

MOLECULAR BIOTECHNOLOGY (SQG3213)

INTELLECTUAL PROPERTY

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- **Intellectual property (IP)** refers to creation of the minds. It comprise of principles to ensure protection to an inventor from breach of use.
- The protection is backed by laws, observed in various forms.
- There are 4 main types of IP:
 - Copyright
 - Trademark
 - Patent
 - Design
- All these types are divided into two categories:
 - 1. Industrial property (patents, trademarks, designs, plants, topographies of circuits, undisclosed information, traditional knowlegde & geographical indications of source)
 - 2. Copyright (for materials of literary & artistic works and broadcastings)

- IP is advantageous to owner; providing control & rewards for innovation used as well as protection.
- **Intellectual property rights (IPRs)** are the rights given to individuals over the creation of their innovations, with certain conditions.
- IPRs add value for commodities, results & activities. It is vital to balance between interests among society.

COPYRIGHT, ©

- A work that results in independent creative effort and not copied from previous work can be considered as original for **copyright**.
- According to the Copyright Act 1987 (Malaysia), copyright is defined **as the exclusive right provided by the law to owners of copyright works to control their works for a specified period.**
- Something created that is similar to existing work without copying any part of it directly or indirectly may also be considered as original copyright.
- However, the extent of originality can only be decided by the courts.

- For a qualified protection:
 - Sufficient work to make the work original in character.
 - The work has been written down, recorded or reduced to material form.
 - The author is qualified for the country he/she applied to or the work is first published in the country.

- Works eligible for protection:
 - Literary works
 - Musical works
 - Artistic works
 - Films which include music videos & karaoke recordings
 - Sound recordings
 - Broadcast
 - Published editions
 - Work of government, government bodies & international bodies
 - Anonymous publications

- Copyright subsist during the life of the author plus 50 years after his/her death, following the year in which the work was first published.
- Copyright provides **original creators** and **their heirs**, protection of their work.
- The use or authorize use of their work depends on them as they hold the **exclusive right** to:
 - Reproduction of the work in any material
 - Public exposure by communication or performance, show, play
 - Recording, including photocopying
 - Broadcasting in any form for distribution
 - Translation for distribution
 - Commercially rent the work to the public

- In terms of ownership, the first owners are the authors:
 - Literary works – writers
 - Work during employment – employer
 - Government works – government
 - Pseudonym / anonymous – publisher
 - Unpublished work with no identity of author – minister in charge of culture
- The creators may sell their rights (work) in return of payment called **royalties**.
- Some copyright works are transferable such as assignment, testamentary disposition & operations of law with an agreement

- The agreement may specify the **exclusive rights, period of transfer, area of rights & number to be reproduced**.
- The **economic rights** provide a time limit of about 50 years after the creator's death and may depend on countries' law. It ceases upon expiry of protection period.
- The right to claim authorship of work and oppose changes gives the creator **moral rights**. It remains for eternity & heirs can exercise it. It protects from:
 - Misrepresentation of author
 - Distortion,
 - Mutilation,
 - Modification of the work.

- As owner of the copyright, the creator has the right to enforce in the law and administratively.
- Copyright protection gives creators recognition & reward for human creativity which can enhance innovation.
- As soon as it exists, a work is protected by copyright but some countries have administrative office / law for copyright registration.
- Someone who wants to use the work can contact the owner / heir.
- However, it is permitted to use limited portions of the work.

TRADEMARKS, TM

- A **trademark** is any sign but more commonly a **distinctive sign** that distinguish goods or services produced / provided from one person to another.
- Stated in section 3, Trade Marks Act 1976 (Malaysia), **trade mark means a mark used or proposed to be used in relation to goods or services for the purpose of indicating or so as to indicate a connection in the course of trade between the goods or services and a person having the right either as proprietor or as registered user to use the mark whether with or without an indication of the identity of that person.**

- Includes **words**, **brands**, **logos**, **colors**, **slogans**, **shapes**, **sounds**.
- It is a trade of origin for marketing for product recognition, therefore important to all businesses.
- A mark is a device, brand, heading, label, ticket, name, signature, word, letter, numeral or any combination thereof.

– There are three types of trademark:

- **1. Service mark**

- - any word, name, symbol, device used in commerce

- **2. Certification mark**

- - any word, name, symbol, device used in commerce with owner's permission by someone else.

- **3. Collective mark**

- - trademark / service mark used in commerce by members of an association.

- Trademarks functions as:
 - Exclusive rights / protection
 - Capable of distinguishing
 - Quality
 - Advertising
 - Asset / economic value

- Qualities of a good trademark:
 - Distinctive
 - Non-descriptive
 - Original
 - Non-deceptive
 - Registrable

- Avoidance of INN stems (pharmaceutical trademarks)

[*-coxib* for [COX-2](#) inhibitors, a type of [anti-inflammatory drugs](#) (e.g. [celecoxib](#));

-mab for [monoclonal antibodies](#) (e.g. [infliximab](#)); see Nomenclature of monoclonal antibodies

- Trademark need not be registered but advisable for claim of ownership.

- Among the benefits of trademark registration:
 - Nationwide notice
 - Ownership evidence
 - Invocation jurisdiction of federal courts
 - Provide a basis for obtaining registration in foreign countries
 - Prevent importation of infringing foreign goods
 - Monopoly of use in association with goods/services registered
 - Trademark protected prior to use

- Trademark is often notated by **TM** and service mark by **SM**. Federal registration symbol **®** may be used once registered with US Patent & Trademark Office.

- Certain marks however, might have already been registered so a search is often done before registration.

- The common law protects the rights for the actual use of a mark:
 - Protects business reputation & goodwill
 - Protects consumers from deception / confusion
 - Facilitates technology transfer
 - Ensures quality control
 - Tools for effective marketing strategy

- Lasts up to 10 years & can be renewed.

- Some trademarks could not be registered:
 - Likely to confuse / deceive public
 - Comprise any scandalous / offensive element
 - Generic terms
 - Words descriptive of the goods or services

- In Malaysia, unregistrable trademarks follow the same guidelines:
 - Consist of word / words/representation of the royals
 - Identical / confusing similar trademarks well known in the country

PATENTS

- For an invention (product / process), **patent** provides an exclusive right for doing something new.
- Patent Act 1983 (Malaysia) define **patent is a grant that entitle exclusive rights to inventors to invent, use or sell his/her invention in Malaysia for the maximum of 20 years from the application date.**

- Patentable materials are products or processes which invention can solve technological problems.
- It gives an inventor the right to stop copying or unpermitted selling of his / her work for a period of time.
- Protection of a patent is generally for 20 years.
- Invention for patent have to fulfill certain specific conditions:
 - Must be new
 - Involve an inventive step
 - Applicable industrially

- As patent is recorded in a document, an invention must provide:
 1. Invention description with enough details
 2. Claims for defining the scope of protection
- Patents rights depend on individual or group inventing it.
- When 2 or more people are involved in a new innovation, all of them shared the patent rights.
- When 2 or more people invent the same product / process separately or individually, and each of them apply for patent; it will be given to those having the earlier priority date.

- Patent has to be applied and filed. The process is tedious and takes time.
- The rights to a patent depend on the country in which it is being filed.
- Aside from protecting the value of invention, patents can also be bought, sold or licensed to others.
- Patented inventions suppress the reinvention of the same product / process.
- It may also stimulate the development of new ideas as it can be improved once the patent expires.

- Patent owner has the "exclusive right" to stop others from:
 - ✓ making,
 - ✓ using,
 - ✓ selling or
 - ✓ offering for sale of the product, or process of making the product, that is described by the patent claims.
- Patent owner **DOES NOT** have the right to exploit the patented invention him-/herself.
- He/she/They has/have only the "exclusive right" to stop others from doing so.

What can be patented?

- Utility patents protect inventions that are a novel, nonobvious, and useful:
 - Process
 - Machine
 - Article of manufacture
 - Composition of matter
 - Or an improvement of any of the above items.

- Design patents are for the new ornamental design of an article of manufacture.
 - E.g.: the look of an athletic shoe.
all Star Wars characters were protected by design patents.
- Plant patents provide patent protection for asexually reproduced any distinct and new variety of plant.

- Malaysia certified a **utility improvement** to a “minor” invention which did not meet the invention steps as in patent but it has to be new.
- Improved utility does not need to involve the inventing steps, can be used in the industry & entitled to only an individual.
- For that, **10 years protection from the date of application** is given & can be **renewed** for a period of **5 + 5 more years**, depending on its use.

6.4 DESIGN

- A **design** is essential and important for product appearance.
- As design is essential for the industry, it is usually refer to as industrial design.
- Under Section 3(1) Industrial Design Act 1996 (Malaysia) **industrial designs mean features of shape, configuration, pattern or ornament applied to an article by any industrial process or means, being featured in which in the finished article it appeals to the eye and are judged by the eyes.**

- Involves features such as **lines, contours, colors, shape, texture** of the product.
- Basically it is the outer appearance of an article that appeals to the eye.
- However, industrial design does not include:
 - A method of principle of construction **or**
 - Features of shape or configuration of an article which:
 - are dictated solely by the function
 - are dependent upon the appearance of another article as an integral part

- For a design to be registered, the criteria are:
 - There must be a design
 - Design must be applied to an article
 - Must be applied by an industrial process
 - Must appeal to & are judged by the eye
 - Must not constitute a method / principle of construction
 - Must be new

- Application shall not be considered new if:
 - Disclose to the public before filing
(exception to official exhibition within 6 months before filing)
 - Was a subject matter of another application having an earlier filing date
 - Differ only in immaterial details / in features commonly used in relevant trade

- Unregistrable design include:
 1. Designs contrary to public order or morality
 2. Offensive designs to religious and moral standards

- Protection of industrial designs adds to commercial value of a product/process/article, encourages creativity, encouraging economic development & provides exclusive rights to make / import and to sell, hire or offer for sale or hire.
- Provide **5 years** protection from filing date with **extension** for further **2 consecutive terms of 5 years** with a **total protection of 15 years**.
- Associated with trademark mostly but applicable to patent & copyright as well.

6.5 OTHER IP RIGHTS

- Various forms and subjects associated to IP:
 - Performer rights in performance & recordings.
 - Trade secrets under confidential agreements.
 - Database right for certain types of databases.
 - Semi-conductor topographies.
 - Plant breeders' rights.
 - Geographical indication of origin.
 - Conditional access technology.
 - Publication right.

6.6 ENFORCING THE RIGHTS

- Private rights of owner.
- Legal action can be taken for a breach of rights.
- To reduce illegal use of IP, advisable to inform notification of IP to other people.

- In Malaysia, IP is maintained by a tribunal appointed by the minister to:
 - Consider & approve application for licence to produce & publish.
 - Arbitrate disputes relating to the licensing by licensing bodies.
- Matters regarding IP that contradicts with the Tribunal may be appealed to the high court.
- Another option is to issue a policy for the IP.

6.7 PERMISSION TO USE IP

- In most cases, have to ask the owner of IP.
- Some uses are, however, not restricted by IP. For example, an IP to be used as a source of technical information.

- For copyright, exception for photocopying for noncommercial research / private study, public performance by non-profit clubs / institutions, for charitable / educational purposes & no admission fee is charged.
- Such cases require permission & can be exempted from paying royalty.
- If permission has been refused, IP may be used by getting a licence or payment.

6.8 PROTECTION AND BENEFIT

- Have to apply for protection & depends whether it can be protected or not.
- Patents & trademarks have to be registered for protection.
- Unregistered IP with automatic protection are copyright, design right and performers rights.
- Protection for a material can be covered by more than one type of IP.

- Different IP rights offer protection in different ways.
- Advisable to apply IP ASAP as disclosure to public before application will be rejected.
- The benefit / exploitation of IP depend on owner's intention of use.
- If a material can benefit others, owner may licence its use for other people. There are certain restrictions in a few areas of IP that does not allow the rule.
- IP can also be sold to gain its benefit but owner will lose his/her rights on the material & need to obtain permission from new owner.

6.9 BIOTECHNOLOGY AND IP

- Biotechnology has increased in importance with the application in wide sectors.
- World Intellectual Property Organization divided invention of biotechnology into:
 1. Processes in creating / modifying living organism and biological material.
 2. The end-products of the processes.
 3. The use of end-products / results.

- Commonly used protection is patent, bound by Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- Generally, natural products could not be patented.
- As biotechnology inventions usually involve genetic resources, before patenting:
 1. Identify novel sequences.
 2. Specify the product.
 3. Specify the functions of product.
 4. The product can be used & serve its purpose.

- Patentable material include:

1. Genes and gene fragments

- full sequence & function(s)
- how product function specifically in nature.
- have to overcome “patent stacking”

2. Gene tests

- tests for screening diseases
- only licensed entities can conduct the tests.
- royalties to holder each time a test is administered

3. Proteins

- enzymes, structures
- drug design & pharmaceutical

4. Stem cells

- embryonic stem cells for study & disease treatment
- patents from stem cells can be issued

5. SNPs (single nucleotide polymorphisms)

- most have no effect on cell function but could influence response to a drug
- used to identify multiple genes associated with complex diseases

- Via patent, inventions are protected without secrecy.
- Through the protection provided, the public are informed of products safety, environmental implications, efficacy and unfair competition.
- Patents provide positive action as transfer of technology is possible while still preserving the exclusive rights of the owner.
- Most countries practiced **first to invent** principle where first invention is provided **property rights for 20 years**.
- If a patent involve alteration of natural product, a sample is required as deposit & can be deposited into any one of the 26 worldwide culture depositories.
- As patent application is confidential until it is issued, using the sequence in public databases might cause a problem if the sequence has been patented.

- **Benefit of patenting in biotechnology:**
 - Discoveries are rewarded.
 - Prohibiting competitors from using inventions without permission / licence.
 - Eliminating duplication process.
 - Exploration of new areas.
 - Ensured access to new invention.

- **Disadvantages:**
 - Increasing cost of inventions.
 - Discouraging product development.
 - Inappropriate reward of patent.
 - Monopoly of certain inventions by companies.

- **Unpatented material / resource / process:**
 - **Life forms including plants & animals.**
 - **New organism.**
 - **Human cloning.**
 - **Germ line modification.**
 - **Human embryos for commercialization.**
 - **Biological processes.**
 - **Nuclear weapons.**

References:

- Bouchoux, D.E. (2012) Intellectual Property: The Law of Trademarks, Copyrights, Patents, and Trade Secrets. Delmar Cengage Learning, USA.