

**INTELLECTUAL PROPERTY RIGHTS, BIOTECHNOLOGY AND  
GENETIC RESOURCES**

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**WIPO ROUNDTABLE ON INTELLECTUAL PROPERTY RIGHTS  
IN AGRICULTURAL BIOTECHNOLOGY**

**AGRICULTURAL BIOTECHNOLOGIES IN DEVELOPING  
COUNTRIES**

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# **INCREASING RELEVANCE OF IPR IN THE CONTEXT OF HUMAN SUSTAINABLE DEVELOPMENT:**

- **TECHNOLOGY TRANSFER**
- **ACCESS TO HEALTH AND MEDICINES**
- **ACCESS TO INFORMATION**
- **BIODIVERSITY ( GENETIC RESOURCES)**
- **FOOD AND AGRICULTURE**
- **PROTECTION OF TRADITIONAL KNOWLEDGE (TK)**

**LAST 15 YEARS A SIGNIFICANT DEBATE ABOUT,  
BIODIVERSITY, FOOD, PROTECTION OF TK AND THE ROLE OF  
IPR HAS TAKEN PLACE.**

## **MOST RELEVANT IPR TOOLS RELATED TO BIODIVERSITY**

- **PATENTS: SPECIALLY IN THE LIGHT OF JUDICIAL OR ADMINISTRATIVE DECISIONES IN THE US AND EUROPE IN THE 80 AND 90**
- **PLANT VARIETY RIGHTS : NATIONAL LAWS MOSTLY BASED IN UPOV 78 O 91 WITH FEW EXCEPTIONS**
- **TRADE SECRETS.**
- **GEOGRAPHICAL INDICATIONS**

# EXAMPLES OF PATENTS ON PLANT RELATED MATERIAL

- *Genes, genetic sequences and plants containing those genes and sequences*
- *Basic and transformation processes*
- *Finished varieties ( in few countries)*

# PATENTS AND GENETIC RESOURCES

In relation to plants it should be considered that patents can be applied to a wide variety of biological material and procedures, among them:

- Isolated DNA sequences that codify for certain proteins
- Isolated or purified proteins
- Seeds
- Plant cells and plants
- Plant varieties, including parental lines
- Processes to genetically modify plants
- Processes to obtain hybrids.

## High emotional debate, which includes among others:

- The moral implications of treating inventions relative to plants, animals, micro-organisms, their components such as genes, gene sequences, proteins, cells, etc. as property.
- The challenges to basic considerations of patent law such as novelty, inventive level, description of the invention, exhaustion of rights and, in some cases, elimination of the distinction between invention and discovery.

The possibility that basic research and commercialization may be discouraged by broad claims of patents involving biotechnological research instruments and due to the conflicts between patents.

## **High emotional debate, which includes among others:**

- The possibility that IPRs on life forms support so-called “biopiracy”, that is, the appropriation of genetic material and traditional knowledge without the consent of the countries and communities and indigenous peoples or without adequate benefit sharing.

## **•SOME CHALLENGES FOR THE IPR**

### **THE DIFFERENCE BETWEEN INVENTIONS AND DISCOVERIES.**

- LINKED TO IT IS THE CASES OF IRREGULAR ACCESS TO GENETIC RESOURCES AND ASSOCIATED TK ( BIOPIRACY) ONE OF THE REASONS BEHIND THE CURRENT NEGOTIATIONS OF AND IR ON ABS UNDER THE CBD.**
- NO INTERNATIONALLY AGREED DEFINITION EXISTS. UNDER DISCUSSION IN THE CBD NEGOTIATIONS.**
- EMBLEMATIC CASES ( WHEATHER OR NOT ACCURATES) IN LA**
- E.G. “ENOLA PATENT” CANCELLED IN 2009 AFTER 9 YEARS OF DISPUTES DUE TO THE LACK OF NOVELTY AND INVENTIVE STEP.**



## **•ISSUES OF INTEREST**

### **THE EXHAUSTION OF RIGHTS AND THE PROTECTED CLAIMS.**

- ARGENTINIAN CASE OF EXPORT OF SOYA DERIVATIVES TO EUROPE AND THE LITIGATION IN SEVERAL COUNTRIES FOR THE INFRACTION TO THE NATIONAL PATENTS ( UK, DEMNARK, ETC)**
- THE GEN IS CONTAINED BUT THE FUNCTION CLAIMED IS NOT. EXPRESSED**
- EU DIRECTIVE ON BIOTECHNOLOGY: THE GENETIC SEQUENCE MUST DISPLAY ITS FUNCTION**
- RETHINKING THE EXHAUSTION OF RIGHTS IN PATENT RIGHTS IS NEEDED?**

## Ley de la Propiedad Industrial Mexicana

Artículo 22.- El derecho que confiere una patente no producirá efecto alguno contra:

**V.- Un tercero que, en el caso de patentes relacionadas con materia viva, utilice el producto patentado como fuente inicial de variación o propagación para obtener otros productos, salvo que dicha utilización se realice en forma reiterada, y**

**VI.- Un tercero que, en el caso de patentes relacionadas con productos que consistan en materia viva, utilice, ponga en circulación o comercialice los productos patentados, para fines que no sean de multiplicación o propagación, después de que éstos hayan sido introducidos lícitamente en el comercio por el titular de la patente, o la persona que tenga concedida una licencia.**

## •ISSUES OF INTEREST

- Defining and setting the limits on essentially biological processes, microbiological and non-microbiological (chemical, etc.) ones are not easy to do, especially in biotechnology, nor do uniform solutions exist in the world ( however some jurisprudence does exist in EPO, etc).
- Some recent cases ( Broccoli pending at the EPO) confirms the legal difficulties for drawing clearly the boundaries.
- Finally the application of a patent for the first synthetic organism in 2007 in US.

# THE COMPLEXITY OF THE INTERNATIONAL FORA AND ITS MUTUAL IMPLICACIONES

## CONVENTION ON BIOLOGICAL DIVERSITY MORE THAN 190 PARTIES

- Prior obtaining of the informed consent of the State and other holders of knowledge or t genetic and ( in some countries) biochemical resource (PIC).
- Mutually agreed terms and the sharing of benefits derived from access to genetic resources and associated traditional knowledge ( MAT AND BS).
- Protection of TK associated to Biodiversity.
- IPR should not contradict CBD objectives.

# THE COMPLEXITY OF THE INTERNATIONAL FORA AND ITS MUTUAL IMPLICACIONES

Johannesburg Summit: mandate to negotiate within the CBD and International Regimen on BS.

Decision VII/19 agrees to call once again the Working Group on Access to Genetic Resources and Distribution of Benefits so that “...in collaboration with the Working Group of Article 8, subparagraph J, on traditional knowledge, and ensuring the participation of indigenous peoples and communities, non-governmental organizations, industry and academic and intergovernmental institutions, it elaborate and negotiate an international regime of access to genetic resources and sharing of benefits in order to adopt an instrument or instruments to effectively implement the provisions of Article 15 and 8, subparagraph J, and the three objectives of the Convention.”

## IP RELATED TOPICS OF INTEREST UNDER DISCUSSION:

- DISCLOSURE OF ORIGIN OF GR AND OR ASSOCIATED TJK IN IPR APPLICATIONS AND THE CERTIFICATE OF COMPLIANCE
- PROTECTION OF TK
- TECH TRANSFER PROVISIONS.

## WTO .

The Doha Declaration that launched the WTO Round of Trade Negotiations under way recommended to the Council of TRIPS to examine the relationship between this agreement and CBD, protection of traditional knowledge and folklore and the new matters submitted by the Members based on the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement, taking the dimension of development fully into consideration.

Difficult discussion about the linkage now reduce to the introduction or not of a disclosure requirement in patent applications ( new article 29 bis).

Final solution pending of the future of the Doha Round.

# **INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES**

- **MULTILATERAL SYSTEM OF ACCESS TO GENETIC RESOURCES AND IPR RELATED PROVISIONS INCLUDING THOSE CONTAINED IN THE SMTA**
- **FARMER´RIGHTS REALIZATION.**



## WIPO

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO was established in October 2000 as a forum for dialogue on the relationship between intellectual property and traditional knowledge, genetic resources and traditional cultural expressions.

Current mandate the development of an instrument or instruments (new convention?) to protect TK, IP and genetic resources and TCE to be submitted by 2011.

Other WIPO bodies: Development Agenda Committee, Patent Committee, PCT Reform, etc.

## CONCLUSION:

➤ IP, BIOTECHNOLOGY AND GENETIC RESOURCES ARE A SUBJECT MATTER IN STATE OF CHANGE.

➤ NEGOTIATIONS AND DISCUSSIONS IN DIFFERENT FORA HAS MUTUAL IMPLICATIONS.

GRACIAS

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