

INTELLECTUAL PROPERTY and BIOTECHNOLOGY

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Introduction

- What is intellectual property ("IP")?
- What is the role of IP?
- What are the main kinds of IP?
- IP Practice



What is Intellectual Property ("IP")?

- A product of the intellect that has commercial value.
- Those rights that are available to protect your creation from unauthorized use by others.
- IP is distinct from the property to which it is attached.
- Owning the physical object is different to owning the IP relevant to that object.



IP ≠ Object

- The Rolls Royce Motor Cars Case Study¹
- Rolls Royce Motor Cars manufactures Rolls Royce and Bentley cars
- Rolls Royce Motor Cars Ltd put up for sale October 1997
- BMW offered US\$560 million, 30 March 1998
- VW offered US\$710 million, 7 May 1998
- VW offered US\$790 million, 3 July 1998

¹ http://www.wipo.int/export/sites/www/sme/en/activities/meetings/singapore_03/singapore_liberman_10.pdf



- What VW thought it had bought for US\$790 million
 - Factory located at Crewe
 - 2,400 skilled workers
 - Bentley trade mark
 - Rolls Royce trade mark
 - Continuous access to engine supply



But,

- On 9 July 1998 Rolls Royce Plc advised VW of 1973 licensing agreement that gave it exclusive control over the "Rolls Royce" trade mark in the event of sale to a foreign buyer
- By 9 July 1998, BMW gave 12 months notice of termination of engine supply agreement
- BMW obtained license from Rolls Royce Plc to "Rolls Royce" trade mark for US\$65 million in the form of a redeemable loan note to be used as investment in new JV company between BMW/Rolls Royce Plc



- What VW ultimately ended up getting for US \$ 790 million
 - Factory located at Crewe
 - 2,400 skilled workers
 - Right to use "Bentley" and "Rolls Royce" trade marks and to make Rolls Royce and Bentley cars up to 1 January 2003
 - After 1 January 2003, BMW to have exclusive right to "Rolls Royce" trade mark and right to manufacture Rolls Royce cars
 - Engine supply assured



CONSTITUTION, Article XIV

Section 10. Science and technology are essential for national development and progress. The State shall give priority to research and development, invention, innovation, and their utilization; and to science and technology education, training, and services. It shall support indigenous, appropriate, and self-reliant scientific and technological capabilities, and their application to the country's productive systems and national life.



Section 11. The Congress may provide for incentives, including tax deductions, to encourage private participation in programs of basic and applied scientific research. Scholarships, grants-in-aid, or other forms of incentives shall be provided to deserving science students, researchers, scientists, inventors, technologists, and specially gifted citizens.



Section 12. The State shall regulate the transfer and promote the adaptation of technology from all sources for the national benefit. It shall encourage the widest participation of private groups, local governments, and community-based organizations in the generation and utilization of science and technology.



Section 13. The State shall protect and secure the exclusive rights of scientists, inventors, artists, and other gifted citizens to their intellectual property and creations, particularly when beneficial to the people, for such period as may be provided by law.



- Science and technology = national development and progress
- Therefore, state shall promote and give priority to research and development, education; regulate technology transfer



What is the role of IP?

Intellectual Property Code of the Philippines (RA 8293)

Section 2 of the IP Code:

"The use of intellectual property bears a social function. To this end, the State shall promote the diffusion of knowledge and information for the promotion of national development and progress and the common good."



What is the role of IP?

• Depends upon the level of development

"At the microeconomic level, patent, copyright, and similar forms of intellectual property protection provide a means by which innovators and investors can recover the investment of time and money needed to bring a new product to the market. At the macroeconomic level, intellectual property promotes economic development by encouraging domestic innovation and foreign direct investment. The intellectual property system also creates a framework in which developing countries can participate in the economic activities of the developed world."¹ (underscoring supplied)

¹ ["]Intellectual Property and Developing Countries: An Overview." Briefing Paper, December 2003. Submitted to USAID Washington



"The empirical findings from the report show that stronger IPRs seem to influence the decisions of individual firms in developed countries by encouraging them to export, invest and transfer their technologies through licensing in developing countries, in particular those with strong technical absorptive activities. It also found that stronger IPRs can hamper access to medicines in developing countries and do not necessarily encourage pharmaceutical innovation that responds to developing country needs. The report stressed that uniform IP laws cannot ensure diversity of access and benefit-sharing from genetic resources and traditional knowledge."1

¹ Intellectual Property and Developing Countries: A review of literature. Prepared for the UK Intellectual Property Office and the UK Department for International Development. 2010



- From a developing country perspective, IP may be useful on several levels:
 - As a resource in research and development: patent databases
 - Accessing technology and innovations in the public domain
 - for innovators, as a business strategy or to maximize assets and recover investments



Kinds of IP

- Copyrights and Related Rights
- Trademarks and Service Marks
- Geographic Indications
- Industrial Designs
- Patents
- Lay-out Designs (Topographies) of IC's
- Protection of Undisclosed Information



- Geographical Indications identify goods as originating in a territory where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin
- e.g. "Bicol pili"



- Industrial Designs Composition of lines, colors or any 3-D form that gives a special appearance to, and can serve as a pattern for, an industrial product
- ID Reg. No. 3-2010-000588





 Lay-out Designs - protection of original lay-out designs of integrated circuits



- Protection of Undisclosed Info
 - secret
 - has commercial value because it is secret
 - subject to reasonable steps to keep it secret
- *e.g.* Coke's secret formula



- **Patent** any *technical solution* of a problem in any field of human activity which is
 - new/novel not prior art
 - involves an inventive step not obvious to a person skilled in the art
 - industrially applicable useful, for practical purpose



- an agreement between the inventor and the government
- mechanism for providing an incentive for scientists to bring inventions to market
- a government-granted limited term monopoly (20 years) to <u>exclude others</u> from using an invention
- Philippine patents are granted by the Intellectual Property Office



Non-patentable inventions (Sec. 22, IP Code)

22.1. Discoveries, scientific theories and mathematical methods;
22.2. Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;
22.3. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods;

22.4. Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro- organisms and non-biological and microbiological processes.



Provisions under this subsection shall not preclude Congress to consider the enactment of a law providing sui generis protection of plant varieties and animal breeds and a system of community intellectual rights protection:

22.5. Aesthetic creations; and

22.6. Anything which is contrary to public order or morality. (Emphasis supplied)



Utility Model Registration

- Applies to inventions that are new and industrially applicable
- Inventive step not a requirement
- Registered without substantive examination
- Term: 7 years, no renewal



Industrial Design Registration

- Applies to new, original and ornamental design of an object
- Only protects appearance of an object and not its function or utility
- Term: 5 years, renewable twice



Trademarks and Service Marks

- any visible sign capable of distinguishing the goods or services of an enterprise
- acquired through registration with the IPO
- term is 10 years from registration; renewable



Unregistrable marks

- Immoral, deceptive, scandalous marks or falsely suggest connection with persons
- Insignia of the Philippines/other countries
- Name, portrait or signature of living individual except if with consent
- Identical/ confusingly similar with
 - registered mark
 - mark with earlier filing date
 - Internationally well-known mark
- Misleading as to nature, quality, characteristics or geographical origin of goods/services



Rights of owner of a registered mark

- Exclusive right to prevent all third parties from using
 - Identical signs
 - Similar signs
 - Containers which are identical or similar
- Use would result in likelihood of confusion

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Copyright

- literary and artistic works
- protected from the moment of creation up to 50 years from creation/death of author
- IP Code requires copies of copyrighted works to be deposited for registration with the National Library or the Supreme Court Library within three (3) weeks from the date of the first public dissemination or performance
- advisable for all copyright owners to deposit their works with the National Library and the Supreme Court for evidentiary purposes in enforcing and defending their copyright



BIOTECHNOLOGY

 Plant varieties or animal breeds or essentially biological process for the production of plants or animals are excluded from patent protection. This exclusion shall not apply to micro- organisms and nonbiological and microbiological processes.



"Since the advent of biotechnology, it has been bringing to forth 'unanticipated inventions'. It was never thought that biotechnology could manipulate either the plant or animal being, and therefore no one has ever thought of the need for evolving a comprehensive patent law on biotechnology for regulation." (Introduction of Guidelines in the Examination of Biotechnological Applications)



DIAMOND vs. CHAKRABARTY

- Distinction between a non-patentable "product of nature" and a patentable "non-naturally occurring composition of matter" was settled for the first time by US SC decision in *Diamond vs. Chakrabarty*, wherein patent was granted for laboratory-engineered bacteria that have the capacity to degrade crude oil.
- A live, man-made microorganism is a non-naturally occurring composition and therefore may be patented.



Guidelines in the Examination of Biotechnological Applications

- **Biotechnological inventions** inventions concerning biological materials, or the process of their production, modification, or utilization.
- Biological material any material containing genetic information, which can replicate directly (on its own), or indirectly, in a given biological system. Biological materials capable of direct replication include plants and animals (and their derivatives), microorganisms, cells and hybridomas. Biological materials that replicate indirectly include viruses, nucleic acids (genes, vectors), and polypeptides (proteins, amino acids) and antibodies.



- **Microorganisms** organisms that are invisible to the naked eye, including bacteria, fungi, unicellular algae, and protozoans.
- Microbiological process any process that makes use, or results in, a microbiological material, comprising steps that may be microbiological or non-microbiological in nature.



Essentially biological process for the production of plants and animals - a process which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals, even if such process involves human intervention-including the provision of technical means, serving to enable or assist the performance of the process. This applies even if other technical steps relating to the preparation of the plant or animal or its further treatment are present in the claim before or after the crossing and selection steps.



Patentability of Biotechnological Applications

- Eligibility should neither be a discovery nor a product of essentially biological processes
- Must still comply with the requirements of novelty, inventiveness and industrial applicability



Enabling disclosure

- When the application refers to a nucleotide or amino acid sequence, the sequence listing forms part of the description, and therefore shall be included in the submission.
- An additional requirement for microorganisms is that a culture of such must have been deposited in a depositary institution before filing the application.

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- Stem cells in evaluating applications relating to stem cells (including their use and derived products), the primary consideration is the origin of such stem cells, i.e., whether the use of the embryo as a base material involved direct destruction or not.
- Direct destruction may include isolation of the embryo such that said embryo will no longer develop into a human. Likewise, the term human embryo represents an organism which is capable of developing into a human being.



Embryonic stem cells that may fall within the exclusion from patentability are those isolated from:

a) earlier stages of the human embryo up to the fetal stem cells (approximately 8th week post fertilization),

b)aborted fetal stem cells and their derivatives, and

c) primary embryonic stem cell lines directly isolated from the human embryo.



Patentability of Plants and Animals

- Plants and animals are patentable if the technical feasibility of the invention is not confined to a particular animal or plant variety. Inventions which concern plants and animals are patentable provided that the application of the invention is not technically confined to a single animal or plant variety
- Plant varieties are not patentable, they can be protected under the Plant Variety Protection Act



Plants versus varieties



From the Guideline in the Examination of Biotechnological Applications, citing Yeats, S. (11 October 2011)Latest Developments in Patenting Plant Inventions in Europe.



 A process for the production of plants or animals which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals is excluded from patentability as being essentially biological. Product of these essentially biological processes are also excluded from patentability.

Claim A: Method for the production of plants having trait X comprising crossing plants A and B and selecting progeny having marker X.

Analysis: The claim is patent ineligible because it includes crossing of plants which is an essentially biological process.



 If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which introduces or modifies a trait in the genome of the plant produced which cannot be the result of mixing of genes, then the process is not excluded.

Claim A: Method of producing a (transgenic) plant having trait X by introducing a vector comprising the sequence of SEQ ID NO: 1.



Public Order and Morality

Under Rule 202 (i) of the Revised IRR, Philippine Patents are not to be granted in respect of biotechnological inventions which concern:

(i) Processes for cloning human beings - defined as any process including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being.
(ii) Processes for modifying the germ line genetic identity of

(ii) Processes for modifying the germ line genetic identity of human beings.



(iii) Uses of human embryos for industrial or commercial purposes - obtained by a method which necessarily involved the destruction of human embryos from which the said product is derived, even the said method is not part of the claim. The point in time at which such destruction takes place is irrelevant.

(iv) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man and animal and also animals resulting from such processes. The substantial medical benefit referred to , includes any benefit in terms of research, prevention, diagnosis or therapy.



(v) Any biological material and method able to seriously endanger human beings, animals, or plant life, or able to cause serious damage to health or environment, including its use likely to jeopardise public order and morality (such as terminator gene technology).



Thank you!