



Workshop
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Biotechnology Initiatives and IPR concerns in Peru

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1. Priority Area for Biotechnology R&D

- Biotechnology development appears in seven policies of Peru's National Long Term Agreement of Governability (**Acuerdo Nacional**)
- CONCYTEC has established Biotechnology as one of five strategic S&T areas to promote and fund graduate studies, R&D and innovation projects in Peru (**National Plan of Science, Technology and Innovation**).
- This priority includes the use of modern biotechnology techniques such as: cell/tissue culture, DNA handling and transformation, use of molecular markers, stem cell manipulation and cloning.
- Specific emphasis in fostering biotechnology applications to the study of, and adding value to, the Peruvian rich **biodiversity**.
- CONCYTEC, the Ministry of Production and the National Center for Strategic Planning have joined efforts to prepare the National Plan of Biotechnology and Genetic Engineering in order to focus and foster R&D and biotech-based enterprises.

National Plan of Biotechnology and Genetic Engineering (NPBGE)

- The NPBGE has received wide support from the Government, the private sector and the main universities (presented in June 2005).
- The Plan includes the creation of a National Centre of Biotechnology and Genetic Engineering, as the central pivot of a research system supplying services, technical and training support.
- The National Centre will be operated through a foundation with the participation of the private sector. It will provide logistic support to companies and to the regulatory system of biotechnology.
- The National Agrarian University has allocated one hectare of land at its campus in La Molina to this project.

Biosafety regulatory system

- A biosafety regulatory system for biotechnology is being implemented with the participation of CONAM and funding from GEF-PNUMA.
- Peruvian Biosafety Law 27104 (Law of prevention of risks derived from the use of biotechnology) and its Regulation (D.S. 108-2002-PCM), regulate the activities to guarantee the safety of GMOs and their products.
- Three sectoral regulations are being established for agriculture, food, and fisheries.
- Peru is a full member of the Cartagena Biosafety Agreement.

Potential applications of modern biotechnology to problem solving in Peru

- Genome studies on Andean crops for improved seed production.
- Development of tropical yellow Bt maize for feed use.
- Transgenic fruits with delayed maturity by reducing the synthesis of ethylene in order to extend shelf life (chirimoya, mango, melon).
- Development of genetically stable herds of alpacas with higher fiber quality through modern biotechnology.
- Development of transgenic trout in part of the 10,000 Andean lakes by inserting salmon genes for enhanced growth rate.
- Medical applications: orphan tropical diseases, TBC, cancer, *H. pilori*.
- Genetically engineered vaccines against malaria.
- Diagnostic kits with local antigens.
- Bioleaching of copper, gold, other metal ores (GM & non GM bacteria)

2. Bill 12033 / 2004: Promotion of Modern Biotechnology

- Proposal prepared by a group of experts gathered by Concytec (introduced to Congress in Nov. 2004). After national consultation it is planned to be voted in the current session of Congress (Oct. 2005).

Art 1: The development of modern biotechnology is declared of national necessity and priority, as a fundamental factor for competitiveness, economic growth and national welfare.

Art 17: Peru will register and recognize IPRs to patents related to modern biotechnology, including inventions or processes or discovery of modes of action of genes or their components, provided they are new and useful, under the Convention of Paris; excepted for complete organisms existing naturally or GM. *(It involves a revision or new interpretation of Andean Decision 486).*

Art 18: Plant varieties resulting from genetic improvement (GM or non GM), will be registered to obtain intellectual property certificates, under the scope of Andean Decision 345. *(A new interpretation of it).*

Bill: National Biotechnology Parks

- Introduced to Congress in January 2005
- Proposal for the development of the first Biotechnology Park: *Lima BioPark*
- Development of managerial capacity , business plans, research and development plans through nurserys or incubators of biotechnology-based innovative enterprises in universities, R&D centres and industrial clusters.

3. Biodiversity concerns in Peru

- Peru has a rich biological diversity which is being withdrawn towards private firms and public R&D centres in developed countries, without official permits (alpaca, ayahuasca, yacon, maca, other).
- Native Peruvian plant species or their components have been patented in developed countries without respecting Peru's IPRs nor indigenous or traditional knowledge.
- GM plants could eventually "contaminate" native varieties of agricultural crops, which may negatively impact poor farmer's lives.
- Peru is interested to obtain products from its biological diversity through biotechnology, based in the exploration of plant, microorganism and animal genes, as potential sources of applications for food, industry and health.
- The current situation of legal IPR regime does not allow patents from modern biotechnology innovations. This do not foster local biotechnology innovation for adding value to local biodiversity

4. Legal framework of IPRs in Peru

- Protection rights for new variety obtentions under Decision 345 of the Andean Community (Common Regime of Rights Protection of Plant Variety Obtentors) is not well applied by INDECOPI, the Peruvian Patents Office, which currently excludes GM varieties.
- Patents on genes and nucleotide sequences not allowed by Art. 15.b of Andean Decision 486 (Common Regime on Industrial Property): *“It will not be considered inventions the whole or a part of living organisms as they are in nature, the natural biological processes, the biological material existing in nature, even if it is isolated, or if it is the genome or germplasm from any living natural organism”*, according to INDECOPI.
- Decision 391 of CAN (Common Regime on the Access to the Genetic Resources) about sovereign rights, and fair and equitable share of benefits derived from the access to biodiversity resources and native knowledge is difficult to implement.

Patenting situation in Peru

- Invention coefficient (number of patent requested by residents per each 10,000 inhabitants) in Peru has decreased from 0.07 a 0.01 between 1978 and 2002, while neighboring countries like Ecuador and Chile have increased their invention coefficients up to 0.26 and 2.77 respectively.
- The rate of dependency register the amount of patents requested by non residents compared to patents requested by residents. In Peru, this rate has increased from 4.78 to 26.6 between 1977 and 2002.

5. Perspectives

- Public meetings have been held with representatives of the industry, agriculture, export, congress, medical, universities, regions, to discuss the biotechnology plan and promotional law, and the biosafety regulatory framework in Peru.
- All scientists, the majority of government high level officers, and most leaders of the private sector are supporting the project of law of promotion of modern biotechnology
- Environmental organizations connected with Greenpeace and other international NGOs have started to oppose the project of law.
- INDECOPI authorities are somewhat reluctant to consider the revision or new interpretation of IPR legislation, because of the long way to follow: Andean Decisions need agreement of 5 countries, which is difficult for the time being.
- Probably, the law of promotion would be approved with some modifications on the IPR articles, at the level of the Congress.

Other perspectives on IPR and Trade

- The negotiations of a Free Trade Agreement between Peru, Colombia, Ecuador and the US have arrived last week at deep differences regarding IPR themes such as:
- Patentability Areas: Andean countries did not accept US request to approve patents on plants & animals; human or animal diagnostics, surgery or therapeutical procedures.
- Second Use: Andeans disagreed on approving patent protection to new uses or new methods of using already known products (drugs).
- However, the US agreed to consider the use of a data base of Andean biodiversity information in the examination of patents requests related to biological material in order to stop patenting Andean biodiversity species or components (biopiracy).

Thank you,

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