most important forum is the Convention on Biological Diversity (hereinafter

CBD), held in 1992, under the sponsorship of the United Nations, in Rio de Janeiro, Brazil.<sup>13</sup> Another is the group of the Like-Minded Megadiverse Countries, created in Cancun, Mexico, in 2002.<sup>14</sup>

The issue was also discussed within the World Trade Organization, as part of the Trade Related Aspects of Intellectual Property Rights (hereinafter TRIPS) conversations during the Doha round and other related forums.<sup>15</sup>

The CBD recognized the value of traditional knowledge and biological resources, extending such recognition to “innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.”<sup>16</sup> CBD also introduced the “informed consent” and “benefit sharing” mechanisms as viable ways of protecting traditional knowledge and biodiversity from unlawful appropriation.<sup>17</sup>

On a more localized level, the Andean Community has also addressed the issue on different Decisions which attempt to create a uniform Andean regulatory system for traditional knowledge and biodiversity, guided mainly by the general principles set forth by the CBD.<sup>18</sup> Additionally, Peru’s own Law No. 27811,<sup>19</sup> one of the first laws in the world to protect traditional knowledge,<sup>20</sup> addressed at the national level the basic concerns of the Peruvian Government regarding the protection of collective knowledge.<sup>21</sup> The law, basically, recognizes that traditional intellectual property rights are not fully effective in addressing the traditional knowledge problem. Inspired by the CBD, the law acknowledges the right and ability of native communities to “dispose of their [traditional] knowledge as they see fit”<sup>22</sup> and to organize their rela-

tions with third parties, as they affect their lives, beliefs, economy and in general their well-being, recognizing their right to control their own economic, social and cultural development.<sup>23</sup>

It is within this international and national context that the U.S. started, in 2003, negotiations for a multilateral Andean Free Trade Agreement.<sup>24</sup> Such effort failed when Ecuador and Colombia started to fall back and delayed the negotiations due to internal problems and widespread opposition to the treaty. Peru continued negotiating bilaterally successfully concluding an agreement, which was signed on December 7, 2005.<sup>25</sup> It was approved by the Peruvian Congress in 2006<sup>26</sup> and by the U.S. Congress in 2007.<sup>27</sup>

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*[T]he U.S. started, in 2003, negotiations for a multilateral Andean Free Trade Agreement.*

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This note will analyze aspects of the U.S. – Peru Trade Promotion Agreement (hereinafter TPA) that relate to biodiversity and traditional knowledge. We will explore how the agreement dealt with the issue and how it reflects on Peru’s prior position, not only in the international arena, but also at the national level.

Part II of this note will give a general overview of how traditional knowledge has been treated and how it has been understood in different contexts and forums, presenting the basic dichotomy of the discussion and the current trends in the matter.

Part III will provide a general description of the TPA and will evaluate how the agreement is dealing with traditional knowledge, highlighting the most important provisions in the different chapters of the document.

Finally, in Part IV, the note will closely examine the effect the agreement will have on Peruvian legislation with regards to traditional knowledge, emphasizing any potential discrepancy with the current legislation –at Andean, as well as national, level- and the possible ways to harmonize such regulatory systems. This part will also revisit already resolved cases, particularly the Maca case, to briefly assess the impact the agreement would have had in its resolution.

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## II. THE TRADITIONAL KNOWLEDGE DICHOTOMY

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At the root of the international regulation of traditional knowledge is an important ongoing debate about how to deal with these rights. International organizations are struggling to balance and harmonize two major trends, the intellectual property approach, represented mainly by the TRIPS Agreement, and the collective heritage approach, represented by the CBD.<sup>28</sup>

As GRAIN stated, there is at “the centre [of this debate, a] monstrous ideological and cultural clash between looking at traditional knowledge as ‘intellectual property,’ thereby privatising [sic] it to serve corporate economic and development strategies, and looking at it as a collective heritage of peoples and communities that States have no business regulating, much less governing.”<sup>29</sup>

An in-depth analysis of this debate would take us through roads far removed from the purpose and focus of this note, the TPA. However, in order to understand the full impact of such a document on traditional knowledge, we must touch the basics of the debate.



## A. THE INTELLECTUAL PROPERTY APPROACH

The first trend in this area is comprised by countries that believe that property rights are necessary to develop and protect traditional knowledge. The U.S. is the biggest supporter of an intellectual property approach to the traditional knowledge problem.<sup>30</sup>

Since the 1980 seminal case of *Diamond v. Chakrabarty*<sup>31</sup> where the U.S. Supreme Court stated, “Congress intends statutory subject matter under the patent law to include anything under the sun that is made by man;”<sup>32</sup> the U.S. has been a supporter of a broad patent system.<sup>33</sup> This position is reflected in the almost unconditional support that the U.S. gave to the adoption of the TRIPS agreement and later, its resistance to agree on any modifications.<sup>34</sup>

The intellectual property approach recognizes that traditional knowledge and the genetic pool of biodiversity related to it, have an intrinsic economic value and can be used as a resource for further developments of science and technology.<sup>35</sup> As almost all the intellectual property rights, this approach’s basic premise is the exclusive appropriation of traditional knowledge or related biodiversity by one property holder, who has the right to exclude others from using such knowledge or natural resource.<sup>36</sup>

Patents are the preferred intellectual property tool in the chapters or sections of free trade agreements related to traditional knowledge.<sup>37</sup> For a patent to be granted the “invention” must have characteristics of novelty, utility and non-obviousness.<sup>38</sup> This does not mean, however, that other intellectual property rights have not been

used. Trademarks are another method of appropriation of traditional knowledge that has been used overtime.<sup>39</sup> The purpose of the trademark protection is to create a mechanism to provide identification for a product as well as a marketing advantage.<sup>40</sup> Every trademark requires distinctiveness to be effective and to fulfill its purpose of distinguishing products between each other.<sup>41</sup>

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### *Patents are the preferred intellectual property tool in the chapters or sections of free trade agreements related to traditional knowledge.*

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In sum, the intellectual property approach focuses the problem from a perspective of maximization of gain and wealth for one or a few individuals or corporations and the creation of incentives to use the property efficiently.<sup>42</sup> As Richard Posner phrased it, “[t]he creation of property rights is a necessary rather than sufficient condition for the efficient use of resources.”<sup>43</sup>

## B. THE COLLECTIVE HERITAGE APPROACH

The other current in this area are countries that believe that traditional knowledge, and all the biological material it relates to, cannot be fully appropriated or monopolized.<sup>44</sup> They argue that this knowledge dates back centuries, if not millennia, and belongs to the communities that created it, who should have an overriding right over it.<sup>45</sup>

These countries approved the CBD and advocated for a different system of rights where there could be appropriation of knowledge and biodiversity, but they would

involve and recognize the people who created the traditional knowledge.<sup>46</sup> This system of rights would be qualified in its scope, may be limited in time, and based on principles of benefit sharing, full disclosure and rights of continued use by the community of origin of the knowledge.<sup>47</sup> The collective heritage approach is also based on the premise that traditional knowledge is almost part of the public domain and cannot be patented because it would lack novelty.

This is recognition of the existence of community property over the knowledge, in the sense that the “community denies to the state or to individual citizens the right to interfere with any person’s exercise of communally owned rights.”<sup>48</sup>

Unlike the intellectual property approach, the collective heritage perspective is not so concerned with creation of value for one or a few individuals but more with the preservation of knowledge and its free availability for future generations, as well as with the freedom of the knowledge creators to determine how to deal with third parties or to even have dealings at all.<sup>49</sup>

## C. THE CURRENT TREND

Over the past decade there have been an increasingly large number of countries that have become aware of their traditional knowledge and biodiversity wealth and have enacted legislation aimed at protecting and regulating the use, export and registration of traditional knowledge and related biodiversity.<sup>50</sup>

This phenomenon has been paralleled by a significant increase of bilateral trade negotiations.<sup>51</sup> These negotiations gave rise to a series of free trade agreements that have

been focusing more and more on the regulation and protection of traditional knowledge and biodiversity.<sup>52</sup>

National legislations and bilateral treaties have been faced with the above mentioned dichotomy and had to make a choice, intellectual property or collective heritage. At first sight the intellectual property approach seems very efficient; however, it has been shown to have some problems mainly by creating enormous inequities in the economies of the countries of origin of such knowledge.<sup>53</sup>

A clear example of these inefficiencies is the case of the Neem tree from India.<sup>54</sup> This tree has been known for centuries to be a medicinal tree for a large number of physical conditions, ranging from a headache to female hygiene after birth.<sup>55</sup> A large pharmaceutical corporation “bio-prospecting” in the area learned about this tree, processed it using some of the traditional methods they learned in India, and produced an extract, which they later patented.<sup>56</sup> The impact in India was enormous. The price of the tree and its by-products skyrocketed. It was no longer accessible to the general population at reasonable prices and some local pharmaceutical companies, who were using the tree’s by-products for years to produce medicines, had to halt production because they were being threatened with litigation and other retaliatory actions.<sup>57</sup>

With trademarks the situation is not so different. Companies have appropriated the name of a product popular among indigenous communities in foreign countries and used for many years by many producers. Regardless of the descriptive or general character of the term in the countries of origin, it was registered in the U.S. as a

trademark because within the U.S. market it may be distinctive.<sup>58</sup> This brought, as a consequence, a restriction of the ability of the people who created the word to use it to generate wealth and to market their own product in the U.S. and in some cases, even in their own countries. A clear example of this practice is the Basmati Rice case where a U.S. company registered the name “Basmati” rice as a trademark, thus precluding, to some extent, the Indonesian farmers’ rights to sale their rice in the U.S. using the name they have been using for centuries.<sup>59</sup>

Despite those examples, the option taken by most of the free trade agreements signed between the U.S. and its trading partners is complete avoidance of the issue or the adoption of the intellectual property approach.<sup>60</sup>

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*Companies have appropriated the name of a product popular among indigenous communities in foreign countries...*

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Some other countries like Australia or New Zealand have adopted in their free trade agreements some aspects of the collective heritage approach.<sup>61</sup> However, the general tendency is to adopt an intellectual property regime for traditional knowledge.<sup>62</sup>

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### III. THE U.S.-PERU TRADE PROMOTION AGREEMENT

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#### A. BACKGROUND OF THE SIGNING AND APPROVAL OF THE TPA

Negotiations for the TPA started with the Andean countries (Ecuador, Colombia and Peru) forming a block and negotiating to-

gether with the U.S. Bolivia was originally invited but participated in the negotiations only as an observer.<sup>63</sup>

The negotiations in chief consisted of thirteen (13) negotiating rounds.<sup>64</sup> At a relatively early stage the negotiations started to suffer from the diversity of interests between the Andean countries and their distinct political reality. In April 2005, during the ninth round of negotiations, held in Lima, Peru, the Ecuadorian President Mr. Lucio Gutierrez was removed from power by a civil *coup-de-etat*.<sup>65</sup> Additionally, members of the House of Representatives in U.S. Congress, who disagreed with the fundamental principles of free trade, tried to stir opposition to the treaty.<sup>66</sup> To make matters worse, in September 2005, during the twelfth round of negotiations, two of the Colombian negotiators resigned blaming their resignation to the “inflexible position of the U.S. Government” and requested the complete withdrawal of Colombia from the negotiations.<sup>67</sup>

Right after these events, in September 2005, the Peruvian President, Mr. Alejandro Toledo, declared his intent to move forward and sign with the U.S. a separate agreement if the other Andean countries did not speed things up.<sup>68</sup>

The group negotiations of the Andean countries reached a breaking point in the thirteenth negotiating round held in Washington D.C. in November 2005. As reported in the Organization of American States’ Foreign Trade Information System (hereinafter SICE), the Andean Countries suspended the negotiations because there was no clear possibility of reaching an agreement regarding Intellectual Property, Agriculture and Textiles, among other issues.<sup>69</sup> It is in this context that Peru decided to continue negotiations on its own

By early December 2005, Peru went ahead with its individual negotiations, leaving a sluggish Ecuador and Colombia in the process, and concluded the agreement on December 7, 2005.<sup>70</sup> The agreement was signed by the U.S. and Peruvian representatives in Washington D.C. on April 12, 2006.<sup>71</sup> Further negotiations were later needed to modify certain aspects of the agreement related to the labor and environment chapters in order to reflect the May 2007 bipartisan agreement reached in Congress.<sup>72</sup> These negotiations resulted in an amendment signed in June 24, 2007.<sup>73</sup>

After signing the agreement the parties started the process of approval in their national Congresses. The Peruvian Congress approved the agreement by Legislative Resolution No. 28766, published in the Official Gazette "El Peruano," on June 29, 2006.<sup>74</sup> Later, the U.S. House of Representatives approved the implementation of the agreement by House Resolution No. 3688 voted under Roll No. 1060 on November 8, 2007.<sup>75</sup> The Senate also approved the implementation of the agreement by vote number 413 on December 4, 2007.<sup>76</sup>

In the signing ceremony of H.R. No. 3688, on December 14, 2007, President Bush addressed the members of Congress and a Peruvian delegation lead by President Alan Garcia.<sup>77</sup> He stated that "[t]he agreement will create a secure, predictable legal framework that will help attract U.S. investors. The Peruvian people understand that expanding trade with the United States will improve their lives." President Garcia complemented these thoughts by stating that "[m]ore investment and more trade, as well as social policies, will contribute to eradicate poverty, protect the environment,

and reduce and control migrations through the world."<sup>78</sup>

## **B. U.S.-PERU AGREEMENTS ON BIODIVERSITY AND TRADITIONAL KNOWLEDGE**

The TPA contains a preamble, twenty three chapters, three annexes, and the Understanding Regarding Biodiversity and Traditional Knowledge (hereinafter "Understanding").<sup>79</sup> This agreement is the first one in the large array of bilateral trade agreements signed by the U.S. that include provisions of any nature expressly addressing the biodiversity and traditional knowledge problem, thus its importance.<sup>80</sup>

Precisely because of that novelty it is necessary to analyze the agreements and other accords relating to traditional knowledge contained in the document and try to determine whether the intent of the parties would be fully served by the texts adopted.

### *I. THE OBLIGATIONS ADOPTED*

The TPA addresses issues related to biodiversity and traditional knowledge in three distinct chapters. These chapters are No. 16, Intellectual Property, No. 18, Environment, and finally in the Understanding. We will briefly look at each one of these chapters in order to ascertain the extent of the commitments involved in the agreement.

#### **A. CHAPTER 16 – THE INTELLECTUAL PROPERTY CHAPTER**

The most relevant aspect of this chapter, as it pertains to our issue, is that Peru agreed to make "all reasonable efforts" to start

patenting plants.<sup>81</sup> Peru also agreed to join UPOV, 1991 revision.<sup>82</sup>

The relevant parts of the Chapter state that "[e]ach Party shall ratify or accede to the [International Convention for the Protection of New Varieties of Plants (1991)] by January 1, 2008, or the date of entry into force of this Agreement, whichever is later."<sup>83</sup> Additionally, the TPA provides that "[n]otwithstanding [any available exclusionary measures under articles 27.2 and 27.3 of the TRIPS], a Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available, [and if protection is already granted] on or after the date of entry into force of this Agreement, [such protection shall be maintained]."<sup>84</sup>

These measures were applauded by the Industry Trade Advisory Committee on Intellectual Property Rights<sup>85</sup> which considered that Peru's increase in its levels of Intellectual Property Rights protection beyond that required by TRIPS is a "testament to the principle that high levels of protection benefit indigenous creators and inventors in the same manner as they do in developed countries."<sup>86</sup> In contrast, they were skeptically received in Peru, where they were sought to be contrary to Andean Community regulations that prohibit the patenting of plants. Additionally, the national trend was oriented towards adopting "[s]pecial and novel regimes" to protect "indigenous peoples seeking to preserve and develop their knowledge for future generations," as well as researchers and companies investing in that research.<sup>87</sup>



B. CHAPTER 18 – THE ENVIRONMENT CHAPTER

In Chapter 18 the parties committed to the conservation and sustainable use of biodiversity and preservation of traditional knowledge. The agreement states in article 18.11 that:

- “1. The Parties recognize the importance of the conservation and **sustainable use** [emphasis added] of biological diversity and their role in achieving sustainable development.
2. Accordingly, the Parties remain committed to promoting and encouraging the conservation and **sustainable use** [emphasis added] of biological diversity and all its components and levels, including plants, animals, and habitat, and reiterate their commitments in Article 18.1.
3. The Parties recognize the importance of respecting and preserving traditional knowledge and practices of indigenous and other communities that contribute to the conservation and **sustainable use** [emphasis added] of biological diversity.
4. The Parties also recognize the importance of public participation and consultations, as provided by domestic law, on matters concerning the conservation and sustainable use of biological diversity.”<sup>88</sup>

These measures have been applauded by most reports available. For instance, the Report of the Trade and Environment Policy Advisory Committee (TEPAC) supports the “commitment the Parties have made to the maintenance of biological diversity,”<sup>89</sup> but it expresses concern by the “use of term ‘sustainable use’ in [the TPA, because] this phrase has recently been interpreted to allow for extensive harvesting and/or use of diverse species [which clearly is] not the intent of the parties,”<sup>90</sup> who most likely “intend[ed] this phrase to have the same meaning as the term ‘sustainability.’”<sup>91</sup>

Opposition to these measures was only expressed by the Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services report (ITAC-3), which stated that although “committed to promoting and encouraging the conservation and sustainable use of biological diversity, neither an FTA nor a TPA is the appropriate place for discussion or commitments on this important subject.”<sup>92</sup>

C. THE UNDERSTANDING REGARDING BIODIVERSITY AND TRADITIONAL KNOWLEDGE

The parties also signed a separate Understanding regarding Biodiversity and Traditional Knowledge, disconnected from the intellectual property, environment or any other chapter of the agreement. The text of the Understanding reads as follows:

“The Governments of the Republic of Peru and the United States have reached the following understandings concerning biodiversity and traditional knowledge in connection with the United States of America – Peru Trade Promotion Agreement signed this day:

The Parties recognize the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development.

The Parties recognize the importance of the following: (1) obtaining informed consent from the appropriate authority prior to accessing genetic resources under the control of such authority; (2) equitably sharing the benefits arising from the use of traditional knowledge and genetic resources; and (3) promoting quality patent examination to ensure the conditions of patentability are satisfied.

The Parties recognize that access to genetic

resources or traditional knowledge, as well as the equitable sharing of benefits that may result from use of those resources or that knowledge, can be adequately addressed through contracts that reflect mutually agreed terms between users and providers.

Each Party shall endeavor to seek ways to share information that may have a bearing on the patentability of inventions based on traditional knowledge or genetic resources by providing:

- a) publicly accessible databases that contain relevant information; and
- b) an opportunity to cite, in writing, to the appropriate examining authority prior art that may have a bearing on patentability.”<sup>93</sup>

As can be seen in the above quoted text, the Understanding recognizes the importance of prior informed consent from the appropriate authority prior to accessing genetic resources, benefit sharing from the use of traditional knowledge and genetic resources, and appropriate examinations to ensure the quality and validity of patents granted on inventions regarding biodiversity or traditional knowledge, particularly regarding the full compliance with the conditions of patentability.<sup>94</sup> It then states that access to genetic resources or traditional knowledge can be adequately addressed through contracts that reflect mutually agreed terms between users and providers.<sup>95</sup>

These mechanisms of recognition of rights of the native communities seem to be a variation or derivation of those included in the CBD. Article 1 of the CBD recognized as one of its objectives “the fair and equitable sharing of benefits arising from utilization of genetic resources, including appropriate access to genetic resources and transfer of relevant technologies.”<sup>96</sup>

However, the Understanding uses different language than the CBD, it also encompasses some different mechanisms and addresses the issues of protection in a different manner. To better understand the Understanding, we will analyze in some detail the particularities of the document in comparison with the CBD and, when appropriate, with TRIPS.

### C. THE PARTICULARITIES OF THE UNDERSTANDING REGARDING BIODIVERSITY AND TRADITIONAL KNOWLEDGE

In order to fully realize the implications of the Understanding, we need to explore how it responded to the traditional knowledge dichotomy, why the parties chose to separate it from the rest of the Agreement, its nature, and the possibilities of enforcement.

#### I. THE OPTION TAKEN; PROPERTY, HERITAGE OR SOMETHING IN BETWEEN?

As we have seen, the traditional knowledge dichotomy permeates the legal fabric of the international agreements, and fires some of the most interesting academic discussions.

This dichotomy is of course reflected in the TPA. The Understanding, read together with the relevant provisions of chapters 16 and 18, takes a mixed ad-hoc approach, where the parties recognize that intellectual property plays a role in defining the indigenous peoples' interests, but also gives great deference to the fact that it is the community, not the state or the government, who owns the actual rights over the subject matter of traditional knowledge.<sup>97</sup>

In this context, the Understanding recognizes that contracts are the best mechanism to address the traditional knowledge problem, giving such knowledge proprietary status;<sup>98</sup> it also attempts to grant some collective heritage rights to the people by recognizing the importance of informed consent and equitable sharing of the economic benefits arising from the use and commercialization of such knowledge.<sup>99</sup>

This ad-hoc approach seems to be in line with Peru's prior statements and declarations regarding the applicability of intellectual property rights to traditional knowledge, as well as with the idea that mutually agreed arrangements to grant access to genetic resources are very effective.

Therefore, the Understanding, although controversial, is a successful milestone in Peru's foreign policy regarding traditional knowledge and biodiversity because it encompasses long fought measures that did not necessarily find great acceptance in the international arena.

#### II. PROBABLE PURPOSES FOR THE UNDERSTANDING

There are not readily available sources to ascertain what the purposes of the Understanding are or to even try to imply its purposes. Its existence is reported by the Industry Trade Advisory Committee on Intellectual Property Rights as early as February 2006; though, it is not reported as such in any of the thirteen negotiation rounds. However, the negotiation reports acknowledge that in the seventh and ninth rounds the biodiversity and traditional knowledge issues were dealt with as part of the intellectual property chapter.<sup>100</sup> The reports recognize that the U.S. negotiators showed flexibility with these

issues and that in the ninth round the U.S. accepted for the first time to include in the agreement the issues of biodiversity and traditional knowledge.<sup>101</sup>

The obvious purpose of the Understanding is the protection of traditional knowledge and biodiversity from illegal appropriation, which is consistent with the purposes of Law No. 27811, which is aimed at "avoid[ing] situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions."<sup>102</sup>

#### A. CONSISTENCY WITH PERU'S PREVIOUS STANDS

Critics of the agreement assert that the Understanding is contrary to everything Peru ever defended in multilateral forums;<sup>103</sup> that Peru "caved-in" to positions long sought by the U.S. in these same forums.<sup>104</sup> But, this is not entirely true. Peru has advocated for the blending of the patent system with the protection of biodiversity and traditional knowledge for a very long time.

For instance, Peru in the Amazon Cooperation Treaty, signed in 1978,<sup>105</sup> agreed with other Amazon basin countries to establish an appropriate system for the exchange of information on environmental conservation policies and measures in their respective territories in order to preserve the ecological balance and conserve species through the rational use of the Amazon's flora and fauna.<sup>106</sup> A similar agreement is contained in the Understanding.

In the 1987 Peruvian proposals during the negotiations for the adoption of TRIPS,

Peru suggested guidelines for a “balanced” approach to negotiations, based on the necessity of third world countries to be able to adjust their legislation in order to create an equilibrium between the “restrictive and monopolistic nature of intellectual property rights” and the “attainment of economic and social development,” as well as, transfer of technology from developed countries to less developed countries.<sup>107</sup>

This is indirectly reflected in the Understanding by means of “equitably sharing [of] benefits arising from the use of traditional knowledge and genetic resources.”<sup>108</sup> This should definitely include transfers of technology and scientific knowledge, as well as, the use of contracts as a means to guarantee “mutually agreed terms between users and providers” of traditional knowledge and biodiversity.<sup>109</sup>

Later in the 90’s, Peru, in an event related to the adoption of the Andean Community Decision No. 391, formally proposed to “link the patent system with the regime of access to genetic resources and with the protection of traditional knowledge.”<sup>110</sup>

More recently, in 2005, Peru manifested its position in the WTO, stating that “inventions relating to plants conserved and traditionally used by indigenous communities do not stand up to more rigorous assessments regarding novelty and inventiveness.”<sup>111</sup> To this Peru added that the “intellectual property, and patent regime in particular can directly contribute to the fulfillment of the objectives of the CBD (in respect of access and benefit-sharing) by [ensuring that] processing of patent applications [produce] ‘good’ [patents], not based on unauthorized or even unlawful acts.”<sup>112</sup>

Although it is clear that the Understanding (as well as agreements in the TPA relating to traditional knowledge and biodiversity) is not completely in-line with the mainstream proposals of the CBD, it is consistent with Peru’s prior commitments, agreements, statements and declarations defended for many years in multilateral forums.

#### B. CLUES FROM WITHIN

The first clue we ought to consider is the separate nature of the Understanding. Why is this a separate document? Why were these provisions not included in the intellectual property chapter? The information available suggests that the Understanding was going to be a part of the intellectual property chapter.<sup>113</sup> We do not know for sure when the position was changed from the incorporation of the issues in the intellectual property chapter to the adoption of the Understanding.

However, this fact suggests that after the thirteenth round, when Peru broke lines with Ecuador and Colombia, there was a loss in the Peruvian strategic bargaining position and a probable withdrawal of the U.S. concession; in this likely situation, the Peruvian negotiators, scrambling to close the negotiations, may have conceded the separation of these agreements and the incorporation of the Understanding to the treaty as a separate document.<sup>114</sup>

On the other hand, some argued that the mere recognition by the U.S. of the “importance of traditional knowledge and biodiversity ... to cultural, economic, and social development” is a victory for Peru, who in the past had to struggle with U.S. patent authorities to procure the reversal or denial

of patents which clearly conflicted with prior traditional art and knowledge.<sup>115</sup>

Also, the language of the Understanding suggests that the Parties by recognizing the importance of informed consent, benefit sharing, and quality patent examination as well as the use of contractual arrangements between users and providers of traditional knowledge, have set the basis for future legal developments either by treaties, national law or other arrangements.<sup>116</sup> It seems like “recognition[s] of importance,” such as these, must have some future effect in the bilateral relations of the parties. It must have an effect, or it would be dead letter and that could not have been the intent of the parties.<sup>117</sup>

#### III. THE PROTECTIVE MECHANISMS

As mentioned before, the Understanding and the CBD are similar in the fact that they both recognize, as mechanism to gain access to genetic resources, the principles of prior informed consent and equitable sharing of the benefits.<sup>118</sup> However, the Understanding goes beyond the CBD.

In reference to informed consent, the CBD grants the authorization to provide consent to the contracting parties, most likely to the member States and their government.<sup>119</sup> The Understanding removes this prerogative from the government and gives it to “the appropriate authority.”<sup>120</sup> Under Peruvian legislation, an appropriate authority could be an indigenous community or farmers’ or field workers’ community [comunidad campesina], duly organized according to national laws, which “controls” the desired genetic resource.<sup>121</sup> This provision may have a negative effect in the administration of



whatever system is developed between the parties to control access to genetic resources; but it is still better than the alternative given by the CBD, because it respects and guarantees the people's independence and sovereignty to decide how and when to deal with third parties.<sup>122</sup>

With regards to benefit sharing, the CBD contemplates the possibility of benefit sharing by contributions from developed countries to developing countries based on mutually agreed terms.<sup>123</sup> The Understanding provides that the sharing of benefits from the use of biodiversity or traditional knowledge should be directly "addressed [by users and providers] through contracts that reflect mutually agreed terms."<sup>124</sup> This benefit sharing mechanism is again more direct. It aims at benefiting precisely the communities who control the resource or knowledge, through contractual arrangements.

Although this system is potentially more beneficial for the communities, because it will put the profits directly in their hands, it is not hard to foresee the kind of problems that will arise from its application. Corruption, agency and authority problems, and fraud, among other issues, are some of the potential problems that immediately come to mind when talking about contracts between large communities of unorganized and uneducated people and, most likely, large corporations interested in their knowledge or biodiversity.

The promotion of "quality patent examination" based on "the appropriate examin[ation] of prior art that may have a bearing on patentability" is a novel and very important covenant.<sup>125</sup> The required "quality examination" allows the Parties to submit to the counterpart's patent authority, "in writ-

ing, ... prior art that may have a bearing on patentability."<sup>126</sup> Literally interpreted, this provision would allow Peru to intervene, possibly as *amicus*, in processes for the granting of patents in the U.S. as long as the "prior art" cited has a "bearing on patentability" or is relevant to the determination of the novelty or usefulness of the invention under examination.<sup>127</sup>

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*Corruption, agency and authority problems, and fraud, among other issues, are some of the potential problems...*

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This is the provision that may hold the key to the achievement of real protection against unfair appropriation of traditional knowledge; this could be the teeth of a seemingly harmless Understanding. However, it may be necessary to enact legislation implementing the agreement.

IV. THE NATURE OF THE DOCUMENT;  
BINDING OR NON-BINDING?

A determination of the binding or non-binding nature of the document is pertinent to the extent that it helps the Parties and the nationals of those parties to know, with certainty, what their rights and duties are under the document and whether they can derive clear and substantial privilege from this document, e.g. a cause of action.

From the language of the Understanding itself, we can infer that this document reflects the Parties aspirations more than actual binding rules of law that both countries would have to follow. First, the name of the document reveals that it is only a clarifying statement. The word "understanding," as relevant

for our purposes, means either "knowledge of the meaning, importance, or cause" of something or the "ability to show insight or tolerance; sympathetic awareness."<sup>128</sup> This word can also be interpreted as a "compact (agreement) implicit between two or more persons or groups."<sup>129</sup> The use of such word and its meaning within the document would suggest that it is a non-binding agreement which implies a Party's knowledge of the other Party's concerns and expresses "sympathetic awareness" to the issues.

Second, the document does not require the Parties to do anything; it is only a series of recognitions of various issues and an invitation to the Party's governments to work together in an "endeavor to seek ways to share information that may have a bearing on the patentability of inventions based on traditional knowledge or genetic resources."<sup>130</sup> This language is most likely non-binding.

V. THE LIKELIHOOD OF COMPLIANCE

Given the previous conclusion, the Understanding is a non-binding document. What can the Parties do, particularly Peru, to enforce the terms of the document and actually obtain support and cooperation in the "patentability of inventions based on traditional knowledge or genetic resources?"<sup>131</sup>

The answer is elusive; however, an expectation of compliance, reciprocity or even principles of international law as broad as *pacta sunt servanda* could stimulate compliance with this so called "soft law."<sup>132</sup> The American Society of International Law (hereinafter ASIL), citing Sir Joseph Gold, stated that "the essential ingredient [of a non-binding instrument] is an expectation that the states accepting these instruments will take their

contents seriously and will give them some measure of respect.”<sup>133</sup>

ASIL maintains that Governments normally negotiate soft law agreements, among other reasons, for flexibility and ability to respond to changing situations.<sup>134</sup> Additionally, they do not have to ensure that their national laws fully comply with those agreements, which sometimes saves resources.<sup>135</sup>

Although ASIL recognizes that soft law instruments cannot be enforced in courts or through “other methods of adjudications,”<sup>136</sup> other studies suggest that soft law could be enforced based on estoppel.<sup>137</sup> Drawing an analogy to principles of contract law, estoppel could create a cause of action under the Understanding. Of course, estoppel is a doctrine which rests in reliance and not any reliance but one reasonably expected under the circumstances.<sup>138</sup> Normally in contract law, this statement means that “it is clearly reasonable for the promisor that the promisee will take the action on which the promise is conditioned.”<sup>139</sup>

Therefore, if Peru were to act against the U.S. based on the Understanding it would have to show that it relied on the Understanding and took action based on the document. How could this be done if the only statement in the document that resembles a promise is an “endeavor to seek ways to share information?”<sup>140</sup> It would be very hard to do. Perhaps the only way would be a showing that Peru started taking action to create a common, “publicly accessible [database of] information”<sup>141</sup> on traditional knowledge and that Peru tried to “cite, in writing, to the [Patent Office] prior art”<sup>142</sup> related to a patent application and the U.S. did not take any action in order to share infor-

mation or its submission was clearly ignored by the patent office. These showings imply a very high burden of proof. Moreover, there are scholars who support the theory that the application of “estoppel to a non-binding instrument is doubtful.”<sup>143</sup>

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*Drawing an analogy to principles of contract law, estoppel could create a cause of action under the Understanding.*

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In conclusion, as Fitzmaurice stated, “the legal character of ‘soft law’ remains ambiguous,” and that ambiguity makes the practical applicability of the document doubtful. Nevertheless, their compliance rests almost completely on the parties “word,” honesty, good reputation, etc., and there could be incentives for compliance derived from those values, as well as from principles of international law, such as reciprocity or *pacta sunt servanda*.

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#### IV. THE TPA’S EFFECT ON PERU’S BIODIVERSITY AND TRADITIONAL KNOWLEDGE LEGISLATION

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A treaty is an agreement between two nations, legally binding in international law, which creates legally binding rights and obligations.<sup>144</sup> In this regard, the adoption of a treaty directly affects national legislation under its scope. The Peruvian Constitution gives a treaty the effect of national law, which immediately affects the legal landscape to accommodate the changes brought by the treaty.<sup>145</sup>

This section will assess those changes emphasizing any potential discrepancy with the current legislation –at Andean as well as national level- and the possible ways to harmonize the terms of the treaty with those of national and Andean legislation.

#### A. EFFECTS AT THE ANDEAN COMMUNITY LEVEL

The Andean Community<sup>146</sup> has comprehensive legislation regarding the protection and exploitation of traditional knowledge and biodiversity. However, given the international nature of this legislation and the fact that for that reason its requirements and principles should be contemplated by and incorporated in Peruvian national law, we will not analyze it extensively.

The main *corpus* of the Andean legislation rests in three main decisions, binding on the member states, which address the issue; these are Decisions No. 391, 486 and 524.<sup>147</sup>

##### I. ANDEAN COMMUNITY DECISIONS

Andean Community Decision No. 391 on access to genetic resources, adopted in 1996, became the first law in the world to establish general principles for the protection of traditional knowledge.<sup>148</sup> It establishes that biodiversity is a “national and regional heritage” and recognizes the traditional knowledge of indigenous peoples related to the use of local genetic resources.<sup>149</sup>

The second decision, Andean Community Decision No. 486 on industrial property, adopted in 2000, prohibits the issuance of patents affecting plants and animals in any member state.<sup>150</sup> The Decision states that the granting of patents “shall be subordinated to

the acquisition of that material in accordance with international, Andean Community, and national law.”<sup>151</sup>

Furthermore, it asserts that if any such patent is granted in violation of its provisions it shall be declared null or void, particularly if the applicant fails to submit a copy of the access permit or the certificate of authorization for the use of traditional knowledge belonging to indigenous communities in a member state.<sup>152</sup>

Finally, the Andean Community Decision No. 524 on the Rights of Indigenous Peoples, had as its main objective, the creation of a working group as a counseling entity aimed at promoting the participation of indigenous people in the economic, social, cultural and political sphere of sub-regional integration.<sup>153</sup>

#### II. ANDEAN DECISIONS VS. TPA; ARE THERE REAL CONFLICTS?

As recognize by Peru in a 2001 W.T.O. document, Andean Community legislation regarding traditional knowledge and biodiversity has the following main objectives:

- “(a) to create the conditions for just and equitable sharing of the benefits derived from access;
- (b) to lay down the bases for recognition and utilization of genetic resources, their by-products and their intangible components, especially in relation to indigenous, Afro-American or local communities;
- (c) to promote the conservation of biodiversity and the sustainable use of genetic resources;
- (d) to promote the strengthening and development of scientific, technological and technical capacity at the local, national and sub-regional levels; and,
- (e) to reinforce the negotiating capacity of the member countries.”<sup>154</sup>

These policy goals are all satisfied by the TPA. As shown above in Section III, the TPA provides in Chapters 16, 18, and in the Understanding, for informed consent to access, which would satisfy the “recognition and utilization” requirement; equitable sharing of benefits; and, freedom of contract, both of which are relevant for the “strengthening” of “technical capacity” and “negotiating capacity” of the local communities. All aimed at the goal of promoting the “conservation of biodiversity and the sustainable use of genetic resources.”<sup>155</sup>

#### *The Decisions set forth above, which conflict with the TPA, are regulations of the Commission of the Andean Community.*

There is, however, one main point of divergence: patents of plants. Andean Community Decision No. 486 expressly prohibits the issuance of patents affecting plants while the TPA provides for this kind of protection and forces the parties to join the UPOV.<sup>156</sup>

GRAIN criticizes this, stating that the Andean countries cannot sign anything conflicting with Andean law until there is a collectively agreed repeal of the conflicted Andean laws. Also, GRAIN contends, the rights of the local communities would be “decimated” by such modification in Andean legislation, and accuses the Toledo administration of “sacrific[ing] much more than the interests of Peru’s citizens.”

Nevertheless, there is hope. The Decisions set forth above, which conflict with the TPA,<sup>157</sup> are regulations of the Commission of the Andean Community. At present it is

likely that the Commission, under its powers granted by Article 22 (e) and (f) of the Andean Sub-regional Integration Agreement or “Cartagena Agreement,”<sup>158</sup> would be amenable to revision of the conflicting provisions of the Decision in order to accommodate the needs of Peru and Colombia.<sup>159</sup>

This is a likely scenario given the fact that the Andean Community has in the past few years undergone constant criticism due to its lack of capacity to adapt to the fast changing reality in Latin-America and because of the political effect that Venezuela’s President, Mr. Hugo Chavez, has had in the institution, particularly after he announced Venezuela’s withdrawal from the Community.<sup>160</sup>

#### B. EFFECTS AT THE NATIONAL LEVEL

The more relevant aspects of the TPA’s effects are at a Peruvian national level. During the past ten years or so, Peru has developed a comprehensible body of law protecting traditional knowledge. Congress has dealt with a large number of proposals and passed the ones better suited to fulfill national policies. This legislation may also conflict with the TPA’s provisions. As stated in the introduction to this part, the Peruvian Constitution gives a treaty the effect of national law, immediately modifying any legislation that opposes its terms.<sup>161</sup>

The main bodies of law regarding biodiversity and traditional knowledge in Peru are the following:

- Legislative Decree No. 823, Industrial Property Law<sup>162</sup>;
- Law No. 26839, Law for the Conservation and Sustainable Use of Biodiversity<sup>163</sup>;
- Law No. 27811, Regime for the Protection of Indigenous Peoples’ Collective Knowl-



edge Associated with Biodiversity<sup>164</sup>,

- Law No. 28216, Law for the Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous People<sup>165</sup>.

The most important of these laws is Law No. 27811. It is Peru's only complete, comprehensive, regulatory scheme designed to protect traditional knowledge and related biodiversity. The other legislation is also relevant but to a lesser extent.

I. THE REGIME FOR THE PROTECTION OF INDIGENOUS PEOPLES' COLLECTIVE KNOWLEDGE ASSOCIATED WITH BIODIVERSITY - LAW NO. 27811

Law No. 27811, Regime for the Protection of Indigenous Peoples' Collective Knowledge Associated with Biodiversity (hereinafter the Law or the Regime) is the "first law protecting traditional knowledge in the world."<sup>166</sup> This statute identifies traditional knowledge as "Collective Knowledge,"<sup>167</sup> and states as its primary objectives (a) the protection, preservation, and development of collective knowledge; (b) the fair and equitable distribution of benefits derived from the use of collective knowledge; (c) the use of collective knowledge to benefit indigenous peoples and mankind in general; (d) the assurance that any use of collective knowledge is conditioned on receipt of the prior informed consent of indigenous peoples; (e) the promotion of indigenous capacity to share and distribute collectively generated benefits; and (f) the prevention of patents for inventions based on collective knowledge of Peruvian indigenous peoples without proper acknowledgement.<sup>168</sup>

The Law created a regime by which existing legal tools and mechanisms were adapted to satisfy the needs of traditional knowledge holders. The statute provides for registry, license agreements, trade secret regulations, and also relies in competition law principles and structures to control the access to and use of traditional knowledge and related biodiversity.<sup>169</sup>

It is not within the scope of this note to analyze the particular details of this statute, but to evaluate whether the adoption of the TPA will affect it.<sup>170</sup>

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*The Law created a regime by which existing legal tools and mechanisms were adapted to satisfy the needs of traditional knowledge holders.*

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As shown above in Section III, parts 2 and 3, the TPA seems to follow the general premises of the Law. With the exception of the patents on plants provisions, which are not addressed in the Law, all other described aspects of the TPA, namely the sustainable exploitation of biological resources and biodiversity, the prior informed consent on access to collective knowledge, the sharing of the benefits of the scientific, commercial or industrial utilization of the knowledge, seem to fall squarely within the scope of the Regime.

This comparison warrants the inference that the Law will not conflict with the TPA and that they will coexist within the Peruvian legal system; the former giving content and applicability to the latter. With appropriate negotiation and lobbying practices, the fundamental premises

of the Regime could be "imported" to the U.S. as part of the possible benefits that could stem from the application and enforcement, voluntary or otherwise, of the Understanding.

II. OTHER NATIONAL EFFORTS TO PROTECT TRADITIONAL KNOWLEDGE

The other pieces of legislation, mentioned before, are relevant to the extent that they show a development in awareness and consciousness about the reality of indigenous people's communities and knowledge. They show how the Peruvian society and the legislator become concerned with the creation of a "special regime for the protection of the knowledge of indigenous and native communities,"<sup>171</sup> which could provide sufficient protection and, at the same time, enough economic incentives to allow these communities to actively participate in their own development.

The latest legislation, Law No. 28216, dating back to 2004, provides for the creation of a National Commission devoted to complement the regime and, along with other objectives, identify and monitor patent requests related to Peruvian collective knowledge, analyze the grant or the basis for a future grant, start actions to oppose the concession of patents based on Peruvian collective knowledge, or seek to render void patents already decided.<sup>172</sup>

Other efforts have also been reflected by legislative initiatives designed to create *in generis* rights where the intellectual property is not held directly by an individual, as is normal, but by the whole community. The proposed legislation would have been

applicable to knowledge which “had no author,” which was known by the whole community, and was used frequently; however, this initiative was never enacted.<sup>173</sup>

It is clear that Peru is committed to the continuation of a policy in favor of protection of traditional knowledge and that the Understanding was an attempt to not forfeit such policy. The results are yet to be seen, but Peru seems determined to continue providing and requiring that the provisions of the Law be respected.

### C. EFFECT THAT THE AGREEMENT WOULD HAVE HAD ON SOLVED CASES

There have been many cases where “bioprospectors” have appropriated, through the patent system, diverse biological resources which are then foreclosed for the indigenous people.<sup>174</sup> The most significant and illustrative is the maca case, which serves as a case study.

#### I. THE MACA CASE

Maca or *Lepidium meyenii* has been grown in Peru for centuries. It is typically an “Andean crop of narrow distribution. It is restricted

today to the [Peruvian] Departments of Junín and Cerro de Pasco at elevations above 3500 m [11,483 ft.] and often reaching 4450 m [14,600 ft.] in the central Andes of Peru.”<sup>175</sup> Peruvians have long been using these edible roots as a source of food. Chroniclers, or Spanish reporters of the conquest, “mention that many natives did not have any other food but maca.”<sup>176</sup>

Maca is also thought to have anticarcinogenic and aphrodisiac properties, and has been used as such.<sup>177</sup> Accounts of its properties date back to the sixteen hundreds when the Spanish conquerors found “well fed babies and tall adults” in the high Andes, which was attributed to their diet based on maca.”<sup>178</sup>

## TABLE 1

Number	Date Requested	Description	Date Granted
6,093,421	Aug. 31, 1999	Extract that can be used for treating cancer and sexual dysfunction	July 25, 2000
6,267,995	March 3, 1999	Extract that can be used for treating cancer and sexual dysfunction	July 31, 2001
6,428,824	Oct. 19, 2001	Extract that can be used for treating cancer and sexual dysfunction	Aug. 6, 2002
6,444,237	Sept. 13, 2001	Combination of herbal ingredients designed to overcome natural inhibitors of human sexual response	Sept 3, 2002
6,552,206	May 2, 2002	Compositions isolated from <i>Lepidium</i> useful for treating and preventing cancer and sexual dysfunction	April 22, 2003
6,878,731	Aug. 14, 2002	Imidazole alkaloid, and its use to treat proliferative diseases, such as but not limited to cancer	April 12, 2005
7,214,390	Feb. 9, 2004	Topical composition which enhances sexual responsiveness of a mammal	May 8, 2007
7,303,772	Nov. 10, 2005	Compositions for the prevention and treatment of circulatory disorders, feminine endocrine disorders, and dermal disorders	Dec. 4, 2007

Source: US Patent Office, USPTO Patent Full-Text and Image Database

Inca legends tell that in “times of the Tawantinsuyo,<sup>179</sup> before going to war the Incas used maca to feed the warriors to increase their energy and vitality. However, after conquering a city the soldiers were prohibited to consume it as a measure to protect women from their sexual impulses.”<sup>180</sup>

In 1998, some “bioprospectors” took dry maca roots from Peru and using a purified extract, they carried out trials on mice to confirm the traditional use of maca as a sexual drive booster, fertility enhancer and aphrodisiac. They were successful.

Later, patents were granted in the U.S. for “inventions” related to maca extracts for pharmaceutical use; for treatment of sexual disorders, etc. Some of those patents are listed in Table 1.

An international patent application was also filed for compositions, and methods of preparing them, from *Lepidium*.<sup>181</sup>

After learning of the existence of this patents and requests, INDECOPI (National Institute for Defense of Competition and the Protection of Intellectual Property, acronym in Spanish), gathered a group of experts to prepare submissions to dispute the validity of the patents granted in the U.S. The group was also empowered to contact the patent offices of the countries designated in the international application so that they could independently evaluate the prior uses and traditions.<sup>182</sup>

The INDECOPI group concluded that:

- the patents granted in the United States did not, meet the requirement of an ‘invention’,
- the international patent application did not, amongst other things, meet the requirements of novelty and inventive step.<sup>2183</sup>

The Group also concluded that there was no evidence that:

- “i) these materials were obtained legally, and
- ii) that there was any provision for the equitable sharing of profits resulting from the use of these patents with Peru.”<sup>2184</sup>

Based on those conclusions and, mainly, on the text of the Understanding, Peru could have cited, “in writing, to the U.S. Patent Office prior art”<sup>2185</sup> which would have had a significant bearing on the patentability of the alleged inventions. Of course, given the non-binding nature of the Understanding, its enforceability will largely depend on the parties will to deal in fairness or, as mentioned above, on reciprocity or the principle of *pacta sunt servanda*.

The other question presented by this problem is, what effect would the U.S. Patent Office give to the Peruvian written submission? The answer is also uncertain. The Patent Office most likely has the discretion to disregard the submission without any further consequence or could also give the submission full persuasive power and decide based exclusively on it.

The main difference with the situation as it stood before the TPA, is that now Peru has a better chance to open the U.S. Patent Office doors to demand review of the patentability of inventions based on traditional knowledge.

## II. OTHER IMPORTANT CASES

### A. THE AYAHUASCA CASE<sup>186</sup>

As previously explained, the U.S. patent system does not recognize or value the traditional knowledge of indigenous groups regarding their regional biodiversity as prior art for the purposes of the patentability analysis.<sup>187</sup> Rather, researchers can obtain a

patent with no recognition for the indigenous knowledge upon which they relied.

This is the case of a researcher, Mr. Loren Miller, who was granted a U.S. plant patent on a strain of the ayahuasca vine.<sup>188</sup> Several years after, tribal leaders learned of the patent and were outraged.

They decided to challenge the patents and in 1999 requested a reexamination of the patent.<sup>189</sup> They succeeded.<sup>190</sup> The arguments made hinged basically in the lack of novelty of the plant invention. The communities contented that the patented ayahuasca was not, “in fact, distinct or new, thus failing the Patent Act’s requirement of novelty; and it also described the ayahuasca as it was already illustrated in scientific literature and known by indigenous Amazonian peoples.”<sup>2191</sup>

### B. THE CAT’S CLAW CASE

Cat’s claw or *Uncaria Tomentosa* is a vine, similar in aspect to the ayahuasca, but armed with spines which resemble cat’s claws; hence the name. This vine has been used by indigenous Amazonian peoples for ages to cure different ailments.<sup>192</sup> Now the vine is subject to at least 32 patents on extracts, methods of isolation of the bioactive components, and methods of increasing its anti-inflammatory properties.

We have not found any cases related to a challenge or other opposition procedure based on the patentability requirements of the Cat’s Claw patents. However, the effect of the TPA in this situation could be the same as that described in the Maca case; although, this conclusion is highly speculative.



## V. CONCLUSION

In its vast diversity, the U.S. is, so far, not very open to accept the legal importance of traditional knowledge.<sup>193</sup> That could soon change. The TPA could be the first step for the U.S. in recognizing, protecting and embracing the world's traditional knowledge, for its own benefit and the benefit of those who, through the years, have created and developed this knowledge.

The effect of such a new policy could be of great importance for developing countries and could eventually create a change of paradigm in the U.S. patent system.

The particular case of the TPA is still highly speculative. Because of its novelty, there are no actions by the parties trying to exercise their rights under the agreement. However, we contend that the effectiveness of the traditional knowledge agreements contained in the TPA, given their non-binding nature, will largely depend on how the

parties deal with each other and how will the agreement develop into national implementation laws.

The future looks bright for the indigenous communities in Peru, but to take full advantage of the new opportunities presented by the TPA, the Peruvian authorities will have to provide them with the tools and the legal advice necessary to exercise and defend their rights. Only time will tell.

## END NOTES

\* This Note is dedicated to my grandmother, Tuli, for her love, tenderness, patience and for teaching me most of what I know about the use of plants to heal.

1. See Antonio Raimondi – Biography, [http://www.peruecologico.com.pe/biogra\\_raimondi.htm](http://www.peruecologico.com.pe/biogra_raimondi.htm) (quoting the Popular Peruvian expression attributed to the Italian explorer, Mr. Antonio Raimondi (1826-1890)) (last visited Oct. 20, 2008).
2. WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO], INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE: BOOKLET NO. 2 at 4, Publ'n No. 920(E) (2000), available at <http://www.wipo.int/tk/en/tk/key.html> (follow WIPO Publication No. 920 [PDF] hyperlink) (last visited Oct. 20, 2008).
3. WIPO, INTELLECTUAL PROPERTY NEEDS AND EXPECTATIONS OF TRADITIONAL KNOWLEDGE HOLDERS, WIPO REPORT ON FACT FINDING MISSIONS ON INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE (1998-1999) at 25, Publ'n No. 768(E) (2001), available at <http://www.wipo.int/tk/en/tk/ffm/report/index.html> (follow the Part 1, Part 2 [PDF] hyperlinks) (last visited Oct. 20, 2008).
4. See Manuel Ruiz et al., The Protection of Traditional Knowledge in Peru: A Comparative Perspective, 3 WASH. U. GLOBAL STUD. L. REV. 755, 758 (2004).
5. See John Tustin, Traditional Knowledge and Intellectual Property in Brazilian Biodiversity Law, 14 TEX. INTELL. PROP. L.J. 131, 132 (2006).
6. International Union for the Protection of New Varieties of Plants, Oct. 23, 1978, 33 U.S.T. 2703, T.I.A.S. 10199.
7. International Undertaking on Plant Genetic Resources, F.A.O. Res. 8/83, 22nd Sess., (Nov. 23, 1983), available at <ftp://ftp.fao.org/ag/cgrfa/Res/C8-83E.pdf> (last visited Oct. 20, 2008).
8. Farmer's Rights, F.A.O. Res. 5/89, 25th Sess., (Nov. 29, 1989), available at <ftp://ftp.fao.org/ag/cgrfa/Res/C5-89E.pdf> (last visited Oct. 20, 2008).
9. See Leanne M. Fecteau, Note, The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy, 21 B.C. THIRD WORLD L.J. 69, 70 (2001).
10. Id.
11. See Tustin, *supra* note 5, at 133-38.
12. See Greg K. Venbrux, When Two Worlds Collide: Ownership of Genetic Resources Under the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights, 7 U. PITT. J. TECH. L. & POL'Y 1 (2005), available at [http://tlp.law.pitt.edu/articles/Vol\\_9\\_Venbrux.pdf](http://tlp.law.pitt.edu/articles/Vol_9_Venbrux.pdf) (last visited Oct. 20, 2008).
13. Convention on Biological Diversity, June 5, 1992, U.N. Doc. DPI/1307 (1992), 31 I.L.M. 818 (1992), available at <http://www.biodiv.org/doc/legal/cbd-en.pdf> (last visited Oct. 20, 2008). [hereinafter CBD].
14. Like-Minded Megadiverse Countries, <http://www.lmmc.nic.in/> (last visited Oct. 20, 2008) (Peru is a member along with Bolivia, Brazil, China, Colombia, Costa Rica, Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Philippines, South Africa, and Venezuela).
15. "We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore." World Trade Organization, Ministerial Declaration of 14 November 2001 at ¶ 19, WT/MIN(01)/DEC/1, 41 I.L.M. 746, 749 (2002).
16. See CBD, *supra* note 13, at art. 8(j); 31 I.L.M. at 826.
17. See id. at art. 15; 31 I.L.M. at 828.
18. See e.g., Andean Cmty. Comm'n Decision No. 345, Common Provisions on the Protection of Rights of Breeders of New Plant Varieties, X Official Gazette of the Cartagena Agreement [O.G.C.A.] 142, 19.24 (Oct. 29, 1993) and Andean Cmty. Comm'n Decision No. 486, Common Intellectual Property Regime, XVI O.G.C.A. 600, 2.48 (Sept. 19, 2000), available at <http://www.comunidadandina.org/ingles/treaties.htm> (last visited Oct. 20, 2008).
19. Law No. 27811, July 24, 2002, Law Establishing the Protection Regime for Indigenous Peoples' Collective Knowledge Associated with Biological Resources [Law No. 27811] [Ley que Establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas Vinculados a los Recursos Biológicos], Official Gazette "El Peruano" [E.P.], Aug. 8, 2002 (Peru), available at <http://www.wipo.int/tk/en/laws/tk.html> (follow the "Peru [PDF]" hyperlink) (last visited Oct. 20, 2008).
20. Ruiz, *supra* note 4, at 773.
21. See Law No. 27811 art. 2(b) (referring to traditional knowledge as "collective knowledge").
22. Id. at art 1.
23. See id. at Tit. V; see also Ruiz, *supra* note 4, at 774.
24. These negotiations were, initially, between Ecuador, Colombia and Peru. Bolivia participated as an observer.
25. Organization of American States' Foreign Trade Information System [SICE], <http://www.sice.oas.org/> (follow "Trade Policy Developments" hyperlink tab; then under "Agreements Signed but Not Yet in Force" follow "Peru-United States" hyperlink) (last visited Oct. 20, 2008).
26. Congress Resolution No. 28766, June 28, 2006, Congress Resolution Approving the "Trade Promotion Agreement Peru-United States" [Resolución Legislativa que Aprueba el "Acuerdo de Promoción Comercial Peru-Estados Unidos"], E.P., June 29, 2006 (Peru).
27. U.S.-Peru Trade Promotion Agreement Implementation Act, Pub. L. No. 110-138 § 101, 2008 U.S.C.A.N. (121 Stat.) 1455 (Supp. 12 2008).
28. See generally Fecteau, *supra* note 9, at 77-85 (explaining the apparent conflict between the TRIPS Agree-

- ment and the CBD Agreement); see generally Insoon Song, Note, Old Knowledge into New Patent Law: The Impact of United States Patent Law on Less-Developed Countries, 16 *IND. INT'L & COMP. L. REV.* 261, 269-79 (2005) (illustrating with cases from India, Madagascar, Pakistan and Thailand the impact of US law on less developed countries).
29. GRAIN & Silvia Rodriguez Cervantes, FTAs: Trading Away Traditional Knowledge 2 (2006), available at <http://www.grain.org/briefings/?id=196> (follow the "Available in PDF" hyperlink) (last visited Oct. 20, 2008).
  30. *Id.* at 3-4.
  31. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
  32. *Id.* at 309 (citing to S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)).
  33. See Song, *supra* note 28, at 267; see generally Robert G. Sterne & Laurence B. Bugaisky, The Expansion of Statutory Subject Matter Under the 1952 Patent Act, 37 *AKRON L. REV.* 217 (2004).
  34. See DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 10, 15, 23-25 (Sweet & Maxwell 1998); see also EDWARD S. YAMBRUSIC, *TRADE-BASED APPROACHES TO THE PROTECTION OF INTELLECTUAL PROPERTY* 88, 95 (1992).
  35. See generally Daniel Gervais, Traditional Knowledge & Intellectual Property: A Trips-Compatible Approach, 2005 *MICH. ST. L. REV.* 137, 147-48 (2005) (discussing international instruments which recognize the indigenous people's rights to exercise control, to the extent possible, over their own economic, social and cultural development).
  36. U.S. Const. art. 1, § 8, cl. 8 (granting and recognizing the power vested in U.S. Congress to grant a temporary exclusive right or "monopoly" for inventors).
  37. GRAIN, *supra* note 29, at 4.
  38. ARTHUR R. MILLER & MICHAEL H. DAVIES, *INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS AND COPYRIGHT IN A NUTSHELL* 11 (3rd ed. 2000).
  39. See generally Song, *supra* note 28, at 275 (describing the case of a U.S. trademark over the word "Basmati").
  40. MILLER & DAVIES, *supra* note 38, at 155.
  41. *Id.* at 165.
  42. See generally Chakrabarty, 447 U.S. at 307 (explaining that Intellectual Property rights (patents) promote progress of science by offering inventors exclusive rights for a limited period as an incentive for their inventiveness).
  43. RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 31 (3rd ed. 1986).
  44. Within this group are the Like-Minded Megadiverse Countries. See *supra* note 14.
  45. See Gregory K. Schlais, The Patenting of Sacred Biological Resources, The Taro Patent Controversy in Hawaii: A Soft Law Proposal, 29 *U. HAW. L. REV.* 581, 593 (2007); see Like-Minded Megadiverse Countries, Cancun Declaration of February 18, 2002, <http://www.lmmc.nic.in/Cancun%20Declaration.pdf>, at 1 (last visited Oct. 20, 2008).
  46. Venbrux, *supra* note 12, at 10-11.
  47. CBD, *supra* note 13, at art. 16; 31 *I.L.M.* at 829.
  48. Harold Demsetz, Toward a Theory of Property Rights, 57 *AM. ECON. REV. PAP. & PROC.* 347-58 (1967), reprinted in *PERSPECTIVES ON PROPERTY LAW*, at 148, 153 (Robert C. Ellickson et al. eds., 2nd ed. 1995).
  49. See Schlais, *supra* note 45, at 610; see also International Undertaking on Plant Genetic Resources, *supra* note 7, at art. 1.
  50. MICHAEL F. BROWN, *WHO OWNS NATIVE CULTURE?* 140 (2003); Ruiz, *supra* note 4, at 762-71.
  51. GRAIN, *supra* note 29, at 1.
  52. *Id.* at 2-3.
  53. See Song, *supra* note 28, at 271-79 (providing illustrations of the inequities mentioned).
  54. See Wikipedia, <http://en.wikipedia.org/wiki/Neem> (providing a brief description of the general characteristics of this tree) (last visited Oct. 20, 2008).
  55. See Song, *supra* note 28, at 271.
  56. *Id.* at 272-73.
  57. *Id.* at 274.
  58. "Under the statutory definition of 'trademark,' the word, name, symbol or device must be used ... 'to identify and distinguish' the goods of the trademark owner from those manufactured or sold by others [t]hus, in the eyes of the purchasing public, a design or pattern ... must, at all costs, distinguish." 1-2 Gilson on Trademarks § 2.01.
  59. Song, *supra* note 28, at 275-79.
  60. GRAIN, *supra* note 29, at 1.
  61. *Id.* at 13-14.
  62. "Since traditional knowledge is rooted in the groups that have developed such knowledge over time, it is necessary to protect the peoples who are the source of the knowledge [by] granting and protecting fundamental economic and non-economic rights held by the people." WIPO, *INTELLECTUAL PROPERTY NEEDS AND EXPECTATIONS OF TRADITIONAL KNOWLEDGE HOLDERS*, WIPO REPORT ON FACT FINDING MISSIONS ON INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE (1998-1999), *supra* note 3, at 210.
  63. SICE, *supra* note 25.
  64. *Id.*
  65. *Id.*
  66. *Id.*
  67. *Id.*
  68. Bilaterals.org, TLC: Colombia y Perú a un paso de claudicar [FTA: Colombia and Peru one step from surrender], [http://www.bilaterals.org/article.php?id\\_article=2680](http://www.bilaterals.org/article.php?id_article=2680) (last visited Oct. 20, 2008); Toledo: Negociación Técnica Llego al Limite [Toledo: Technical Negotiation reached its Limit], Peru21 (Peru), Oct. 28, 2005 (on file with Currents: The International Trade Law Journal).
  69. SICE, *supra* note 25 (follow "14-22 November 2005, Washington, D.C.: XIII round of negotiations" hyperlink) (last visited Oct. 20, 2008).
  70. SICE, *supra* note 25.
  71. Congress Resolution No. 28766; see also Tratado de Libre Comercio Peru-EE.UU. [Free Trade Agreement Peru - U.S.], [http://www.tlperu-eeuu.gob.pe/index.php?n\\_categoria1=209&ncategoria2=215](http://www.tlperu-eeuu.gob.pe/index.php?n_categoria1=209&ncategoria2=215) (last visited Oct. 20, 2008); United States Trade Representative [hereinafter U.S.T.R.], Final Text of the United States - Peru Trade Promotion Agreement, [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Peru\\_TPA/Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/Section_Index.html) (last visited Oct. 20, 2008).
  72. Editorial, US Officials Reach Agreement on Trade Deals to Open Way for Peru, Panama, Other Pacts, *Int'l Herald Trib.*, May 10, 2007 (on file with Currents: The International Trade Law Journal).
  73. See United States-Peru Trade Promotion Agreement Implementation Act, Pub. L. No. 110-138, § 101(a)(1), 2008 U.S.C.C.A.N. (121 Stat.) 1455.
  74. Congress Resolution No. 28766.
  75. H.R. 3688, 110th Cong. (2007) (enacted) (Voted by House Roll No. 1060 of Nov. 8, 2007).
  76. *Id.* (Voted by Senate Vote No. 413 of Dec. 4, 2007).
  77. President Bush and President Garcia of Peru sign H.R. 3688, available at [www.whitehouse.gov/news/releases/2007/12/20071214-8.html](http://www.whitehouse.gov/news/releases/2007/12/20071214-8.html).
  78. *Id.*
  79. U.S.T.R., U.S. - Peru Trade Promotion Agreement, [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Peru\\_TPA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Section_Index.html) (last visited Oct. 20, 2008).
  80. Martin Vaughan, US-Peru Deal Includes First Ever Traditional Knowledge Provisions, Dec. 9, 2005, <http://ip-watch.org/weblog/index.php?p=173> (last visited Oct. 20, 2008).
  81. U.S.-Peru Trade Promotion Agreement art. 16.9, 16-15 ¶ 2, Apr. 12, 2006 as amended June 24, 2007, available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Peru\\_TPA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Section_Index.html) (last visited Oct. 20, 2008).
  82. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at art. 16-1 ¶ 3(c).
  83. *Id.*
  84. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at art. 16-9, 16-15 ¶ 2.
  85. Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), Advisory Committee Report to the President, the Congress and the United States Trade Representative on the U.S.-Peru Trade Promotion Agreement 5, Feb. 1, 2006, [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Peru\\_TPA/Reports/asset\\_upload\\_file473\\_8978.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Reports/asset_upload_file473_8978.pdf).
  86. *Id.*
  87. Ruiz, *supra* note 4, at 778.
  88. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at art. 18-11, 18-9.
  89. Trade and Environment Policy Advisory Committee (TEPAC), Advisory Committee Report to the President, the Congress and the United States Trade Representative on The U.S.-Peru Trade Promotion Agreement 10, Feb. 1, 2006, [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Peru\\_TPA/Reports/asset\\_upload\\_file111\\_8989.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Reports/asset_upload_file111_8989.pdf) (last visited Oct. 20, 2008).
  90. *Id.*
  91. *Id.*
  92. Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3], Advisory Committee Report to the President, the Congress and the United States Trade Representative on the U.S. - Peru Trade Promotion Agreement 9, Feb. 1, 2006, [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Peru\\_TPA/Reports/asset\\_upload\\_file380\\_8969.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Reports/asset_upload_file380_8969.pdf) (last visited Oct. 20, 2008).
  93. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge.
  94. *Id.* at ¶ 3.
  95. *Id.* at ¶ 4.

96. CBD, *supra* note 13, at art. 1; 31 I.L.M. at 823.
97. U.S.-Peru Trade Promotion Agreement, *supra* note 81.
98. *Id.* at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶ 5.
99. *Id.* at ¶ 3.
100. SICE, *supra* note 25
101. *Id.* (follow “18-22 April 2005, Lima, Peru: IX round of negotiations” hyperlink).
102. Law No. 27811, at art 5(f).
103. GRAIN, *supra* note 29, at 2.
104. *Id.*
105. Treaty for Amazonian Cooperation, July 13, 1978, 17 I.L.M. 1045.
106. Committee on Trade and Environment, Peru’s Experience of the Protection of Traditional Knowledge and Access to Genetic Resources, WT/CTE/W/176 (Oct. 27, 2000).
107. EDWARD S. YAMBRUSIC, TRADE BASED APPROACHES TO THE PROTECTION OF INTELLECTUAL PROPERTY 183 (1992) (quoting from Peruvian Proposal for Negotiations on Trade Related Aspects of Intellectual Property Rights, MTN.GNG/NG11/W/45, Oct. 28, 1987).
108. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶ 3(2).
109. *Id.* at ¶ 4.
110. Council for Trade-Related Aspects of Intellectual Property Rights, Article 27.3(b), relationship between the TRIPS agreement and the CBD and protection of traditional knowledge and folklore, Communication from Peru: Biodiversity, Traditional Knowledge and Intellectual Property: Peru’s Position in Relation to Disclosure of Origin and Legal Provenance, IP/C/W/447 (June 8, 2005).
111. *Id.* at 4.
112. *Id.*
113. Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), *supra* note 85; Tratado de Libre Comercio Peru-EE.UU., <http://www.tlperu-eeuu.gob.pe> (providing information in Spanish).
114. See generally Tratado de Libre Comercio Peru – EE.UU., <http://www.tlperu-eeuu.gob.pe> (last visited Oct. 20, 2008) (the author conjectures based on information posted on the Peruvian TPA website).
115. Vaughan, *supra* note 80.
116. The language of the Understanding “recognizes” the importance of all the above mentioned aspects of the traditional knowledge problem; this in all likelihood implies that the recognition will have a further legal effect aimed at protecting these newly recognized principles.
117. The Understanding, binding or not, expresses the parties desires that the actions there stated be taken. See MALGOSIA FITZMAURICE & OLUFEMI ELIAS, CONTEMPORARY ISSUES IN THE LAW OF TREATIES 42 (2005).
118. CBD, *supra* note 13, at art. 15(5), (7); 31 I.L.M. at 828.
119. See Elizabeth Longacre, Note, Advancing Science while Protecting Developing Countries from Exploitation of their Resources and Knowledge, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 963, 978 (2003).
120. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶ 3
121. “Prior informed consent” means authorization given under this protection regime, by the representative organization of the indigenous peoples possessing collective knowledge.” Law No. 27811, at art. 2(c).
122. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶ 4.
123. CBD, *supra* note 13, at art. 15(7); 31 I.L.M. at 828.
124. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶¶ 3, 4.
125. *Id.* at ¶¶ 3, 5(b).
126. *Id.* at ¶ 5(b).
127. This seems *contra* to U.S. legislation. See Pecteau, *supra* note 9, at 97 (citing to 35 U.S.C. §§ 102(a), (g) to support the assertion that U.S. law excludes foreign prior use as prior art for patentability purposes).
128. OXFORD ADVANCED LEARNER’S DICTIONARY 1392 (4th ed. 1994).
129. WEBSTER’S II NEW RIVERSIDE UNIVERSITY DICTIONARY 1258 (1988).
130. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶ 5.
131. *Id.*
132. See generally INTERNATIONAL COMPLIANCE WITH NON-BINDING ACCORDS 5-11 (Edith Brown Weiss ed. 1997) (discussing compliance with “soft law”); see also FITZMAURICE & ELIAS, *supra* note 117, at 34-35.
133. INTERNATIONAL COMPLIANCE WITH NONBINDING ACCORDS, *supra* note 132, at 4.
134. *Id.* at 5; FITZMAURICE & ELIAS, *supra* note 117, at 35.
135. INTERNATIONAL COMPLIANCE WITH NONBINDING ACCORDS, *supra* note 132, at 5.
136. *Id.* at 6.
137. FITZMAURICE & ELIAS, *supra* note 117, at 37.
138. ALLAN FARNSWORTH, CONTRACTS 90-98 (4th ed. 2004).
139. *Id.* at 95.
140. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge.
141. *Id.*
142. *Id.*
143. FITZMAURICE & ELIAS, *supra* note 117, at 37, 46.
144. See generally FITZMAURICE & ELIAS, *supra* note 117, at 8 (explaining the legal nature of treaties).
145. Constitution of the Republic of Peru [Constitución Política del Perú] art. 55, enacted on Dec. 29, 1993, E.P., Dec. 30, 1993 (Peru) available at [http://www.congreso.gob.pe/\\_ingles/CONSTITUTION\\_29\\_08\\_08.pdf](http://www.congreso.gob.pe/_ingles/CONSTITUTION_29_08_08.pdf) (last visited Oct. 6, 2008).
146. Andean Cmty., <http://www.comunidadandina.org/endex.htm> (last visited Oct. 20, 2008).
147. See <http://www.comunidadandina.org/ingles/treaties.htm> (last visited Oct. 20, 2008).
148. Ruiz, *supra* note 4, at 769.
149. Andean Cmty. Comm’n Decision 391, Common Regime on Access to Genetic Resources, XII O.G.C.A. 213, 2.15 (July. 17, 1996) available at <http://www.comunidadandina.org/endex.htm> (click “Treaties and Legislation” on the far right side and scroll down to 391).
150. Compare Andean Cmty. Comm’n Decision 486, XVII O.G.C.A. 600 2.48 (Set. 19, 2000), at art. 20(c), and Andean Cmty. Comm’n Decision 345, X O.G.C.A. 142 19.24 (Oct. 29, 1993) (regulating breeder’s rights). Do these decisions present a contradiction in the Andean system?
151. Andean Cmty. Comm’n Decision 486, XVII O.G.C.A. 600 2.48 (Set. 19, 2000), at art. 3.
152. *Id.* at art. 75.
153. Andean Cmty. Comm’n Decision 524, Working Group on the Rights of Indigenous People, art. 1, XVIII O.G.C.A. 814 2.15 (July 9, 2002).
154. Council for Trade-Related Aspects of Intellectual Property Rights, Communication from Peru, IP/C/W/24 6 (Mar. 14, 2001).
155. *Id.*
156. Andean Cmty. Comm’n Decision 486; U.S.-Peru Trade Promotion Agreement, *supra* note 81.
157. Mainly Decision No. 486, but also Decision No. 391.
158. “Article 22.- It is the responsibility of the Andean Community Commission: e) To approve and amend its own regulations; f) To approve, reject or amend the proposals submitted to it by the Member Coun-
- tries, individually or collectively, or by the General Secretariat.” Official Codified Text of the Andean Subregional Integration Agreement (Cartagena Agreement), 8 I.L.M. 910 (1969) as amended and reprinted in Andean Cmty. Comm’n Decision 563, XIX O.G.C.A. 940 (July 1, 2003), available at <http://www.comunidadandina.org/ingles/normativa/D563e.htm> (last visited Nov. 03, 2008).
159. See Office of the U.S.T.R. Trade Facts, Free Trade with Colombia Summary of the United States – Colombia Trade Promotion Agreement, 1 (2007) [http://www.ustr.gov/assets/Document\\_Library/Fact\\_Sheets/2007/asset\\_upload\\_file224\\_13073.pdf](http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file224_13073.pdf) (last visited Aug. 29, 2008).
160. See generally Carlos Malamud, Venezuela’s Withdrawal from the Andean Community of Nations and the Consequences for Regional Integration (Part I) (2006) [http://www.realinstitutoelcano.org/analisis/983/983\\_Malamud\\_Venezuela\\_CAN\\_partI.pdf](http://www.realinstitutoelcano.org/analisis/983/983_Malamud_Venezuela_CAN_partI.pdf) (translation) (explaining the context in which Venezuela announced its withdrawal from the Community) (last visited Nov. 03, 2008); see also Ariela Ruiz Caro, Andean Community: Requiero for a Dream II (2006) <http://americas.irc-online.org/am/3287> (last visited Nov. 03, 2008).
161. Constitution of the Republic of Peru art. 55.
162. Legislative Decree No. 823, Apr. 23, 1996, Industrial Property Law [Ley de Propiedad Industrial], E.P., Apr. 24, 1996 (Peru).
163. Law No. 26839, June 17, 1997, Law for the Conservation and Sustainable Use of Biodiversity [Ley sobre la Conservación y Aprovechamiento Sostenible de la Diversidad Biológica], E.P., July 16, 1997 (Peru).
164. Law No. 27811.
165. Law No. 28216, Law for the Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous People [Ley de Protección al Acceso a la Diversidad Biológica Peruana y los Conocimientos Colectivos de lo Pueblos Indígenas], E.P., May 1, 2004 (Peru).
166. Ruiz, *supra* note 4, at 773-74.
167. Law No. 27811, at art. 2(b).
168. *Id.* at art. 5.
169. *Id.*
170. Ruiz, *supra* note 4.
171. Legislative Decree No. 823.
172. See generally Law No. 28216.
173. Legal Initiative No. 2754/2001-CR, Peruvian Congress, 2001-2006 Sess., May 3, 2002 (in file with publication) (in Spanish).
174. See Song, *supra* note 28, at 271-79.

175. ANDEAN ROOTS AND TUBERS: AHIPA, ARRACACHA, MACA AND YACON 182 (M. Hermann & J. Heller eds. 1997).
176. Id.
177. See Begoña Venero Aguirre, *Traditional Knowledge and Patents Relating to Lepidium Meyenii: An Example Not to be Followed*, *The Courier ACP-EU Dossier*, No. 201, 37-38, Nov.-Dec. 2003, available at [http://ec.europa.eu/development/body/publications/courier/courier201/pdf/en\\_037.pdf](http://ec.europa.eu/development/body/publications/courier/courier201/pdf/en_037.pdf) (last visited Nov. 03, 2008).
178. ANDEAN ROOTS AND TUBERS: AHIPA, ARRACACHA, MACA AND YACON, *supra* note 175, at 184.
179. Quechua name for “the four quarters” or more literally “the four nations” (author note).
180. ANDEAN ROOTS AND TUBERS: AHIPA, ARRACACHA, MACA AND YACON, *supra* note 175, at 184.
181. See Venero, *supra* note 177.
182. Id.
183. Id.
184. Id.
185. U.S.-Peru Trade Promotion Agreement, *supra* note 81, at Understanding Regarding Biodiversity and Traditional Knowledge, at ¶ 5(b).
186. See National Geographic, <http://www.nationalgeographic.com/adventure/0603/features/peru.html> (giving an entertaining and enlightening reading trip to the world of the ayahuasca) (last visited Nov. 03, 2008).
187. See 35 U.S.C. §§ 102(a), (g).
188. Fecteau, *supra* note 9, at 85 (citing to U.S. Plant Patent No. 5751 (issued June 17, 1986)).
189. Id. at 86.
190. Id.
191. Id. at 86.
192. See Rain Tree Nutrition, <http://www.rain-tree.com/catclaw.htm> (reporting that cat’s claw use dates back at least 2000 years) (last visited Nov. 03, 2008).
193. Fecteau, *supra* note 9, at 97.



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