

“The intergovernmental framework on patent policy concerning the bill for a Law on the Conservation and Sustainable Exploitation of Plant Genetic Resources for Food and Agriculture”

A talk for a Mexican Chamber of Deputies seminar on the bill

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In order that laws achieve their objectives, it is necessary to construct effective measures to enforce those laws. To approve norms without the mechanisms and funds to ensure compliance with laws could result in a State of Law that worsens or makes more difficult the problem that the law would seek to resolve or mitigate. Given the very deteriorated state of biodiversity and genetic resources (GR) for food and agriculture, as the UN Food and Agriculture Organization has documented, a badly conceived or implemented law could worsen an already dangerous situation for sustainable food security. It is urgent that mega-biodiverse countries such as Mexico not create “access regimes of such [intellectual property rule] stringency that they defeat the capacity of their own scientists to understand what is happening to biodiversity.”¹

This talk will deal, in the first place, with an enforcement mechanism now being discussed in the World Intellectual Property Organization (WIPO) concerning GR and traditional knowledge (TK). Part of this debate concerns the question of how to finance those who are the primary custodians of *in situ* (in the field) biodiversity to prevent further erosion of biological resources that are not only the raw materials of food and agriculture, but also perhaps of half of all medicines. Then the talk will deal with a proposed amendment to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) in the World Trade Organization (WTO). This amendment, once adopted, could affect the content and implementation of the bill.

WIPO and the protection of Genetic Resources and Traditional Knowledge

The problem taken up by the bill is also being debated at the sessions of WIPO’s Intergovernmental Committee on Intellectual Property, and Traditional Knowledge, Genetic Resources and Folklore (Committee). Since Mexico is a member of WIPO, ideas from this debate should be incorporated into the bill, especially regarding its enforcement measures.

I don’t know the Mexican government’s positions in the Committee debates, but Mexican representation in the Committee’s work does not have to be limited simply to government representatives. The WIPO Secretariat facilitates the participation of representatives of accredited indigenous groups and non-governmental organizations, at present more than 110 groups and organizations. WIPO finances the participation of accredited indigenous groups in the annual General Assembly, as well as in the Committee’s sessions.² Since the Committee functions in terms of the work program approved by the General Assembly, interested indigenous groups and NGOs should participate in the General Assembly to understand and intervene in the systematic context of the protection of GR

and TK. For example, the General Assembly discusses such fundamental questions as whether Intellectual Property Rights are compatible with TK.³

The WIPO Secretariat initiated part of the Committee work program with visits to WIPO member countries to discuss the Committee's work and study how WIPO might help in the protection of GR and TK. The Secretariat organizes seminars and workshops in which experts inform governmental delegations of academic work on the subjects under negotiation at WIPO. The most recent workshop, on December 12, 2007 in Geneva, was dedicated to building the capacity of communities to protect TK and GR. (www.wipo.int/meetings)

Before drafting laws, ensure that there are mechanisms to enforce the laws

In a seminar held during a Committee session in 2004, Professor Peter Drahos, of the National University of Australia argued that WIPO members did not have the adequate political conditions to enforce rules protecting GR and CT.⁴ Professor Drahos suggested that in order to make *in situ* conservation of GR and CT viable, it was first necessary to construct and "enforcement pyramid" for those rules.

The bottom floor of the pyramid would be comprised by the indigenous and campesino groups that have conserved and developed GR and TK for centuries. The second floor corresponded to State entities that should support these groups in their daily labors of the conservation and sustainable use of genetic wealth shared by the State and the groups whose stewardship of that wealth predates the foundation of many States and whose stewardship often crosses State boundaries. The top floor consists of the monitoring of State compliance with the commitments States have made to intergovernmental legal instruments that regulate GR, CT and biodiversity. Professor Drahos has suggested the creation of an entity that would monitor compliance with the Convention on Biological Diversity (CBD), the FAO Treaty on Plant Genetic Resources for Food and Agriculture and the legal instrument that results from the Committee discussions in WIPO. One result of this co-operation among international agencies would be that GR and CT would be more difficult to expropriate, as has occurred in hundreds of bio-piracy cases documented by NGOs and governments.

The legal architecture proposed by Professor Drahos is, of course, very ambitious. He supposes that there are Reasons of State not only to respect and defend the rights of indigenous and campesino groups in their Constitutions, but to support those groups in order that they carry out their responsibilities within this enforcement pyramid. In other words, Professor Drahos foresees a political and technical cooperation between the State and indigenous and campesino groups that seldom exists in many States.

Given the hostility that is not only historic but continues between many governments and the indigenous groups residing within State borders, discovering a reason for the State to cooperate with indigenous and campesino groups may appear to be a utopian quest, above all in North America. But a law that marginalize these groups in order to support only academic and corporate plant breeders leads towards a future of *ex situ* germ-plasma banks and ethnological reconstructions of TK, and not the living development of biodiversity.

Scientific plant breeders do not always recognize that *ex situ* GR wealth was expropriated in most cases. But they do recognize that *ex situ* conservation is less sustainable than *in situ* conservation that increases GR wealth, provided that it is protected. It is in the interest of States to support the *in situ* conservation of GR and TK, since, on the one hand, it is a matter of food survival, and on the other hand, the preservation of the fundamental genetic wealth of agro-ecosystems.

Granting licenses for the use of GR and TK for a specified limited time could in theory be a way of generating funds to regulate the sustainability of GR use. Such licenses could be specified according to the exclusivity (or not) of the license use, of the for profit status (or not) of the licensee and whether or not the licensed GR and TK results in a patented product.

Conceptual difficulties that impede the conservation and sustainable use of GR and TK

There are at least two difficulties that impede the State from discovering a reason to not choose to privatize GR or to bet on the market as the only solution to ongoing genetic erosion. First, it is difficult to calculate the value of the GR and TK that is indispensable to food and agriculture. Yet without an estimate of such value, whether patented or not, it is difficult to negotiate the price of a license to lease GR and TK. Firms that benefit from GR and TK in their products or processes would pay for their use a very low percentage of sales of those products or processes. States, for their part, would be responsible for reimbursing indigenous and campesino groups for their services to bio-diversity, as well as for the development of indigenous plant varieties.

Although WIPO registers most patents that have been granted nationally, it does not investigate the economic value of royalties and licensing fees paid for the use of patented products or processes. It is urgent that WIPO begin such a program of economic research for products incorporating GR and TK. Nor is the value of GR and TK to unpatented products or process well studied. There are some academic estimates of this value. For example, the value of spring wheat GR to bread sales was estimated at \$2.5 billion annually at the end of the 1980s.⁵ The value consists not only in the GR and TK that increase wheat yields, but also in the wheat variety diversity that enables it to resist disease. FAO estimated in 1998 that if the seed industry were to reimburse countries of origin of germ-plasma in patented seeds, those countries would receive a total of \$150 million annually.⁶ According to the FAO methodology, royalties paid by pharmaceutical companies for GR royalties for plant derived medicines would be much higher.

The second difficulty for the State to find a reason to support the indigenous and campesino *in situ* conservation, is the attitude that such conservation can be achieved by commercial contracts, such as the access and benefit sharing contracts for GR and TK. We know already, according to the European Union's Commission on Energy, that the market has done nothing to reduce global warming, but that it has enriched contaminating companies that have sold their carbon emission credits given to them by the State.⁷ There has not been yet a similar recognition of the failure of market mechanisms to halt or even reduce GR and TK erosion.

GR samples are presently sold very cheaply in bio-prospection contracts between States and transnational corporations. It is not just the case that the payment is insufficient to enable the States to

carry out their commitments to the CBD and the FAO Treaty, but that the contracts' concept of GR and TK as raw materials is wrong. For example, in a contract between the pharmaceutical firm Merck and Costa Rica, Merck received for an unlimited time the right to patent products that might result from any or all of 10,000 biological samples, in exchange for a million dollars and some bio-prospection equipment. In the debates concerning the proposed amendment of TRIPs, the United States cited this bio-prospection contract as a model for complying with Article 8 of the CBD concerning access and benefit sharing agreements for bio-prospection.⁸

Bilateral Investment Treaties (BIT) and Free Trade Agreements (FTA) further exemplify the attitude that deals with GR and TK as a commercial raw material. Bio-prospected germ-plasma is defined as an "investment." Accordingly, a national laboratory that discovers a new medicine derived from that germ-plasma would be in alleged violation of the investor's rights under the BIT and/or FTA. BITs and FTAs offer investors protectionism almost without limits and with the right to sue the participating States in international dispute settlement tribunals for failure to enforce foreign investor rights.⁹ Furthermore, the FTAs and BITs effectively annul the exemptions to patenting won by developing countries in Article 27 of TRIPs. In order for the conservation and sustainable use of GR and TK to prosper, it will be necessary to subordinate the chapters on intellectual property and investment in bilateral agreements to revised multilateral agreements.

The proposal to amend TRIPs

In May 2006, Brazil, India, Pakistan, Perú, Thailand and Tanzania proposed an amendment to Article 29 of TRIPs (WT/GC/W/564).¹⁰ The proposal, like so many proposals in the Doha Round, remains without agreement.¹¹ Mexico has supported the U.S. position that the Doha negotiations should go forward without the amendment.¹² However, there is no legal reason why the proposed amendment could not be included as provision in the Chamber of Deputies bill to protect GR and TK.

The amendment requires that patent applicants would have to disclose to patent examiners information about "biological resources" and TK used in the products or processes for which grant of patent was sought. There are three principal purposes for the proposed modification:

1. To make TRIPs supportive of the objectives of the CBD, especially Article 8, on Access and Benefit Sharing, that could result in royalties paid for the use of GR and TK in patented products or processes;
2. To aid in the prevention of bio-piracy and in the revocation of patents already granted on the basis of incomplete or unsatisfactory information;
3. To improve patent quality upon ensuring that more complete information demonstrates that the applicant has satisfied the legal criteria for granting a patent. The problem of bad patent quality is sufficiently notorious to have resulted in a U.S. Supreme Court decision in May 2007 that required more complete and transparent documentation from patent applicants (*KRS International Inc. v. Teleflex Inc. et al.*).

Developed countries, with the exception of Norway, opposed the amendment. These WTO members argued that bilateral agreements were the most effective means to comply with the CBD and that the amendment would introduce great uncertainty about the validity of the patent system. Norway, while supporting the developing country proposed amendment, added a modification to the amendment in June 2006 so that information disclosed about GR and TK could not be applied retroactively to annul a patent already granted. (WT/GC/W/566) After more than a year, least developed countries reluctantly accepted the Norwegian modification, including the Group of 41 African countries that understood the modification to be compatible with its position on not patenting life forms.¹³ Norway also proposed that TRIPS not only be coherent with the CBD but also with the FAO treaty on seeds.

Despite the modification, countries rich in patents still are opposed strongly to this proposal to prevent bio-piracy and improve patent quality. Nevertheless, the reform movement on patent quality is gaining legal weight, due to the number of patents that are used to frustrate innovation and competition (complementary theoretical purposes of the patent regime that large patent holders violate too often). It has gotten to the point where firms spend more on patent lawyers than they do on research and development of products, which is perhaps a paradise for lawyers. However, this situation is hell for those who are prosecuted for involuntarily violating a patent unjustly granted, as is the case with rapeseed, in which a patent was granted for transposing one gene in a genome of 40,000 genes, while the alleged patent violation concerned the breadth of the genome. (Monsanto Canada v. Schmeisser).¹⁴

To conclude: at this time, access and benefit sharing contracts and patents do not guarantee the sustainability of GR nor of TK. The cooperation of indigenous and campesino groups and of governments is needed to construct and manage a multilateral legal framework that gives effective for their protection.

¹ Peter Drahos and Geoff Tansey. "Postcards from International Negotiations" in *The Future Control of Food*. Earthscan/IDRC Books. 2008. <http://www.idrc.ca/en/ev-118094-201-1-DO_TOPIC.html>

² "Fondo voluntario de la OMPI para las Comunidades Indígenas y Locales Acreditadas: preguntas y respuestas." <http://www.wipo.int/export/sites/www/tk/es/ngoparticipation/voluntary_funds> and "The WIPO Voluntary Fund." World Intellectual Property Organization. Booklet No. 3. 2008. <<http://www.wipo.int/freepublications/en/tk/936/936E/pdf>>

³ Daniel Gervais. "Traditional Knowledge and Intellectual Property: A TRIPS Compatible Approach" en *IPR Protection and TRIPS Compliance: Issues and Implications*. Ed. Veena. Icfai University Press: Hyderabad, India. 2007.

⁴ Peter Drahos. "Towards an International Framework for the Protection of Traditional Group Knowledge and Practice." UNCTAD - Commonwealth Secretariat Workshop. Geneva. February 4-6, 2004. <http://cgkd.anu.edu.au/menus.PDFs/Drahos_tkframework.pdf>

⁵ Michael Halewood and Kent Nnadozie. "Giving Priority to the Commons: the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)." en *The Future Control of Food*. *op cit*.

⁶ "Global Seed Industry Concentration." ETC Group. Communiqué No. 90. September-October 2005.
<<http://www.etcgroup.org>>

⁷ Patrick Bond. "De soluciones falsas a soluciones reales para el Cambio Climático." *MRZine*. July 7, 2008.
<<http://www.biodiversidadla.org/content/view/full/42329>>

⁸ "The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore." A Communication from the United States. World Trade Organization. WTO/IP/C/W/434. November 26, 2004.

⁹ Carlos Correa. "Bilateral investment agreements: Agents of new global standards for the protection of intellectual property rights?" GRAIN. August 2004. < <http://www.grain.org/rights/tripsplus.cfm?id=59>>

¹⁰ Most of the following analysis is based on Steve Suppan, "Amending WTO intellectual property rules to prevent bio-piracy and improve patent quality," Institute for Agriculture and Trade Policy, July 2006 en
<<http://www.tradeobservatory.org/library.cfm?refID+88376>>

¹¹ *Inside U.S. Trade*. "Lamy Calls Late July Doha Ministerial; Revised Texts Expected Next Month." June 27, 2008.

¹² *Bridges*. "TRIPS Negotiations: New Reports and Non-Papers Are Presented." June 11, 2007. Vol. 12. No. 21.
<<http://www.ictsd.org/weekly/08-06-11/story5.htm>>

¹³ *Bridges Trade Bio Res*. "LDC Group Supports Biodiversity Amendment in WTO Council on Intellectual Property. November 2, 2007. Vol. 7. No. 19. < <http://www.ictsd.org/biores/07-11-02/inbrief.htm>>

¹⁴ Center for Food Safety. *Monsanto v. U.S. Farmers*. 2005.
<<http://www.centerforfoodsafety.org/pubs/CFSMonsantovsFarmerReport1.13.05.pdf>>