UNIT –I

Intellectual property rights

Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.

Intellectual property rights are customarily divided into two main areas:

(i) Copyright and rights related to copyright

The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author.

Also protected through copyright and related (sometimes referred to as "neighbouring") rights are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work.

(ii) Industrial property

Industrial property can usefully be divided into two main areas:

One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin).

The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive.

Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets.

Types of Patents

The U.S. Patent and Trademark Office (USPTO) issue several different types of patent documents offering different kinds of protection and covering different types of subject matter. A recently issued USPTO patent document is one of six types, generally described below

I. Utility Patent: Issued for the invention of a new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof, it generally permits its owner to exclude others from making, using, or selling the invention for a period of up to twenty years from the date of patent application filing
II. Design Patent: Issued for a new, original, and ornamental design embodied in or applied to an article of manufacture, it permits its owner to exclude others from making, using, or selling the design for a period of fourteen years from the date of patent grant.
III. Plant Patent : Issued for a new and distinct, invented or discovered asexually reproduced plant including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, it permits its owner to exclude others from making, using, or selling the plant for a period of up to twenty years from the date of patent application filing.
IV. Reissue Patent : Issued to correct an error in an already issued utility, design, or plant patent, it does not affect the period of protection offered by the original patent. However, the scope of patent protection can change as a result of the reissue patent.

V. Defensive Publication (DEF) : Issued instead of a regular utility, design, or plant patent, it offers limited protection, defensive in nature, to prevent others from patenting an invention, design, or plant.

VI. Statutory Invention Registration (SIR) : This document replaced the Defensive Publication in 1985-86 and offered similar protection.

Patent

A patent is a right granted to the owner of an invention that prevents others from making, using, importing or selling the invention without his permission.

A patentable invention can be a product or a process that gives a new technical solution to a problem. It can also be a new method of doing things, the composition of a new product, or a technical improvement on how certain objects work.

Once it is granted, its term of a patent is 20 years from the Date of Filing, subject to the payment of annual renewal fees.

Trademark

A trademark is a sign that you can use to distinguish your business' goods or services from those of other traders. A trademark can be represented graphically in the form of your company's logo or a signature.

Through a registered trademark, you can protect your brand (or "mark") by restricting other people from using its name or logo. Once acquired, a trademark can last indefinitely as long as you renew it every 10 years. Because a registered trademark is a form of IP, you can license or assign it to others.

Trade Mark Classification

The following can be registered as a trade mark but a mark must be distinctive and capable of distinguishing your goods or services from similar ones of other traders:

Letters
Words
Names
Signatures
Labels
Devices
Tickets
Shapes
Colors

Design

A design refers to the features of a shape, configuration, pattern or ornament applied to an article by any industrial process. If you register a design, you will be protecting the external appearance of the article. Registered Designs are used primarily to protect designs for industrial use.

To qualify for registration, a design must, in general, satisfy two key criteria:

1. The Design must be new – The registered design must not have been registered in Singapore or elsewhere, or published anywhere in the world before the date of application of the first filing. Thus the owner of a design should be careful not to disclose the design to anyone until a design application is filed.

Generally, a design is not new if it:

- Has been registered;
- Has been published anywhere in the world, in respect of the same or any other article; or

- Differs only in immaterial details, or features, from other designs that are commonly found in trade.

2. The Design must be industrially applied onto an article – The registered design has to be applied to an article by an industrial process. This means that more than 50 copies of the article must have been or are intended to be produced for sale or hire.

Designs that cannot be registered

Under the Registered Designs Act and Rules, the following cannot be registered:

- Designs that is contrary to public order or morality.
- Computer programmes or layout designs of integrated circuits.
- Designs applied to certain articles; such as wall plaques, medals and medallions, and printed matter primarily of a literary or artistic character (e.g. calendars, certificates, coupons, greeting cards, leaflets, maps, playing cards, postcards, stamps, and similar articles).
- Methods or principles of construction.
- Designs that is solely functional.
- Designs that is dependent upon the appearance of another article, of which it is intended by the designer to form an integral part of another article, so that either article may perform its function.

Copyright

Copyright protects works like novels, computer programmes, plays, sheet music and paintings. Generally, the author of a copyright work has the right to reproduce, publish, perform, communicate and adapt his work. These exclusive rights form the bundle of rights that we call copyright and enable the owner to control the commercial exploitation of his work.

What is protected by copyright?

Copyright protects the expression of ideas (e.g. words and illustrations). Ideas alone are not protected.

The following may be protected under copyright law:

- Literary works (e.g., written works, source codes of computer programs)
- Dramatic works (e.g.,. scripts for films and dramas)
- Musical works (e.g., melodies)
- Artistic works (e.g., paintings, photographs)
- Published editions of the above works
- Sound recordings
- Films
- Television and radio broadcasts
- Cable programmes
- Performances

What is not protected by copyright?

Subject matter not protected by copyright include:

- Ideas or concepts
- Discoveries
- Procedures
- Methods
- Works or other subject matter that have not be made in a tangible form in a recording or writing
- Subject matter that is not of original authorship

Traditional Knowledge

Traditional knowledge (TK) is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.

Traditional knowledge can be found in a wide variety of contexts, including: agricultural, scientific, technical, ecological and medicinal knowledge as well as biodiversity-related knowledge.

Traditional knowledge and intellectual property

Innovations based on TK may benefit from patent, trademark, and geographical indication protection, or be protected as a trade secret or confidential information. However, traditional knowledge as such - knowledge that has ancient roots and is often oral - is not protected by conventional intellectual property systems. While the policy issues concerning TK are broad and diverse, the IP issues break down into two key themes:

Defensive protection

Defensive protection refers to a set of strategies to ensure that third parties do not gain illegitimate or unfounded IP rights over TK. These measures include the amendment of WIPO-administered patent systems (the International Patent Classification system and the Patent Cooperation Treaty Minimum Documentation). Some countries and communities are also developing TK databases that may be used as evidence of prior art to defeat a claim to a patent on such TK. WIPO has developed a toolkit to provide practical assistance to TK holders on documenting TK.

Positive protection

Two aspects of positive protection of TK by IP rights are being explored:

- Preventing unauthorized use, and
- Active exploitation of TK by the originating community itself.

Geographical indication

A geographical indication (GI) is a sign that identifies a product as originating from a particular location which gives that product a special quality or reputation or other characteristic. Well-known examples of GIs include Bordeaux (wine), Darjeeling (tea) and Tuscany (olive oil).

GIs that are not protected

It is important to note the following instances where a GI will not be protected:

- It is immoral or against public order;
- It is no longer in use or no longer protected in the country of origin;
- It has become the common name in Singapore for the goods or services which it identifies; [for wines and spirits] it has been used continuously for at least 10 years preceding 15 April 1994 or in good faith preceding that date;
- It is confusingly similar to a trade mark for which rights had been acquired before the GI is protected in its country of origin; or
- It is the name of a person or a predecessor in a particular business.

Importance of Intellectual Property Rights

The intellectual property rights were essentially recognized and accepted all over the world due to some very important reasons. Some of the reasons for accepting these rights are:-

a) To provide incentive to the individual for new creations.

b) Providing due recognition to the creators and inventors.
c) Ensuring material reward for intellectual property.
d) Ensuring the availability of the genuine and original products

Patentability

Within the context of a national or multilateral body of law, an invention is patentable if it meets the relevant legal conditions to be granted a patent. By extension, patentability also refers to the substantive conditions that must be met for a patent to be held valid.

Patentable

Patentable, statutory or patent-eligible subject matter is subject matter, which is susceptible of patent protection. The laws or patent practices of many countries provide that certain subject matter is excluded from patentability, even if the invention is novel and non-obvious. Together with novelty, inventive step or nonobviousness, utility, and industrial applicability, the question of whether a particular subject matter is patentable is one of the substantive requirements for patentability.

Not patentable:-

1. An invention, that is frivolous or that claims anything obviously contrary to well established natural laws;
2. An invention, the primary or intended use of which would be contrary to law or morality or injurious to public health;
3. The mere discovery of a scientific principle or the formulation of an abstract theory;
4. The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;
5. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
6. The mere arrangement or rearrangement or duplication of known devices, each functioning independently of one another in a known way;
7. A method of agriculture or horticulture;
8. Inventions relating to atomic energy.
9. Any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or animals.
10. Plants and animals in whole or any part thereof other than microorganisms.
11. Mathematical or business method or a computer program per se or algorithms.
12. Literary, dramatic, musical or artistic works, cinematographic works, television productions and any other aesthetic creations.
13. Mere scheme or rule or method of performing mental act or playing game.
14. Presentation of information.
15. Topography of integrated circuits.
16. An invention, which in effect, is traditional knowledge or is based on the properties of traditional knowledge.

Patents on Life

Patents are government guarantees that provide an inventor with exclusive rights to use, sell or manufacture an invention for a set period of time. A patent is usually granted for 20 years. Patents should be granted only to human inventions, not discoveries. Existing living organisms -

plants and animals as well as their genes - are no-one's invention and should therefore never be patented and put under private control.

However, over the past decades patents on plants and animals as well as genes and parts of human bodies have been repeatedly granted by the patent offices of industrialised countries. Patenting of GE organisms allows industry to take control of and exploit common organisms and genetic material as exclusive private property that can be sold to or withheld from farmers, breeders, scientists and doctors. Technology agreements and fees on seeds, facilitated by patents, deprive farmers of their generations-old right to freely replant and exchange their seeds.

Vast, unsubstantiated patent claims on DNA also deter scientists from research in areas that have already been claimed by big companies with large legal budgets.

Patents for biological inventions

Patents are not available for gene sequences, DNA, RNA or nucleic acid sequences that replicate the genetic information that exists in any human's or in any other organism's DNA blueprint or genome. This is regardless of whether the genetic material was isolated or man made.

A standard patent can be obtained for isolated bacteria, cell lines, hybridomas, some related biological materials and their use, and genetically manipulated organisms. Examples of patentable inventions include:

- Isolated Bacteria And Other Prokaryotes, Fungi (Including Yeast), Algae, Protozoa, Plasmids, Viruses, Prions
- Cell Lines, Cell Organelles, Hybridomas
- Genetic Vectors And Expression Systems
- Apparatus Or Processes For Enzymology Or Microbiology
- Compositions Of Micro-Organisms Or Enzymes
- Propagating, Preserving Or Maintaining Micro-Organisms
- Mutagenesis Or Genetic Engineering
- Fermentation Or Enzyme Using Processes To Synthesise A Desired Compound Or Composition
- Measuring Or Testing Processes Involving Enzymes Or Micro-Organisms
- Processes Using Enzymes Or Micro-Organisms To Liberate, Separate, Purify Or Clean
- The Use Of Micro-Organisms To Produce Food Or Beverages.

Patents for genetic modification or manipulation

A standard patent can also be obtained for inventions involving:

- Genotypically or phenotypically modified living organisms, for example, genetically modified bacteria, plants and non-human organisms (patenting of plant varieties is described in Plant Breeder's Rights)
- Isolated polypeptides and proteins.
- Examples of patentable inventions include:
- Synthetic DNA or nucleic acid sequences only where the genetic information does not exist in any human's or in any other organism's DNA blueprint or genome.
- An isolated protein expressed by a gene
- Vectors (such as plasmids or bacteriophage vectors or viruses) containing a transgene
- Methods of transformation using a gene
- Host cells carrying a transgene
- Higher plants or animals carrying a transgene

- Organisms for expression of a protein from a transgene
- General recombinant DNA methods such as PCR and expression systems.

Patents for DNA or gene sequences

Human beings and the biological processes for their generation are not patentable. Patents are not available for gene sequences, DNA, RNA or nucleic acid sequences that replicate the genetic information that exists in any human's or in any other organism's DNA blueprint or genome. This is regardless of whether the genetic material was isolated or man made.

Although standard patents can be obtained for biological material such as micro-organisms, peptides and organelles, this material is only patentable if it has been isolated from its natural environment, or has been synthetically or recombinantly produced.

Patent specifications must also describe a specific use for a biological material. For example, although patents are not provided for genes, if the specification discloses a specific use for the gene, such as its use in the diagnosis or treatment of a specific disease, or its use in a specific enzymatic reaction or industrial process, then patent protection is available for methods of using the gene.
Standard patents as they apply to biological inventions

The usual requirements for a standard patent must also be met. There are also specific description requirements for microbiological inventions:

- Involves the intervention of a technologist to produce something that differs in some way from the natural source material. A patent cannot be granted for biological materials in their natural environment. For example, a biologically pure culture of a naturally occurring microorganism or the isolation and cultivation of a naturally occurring microorganism would satisfy the requirement for technical intervention.
- Is new in the sense of not previously being publicly available. A patent cannot be granted for subject matter that has previously been made publicly available.
- Is inventive when compared to the prior art.
- Has been fully described in the sense that sufficient information is provided to allow someone to make the product or perform the process.
- Has a demonstrated use. A patent cannot be granted for a mere discovery. The use to which the invention is to be put (for example: for the treatment of diseases such as cancer or multiple sclerosis) must also be fully described. There must be an actual use for an invention rather than speculation as to future uses.

WIPO

The World Intellectual Property Organization (WIPO) is one of the 17 specialized agencies of the United Nations. WIPO was created in 1967 "to encourage creative activity, to promote the protection of intellectual property throughout the world."
WIPO currently has 188 member states, administers 26 international treaties, and is headquartered in Geneva, Switzerland. The current Director-General of WIPO is Francis Gurry, who took office on October 1, 2008.

World Intellectual Property Organisation (WIPO) carries out a wide variety of tasks related to the protection of IP rights. These include assisting governments and organizations to develop the policies, structures and skills needed to harness the potential of IP for economic development; working with Member States to develop international IP law; administering treaties; running global

registration systems for trademarks, industrial designs and appellations of origin and a filing system for patents; delivering dispute resolution services; and providing a forum for informed debate and for the exchange of expertise.

Basically the Convention Establishing the World Intellectual Property Organization (WIPO), concluded about categorization that "intellectual property shall include rights relating to:

1. Literary, artistic and scientific works,
2. Performances of performing artists, phonograms and broadcasts,
3. Inventions in all fields of human endeavor,
4. Scientific discoveries,
5. Industrial designs,
6. Trademarks, service marks and commercial names and designations,
7. Protection against unfair competition

Intellectual property rights – systems in India

Copyright

India is a signatory to the Berne Convention on copyright. However, it may be a good idea to register your copyright as doing so may help to prove ownership if there are criminal proceedings against infringers. In most cases though, registration is not necessary to maintain a copyright infringement claim in India. Registration is made, in person or via a representative, with the Copyright Office. Since 2016, copyright policy was moved to India's Ministry of Commerce and Industry. All IPRs are now administered by the Department for Industrial Property and Promotion (DIPP).

Internet piracy of films, music, games and software is an issue in India, as is unauthorised copying of physical books.

Patents

India's Patents Act of 1970, 2003 Patent Rules and the 2016 Patent Amendment Rules set out the law concerning patents. As in the UK, there is no provision for utility model patents.

The regulatory authority for patents is the Patent Registrar under the office of the Controller General of Patents, Designs and Trade Marks, which is part of India's Ministry of Commerce and Industry. Patents are valid for 20 years from the date of filing an application, subject to an annual renewal fee.

India's patent law operates under the 'first to file' principle – that is, if two people apply for a patent on an identical invention, the first one to file the application will be awarded the patent.

Designs

The laws governing designs are the Designs Act 2000 and the Designs Rules 2001. Designs are valid for a maximum of ten years, renewable for a further five years.

Trademarks

India's trademark laws consist of the 1999 Trade Marks Act and the Trade Marks Rules of 2002 and 2017. The regulatory authority for patents is the Controller General of Patents, Designs and Trade Marks under the Department of Industrial Policy and Promotion. The police now have more robust powers in enforcing trademark law, including the ability to search premises and seize goods suspected of being counterfeit without a warrant. But these powers are tempered by the requirement for the police to seek the Trade Mark Registrar's opinion on the registration of the

mark before taking action. This adds to the delay and may result in counterfeit goods being removed or sold.

Trade names also constitute a form of trademark in India, with protection, irrespective of existing trade names, for those wishing to trade under their own surname.

Because of the widespread practice of 'cybersquatting' – the registration in bad faith of marks by third parties registering domain names for certain well known marks in order to sell them to the original rights owners – it is advisable for rights owners to register their domain names in India as trade marks as soon as possible.

Registration takes up to two years. A trademark in India is valid for ten years and can be renewed thereafter indefinitely for further ten-year periods.

Registering and enforcing intellectual property rights in India

To enjoy most types of intellectual property (IP) rights in India, you should register them.

For patents, individual registrations must be made in India, but for rights other than industrial designs you can apply under the terms of the Patent Cooperation Treaty, which is usually easier and quicker.

For trademarks, you should register them within India, either through the domestic trade mark system or under the Madrid system.

For copyright, no registration is required but registering copyrights with the copyright authorities is advisable.

'Priority rights' under the Paris Convention can help in the local registration of trade marks, designs and patents by allowing rights previously registered elsewhere to become effective in India, if filed within a time limit.

Where to get intellectual property help in India

Whether you're resident in and doing business in India, or trading internationally with the country, there are a number of professional organisations that can offer you advice and support:

- The British High Commission, New Delhi offers advice on working with India, including details of cultural relations. It provides a full range of diplomatic, consular and business-related services: https://www.gov.uk/government/world/organisations/british-high-commission-new-delhi
- The UK India Business Council (UKIBC) helps and supports British businesses with regard to trade with India: http://www.ukibc.com
- The Department for International Trade (DIT) India has a range of online information on doing business in India: https://www.gov.uk/government/world/organisations/department-for-international-trade-india
- Local law firms in India can offer you legal advice and services specific to your business. The Chambers and Partners website offers a search facility listing Indian local law firms: http://www.chambersandpartners.com/Asia/Search/Location/110

Intellectual Property Rights (Biotechnology)

Biotechnology intellectual property rights is the legal ownership of an interest in a patent, trademark or trade secret. This means that another company cannot use those assets without permission of the company established as the official owner. In health care, intellectual property

rights give their owners exclusive use of pharmaceuticals, brand names and more. Intellectual property rights are often the primary driver of value for these companies, particularly in biotech.

Biotechnology intellectual property rights provide health care companies with a means to protect their claim to and ownership of these assets through common law, state law or federal law. There is some controversy over intellectual property rights in biotechnology. Those in favor argue that they provide a key incentive for developers to innovate, because these protections will allow them to be financially rewarded for successful innovations. Those opposed to the strict enforcement of these protections argue that broader sharing of information would reduce prices and increase access to care, especially in developing countries.

Intellectual property rights—biotechnology examples

Here is one example of how intellectual property rights work in the health care industry. Federal protection allows companies to use the ® symbol with a trade name to indicate that it has a registered trademark and that no one else can use that name. More than one company may sell the same chemical compound, which means the same drug, but only one company can legally use the trademarked name to market that drug.

For example, while many companies sell the antidepressant drug fluoxetine hydrochloride, only Eli Lilly can call it Prozac. Likewise, only Roche can use the trademarked name Tamiflu to market a drug called Oseltamivir that is designed to prevent and treat influenza. Trademarks aren't just used with drugs, however; they're also used with hospital names, physician practice names and other entities with distinct branding. This is of major importance to companies in this business environment, where branding, marketing and images are central components of business operations and strategic positioning.

As another example, biotechnology companies use patents to protect their intellectual property rights to drug delivery devices. AstraZeneca owns the intellectual property rights to the Symbicort Turbuhaler, which is the drug budesonide/formoterol in a dry powder inhaler for the maintenance treatment of asthma and COPD. Other health care companies use patents to protect their intellectual property rights to devices such as splints, prostheses, vision testing machines and the computer systems used in health care management.

Gene Patenting:

Although patents have been granted on nucleotide sequences for >30 years, there has been much recent controversy surrounding the patenting of genes. Genome sequencing initiatives coupled with improved techniques for identifying and sequencing genes, has resulted in an exponential increase in the number of gene patents in the last decade.

As a result, the obscure world of gene patenting is now being scrutinized closely in many different sectors, not least because the effect of these patents is felt in everyday life, especially healthcare. For example, in Europe, a European Parliament resolution regarding the patenting of BRCA 1 and BRCA 2 (breast cancer associated) genes was passed calling on the EPO (European Patent Office) to ensure that all patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment.

The resolution identified two European patents related to BRCA 1 and BRCA 2 and asked that an official objection be filed against these patents. The importance of intellectual property in India is well established at all levels- statutory, administrative and judicial. India ratified the agreement establishing the World Trade Organisation (WTO). This Agreement, inter-alia, contains an

Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which came into force from 1st January 1995.

Patenting of Life Forms and GMO:

Life forms such as microorganisms, plants and animals, are not patentable in India under the provisions Indian patent Act (1970). However, patent can be obtained for various biotechnological processes and product applications within the scope of International conventions. In America, Europe and other developed countries, microorganisms isolated from nature or are obtained by simple manipulations are not patentable. But microorganisms obtained by novel techniques like genetic engineering are patentable.

The first patent of GMO (Genetically Modified Organisms) was allowed by US Supreme Court in 1980 as described in utility patent. A maize plant over producing tryptophan amino acid was patented in USA in 1985. This was beginning of patenting of high organisms for patenting. For animals, a patent was granted in 1988 for 'oncomouse', genetically modified mouse in USA.

In USA, non-naturally occurring non-human multi-cellular organisms are now considered patentable by US patent and trademark office. This clearly excludes humans and human parts. There is long debate about patenting of life forms including GMO and several organizations and religious groups are opposing the patenting of these life forms.

Copyrights:

India's copyright law, laid down in the Indian Copyright Act, 1957 as amended by Copyright (Amendment) Act, 1999, fully reflects the Berne Convention on Copyrights, to which India is a party. Additionally, India is party to the Geneva Convention for the Protection of rights of Producers of Phonograms and to the Universal Copyright Convention. India is also an active member of the World Intellectual Property Organisation (WIPO), Geneva and UNESCO.

The copyright law has been amended periodically to keep pace with changing requirements. The recent amendment to the copyright law, which came into force in May 1995, has ushered in comprehensive changes and brought the copyright law in line with the developments in satellite broadcasting, computer software and digital technology. The amended law has made provisions for the first time, to protect performer's rights as envisaged in the Rome Convention.

Trade Secrets:

Trade secrets often include private proprietary information that allows a definite advantage to the owner. This can be illustrated by the popular example of Coca-Cola brand syrup formula which is not known publically under trade-secret.

Trade secrets in the area of biotechnology may include material like:

I. Hybridization conditions
II. Cell lines
III. Corporate merchandising plan or
IV. Customer lists.

Unlike patents, trade secrets have an unlimited duration and therefore may not be required to satisfy the more difficult conditions laid down for patent applications. Disclosure of a trade secret and its unauthorized use can be punished by the court and the owner may be allowed compensation. However if a trade secret becomes public knowledge by independent discovering or other means, it is no longer protectable.

Case study: the Iguana Management Programme

The Green Iguana Iguana iguana of Latin America is a highly prized source of meat and eggs. Green Iguanas are arboreal herbivores which can grow up to 2m in length and can weigh as much as 6kg (about 82% of the lizard is edible). They need about half as much food as a chicken or rabbit

to produce the same amount of meat. The species is now widely threatened because of excess hunting and habitat destruction.

Research into the reproductive behavior of the Green Iguana was begun in 1983 and resulted in development of new management techniques for ranching. A 'genetic brood stock' of adult iguanas which are larger, faster growing and more productive has been developed. The research has largely been the work of the Pro Iguana Verde Foundation (formed by Dagmar Werner in 1985). The Foundation's programme for training and advice on Iguana ranching is called the Iguana Management Programme (IMP). The IMP is based in Costa Rica but it is intended to implement it throughout Latin America and possibly elsewhere.

The primary purpose of the IMP is to conserve living natural resources; its basic premise is that if farmers can raise iguanas as a food crop, the status of the wild species will be improved and forest clearance might be reduced. Farmers adopting iguana ranching would have to protect or re-establish areas of forest to provide food for stock. Research indicates that meat production per hectare by iguanas is approximately three times higher than by cattle. Income can be derived from selling iguanas and their products (meat, eggs, leather) and products from the forest.

The new technology and expertise which have been incorporated into an iguana ranching model are being applied for an industrial purpose (i.e. agriculture) and are of commercial value; they thus fall within the area of intellectual property law as applied to biotechnology. The biotechnological components of the ranching model are the genetic brood stock (the Fundacion has 'bioengineered' an improved stock of Green Iguanas) and the husbandry procedures (egg laying and incubation, nutrition, disease control, release and harvesting). These are forms of 'original or traditional biotechnology', as opposed to 'new biotechnology' which is largely laboratory-based and dependent upon human manipulation of genetic material.

Intellectual property rights provide the means for compensating the Fundacion for its efforts. The technologies involved in the IMP are vulnerable to piracy. Much of the work of the Fundacion is contained in the genetic make-up of the Genetic Brood Stock. Once these Iguanas are transferred or sold the Fundacion loses its direct control over the animals. In addition, the success of the Iguana ranching model is dependent on the expertise to use the technologies efficiently; this is information which took years to develop but which can be pirated very easily once a license is purchased. The Fundacion needs to be able to disseminate its innovations and expertise in the security of knowing that it cannot be re-sold by pirates and that there will be no reduction of the licensing potential. Only internationally recognized intellectual property law can provide these types of protection.

Because of the uncertainties of the world's intellectual laws with regard to biotechnology the availability of protection for the most important components of the IMP is questionable. At present there is widespread discrimination against the application of intellectual property rights to natural genetic materials and in favor of human-modified genetic materials. This provides no incentives for exploitation of useful genetic materials in the natural environment, even though in developing countries natural resources are obvious subjects for investment. However, one important way to limit conversion of natural resources is to ensure that fair value is paid for current uses of the existing resource base. Intellectual property rights could be a means of influencing developing countries to maintain and develop diverse resources in return for the value that these resources render to the world community.

UNIT –II

Type of Patent Applications

1. Ordinary Application, i.e., an Application which has been filed directly in the Indian Patent Office.
2. Convention Application.
3. PCT Application.
4. Divisional Application, which can result from division of a Patent Application.
5. Patent of Addition, which may be filed subsequent to the Filing of an Application for Patent, for an improvement or modification.

Filing of a patent application

A patent application shall be filed on Form-1 along with Provisional / Complete Specification, with the prescribed fee as given in First Schedule at an appropriate office. However, a provisional specification cannot be filed in case of a Convention Application (either directly or through PCT routes) (For further description of Provisional/Complete Specifications) Normal fee shall be applicable for applications containing up to thirty pages in specification and up to 10 claims. If the specification exceeds thirty pages or claims are more than ten in number, additional fee as given in First Schedule is payable.

Steps for e-filing of Patent Application

1. For using this Portal click on link ***'On-line Registration for New User'***
2. Complete On-line Registration process for getting User ID & Password.
3. Login to e-Patent portal after successful registration.
4. Download **Client Software** for preparing Patent Application(s) offline.
5. Complete the Patent Application offline and generate an XML file using **Client Software**.
6. After creating Application (XML) file offline, digitally sign the XML file (Max. file size permitted 15 MB) for uploading to the IPO Server.
7. Login to e-Patent portal for uploading Application XML file on IPO Server.
8. Upload & submit digitally signed XML file to IPO Server.
9. Process the Application for EFT (Electronic Fee Transaction).
10. Review Application Status on e-Patent Portal.
11. On successful EFT, acknowledgement details would be displayed/ generated.
12. Print the Acknowledgement.
13. Detailed user manual in pdf format is uploaded on the official website where Certifying Authority, Authorised Bank, Prerequisites of e-filing, Procedure and guidelines of e-filing of Patent Applications are described in detail.

Filing of a patent application

A patent application shall be filed on Form-1 along with Provisional / Complete Specification, with the prescribed fee as given in First Schedule at an appropriate office. However, a provisional specification cannot be filed in case of a Convention Application (either directly or through PCT routes) Normal fee shall be applicable for applications containing up to thirty pages in specification and up to 10 claims. If the specification exceeds thirty pages or claims are more than ten in number, additional fee as given in First Schedule is payable.

Patent Cooperation Treaty (PCT)

The PCT is an international treaty with more than 145 Contracting States.1 The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent Offices in what is called the "national phase".

PCT procedure:

Filing: you file an international application with a national or regional patent Office or WIPO, complying with the PCT formality requirements, in one language, and you pay one set of fees.

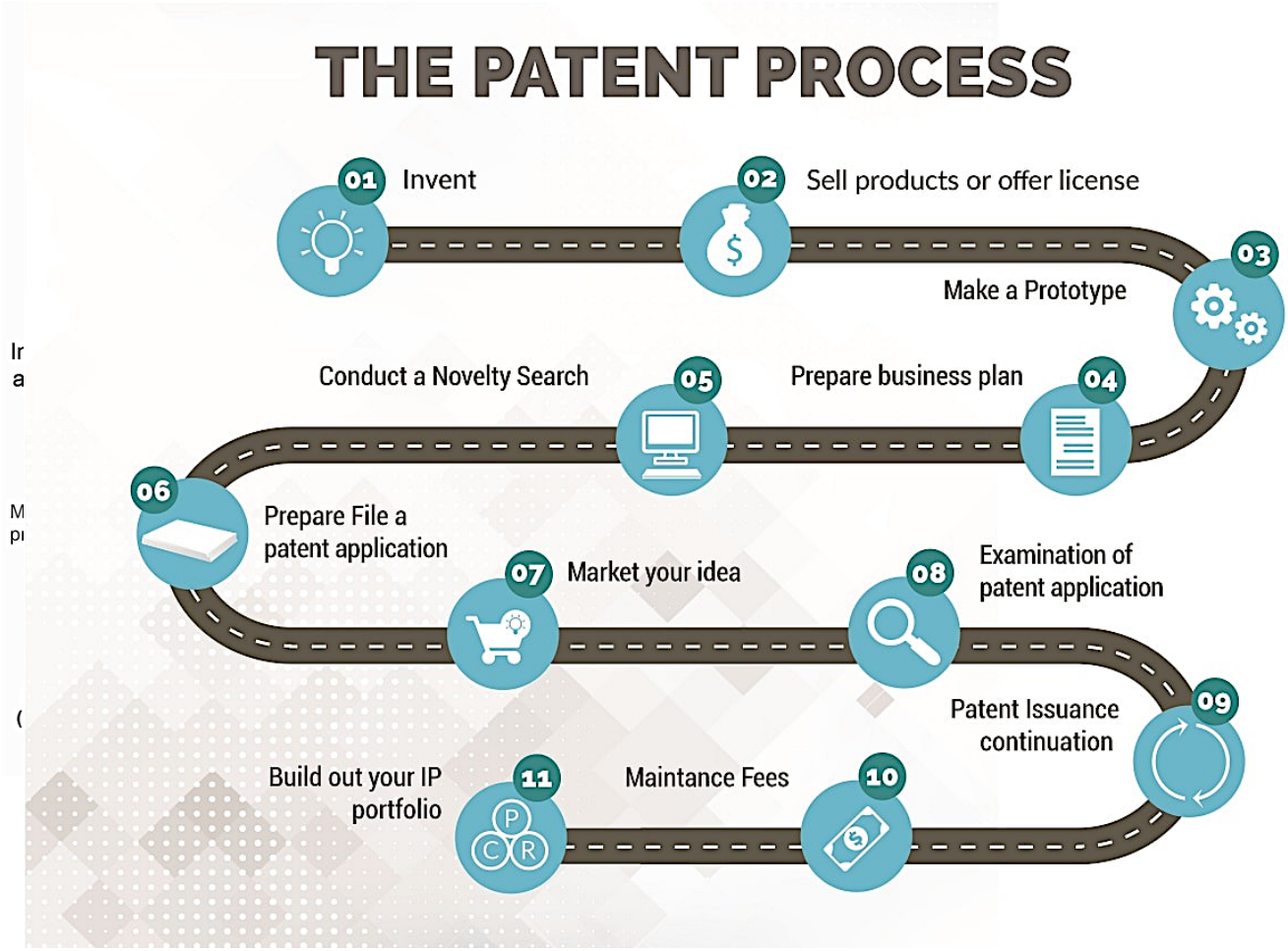
International Search: an "International Searching Authority" (ISA) (one of the world's major patent Offices) identifies the published patent documents and technical literature ("prior art") which may have an influence on whether your invention is patentable, and establishes a written opinion on your invention's potential patentability.

International Publication: as soon as possible after the expiration of 18 months from the earliest filing date, the content of your international application is disclosed to the world.

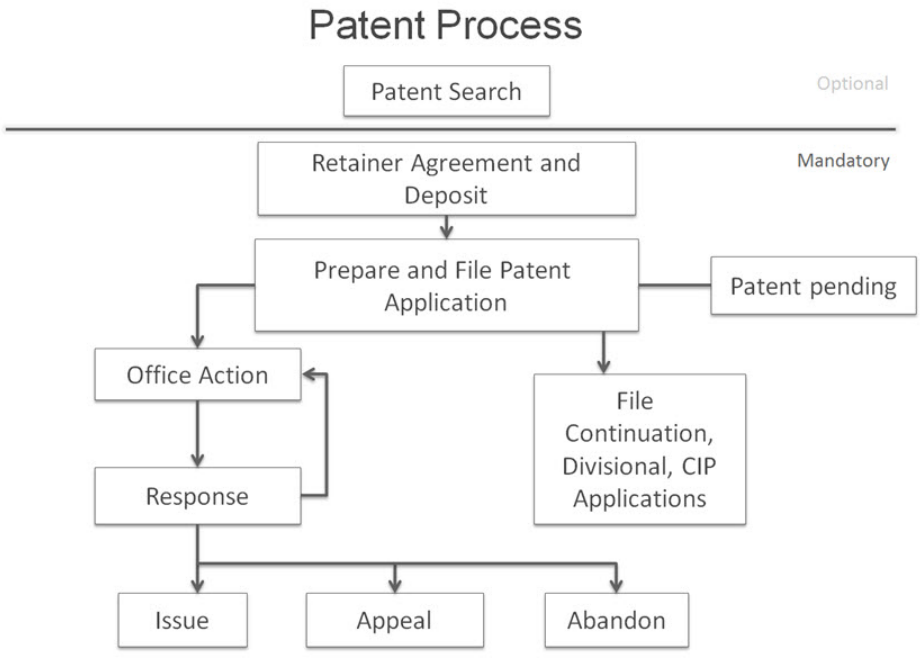
Supplementary International Search (optional): a second ISA identifies, at your request, published documents which may not have been found by the first ISA which carried out the main search because of the diversity of prior art in different languages and different technical fields.

International Preliminary Examination (optional): one of the ISAs at your request, carries out an additional patentability analysis, usually on an amended version of your application.

National Phase: after the end of the PCT procedure, usually at 30 months from the earliest filing date of your initial application, from which you claim priority, you start to pursue the grant of your patents directly before the national (or regional) patent Offices of the countries in which you want to obtain them.



The patent process timeline may be drawn out and expenses incurred over and above the cost of preparing and filing the patent application. The discussion below is directed to the typical life cycle of a normal patent application.



The overall patent process timeline begins with a patent search. It is an optional step and you need not conduct a formal patent search. However, there are advantages in conducting an informal Do-it-Yourself patent search. (Click here for DIY patent search instructions from the USPTO). The reason is that the cost of conducting a formal patent search through a patent search firm may outweigh its benefits as discussed below.

After the patent search, the next step is to file a patent application with the United States Patent and Trademark Office. Upon filing the patent application, your product is now **patent pending**. Some refer to this stage as being **patent protected** but the phrase "patent protected" is misleading. The product is patent pending but not patent protected in its fullest sense. The product is protected in that the filing date of the patent application prevents others from learning of your idea through your marketing efforts and filing their own patent application on your idea. The reason is that any third party filing will be junior to your first filed patent application. As such, your idea is patent protected in the sense of its pendency. By no means does patent pendency provide any sort of **enforceable rights** to stop others from marketing your idea in the marketplace. For that, you would have to wait till your patent application matures into a patent.

If your first filed patent application was filed as a provisional patent application then a follow up non-provisional patent application must be filed within one year. If the patent application was filed as a non-provisional patent application, then it has entered the queue for examination. Examination is typically based on a first come, first served basis. Normally, utility patent application are examined within **about 1-3 years** depending on the then current backlog at the Patent Office and the art unit your patent application is assigned to by the Patent Office.

The 1-3 year time period you have to wait for your patent application to be examined can be cut down to a time period of about 6 months by filing a prioritized examination request. This is a pure pay-to-play system. The prioritized examination moves your patent application from the back of the line to the front. If the issuance of the patent is important to potential investments, sales, enforcement strategy or other business purpose, then prioritized examination is a great tool to expedite examination, and hopefully, issuance of a patent. If one of the inventors is over 65, then the examination process can also be accelerated by filing a petition based on the inventor's age. Otherwise, in my opinion, waiting and redirecting the fee you would have spent on prioritized examination to marketing or product development may be more useful.

Once your patent application is examined, the Patent Office will mail an office action. The office action is simply the official stance of the patent office on whether they will grant or deny one or more claims in the patent application. This is the merely the initial opinion of the Patent

Office. The patent attorney's role is to convince the examiner that the claims are patentable by amending the claims and providing arguments to support patentability of your invention. Most patent applications at the Patent Office are initially rejected. Hence, the mere rejection of the claims of the patent application is not a good indicator of how prosecution will go for the patent application. Instead, it is better to take a substantive review of the cited prior art references and have a discussion as to whether the examiner cited relevant or art that would be easy to overcome. A patent attorney responds to the office action by preparing claim amendments and arguments in support of patentability.The **office action and response cycle** is should be completed at least once or twice to get a good feel for the examiner's stance on the matter. If successful, then a patent is issued and you may at that point enforce your patent against your competitors. If unsuccessful, then an appeal can be made to the Patent Trial and Appeal Board (PTAB). If marketing of the product is not doing well, then you can always abandon the patent application without incurring any further costs.

Throughout the entire pendency of the patent application, all persons involved in the patent application have a **duty to disclose** relevant information that might cause the examiner to reject the patent application through an information disclosure statement.

Overall, the patent process timeline is a **long drawn out process** which can be shortened by petition. Moreover, the costs associated with the patent process does not end with the filing of the patent application. There are other **downstream costs** due to further communications between the patent attorney, the patent office and the client.

I invite you to contact me with your patent questions at (949) 433-0900. Please feel free to forward this article to your friends. As an Orange County Patent Attorney, I serve Orange County, Irvine, Los Angeles, San Diego and surrounding cities.

License Agreement

This License Agreement is made on [AGREEMENT DATE][(the "Effective Date")] between [PARTY A NAME], [whose principal place of residence is at / a [CORPORATE JURISDICTION] corporation with its principal place of business at [PARTY A ADDRESS]] (the "[PARTY A ABBREVIATION]") and [PARTY B NAME], [whose principal place of residence is at / a [CORPORATE JURISDICTION] corporation with its principal place of business at] [PARTY B ADDRESS]] (the "[PARTY B ABBREVIATION]").

The parties agree as follows (the capitalized terms used in this agreement, in addition to those above, being defined in section [DEFINITIONS]).

Grant of License

Exclusive Grant. The Licensor grants to the Licensee an exclusive, non-transferable license to develop and commercialize the Licensed Products, market and sell Licensed Products anywhere in the Licensed Territory, and sub-license the Licensed Patents, in accordance with the terms of this agreement.

Licensee's Use of Licensed Patents. The Licensee shall use the Licensed Patents only in accordance with this agreement.

Reservation of Rights. Any rights not expressly granted to the Licensee in this agreement are reserved to the Licensor. The Licensee does not acquire any interest other than the rights to the Licensed Patents granted under this agreement.

Royalties. In exchange for the [DELIVERABLE], [PARTY B] shall pay [PARTY A] the Royalties Fees, and down payment, according to section [PAYMENT OF ROYALTIES].

Payment of Royalties Fees

Down Payment. On the Effective Date, [PARTY B] shall pay [PARTY A] a down payment of $[DOWN PAYMENT AMOUNT].

Registration and Maintenance of Intellectual Property

Registration and Maintenance Efforts. shall use reasonable efforts to register and maintain the registration of the Licensed Intellectual Property.

Development and Commercialization

Confidentiality Obligations. The parties shall continue to be bound by the terms of the non-disclosure agreement between the parties, dated [DATE] and attached to this agreement on [ATTACHMENT].

Patent Markings. [PARTY B] shall mark all Licensed Goods and containers of Licensed Goods in accordance with applicable patent marking Laws.

Use of Name. Neither party will use the other party's name, logos, trademarks, or other marks without that party's written consent.

Export Compliance. [PARTY B] shall be solely responsible for obtaining all licenses, Permits or authorizations as required from time to time by the United States and any other government for any export.

Insurance National Phase Patent Application in India – Procedure:

Publication: Every patent application is published after 18 months from the date of filing or priority. Once published, the application is deemed to have entered the public domain.

Request for Examination: An Applicant should file Request For Examination (RFE) within 48 months from priority date filing. The application is taken up for examination in the chronological

order of RFE filing. Within a period of 3 months, the examiner establishes the examination report. The Controller forwards the report (also known as First Examination Report, FER) to the applicant or his agent. Further, the applicant has to comply with the requirements imposed on him within a period of 6 months from the date on which the FER is forwarded to him, else the application is deemed to have been abandoned.

Grant of Patent:

The Patent is granted as expeditiously as possible when the application has not been refused by the Controller, or the application has not been found to be in contravention of any of the provisions of the Patent Act.

PCT Fees:

The official fee for filing a PCT application and request for examination would be minimum US$470 for a large entity, but only US$94 for a small entity, and it varies depending on the number of pages and claims. Further, to know more about PCT patent application filing services, you may read PCT Application Filing in India.

Exclusive Patent License Agreement

An exclusive patent license agreement affords a single licensee (business) the rights to manufacture and sell a government invention for any commercial application worldwide.

Partially-exclusive Patent License Agreement

A partially-exclusive license allows multiple companies to obtain rights to manufacture and sell a government invention but only in certain, specified commercial applications or in certain, defined geographic locations.

Non-exclusive Patent License Agreement

Non-exclusive licenses can allow any number of companies to obtain the same government technology and use it in many different products or commercial applications and make it for sale in many different geographic locations.

What Is a Patent Disclosure?

A patent disclosure is a public claim of data about an invention. In general, it is any part of the patenting process in which data regarding an invention is disclosed. A good disclosure tells someone else how to create the product.

Why Is a Patent Disclosure Important?

The U.S. Constitution gives Congress the right to offer exclusive rights to people for their inventions for set periods of time. This is only if and when the inventor agrees to adequately disclose the invention in writing.

A formal patent disclosure is used by people who are involved in preparing a patent application, such as inventors and attorneys. It stipulates a set of claims regarding the invention, as well as other data that reveals the unique nature of the product. It should be expressed in writing with the United States Patent and Trademark Office (USPTO) as part of the patent application.

Formal patent disclosures done successfully with the USPTO can result in several advantages for the inventor:

- Investments
- Competitive advantage
- Market share

Disclosure and confidentiality

This section is in some sense a preliminary to **Part 5: Protecting your idea** . The dangers of disclosure are real, and need to be taken seriously as soon as you start thinking about your invention. But it is important to understand that **protecting your idea against disclosure** is not quite the same as **protecting your idea against infringement**.

Protecting your idea against disclosure depends largely on your own common-sense measures, which you should take from the day you first think of your idea. Protecting your idea against infringement depends largely on the correct use of formal legal procedures **when the time is right to use them**. This is why Parts 1-4 precede Part 5!

(An exception is **Part 5** > **Confidential information and non-disclosure agreements**, which it may be helpful to read in conjunction with this section.)

Assessing the risk of disclosure

Disclosing an idea without adequate legal protection is always dangerous. The main risks are:

- Someone may use knowledge of your idea for their own gain - which usually means your loss.
- Disclosure **now** may prevent you from obtaining a worthwhile patent **later**.

In the very earliest stages of an idea, the problem for many inventors is twofold:

- It is usually inadvisable to apply too early for a patent. The timing of a patent application can be critical - see **Part 5** > **The patenting process**.
- Yet in order to make progress with an invention, some disclosure may be unavoidable.

How then should you protect your idea in the early stages of its development?

Disclosure risks fall broadly into two categories:

- **Disclosure to individuals during private meetings:** This type of risk is controllable as long as you take a few basic precautions, detailed below.
- **Public disclosure**: The dangers here are less obvious. Particularly problematic areas are:

- **Media publicity** and **competitions**. Both may be useful **after** you have legally protected your idea but definitely not before it.
- Inventions which originate as **student projects** - especially if there is a requirement to exhibit or publish your work. Teaching staff often do not understand that any form of public display of an idea legally constitutes disclosure and can have serious consequences.

The **patent or invention non-disclosure agreement** is a Unilateral non-disclosure agreement (NDA) that is used to protect an invention. Due to the confidential nature of an unexecuted idea for a product, an NDA can be essential to the owner of the invention when they choose to disclose the ideas, business strategies, prototypes etc. to potential investors, developers and the like. Even owners of patented inventions can fall victim to damages of misappropriated data and it is recommended that an NDA is used before and after the patenting process. The disclosing party should have the receiving party sign the documentation first while clearly stating the confidential nature of the information at hand.

Patent infringement and Litigation

Patent infringement is the act of making, using, selling, or offering to sell a patented invention, or importing into the United States a product covered by a claim of a patent without the permission of the patent owner. Further, you may be considered to infringe a patent if you import items into the United States that are made by a patented method, unless the item is materially changed by subsequent processes or becomes a trivial and nonessential component of another product. A person “infringes” a patent by practicing each element of a patent claim with respect to one of these acts. Further, actively encouraging others to infringe patents, or supplying or importing components of a patented invention, and related acts can also give rise to liability in certain cases.

Indirect infringement

In certain jurisdictions, there is a particular case of patent infringement called "indirect infringement." Indirect infringement can occur, for instance, when a device is claimed in a patent and a third party supplies a product which can only be reasonably used to make the claimed device.

Many businesses believe that receiving a patent offers complete protection against infringement. However, when a patent is threatened, patent holders must take more drastic measures to protect their interests. Patent litigation includes legal actions to protect patents against infringement, and may result in monetary damages or an injunction against the infringement.

Patent Infringement Litigation: The Basics

Patent infringement occurs when another party makes, uses, or sells a patented item without the permission of the patent holder. The patent holder may choose to sue the infringing party to stop his or her activities, as well as to receive compensation for the unauthorized use. Since intellectual property is governed by federal law, the patent holder must sue the unauthorized party in federal district court.

Patent holders must bring infringement actions within six years from the date of infringement; if the suit is not brought in this time limit, it is time-barred, ratifying the infringement. While patent litigation proceeds much like any other federal case, the complicated legal issues surrounding patent validity and infringement are reserved for the court's determination, although some patent litigation cases use juries for other aspects of the overall case.

Defenses to a Patent Infringement Lawsuit

The alleged infringer typically counters the patent holder's suit by alleging that the patent is not valid. Patents are invalid if the holder included fraudulent information in the U.S. Patent and Trademark Office application; if the patent resulted from anticompetitive business activities; or if the alleged infringer can show that the patent did not meet the requirements of novelty and nonobviousness required for patent protection. Novelty requires that the invention be entirely new, while nonobviousness means that the invention cannot be a variation or an obvious improvement of an existing invention.

The patent holder bears the burden of proof to show that the defendant infringed the patent. The plaintiff must prove infringement by a preponderance of the evidence. This standard means that the greater weight of the evidence must show that the patent is infringed.

Different Types of Patent Infringement

There are different ways another party may infringe on your patent, including:

- **Direct Infringement:** This occurs when a product covered by a patent is manufactured without permission.
- **Indirect Infringement:** An indirect infringer may induce infringement by encouraging or aiding another in infringing a patent.
- **Contributory Infringement:** This occurs when a party supplies a direct infringer with a part that has no substantial non-infringing use.
- **Literal Infringement:** This exists if there is a direct correspondence between the words in the patent claims and the infringing device.

Patent Licensing

Patent licensing may come about in different ways, and patent licenses can be classified as exclusive or non-exclusive. A patent grants its owner the right to exclude others from practicing the patented invention, and it does not give the patent owner the right to practice the patented invention. Licenses should be understood in this context.

Exclusive license:

Under an exclusive license, a patent owner transfers all indicia of ownership to the licensee only retaining the title to the patent. From the point of view of the patent owner, he surrenders all rights under the patent (including the right to sue for infringement and the right to license) to the licensee. In essence, the licensee steps into the shoes of the patent owner and acquires the right to sub-license the patent and sue for patent infringement. However, the exclusivity can be limited by a field of use. That means that the licensee gets a promise from the patent owner that the patent will not be licensed to anyone else in a stipulated field of use.

Non-exclusive license:

By granting a non-exclusive license, the patent owner essentially promises not to sue the licensee for patent infringement. Some people think that by acquiring a non-exclusive license the licensee acquires the freedom to operate in the space protected by the licensed patent, but this may or may not be the case. It depends on whether or not the licensee's products infringe other patents.

GUIDELINES AND APPLICATION FORM FOR FINANCIAL ASSISTANCE FOR PATENTING IN INDIA

National Research Development Corporation gives financial assistance to scientists and researchers working in universities, R&D institutions and laboratories and also to individuals in scientific and industrial fields for patenting their inventions which are proved to be workable, advantageous, useful and commercially viable. Guidance for patenting matter is provided herewith.

1. Application for financial assistance (FA) for patenting must be submitted to NRDC on the requisite forms along with a non-refundable processing fee of ₹ 500 (only for individual applicants) through a DD in the favour of National Research Development Corporation payable at New Delhi.

2. FA for patenting is given to Indian National only for protecting inventions i.e. a new product of process involving an inventive step and capable of industrial application.

3. There is no bar to the number of cases for FA.

4. Decision of the Corporation is final in this regard and no further correspondence will be entertained.

5. FA for patenting is given normally to individuals working in Univertisities, Laboratories and R&D Institutes, Micro, Small and Medium Enterprises, etc.

6. Invention should be either an original product/process or an improvement on present product/process so as to increase utility of the product/process by enhancing consumer advantages like reducing cost/effort of the user/weight or volume, or by improving performance/accuracy/reliability/life/versatility etc. It is preferable that the invention should have been practically tried out and established.

7. If the inventor is employed, he should forward this application through his employer.

8. The invention may be referred, if necessary to outside experts working in Government organization, educational institutions or public organizations to solicit opinion. The patent office may also be consulted. While all possible care for the safety and secrecy of the inventions received will be taken, the Corporation will not be responsible for any loss or damage due to leakage of information pertaining to the invention. Inventors are advised to seek prior protection by filling provisional patents Under Patents Act 1970 as amended by the Patents (Amendment) Act 2002, Patent Rule 2003, Patents (Amendment) Rule 2005 and Patents (Amendment) Rule 2006.

9. FA shall not be granted if the subject matter of the inventions relates to the following as per Section 3 of Patents Act.

- An invention which is frivolous or contary to well established natural laws, e.g., perpetual motion machine.
- Invention's primary or intended use or commercial exploitation is contrary to law or morality or injurious to public health. e.g. any devices, apparatus or machine for theft, gambling apparatus or method for gambling, method of adulteration of food etc.
- Scientific theories or mathematical models.
- Substances obtained by a mere admixture e.g. a mixture of different types of medicament or medicine to cure multiple diseases.
- Mere arrangement or re-arrangement or duplication of known devices each functioning independently or one another in a known way. e.g. Fixing a fan under an umbrella.
- Method of Agriculture or Horticulture e.g. Method of cultivation of algae or Mushroom.
- Plant or animal varieties or essentially biological processes for the production of such plants or animal varieties, other than microbiological processes.
- Scheme, rules or methods such as those for doing business or a computer program per se, performing purely mental acts or playing games.
- Discoveries of materials or substance already existing in nature.
- Method of treatment of humans or animals or diagnostic method practiced on humans or animals. e.g. Method of treatment of malignant tumour cells, method of removal of dental plaque and carries.
- An invention, which in effect, is traditional knowledge or aggregation/duplication of known properties of traditionally known component(s).
- Inventions in the nuclear field (Section 4 of Patents Act).
- The disclosure of an invention has become part of prior art by a description of invention in a published writing or publication in other tangible forms (a document, manuscript, pictures including photographs, drawings or films etc.)
- A more scheme or rule or method of performing mental act or method of playing game.
- Topography of integrated circuit.
- An invention which in effect is traditional knowledge.
- Presentation of information

10. Financial assistance shall be granted only if your invention is new (novel), useful (industrially applicable) and non-obvious (exhibit a sufficient "Inventive Step") and the disclosure of the invention must meet certain standards.

- **Novelty :** An invention is new if there is any difference between the invention and current knowledge or the 'prior art'.

  An invention is considered to be new if it does not form part of the state of-the-art. The state-of-the-art is held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filling or priority date. An earlier disclosure is not prejudical, however, if it occurs no earlier than twelve months preceding the filing of the patent application to display at an official or officially recognized exhibition.

  Any disclosure of the invention before the date of filling, whether or not by the applicant himself, may be invoked against him as being comprised in the state-of-the-art.

- **Inventive step (non-obviousness) :** An invention will be considered as involving an inventive step if,having regard to the state-of-the-art, it is not obvious to a person skilled in the art. In other words, it must not be possible for an average expert to make the invention by mere routine work.

  Determining whether or not the invention involves an inventive step depends on the specific details of each patent application and in particular the subject-matter of each claim. According to the circumstances, various factors are taken into account, such as the unforeseen technical effect produced by a new combination of known elements, selection of particular operating conditions within a known range, the degree of difficulty the person skilled in the art must overcome when combining several known documents, and secondary considerations such as the fact that the invention solves a long standing technical problem for which there may have been many attempts to solve.

  Some examples of what may not be considered as inventive are: mere change of size; making portable; the reversal of part; the change of material; aggregation or mere substitution by an equivalent part of function. These are not considered to be inventive enough to merit a patent.

- **Industrial applicability (utility):** An invention must be capable of being made or used in some kind of industry. This means that the invention must take the practical form or an apparatus or device, a product such as some new material or substance or and industrial process or method of operation.

  An invention to be patentable must be useful or has some utility. The element of commercial or pecuniary success has no relation to the question of utility. However, where the improvement by reason of cheaper production, such a consideration is of

the every essence of the patent itself and the question is of thing claimed can not be considered an invention unless that condition is fulfilled.

If the invention gives the result as promised in the specification, objection on the ground of usefulness should fail. The usefulness of an alleged invention depends not on whether by following the directions in the complete specification all the results not necessary for commercial success can be obtained,but on whether by such directions the effect that the application/patentee professed to produce could be obtained.

The usefulness of the invention is to be judged by the reference to the state of things at the date of filing of the patent application. If the invention was then useful, the fact that subsequent improvement have replaced the patentable invention render it obsolete and commercially of no value, does not invalidate the patent.

- **Adequacy of disclosure:** An additional requirement of patentability is whether or not be invention is sufficiently disclosed in the application.

  It is therefore imperative that the description should disclose the invention in a manner sufficiently clear and complete for the invention to be evaluated, and to be carried out by a person having ordinary skill in the art.

  Specific operative embodiments or examples of the invention must be set out in the description. Examples and other descriptive passages should be of a scope sufficient to justify the scope of the claims. The claims must be clear and concise and fully supported by the description.

  There is a requirement that the application should relate to one invention only, or to a group on inventions so linked as to from a single general concept. This requirement, referred to as "Unity of Invention" is particularly important when claims are being drafted.

11. The applicant shall pay the patent annuity which becomes due at the time of grant and thereafter to keep the patent alive and enforceable.

The present schedule is as follows:

Annual Maintenance Fee				For Individual(s)	For Legal entities other than Individual(s)
Before expiration for	2nd year	In respect of	3rd year	₹ 500	₹ 2,000/
"	3rd year	"	4th year	₹ 500	₹ 2,000
"	4th year	"	5th year	₹ 500	₹ 2,000
"	5th year	"	6th year	₹ 500	₹ 2,000
"	6th year	"	7th year	₹ 1,500	₹ 6,000
"	7th year	"	8th year	₹ 1,500	₹ 6,000
"	8th year	"	9th year	₹ 1,500	₹ 6,000
"	9th year	"	10th year	₹ 1,500	₹ 6,000
"	10th year	"	11th year	₹ 3,000	₹ 12,000
"	11th year	"	12th year	₹ 3,000	₹ 12,000
"	12th year	"	13th year	₹ 3,000	₹ 12,000
"	13th year	"	14th year	₹ 3,000	₹ 12,000
"	14th year	"	15th year	₹ 3,000	₹ 12,000
"	15th year	"	16th year	₹ 5,000	₹ 20,000
"	16th year	"	17th year	₹ 5,000	₹ 20,000
"	17th year	"	18th year	₹ 5,000	₹ 20,000
"	18th year	"	19th year	₹ 5,000	₹ 20,000
"	19th year	"	20th year	₹ 5,000	₹ 20,000

* The patent annuity is to be paid every year or for the entire period.

12. The inventor should conduct an patent search, if possible before filing this application, to ascertain clearly the novelty aspect of the invention.

Suggested Website, for conducting patent search, are:

www.ipindia.nic.in; www.patinfo.nic.in

www.uspto.gov; www.wipo.int; www.epo.org;

For further information and any query, please contact:

Arunabha Pradhan
Chief (Promotional Programme)
Intellectual Property Consultancy and Management Division
National Research Development Corporation
[An Enterprise of DSIR, Ministry of Science & Technology, Govt. of India]
'Anusandhan Vikas' 20-22 Zamroodpur Community Centre,
Kailash Colony Extension,
New Delhi-110 048
Phone: 011-29240401-08 ext 439
Fax: 011- 29240409, 10
E mail: apradhan@nrdc.in, write2@nrdc.in
Visit us at www.nrdcindia.com to download Applicantion Form and Guidelines

INSTRUCTIONS FOR FILLING-UP OF APPLICATION FORM

General

(i) All relevant technical and other details and diagrams must be submitted in the application forms. Information asked should be correct and given in full.

(ii) Wherever annexures are attached separately, the annexure number should correspond to that of the item for which the annexure is being attached. For example, the additional information provided on separate sheet for item 2 pertaining to the particulars of the applicant should be labelled as Annexure-Item-2.

(iii) Wherever any date is to be filled it should be given in the format DD-MM-YY. For example 14th Feb. 1996 is given as 140296.

A. Title of invention (s.no. 1)

Invention title should be brief, concise, appropriate and reflective of the invention and should be composed within 120 characters.

B. Brief statement about subject area(s) to which the invention relates (s.no.2)

Under brief description the applicant should give the abstract of the invention, highlighting all the major essential features of the invention in not more than 250 words.

C. Particulars of inventor(s) (s.no. 3)

Name and addresses of all individuals responsible for the development should be indicated in S.No. 2. If inventors are more than 5, then the particulars of the remaining inventors may be put in the same format, on a separate sheet.

NAME: Leave one box blank after each word. For example, Prashant Kumar Tyagi should be written as:

P	R	A	S	H	A	N	T		K	U	M	A	R		T	Y	A	G	I

QUALIFICATIONS: Fill in the appropriate code for your highest qualification as per table given below:

Subject	Diploma	Bachelor	Master	M.Phil	Ph.D	Subjects	Diploma	Bachelor	Master	M.phil	Ph.D
Sciences	DO1	BO1	MO1	LO1	PO1	Medicine	DO5	BO5	MO5	LO5	PO5
Social Science	DO2	BO2	MO2	LO2	PO2	Pharmacy	DO6	BO6	MO6	LO16	PO6
Agriculture	DO3	BO3	MO3	LO3	PO3	Technology	DO7	BO7	MO7	LO7	PO7
Management	DO4	BO4	MO4	LO4	PO4	Others	DO8	BO8	MO8	LO8	PO8

D. Address of inventor (s.no. 4)

Address, Telephone No. and Fax No. of the First Inventor/Group Leader should be filled in the given boxes and that of the remaining inventors should be given on separate sheets in the same format. **Any change in address should be intimated immediately, so that, correspondence from NRDC is correctly addressed.**

E. Stage of development (S.no. 7)

Choose the appropriate code for the stage of development. See the 'Process' or 'Product' category according to your invention.

(a) Process

Stage of Development	Codes
Lab Scale	LS
Pilot Scale	PS
Semi Commercialized	SC
Commercialized	CO
Commercially Proven	CP

(b) Product

Stage of Development	Codes
Static Model	SM
Prototype	PR
Working Model	WM
Commercialized	CM
Commercially Proven	PN

F. Test status (s.no. 8)

Test Status	Codes
Not Tested	NT
Self Tested	ST
Tested by Govt. Agency	TG
Tested by Private Agency	TP
Tested by Industry	TI

Full details of the tests and quantitative data obtained during test should be provided.

G. Drawbacks in the existing state-of-the-art (s.no. 15)

Indicate the drawbacks in the existing state-of-the-art, which prompted the Inventor for the Invention.

H. Objectives of the invention (s.no. 19)

List the main objectives to be attained by the invention.

I. Advantages over all other known alternatives (s.no. 21)

Indicate the advantages in terms of reductions in capital cost, operating cost for the same performance.

Improved performance, productivity, robustness, reliability, safety, layout, service ability, range of applications, utility, directly or as an attachment may be labelled under the advantages.

J. Detailed description (s.no. 22)

It should be typed on one side of A4 size paper leaving left and right margins and should not exceed more than ten pages. The detailed description should give the specifications, performance characteristics, limitation, principle of design/construction, details of method of construction/process/manufacture etc. It should be supported by relevant drawing, diagrams and circuit details, as required.

In a complete disclosure, while the prior art setting may be mentioned in general terms in the description, the essential novelty, the essence of the invention, must be described in such details, including proportion and techniques where appropriate, so as to enable those persons skilled in the art to make and use the invention, as of the filling date of the application.

Specific operative embodiments or examples of the invention must be set out in the description. Examples and other descriptive passages should be of a scope sufficient to justify the scope of the claims.

In addition, there is a requirement that the application should relate to one invention only. This requirement, referred to as "unity of invention" is particularly important for the purpose of drafting the claims.

[Case No. 2]
Experimental use exception and testing of patented drugs for marketing approvals

Guanidinobenzoic Acid Derivatives Case

The Second Petty Bench, the Supreme Court
Decided on April 16, 1999
Case No. 1998(ju)153

Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries,

On April 16, 1999, the Supreme Court of Japan rendered a decision on the issue of experimental use exemption and tests done by generic drug makers during a patent term. The Court found that tests carried out during a patent term in an attempt to obtain governmental approvals for manufacture and sales of patented drugs after the expiration of a patent do not constitute patent infringement under Article 69(1) of the Patent Act. This Supreme Court decision puts the question to restf in favor of generic drug manufacturers from a judicial point of view.

BACKGROUND

This matter started when a French pharmaceutical company, Synthelabo, sued several Japanese generic drug manufacturers at the Toyama and Nagoya District Courts in 1995. Synthelabo accused the Japanese drug manufacturers of infringing on its two patents which had their terms extended because of the TRIPS related patent law amendment introducing a uniform 20 years patent term. The generic manufacturers carried out tests during the patent term in an attempt to obtain governmental approvals for manufacture and sale after the expiration of the patents. The defense was that since the use of the patented inventions was for "experiment or research," it did not constitute patent infringement under Article 69(1) of the Patent Act, which exempts the working of a patented invention for the purpose of experiment or research from the scope of patent protection. Also, because the defendants were preparing for the manufacture and sale after the expiration of the patents when the patent law amendment was announced to extend the patent term, they had, according to the defendants, a kind of intermediate user rights based on transitory provisions that accompanied the law amendment.

The Nagoya District Court granted preliminary injunctions in three separate rulings (see, for example, Synthelabo v. Taiyo Yakuhin Kogyo K.K., case No. 1995(yo)771 on March 6, 1996). The court found that the experimental exemption of Article 69(1) was not applicable because the tests carried out by the generic manufacturers were not for the products. Because both of the patents expired on March 26, 1996, the preliminary injunctions lasted only 20 days. The Toyama District Court denied preliminary injunction orders, but in appeal the Kanazawa branch of the Nagoya High Court granted such orders on March 16, 1996 for essentially the same reasons as those given by the Nagoya District Court.

Probably, the judges in these courts had in mind an earlier Tokyo District Court decision for the Ethofumesate case which was part of the global litigations between Monsanto and Stauffer, in which it was found that: “the experiments on agricultural chemicals carried out in the present case for obtaining government registration required for the sales of such chemicals were not intended to advance technology and were only for the sale of the accused herbicide, and therefore do not fa11 under the ‘experiment or research’ provided under Article 69 of the Patent Act.”

These decisions were followed by a rush of lawsuits against generic drug manufacturers. It then became clear from a decision rendered on July 18, 1997 that the Tokyo District Court believed that tests carried out by generic drug manufacturers were for "experiment or research" under Article 69(1) and therefore the experimental use exemption was applicable. This was in clear contrast to the finding of the Nagoya District and High Courts.

The Osaka District Court found infringement, but was reluctant to give any relief to patentees because the amounts of patented drugs made and used by generic drug manufacturers were very small and the damages amounted to only several hundreds of US dollars' worth. In more recent decisions, the same Osaka District Court found no infringement under Article 69. The German Supreme Court decision in the so-called Clinical Trial II case 6 may have influenced these two courts.

After many decisions along the lines discussed above from various district courts, on March 31, 1998, the Tokyo High Court, which is most experienced in patent matters, rendered an eagerly awaited decision on this issue. The court rejected an appeal made by Otsuka Pharmaceuticals against the above-mentioned Tokyo District Court decision in which experiments carried out by a generic drug manufacturer for obtaining a governmental approval for sale after the expiration of a patent were found not to constitute patent infringement under the experimental use exemption.

In January and February 1999, the Osaka and Nagoya High Courts rendered several further decisions on this issue. The two courts found that the experimental use exemption was applicable for such testing, which is basically in agreement with the Tokyo High Court. This is in contrast to two other decisions another division of the Nagoya High Court handed down in December 1998 and January 1999 in which no remedies were given to the plaintiff because damages were minimal, but patent infringement was found for such tests.

PROCEEDINGS AT THE LOWER COURTS

The present appeal before the Supreme Court originates from a Kyoto District Court decision of May 15, 1997 (Case No. 1996(wa)1898) and a subsequent Osaka High Court decision of May 13, 1998 (Case No. 1997(ne)1476). In the original lawsuit at the Kyoto District Court, Ono Pharmaceuticals asked for an injunction based on an expired patent. Ono's patent (No. 1122708) had expired on January 21, 1996. Ono argued that because the defendant carried out experiment during the patent term in order to obtain a government approval for manufacture and sale of a drug which falls under the scope of

the patented invention, it infringed on Ono's patent and therefore should not be able to sell the approved drugs even after the expiration of the patent term. Since it normally takes at least two and a half years for generic drug manufacturers to obtain governmental approval and start the sale of their products from the start of the experiment, if the defendant did not infringe on Ono's patent, according to Ono, it could not sell the accused product for at least two and a half years after the expiration of the patent. The defendant did not dispute the fact that it carried out the experiment during the patent term. The issues raised were: whether the accused product falls under the scope of the patented claims; whether the experiment constituted patent infringement; whether it is possible to issue an injunction against the sale of the accused product based on an expired patent; and whether it is possible to issue an injunction against the sale of the accused product based on past illegal acts.

In its decision of May 15, 1997, the Kyoto District Court did not find any basis in the statutes for granting an injunction based on an expired patent. The Court stated that:

> "If rights to obtain an injunction order can be enforced even after the patent expires, it would amount to the same results as the patent term being extended. This goes against the reasons for providing the fixed term for patents and allowing limited extensions."

This court did not consider whether the experiments carried out by the defendant are exempted from patent infringement under Article 69(1) of the Patent Act.

Ono appealed this decision before the Osaka High Court, and added a claim for damages of 8,711,391 yen (about 73,000 US dollars) for infringement during the patent term and the two and a half year period after the expiration of the patent.

The Osaka High Court directly answered the question of experimental use exemption. The Court stated in its decision that:

> "Therefore, even though the provision for 'the working of the patented invention for the purpose of experiment and research' discussed above contains no literal qualifications, it is clear that the manufacture and stocking of patented products in preparation for sale after the expiration of the patent term is not all owed under the guise of 'experiment and research.' However, the outcome of 'experiment and research' is not necessarily directly related to tangible fruits and may not contribute directly to the development of science and technology. Rather, it can often be the case that information which can be used merely as the foundation of future scientific and technological developments may be obtained as a result of multifaceted examination and analysis of the patented invention, and such information may only indirectly contribute to the progress of science and technology. Thus, it would not be appropriate to interpret `experiment and research' only as cases in which direct and specific fruits are gathered."

In response to the argument of Ono that it would be unfair for original drug developers if

the generic drug manufacturers could perform experiments during the patent term in view of the greater obstacles before original drug manufacturers, such as long research periods, high investments and erosion of patent terms due to lengthy governmental approval processes, the court stated that:

> "However, the issue of erosion of the patent term has been addressed in the patent law amendment of 1987, which allowed the limited extension of the patent term specifically for pharmaceuticals, etc. (Article 67(2) of the Patent Act; even if such extension is insufficient, it is a matter of legislation and policy), and it cannot be denied that an early entry of generic drugs into the market is beneficial to the general public. It would not be appropriate to place an emphasis only on the profits of original drug manufacturers."

In this decision, the Osaka High Court did not consider the rest of the issues raised by the parties and rejected the appeal.

HELD

As shown in the English translation below, the decision of the Supreme Court is short. The Court emphasized the importance of the balance between monopolizing rights enjoyed by the patentee during a limited period of time and benefits of the public resulting from the disclosure of inventions. It reasoned that if experiments done by generic drug manufacturers during the patent term constitute patent infringement despite the provisions of Article 69(1) of the Patent Act, an arbitrary extension of the patent term would effectively result, and such extension is not allowable under the Patent Act, which clearly limits the patent term.

COMMENTS

This decision was rendered unusually quickly. It took less than one year for the Supreme Court to issue a decision with its own opinion. This is clearly one of welcome signs for changes in the Japanese judicial system in general. This type of the appeal used to take two years or more to decide, if the Supreme Court chose to address some substantive issues. Inconsistent positions taken by courts on basically the same issue probably forced the Supreme Court to act fast. In fact, this speed is what the Court has recently been preaching. With the new Code of Civil Procedure, which contains a number of specific measures to allow courts to finish cases within shorter periods of time, having come into effect in January 1998, the Supreme Court has been publicly emphasizing the importance of speed whenever possible.

On the other hand, many of the issues raised during the lower court proceedings in this particular case and in other similar cases were left untouched in this decision. For example, the relationship between the patent term extension for pharmaceutical patents and the experimental use exemption is an important issue, and it would have been better to have the Supreme Court's opinions on it. Such omission of issues from this decision may be understood as a signal from the Supreme Court that such issues are not considered important. However, this is not clear. The lack of details is evident when compared

with extensive expositions made by the German Supreme Court in comparable cases in Germany.

* * *

Translation of the Supreme Court decision of April 16, 1999
on the issue of experimental use exemption and generic drugs

The Second Petty Bench, the Supreme Court
Decided on April 16, 1999
Case No. 1998(ju)153

Appellant-defendant: Kyoto Pharmaceutical Industries, Ltd.
Appellee-plaintiff: Ono Pharmaceuticals Co., Ltd.

Against the decision the Osaka High Court rendered on May 13, 1998 in a case involving a request for an injunction on pharmaceutical products (Case No. 1997(ne)1476) between the above-mentioned parties, an appeal has been filed by the Appellant. Therefore, this court decides as follows:

MAIN TEXT

The present appeal is rejected, and the cost of this appeal is to be borne by the Appellant.

REASON

Concerning the reasons for requesting the acceptance of the appeal set forth by the attorneys for the Appellant, Keizo TAKASAKA, Yoichiro NATSUZUMI, Hanroku TORIYAMA, Yasuaki IWAMOTO, Hirofumi ATA, and Yoichi TANABE:

1. In the present lawsuit, the Appellant, who owns a patent on chemical substances and drugs which contain them as effective components, has demanded an injunction against the sale of the Appellee's drugs and a damages award, arguing that the manufacture and use of drugs which are identical to the patented drugs in terms of their effective components, dosages, usage, quantities, indications, efficacy, etc. during the patent term for the purpose of obtaining data that accompany an application for the approval of manufacture under Article 14 of the Pharmaceutical Affairs Law constitute infringement on the patent. The Appellee, on the other hand, has argued that it did not infringe on the patent owned by the Appellant because, for example, the above-mentioned acts would qualify for "the working of the patented invention for experiment and research" under Article 69(1) of the Patent Act.

2. When a party has a patent on chemical substances or drugs which contain such chemical substances as effective components, even if a third party carries out the necessary experiments for obtaining data to be filed accompanying an application for

UNIT –III

UNIT –IV

GATT

General Agreement on Tariffs and Trade (GATT), set of multilateral trade agreements aimed at the abolition of quotas and the reduction of tariff duties among the contracting nations. When GATT was concluded by 23 countries at Geneva, in 1947 (to take effect on Jan. 1, 1948), it was considered an interim arrangement pending the formation of a United Nations agency to supersede it. When such an agency failed to emerge, GATT was amplified and further enlarged at several succeeding negotiations. It subsequently proved to be the most effective instrument of world trade liberalization, playing a major role in the massive expansion of world trade in the second half of the 20th century. By the time GATT was replaced by the World Trade Organization (WTO) in 1995, 125 nations were signatories to its agreements, which had become a code of conduct governing 90 percent of world trade.

GATT held a total of nine rounds

GATT and WTO trade rounds					
Name	**Start**	**Duration**	**Countries**	**Subjects covered**	**Achievements**
Geneva	April 1947	7 months	23	Tariffs	Signing of GATT, 45,000 tariff concessions affecting $10 billion of trade
Annecy	April 1949	5 months	13	Tariffs	Countries exchanged some 5,000 tariff concessions
Torquay	September 1950	8 months	38	Tariffs	Countries exchanged some 8,700 tariff concessions, cutting the 1948 tariff levels by 25%
Geneva II	January 1956	5 months	26	Tariffs, admission of Japan	$2.5 billion in tariff reductions
Dillon	September 1960	11 months	26	Tariffs	Tariff concessions worth $4.9 billion of world trade
Kennedy	May 1964	37 months	62	Tariffs, Anti-dumping	Tariff concessions worth $40 billion of world trade
Tokyo	September 1973	74 months	102	Tariffs, non-tariff measures, "framework" agreements	Tariff reductions worth more than $300 billion achieved
Uruguay	September 1986	87 months	123	Tariffs, non-tariff measures, rules, services, intellectual property,	The round led to the creation of WTO, and extended the range of trade

				dispute settlement, textiles, agriculture, creation of WTO, etc.	negotiations, leading to major reductions in tariffs (about 40%) and agricultural subsidies, an agreement to allow full access for **textiles** and clothing from developing countries, and an extension of intellectual property rights.
Doha	November 2001	?	159	Tariffs, non-tariff measures, agriculture, labor standards, environment, competition, investment, transparency, patents etc.	The round has not yet concluded. Bali Package signed on the 7th December 2013.

GATT's normal business involved negotiations on specific trade problems affecting particular commodities or trading nations, but major multilateral trade conferences were held periodically to work out tariff reductions and other issues. Seven such "rounds" were held from 1947 to 1993, starting with those held at

Geneva in 1947 (concurrent with the signing of the general agreement);

At Annecy, France, in 1949;

At Torquay, Eng., in 1951; and

At Geneva in 1956 and again in 1960–62.

The most important rounds were the so-called Kennedy Round (1964–67),

The Tokyo Round (1973–79), and

Tthe Uruguay Round (1986–94), all held at Geneva.

These agreements succeeded in reducing average tariffs on the world's industrial goods from 40 percent of their market value in 1947 to less than 5 percent in 1993.

TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation as applied to nationals of other WTO Members.[3] It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994.

The TRIPS agreement introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property to date. In 2001, developing countries, concerned that developed countries were insisting on an overly narrow reading of TRIPS, initiated a round of talks that resulted in the Doha Declaration. The Doha declaration is a WTO statement that clarifies the scope of TRIPS, stating for example that TRIPS can and should be interpreted in light of the goal "to promote access to medicines for all."

Specifically, TRIPS requires WTO members to provide copyright rights, covering content producers including performers, producers of sound recordings and broadcasting organizations; geographical indications, including appellations of origin; industrial designs; integrated circuit layout-designs; patents; new plant varieties; trademarks; trade dress; and undisclosed or confidential information. TRIPS also specifies enforcement procedures, remedies, and dispute resolution procedures. Protection and enforcement of all intellectual property rights shall meet the objectives to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The requirements of TRIPS

TRIPS requires member states to provide strong protection for intellectual property rights. For example, under TRIPS:

- Copyright terms must extend at least 50 years, unless based on the life of the author. (Art. 12 and 14)[5]
- Copyright must be granted automatically, and not based upon any "formality," such as registrations, as specified in the Berne Convention. (Art. 9)
- Computer programs must be regarded as "literary works" under copyright law and receive the same terms of protection.
- National exceptions to copyright (such as "fair use" in the United States) are constrained by the Berne three-step test

- Patents must be granted for "inventions" in all "fields of technology" provided they meet all other patentability requirements (although exceptions for certain public interests are allowed (Art. 27.2 and 27.3)[6] and must be enforceable for at least 20 years (Art 33).
- Exceptions to exclusive rights must be limited, provided that a normal exploitation of the work (Art. 13) and normal exploitation of the patent (Art 30) is not in conflict.
- No unreasonable prejudice to the legitimate interests of the right holders of computer programs and patents is allowed.
- Legitimate interests of third parties have to be taken into account by patent rights (Art 30).
- In each state, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPS signatories under the principle of national treatment (with certain limited exceptions, Art. 3 and 5).[7] TRIPS also has a most favored nation clause.

Many of the TRIPS provisions on copyright were copied from the Berne Convention for the Protection of Literary and Artistic Works and many of its trademark and patent provisions were modeled on the Paris Convention for the Protection of Industrial Property. It is the case of the protection of software and database.

"1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).
2. Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself."

Madrid Protocol

The Madrid system (officially the Madrid system for the international registration of marks) is the primary international system for facilitating the registration of trademarks in multiple jurisdictions around the world. Its legal basis is the multilateral treaty Madrid Agreement Concerning the International Registration of Marks of 1891, as well as the Protocol Relating to the Madrid Agreement (1989).

The Madrid system provides a centrally administered system of obtaining a bundle of trademark registrations in separate jurisdictions. Registration through the Madrid system does not create an 'international' registration, as in the case of the European Community Trade Mark[1] system; rather, it creates a bundle of national rights able to be administered centrally. Madrid provides a mechanism for obtaining trademark protection in many countries around the world which is more effective than seeking protection separately in each individual country or jurisdiction of interest.

The Madrid Protocol system provides for the international registration of trade marks by way of one application that can cover more than one country. The opportunity of having a single registration to cover a wide range of countries gives advantages, both in terms of portfolio management and cost savings, as opposed to a portfolio of independent national registrations.

Madrid now permits the filing, registration and maintenance of trade mark rights in more than one jurisdiction, provided that the target jurisdiction is a party to the system. The Madrid system is administered by the International Bureau of the World Intellectual Property Organization (WIPO) in Geneva, Switzerland. There are 90 countries registered with the Madrid System.

History and development

The Madrid system comprises two treaties; the Madrid Agreement Concerning the International Registration of Marks, which was concluded in 1891, and entered into force in 1892, and the Protocol Relating to the Madrid Agreement, which came into operation on 1 April 1996. The Madrid Agreement and Madrid Protocol were adopted at diplomatic conferences held in Madrid, Spain.

The Madrid Agreement was originally intended to provide for an international registration system, but did not achieve this for two significant reasons:

1. The lack of international acceptance. Many non-member countries, including the United Kingdom, the United States, and Central American, South American and Asian countries, such as Japan, were not adherents, which undermined recognition of the system as a truly "international" regime. Significantly, many of these countries

represent the largest numbers of trademark filings and registrations in the world; and

2. The mere forwarding by the International Bureau of a uniform application to member countries, rather than the registration of the applicable trademark in the national trademark registers, precludes an actual "registration" system.

Hague – The International Design System

The Hague System for the International Registration of Industrial Designs provides a practical business solution for registering up to 100 designs in over 65 territories through filing one single international application.

Two Acts of the Hague Agreement are currently in operation – the 1999 Act and the 1960 Act. In September 2009, it was decided to freeze the application of the 1934 Act of the Hague Agreement, thus simplifying and streamlining overall administration of the international design registration system.

The 1934 Act

The application of the 1934 Act was frozen as of January 1, 2010, meaning that no new registration or designation under the 1934 Act could be entered in the International Register as of that date. However, the renewal of existing designations under the 1934 Act and the recording in the International Register of any change affecting such designations will continue to be possible up to the maximum duration of protection under the 1934 Act (15 years).

General

The WIPO Secretariat publishes a Guide to the International Registration of Industrial Designs for users of the Hague system.

The Hague Agreement, concluded in 1925, was revised at London in 1934 and at The Hague in 1960. It was completed by an Additional Act signed at Monaco in 1961 and by a Complementary Act signed at Stockholm in 1967, which was amended in 1979. As noted above, a further Act was adopted at Geneva in 1999.

The Hague Agreement created a Union, which, since 1970, has had an Assembly. Every member of the Union that has adhered to the Complementary Act of Stockholm is a member of the Assembly. Among the most important tasks of the Assembly are the adoption of the biennial program and budget of the Union and the adoption and modification of the implementing regulations, including the fixing of the fees connected with the use of the Hague system.

The 1999 Act of the Agreement is open to any WIPO Member State and to certain intergovernmental organizations. Instruments of ratification or accession must be deposited with the Director General of WIPO. While the 1960 Act remains open to States party to the Paris Convention for the Protection of Industrial Property (1883), it is the more advantageous 1999 Act that governments of prospective Contracting Parties are encouraged to join.

Budapest Treaty

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure Adopted in 1977, the Budapest Treaty concerns a specific topic in the international patent process: microorganisms. All states party to the Treaty are obliged to recognize microorganisms deposited as a part of the patent procedure, irrespective of where the depository authority is located. In practice this means that the requirement to submit microorganisms to each and every national authority in which patent protection is sought no longer exists.

The main feature of the Treaty is that a contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for such purposes, the deposit of a microorganism with any "international depositary authority", irrespective of whether such authority is on or outside the territory of the said State.

The Treaty makes the patent system of the contracting State more attractive because it is primarily advantageous to the depositor if he is an applicant for patents in several contracting States; the deposit of a microorganism under the procedures provided for in the Treaty will save him money and increase his security. It will save him money because, instead of depositing the microorganism in each and every contracting State in which he files a patent application referring

to that microorganism, he will deposit it only once, with one depositary authority. The Treaty increases the security of the depositor because it establishes a uniform system of deposit, recognition and furnishing of samples of microorganisms.

The Treaty does not provide for the institution of a budget but it does create a Union and an Assembly whose members are the States which are party to the Treaty. The main task of the Assembly is the amendment of the Regulations issued under the Treaty. No State can be requested to pay contributions to the International Bureau of WIPO on account of its membership in the Budapest Union or to establish an "international depositary authority".

The Budapest Treaty was concluded in 1977.

The Treaty is open to States party to the Paris Convention for the Protection of Industrial Property (1883). Instruments of ratification or accession must be deposited with the Director General of WIPO.

Depositable subject matter

IDA's have accepted deposits for biological materials which do not fall within a literal interpretation of "microorganism". The Treaty does not define what is meant by “microorganism.” The range of materials able to be deposited under the Budapest Treaty includes:

- cells, for example, bacteria, fungi, eucaryotic cell lines, plant spores;
- genetic vectors (such as plasmids or bacteriophage vectors or viruses) containing a gene or DNA fragments;
- organisms used for expression of a gene (making the protein from the DNA).

There are many types of expression systems: bacterial; yeast; viral; plant or animal cell cultures;

- yeast, algae, protozoa, eucaryotic cells, cell lines, hybridomas, viruses, plant tissue cells, spores, and hosts containing materials such as vectors, cell organelles, plasmids, DNA, RNA, genes and chromosomes;
- purified nucleic acids; or

- deposits of materials not readily classifiable as microorganisms, such as “naked” DNA, RNA, or plasmids

WIPO Treaty

WIPO is the global forum for intellectual property (IP) services, policy, information and cooperation. We are a self-funding agency of the United Nations, with 192 member states. Our mission is to lead the development of a balanced and effective international IP system that enables innovation and creativity for the benefit of all. Our mandate, governing bodies and procedures are set out in the WIPO Convention, which established WIPO in 1967.

The World Intellectual Property Organization Copyright Treaty (WIPO Copyright Treaty or WCT) is an international treaty on copyright law adopted by the member states of the World Intellectual Property Organization (WIPO) in 1996. It provides additional protections for copyright deemed necessary due to advances in information technology since the formation of previous copyright treaties before it. It ensures that computer programs are protected as literary works (Article 4), and that the arrangement and selection of material in databases is protected (Article 5). It provides authors of works with control over their rental and distribution in Articles 6 to 8 which they may not have under the Berne Convention alone. It also prohibits circumvention of technological measures for the protection of works (Article 11) and unauthorized modification of rights management information contained in works (Article 12). As of February 2016, the treaty has been ratified by 94 states.

There have been a variety of criticisms of this treaty, including that it is too broad (for example in its prohibition of circumvention of technical protection measures, even where such circumvention is used in the pursuit of legal and fair use rights) and that it applies a "one size fits all" standard to all signatory countries despite widely differing stages of economic development and knowledge industry.

Implementation

The WIPO Copyright Treaty is implemented in United States law by the Digital Millennium Copyright Act (DMCA). By Decision 2000/278/EC of 16 March 2000, the Council of the European

Union approved the treaty on behalf of the European Community. European Union Directives which largely cover the subject matter of the treaty are: Directive 91/250/EC creating copyright protection for software, Directive 96/9/EC on copyright protection for databases and Directive 2001/29/EC prohibiting devices for circumventing "technical protection measures" such as digital rights management.

Hague Agreement Concerning the International Deposit of Industrial Designs

The Hague Agreement Concerning the International Deposit of Industrial Designs, also known as the Hague system provides a mechanism for registering an industrial design in several countries by means of a single application, filed in one language, with one set of fees. The system is administered by WIPO.

Instruments

The Hague Agreement consists of several separate treaties,[2] the most important of which are: the Hague Agreement of 1925, the London Act of 2 June 1934,[3] the Hague Act of 28 November 1960 (amended by the Stockholm Act),[4] and the Geneva Act of 2 July 1999.[5]

The original version of the Agreement (the 1925 Hague version) is no longer applied, since all states parties signed up to subsequent instruments. The 1934 London Act formally applied between a London act state that did not sign up to the Hague and/or Geneva Act in relation with other London act states until October 2016. Since 1 January 2010, however, the application of this act had already been frozen.

Countries can become a party to the 1960 (Hague) Act, the 1999 (Geneva) Act, or both. If a country signs up to only one Act, then applicants from that country can only use the Hague system to obtain protection for their designs in other countries which are signed up to the same Act. For instance, because the Japan has only signed up to the 1999 (Geneva) Act, applicants which qualify to use the Hague system because their domicile is in the European Union can only get protection in countries which have also signed up to the 1999 Act or to both the 1999 and 1960 Acts.

Qualification to use the Hague system

Applicants can qualify to use the Hague system on the basis of any of the following criteria:

- The applicant is a national of a Contracting Party (i.e. member country)
- The applicant is domiciled in a Contracting Party
- The applicant has a real and effective industrial or commercial establishment in a Contracting Party
- The applicant has its habitual residence in a Contracting Party (only available if the Contracting Party in question has adhered to the 1999 (Geneva) Act)

An applicant who does not qualify under one of these headings cannot use the Hague system. The Contracting Parties include not only individual countries, but also intergovernmental organisations such as the African Intellectual Property Organization (OAPI) and the European Union. This means an applicant domiciled in an EU member country that is not a Contracting Party, such as Austria or the United Kingdom, can nevertheless use the Hague system on the basis of his or her domicile in the European Union.

Application requirements

An application may be filed in English, French, or Spanish, at the choice of the applicant. The application must contain one or more views of the designs concerned and can include up to 100 different designs provided that the designs are all in the same class of the International Classification of Industrial Designs (Locarno Classification).

The application fee is composed of three types of fees: a basic fee, a publication fee, and a designation fee for each designated Contracting Party.

Examination and registration procedure

The application is examined for formal requirements by the International Bureau of WIPO, which provides the applicant with the opportunity to correct certain irregularities in the application. Once the formal requirements have been met, it is recorded in the International Register and details are published electronically in the International Designs Bulletin on the WIPO website.

If any designated Contracting Party considers that a design which has been registered for protection in that Contracting Party does not meet its domestic criteria for registrability (e.g. it finds that the design is not novel), it must notify the International Bureau that it refuses the registration for that Contracting Party. In every Contracting Party that does not issue such a refusal, the international registration takes effect and provides the same protection as if the design(s) had been registered under the domestic law of that Contracting Party.

Duration & renewal

The duration of an international registration is five years, extendable in further five-year periods up to the maximum duration permitted by each Contracting Party. For the 1934 London Act the maximum term was 15 years.

Renewals are handled centrally by the International Bureau. The applicant pays a renewal fee and notifies the International Bureau of the countries for which the registration is to be renewed.

Naming

The agreement was concluded at the Dutch city The Hague.

Patent Cooperation Treaty (PCT)

The Patent Cooperation Treaty (PCT) makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a PCT Contracting State. It may generally be filed with the national patent office of the Contracting State of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of WIPO in Geneva.

PCT applicants generally pay three types of fees when they file their international applications:

- International filing fee of approximately 1,450 US dollars (depending on the applicable exchange rate),

- Search fee, which can vary from approximately 410 to 2,400 US dollars, depending on the International Searching Authority chosen, and a
- Small transmittal fee which varies depending on the receiving Office.

A 90% reduction on the international filing fee, the supplementary search fee and the handling fee applies to nationals of LDCs and residing in an LDC. If there are several applicants, each must satisfy those criteria. For more details, including the list of the PCT Contracting States the nationals and residents of which are eligible for such fee reductions, please refer to: Applicability of 90% Reduction in Certain PCT Fees.

Patent Law in India: Introduction:

The Patents Act 1970, along with the Patents Rules 1972, came into force on 20th April 1972, replacing the Indian Patents and Designs Act 1911. The Patents Act was largely based on the recommendations of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. One of the recommendations was the allowance of only process patents with regard to inventions relating to drugs, medicines, food and chemicals.

Later, India became signatory to many international arrangements with an objective of strengthening its patent law and coming in league with the modern world. One of the significant steps towards achieving this objective was becoming the member of the Trade Related Intellectual Property Rights (TRIPS) system. Significantly, India also became signatory of the Paris Convention and the Patent Cooperation Treaty on 7th December 1998 and thereafter signed the Budapest Treaty on 17th December 2001.

History:

Being a signatory to TRIPS, India was under a contractual obligation to amend its Patents Act to comply with its provisions. India had to meet the first set of requirements on 1st January 1995 to give a pipeline protection till the country starts granting product patent.

On 26th March, 1999, Patents (Amendment) Act, 1999 came into force retrospective effect from 1st January, 1995. The main amendments are as follows:

Section 5(2) was introduced which provides for filing of applications for patent in the field of drugs, medicines and agro-chemicals. These applications were kept pending in the mailbox or black box. This mailbox was to be opened on 1st January 2005.

Provision of Exclusive Marketing Rights (EMR) was brought in by way of Chapter IV A. Thus, pipeline protection was provided for pharmaceutical and agro-chemical manufacturers whose applications for product were lying in black box.

Section 39 was omitted from the Act, thereby enabling the Indian residents to file the applications for in an outside India simultaneously.

Chapter II (A) was inserted in the Indian Patent Rules dealing with International Applications under PCT.

The second phase of amendment was brought in by the Patents (Amendment) Act, 2002 which came into force on 20th May 2003. The main features of the amendments included:

I. Term of patent was extended from 14 to 20 years, wherein the date of patent was the date of filing of complete specification. Also the difference in term of a drug/food patent and other patent was removed.
II. The definition of "invention" was made in conformity with the provisions of TRIPS Agreement by introducing the concept of inventive step, thereby enlarging the scope of invention.
III. Deferred examination system was introduced.
IV. Introdutcion of the provision of publication of application after 18 months from the date of filing thereby bringing India at par with the rest of the world.
V. Microorganisms became patentable, whereas inventions relating to traditional knowledge were included in the list of "what are not inventions".
VI. The concept of unity of invention in accordance with EPC and PCT.
VII. Section 39 was reintroduced thereby prohibiting the Indian residents to apply abroad without prior permission or first filing in India.
VIII. Provisions of Appellate Board were brought in by inserting section 116. All appeals to the decision of the Controller would be appealable before the Appellate Board. The Head Quarter of the Appeallate Board is to be in Chennai.

IX. Section 117 provided for Bolar provision for the benefit of agrochemical and pharmaceutical industry.

The third and final amendment to the Patents Act, 1970 came by way of Patents (Amendment) Ordinance, 2004, which was later replaced by The Patent (Amendment) Act, 2005, and Patents (Amendment) Rules, 2006 with retrospective effect from 1st January, 2005. With the third amendment India met with the international obligations under the TRIPS. Significant achievements of this amendment were:

Deletion of section 5, opening of mailbox and grant of product patents. Thus this amendment led to the dawn of the "product patent regime" in India.

Abolition of Exclusive Marketing Rights (EMR).

Current Position:

The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 (hereinafter referred to as the Act) and Patents Acts Rules, 2006 (hereinafter referred to as the Rules)

The Head Patent Office is located at Kolkata and its branch offices are located at Delhi, Mumbai and Chennai. Patent system in India is administered by the Controller General of Patents, Designs, Trademarks and Geographical Indications. Each office has its own territorial jurisdiction for receiving patent applications and is empowered to deal with all sections of Patent Act.

The jurisdiction for filing the patent application depends upon:

- Indian applicant(s): determined according to place of residence, place of business of the applicant or where the invention actually originated.
- Foreign applicant(s): determined by the address for service in India.

UNIT -V

Ethics

The field of ethics (or moral philosophy) involves systematizing, defending, and recommending concepts of right and wrong behavior. Philosophers today usually divide ethical theories into three general subject areas: metaethics, normative ethics, and applied ethics. Metaethics investigates where our ethical principles come from, and what they mean. Are they merely social inventions? Do they involve more than expressions of our individual emotions? Metaethical answers to these questions focus on the issues of universal truths, the will of God, the role of reason in ethical judgments, and the meaning of ethical terms themselves. Normative ethics takes on a more practical task, which is to arrive at moral standards that regulate right and wrong conduct. This may involve articulating the good habits that we should acquire, the duties that we should follow, or the consequences of our behavior on others. Finally, applied ethics involves examining specific controversial issues, such as abortion, infanticide, animal rights, environmental concerns, homosexuality, capital punishment, or nuclear war.

Bioethics

Ethics is a philosophical discipline pertaining to notions of good and bad, right and wrong—our moral life in community. Bioethics is the application of ethics to the field of medicine and healthcare. Ethicists and bioethicists ask relevant questions more than provide sure and certain answers.

What is the right thing to do and the good way to be? What is worthwhile? What are our obligations to one another? Who is responsible, to whom and for what? What is the fitting response to this moral dilemma given the context in which it arises? On what moral grounds are such claims made?

Bioethicists ask these questions in the context of modern medicine and healthcare. They draw on a pluralistic plethora of traditions, both secular and religious, to spawn civil discourse on contentious issues of moral difference and others on which most people agree. Bioethicists foster public knowledge and comprehension both of moral philosophy and scientific advances in healthcare. They note how medical technology can change the way we experience the meaning of health and illness and, ultimately, the way we live and die.

Bioethics is multidisciplinary. It blends philosophy, theology, history, and law with medicine, nursing, health policy, and the medical humanities. Insights from various disciplines are brought to bear on the complex interaction of human life, science, and technology. Although its questions are as old as humankind, the origins of bioethics as a field are more recent and difficult to capture in a single view.

When the term "bioethics" was first coined in 1971 (some say by University of Wisconsin professor Van Rensselaer Potter; others, by fellows of the Kennedy Institute in Washington, D.C.), it may have signified merely the combination of biology and bioscience with humanistic knowledge. However, the field of bioethics now encompasses a full range of concerns, from difficult private decisions made in clinical settings, to controversies surrounding stem cell research, to implications of reproductive technologies, to broader concerns such as international human subject research, to public policy in healthcare, and to the allocation of scarce resources. This array of interest is neatly summarized under the rubric of the Center for Practical Bioethics' four domains: Aging and End of Life, Clinical and Organizational Ethics, Life Sciences, and Disparities of Health and Healthcare.

Cloning

Any discussion about cloning needs to begin with careful definitions. Cloning can occur

at the level of DNA,
at the level of the single cell, or
at the level of the whole organism.

Typically, ethical attention is focused upon cloning in the context of the genetic copying of a whole organism. While the cloning of non-mammals has occurred in research contexts for many years, the cloning of the first

mammal, Dolly the sheep, surprised many in the scientific community. What quickly followed was the cloning of other species and intense speculation about the possible cloning of humans. Cloned human embryos have been produced, but there are no reliable reports that any have been implanted in a woman's uterus, let alone developed to birth. Cloning to birth has come to be called 'reproductive cloning', whereas cloning embryos so that their stem cells may be extracted for possible research or therapeutic use has come to be called 'therapeutic cloning'. The key ethical issue with therapeutic cloning is the moral status of the cloned embryo, which is created solely for destruction. The ethical issues with reproductive cloning include genetic damage to the clone, health risks to the mother, very low success rate meaning loss of large numbers of embryos and fetuses, psychological harm to the clone, complex altered familial relationships, and commodification of human life.

Reproductive Technology

Assisted reproductive technology (ART) is a medical intervention developed to improve an 'infertile' couple's chance of pregnancy. 'Infertility' is clinically accepted as the inability to conceive after 12 months of actively trying to conceive. The means of ART involves separating procreation from sexual intercourse - the importance of this association is addressed in bioethics.

Some techniques used in clinical ART include: artificial insemination; in vitro fertilisation (IVF); gamete intra-fallopian transfer (GIFT); gestational surrogate mothering; gamete donation; sex selection and pre-implantation genetic diagnosis. Issues addressed in bioethics are the appropriate use of these technologies and the techniques employed to carry out procedures for quality and ethical reviews.

Assisted reproductive technology and its use directly impact the foundational unit of society – the family. ART enables children to be conceived who have no genetic relationship to one or both of their parents. Children can also be conceived who will never have a social relationship with one or both of their genetic parents, e.g. a child conceived using donor sperm. Non-infertile people in today's society including both male and female homosexual couples, single men and women, and post-menopausal women are seeking the assistance of ART. Concerns in all situations include the child and his or her welfare, including the right to have one biological mother and father. The fragmented family created by ART can disconnect genetic, gestational and social child-parent relationships which have typically been one and the same in the traditional nuclear family.

Other important bioethical issues include the appropriate use of pre-implantation genetic diagnostic screening, use, storage and destruction of excess IVF embryos, and research involving embryos. ART research requires human participants, donors and donated embryos, oocytes and sperm.

Ethical issues that arise in ART research surround the creation and destruction of embryos. One approach in bioethics involves preserving justice, beneficence, non-maleficence and the autonomous interests of all involved. Bioethicists contribute to ethical guidelines and moral evaluations of new technologies and techniques in ART as well as topublic discourse that leads to development of national regulations and restrictions of unacceptable practices.

Reproductive cloning - Basic scientific concepts

A gene is a hereditary unit consisting of a sequence of DNA that occupies a specific location on a chromosome. Chromosomes consist of long coiled chains of genes and are found within all nucleated cells in the human body. Human beings normally have 23 pairs of chromosomes; one of each pair is inherited from the genetic mother and one from the genetic father.

In sexual reproduction, a child receives half of their genes from the mother (contained in the egg) and half from the father (contained in the sperm). The combination of maternal and paternal genes which occurs at fertilisation forms the basis of human genetic variety and diversity. A small amount of genetic material is contained within mitochondria within the egg and this mitochondrial DNA is passed on to the child entirely from the mother.

In embryo splitting, an early human embryo divides into two genetically identical embryos which are then capable of developing independently. This process may happen spontaneously and is the mechanism whereby genetically identical twins (technically described as monozygotic twins) are formed. Embryo splitting can also be induced artificially.

In reproductive cloning the entire genetic code (except for the mitochondrial DNA) is reproduced from a single body cell of an adult individual. The most common cloning technique is somatic cell nuclear transfer (SCNT). The procedure is as follows[1]:

- The nucleus is removed from an egg leaving the cytoplasm and mitochondria (cellular components derived from the mother)
- A body (or somatic) cell is taken from an adult individual who is to be cloned. The DNA is extracted from the nucleus and inserted into the prepared egg.
- The new cell is then induced to divide using either chemical or electrical stimulation, thereby commencing the development of an embryo.
- After several days the dividing embryo is then placed into the womb of the recipient and allowed to develop to term. The result is a clone – an individual that is the genetic duplicate of the individual from whom the original body cell was taken. To date this process has not been proven to occur in a human being. If it did so, it is important to note that the resulting child would neither be the individual's son or daughter, nor their twin brother or sister. The child would truly be a new category of human being – a clone.

Benefits of Genetic Engineering

The use of genetic engineering and the creation of genetically modified crops has resulted in many benefits for the agricultural world. The most noticeable benefit is that genetic engineering has made it possible to produce more crops in a shorter time period. Due to the modifications that make crops resistant to diseases, it has been possible to increase overall yields. Many genetically modified crops are also designed to grow at a faster rate, which also helps increase overall yield.

Genetic engineering has also increased yield by making it possible to grow crops in regions that would otherwise be unsuitable for agriculture, such as areas with salty soil, areas that are drought prone and areas with low amounts of sunlight. Through genetic engineering, crops have been modified to tolerate salty soils, be more drought resistant and increase their rate of photosynthesis to take advantage of limited sunlight.

In addition to increasing productivity, genetic engineering has had several other benefits to agriculture. By modifying crops so that they are resistant to diseases and insects, less chemical pesticides have to be used to combat diseases and pests. Also, if crops are genetically modified to include components of fertilizers, less chemical fertilizers have to be placed on the fields.

By reducing the amount of chemical pesticides and fertilizers, there will be less harm done to the environment. Genetic engineering has also made it possible to produce new varieties of crops by mixing genes from multiple different species. For example, pluots are a new type of fruit that was produced when the genes of plums and apricots were mixed.

Problems with Genetic Engineering

Although there are many benefits of genetically engineered crops, there are also some major issues and concerns associated with these types of crops. One major concern is that as pests experience constant exposure to the pesticide or herbicide that is genetically inserted into the crops, they will develop genetic resistance to the chemical. If the pests develop genetic resistance, eventually the genetically modified crops would no longer be successful at preventing harm and would become obsolete.

Another major concern about genetic engineering is the long-term effects on human health and the environment. There is little known about the long-term effects of genetically engineered crops, and this makes many people cautious about their use.

In terms of human health, there are concerns that genetically engineered crops could contain harmful toxins if the cells mutate, that produce may be lower in nutrition and that the creation of novel varieties of crops could lead to the development of new and unknown food allergies.

In terms of the potential harm to the environment, there is concern that once genetically modified organisms are released into the wild, they cannot be controlled and they could cause harm to the natural ecosystem. The genetically modified organisms could potentially out-compete native non-pest organisms or prey on non-pest organisms. These new organisms could also interbreed with native organisms and create new species that may not be desirable.

The goal of genetic engineering is to make debilitating diseases a thing of the past. While this is a noble goal, this branch of science also has risks. Learn about the pros and cons of genetic engineering and decide for yourself if the benefits outweigh these risks.

Benefits and Risks of Genetic Engineering

Applications

Genetic engineering has applications in many fields; medicine, agriculture, the environment, and food production. It can be described rather generally as any genetic manipulation that allows an organism to perform new functions or produce new substances.

The unravelling of DNA and the mapping of a diverse range of organisms such as humans, dogs and viruses, is giving us unprecedented knowledge into how nature works. Knowing the fundamentals of how a cancer spreads, the tricks a virus uses to replicate inside our cells, or what prompts a brain to degenerate in Alzheimer's patients, equips science with the tools to counter these harsh realities of life.

But the technology is not without its critics, and just as genetic engineering has many plus points, there are also some cons that must be considered.

Pros of Genetic Engineering

In looking at the pros and cons of genetic engineering, we'll consider the technology in the fields of agriculture, food production, and medicine.

Many crops such as rice, maize, and potatoes are being genetically engineered in several ways. Proponents argue that the benefits are many; 1) higher crop yields 2) more nutritious food 3) crops can be grown in harsh environments 4) they are more resistant to pests thus eliminating the use of potentially hazardous pesticides 5) undesirable characteristics can be removed 6) food can have a better flavour and a longer shelf life and 7) they can also be used as a cheap source of medicine.

To treat many life-threatening illnesses genetic engineering aims to replace faulty genes with perfect working copies. The potential is incredible. However, whilst there have been some small successes in gene therapy trials to cure vision impairment and also X-SCID (where people lack an effective immune system) - it's fair to say that so far the technology hasn't lived up to expectations. It's an extraordinarily difficult job to get a gene to exactly where you want it in the body, and for it to function in the way that you want it to. Plus our expectations were probably too high from the start.

Cons of Genetic Engineering

In terms of gene therapy this can be a dangerous procedure. A virus is being used as a vector to get the genes inside, and some fear that even though the virulence factors have been silenced, danger is still at hand. There's also a risk that a gene could land in a spot other than where you want it and cause harm by being expressed in unusual ways. There have been several deaths in gene therapy trials, most famously that of Jesse Gelsinger in 1999.

Opposition to the use of genetic engineering in food and agriculture centres on several fears. Namely that any gene for herbicide resistance may spread into other crops and create some form of superweed; or that a genetic modification that is passed on say through pollination, might pose a hazard to the ecosystem. There's also a concern that unusual gene expression may lead to crops causing more allergic reactions in consumers.

There are many more pros and cons of genetic engineering than the few that are listed here, and all are argued passionately by advocates on both sides, many clutching reams of data to back up their arguments. That makes it very difficult for the lay person to understand exactly what is going on, especially when combatants (if that's not too strong a word) seem equally eminent and well qualified.

What is certain is that even though many are concerned with its speed of introduction, fearing that it is going too fast for society to understand any and all possible implications, genetic engineering is here to stay.

Biological warfare

Biological warfare (BW)—also known as germ warfare—is the use of biological toxins or infectious agents such as bacteria, viruses, and fungi with the intent to kill or incapacitate humans, animals or plants as an act of war. Biological weapons (often termed "bio-weapons", "biological threat agents", or "bio-agents") are living organisms or replicating entities (viruses, which are not universally considered "alive") that reproduce or replicate within their host victims. Entomological (insect) warfare is also considered a type of biological weapon. This type of warfare is distinct from nuclear warfare and chemical warfare, which together with biological warfare make up NBC, the military acronym for nuclear, biological, and chemical warfare using weapons of mass destruction (WMDs). None of these are conventional weapons, which are primarily due to their explosive, kinetic, or incendiary potential.

Biological weapons may be employed in various ways to gain a strategic or tactical advantage over the enemy, either by threats or by actual deployments. Like some of the chemical weapons, biological weapons may also be useful as area denial weapons. These agents may be lethal or non-lethal, and may be targeted against a single individual, a group of people, or even an entire population. They may be developed, acquired, stockpiled or deployed by nation states or by non-national groups. In the latter case, or if a nation-state uses it clandestinely, it may also be considered bioterrorism.[1]

There is an overlap between biological warfare and chemical warfare, as the use of toxins produced by living organisms is considered under the provisions of both the Biological Weapons Convention and the Chemical Weapons Convention. Toxins and psychochemical weapons are often referred to as midspectrum agents. Unlike bioweapons, these midspectrum agents do not reproduce in their host and are typically characterized by shorter incubation periods.[2]

Ethical aspects of gene therapy

Gene therapy consists of a wilful modification of the genetic material in cells of a patient in order to bring about a therapeutic effect. This modification usually occurs by introducing exogenous DNA using viral vectors or other means. Although gene therapy is still in its infancy as a clinically useful therapeutic modality, a discussion of the ethical issues is useful in several respects because it involves ethical principles of broad applicability in clinical medicine. Furthermore, many current applications of genetic engineering in medicine

(DNA vaccines, therapeutic use of encapsulated genetically modified cells) are conceptually close to gene therapy, so that the border between gene therapy in the narrow sense and other gene-based therapies is getting fuzzier as time goes by.

Two conceptual distinctions are central to an understanding of the ethical issues of gene therapy:

1 - Therapy vs. enhancement. There is a consensus that gene therapy should be therapy, i.e. the correction of bona fide disease conditions, rather than enhancement, which would mean "improving the human species" (whatever that means...) and therefore would entail the introduction in human subjects of novel characteristics going beyond the usual, medical, understanding of health (i.e. health as absence of serious disease).

2 - Somatic vs. germ line gene therapy. All current research on humans deals with somatic gene therapy. In these projects somatic cells such as bone-marrow, liver, lung or vascular epithelium etc. are genetically modified. Since the germ line is not affected, all effects of therapy end with the life of the patient, at the very latest. In fact, most somatic therapies will probably require repeated applications, much like ordinary pharmacological treatments.

Initially, gene therapy was conceptualised mainly as a procedure to correct recessive monogenic defects by bringing a healthy copy of the deficient gene in the relevant cells. In fact, somatic gene therapy has a much broader potential if one thinks of it as a sophisticated means of bringing a therapeutic gene product to the right place in the body. The field has moved increasingly from a "gene correction" model to a "DNA as drug" model (ADN médicament, A. Kahn). This evolution towards an understanding of gene therapy as "DNA-based chemotherapy" underscores why the ethical considerations for somatic gene therapy are not basically different from the well-known ethical principles that apply in trials of any new experimental therapy

- Favourable risk-benefit balance (principle of beneficence/non-maleficence);
- Informed consent (principle of respect for persons);
- Fairness in selecting research subjects (principle of justice).

Clearly, the mere fact that gene therapy has to do with genes and the genome does not, in itself, make it "special" or "suspicious".

A further distinction ought to be made between in vivo and ex vivo somatic gene therapy. Ex vivo procedures entail the extraction of cells from the patient's body (for instance bone-marrow cells), genetic modification of the cells using appropriate vectors or other DNA-transfer methods and reimplantation of the cells in the patient. In vivo therapy uses a vector or DNA-transfer technique that can be applied directly to the patient. This is the case of current experiments aimed at correcting the gene defect of cystic fibrosis by exposing lung epithelium to adenovirus-derived vectors containing the CFTR gene. In the in vivo case, the potential for unintended dissemination of the vector is more of an issue. Therefore, biological safety considerations must also be subjected to ethical scrutiny in addition to the patient-regarding concerns already mentioned.

In germ line therapy, the DNA of germ cells would be affected, the objective being to correct a genetic defect once and for all, in all descendants of the therapy recipient who will inherit the modified allele. Although germ line therapy is far more speculative than somatic gene therapy at this time, it is widely discussed because it raises important and difficult ethical questions that have relevance for other medical practices as well. The consensus against germ line therapy is broad, but not unanimous. The ethical debate on germ line therapy has usually revolved around two kinds of issues:

1 - Germ line therapy is "open-ended" therapy. Its effects extend indefinitely into the future. This basically fits the objective of germ line therapy (assuming that it becomes possible one day), namely to correct a genetic defect once and for all. But precisely there lies also an ethical problem: an experiment in germ line therapy would be tantamount to a clinical experiment on unconsenting subjects, which are the affected members of future generations. This raises a number of very complex questions and is, in my view, an important but not

necessarily overriding argument. A recent symposium on germ line engineering has concluded with a cautious "yes-maybe" for germ line gene therapy (see references).

2 - Germ line therapy may involve invasive experimentation on human embryos. Although there are other potential targets for germ-line interventions, much of the discussion revolves around the genetic modification of early embryos, where the germ line has not yet segregated from the precursors of the various somatic cell types. As a result, the ethical assessment of germ line gene therapy will hinge in part on the ethical standing accorded to the early human embryo and the moral (dis)approval of early embryo experimentation. Those who believe the early embryo to be the bearer of considerable intrinsic moral worth or even that it is "like" a human person in a morally-relevant sense will conclude that embryo experimentation is to be rejected and germ-line therapy as well. Others think that it is only later in development that humans acquire those features that make them ethically and legally protected human subjects to the fullest degree. For them, the use of early embryos is not objectionable and germ line therapy cannot be ruled out on these grounds alone. As might be expected in view of the moral pluralism of modern societies, the policies of European countries differ in this respect: some permit some invasive research on human embryos (UK, Spain, Denmark), others ban it (Germany, Norway), others are still undecided. More generally, embryo-centred controversies are expected to increase as the field of embryonic stem-cell research becomes ever more promising. It is expected that this field will catch much of the public attention that was devoted to gene therapy in the nineties.

Clearly, the question of the ethical standing of the human embryo is also of major importance for other medical procedures in reproductive medicine such as in-vitro fertilisation, pre-implantation diagnosis, experimentation on human embryos in general and abortion.

To go back to gene therapy, or rather to the therapeutic innovations due to genetic engineering such as DNA vaccines: some of these could potentially benefit a great number of people world-wide, contrary to early developments of genetic engineering in medicine, which where largely geared towards the health problems of rich countries. Although the course of biomedical progress is often unpredictable, the setting of research priorities does raise troubling issues of social ethics.

Patents & Biopiracy

Indigenous people posses important traditional knowledge that have allowed them to sustainably live and make use of biological and genetic diversity within their natural environment for generations. Traditional Knowledge naturally includes a deep understanding of ecological processes and the ability to sustainably extract useful products from the local habitat.
Most Traditional Knowledge is handed down through generations. Components of Traditional Knowledge that are especially relevant to our global survival include knowledge of:

- Food, crop varieties and agricultural/farming practice
- Sustainable management of natural resources and conservation of biological diversity
- Biologically important medicines

The conservation of species, habitat, and biodiversity are essential to the continued survival of indigenous and rural people. By conserving the customs and habitat of indigenous persons we concurrently reduce emissions from deforestation and ecosystem degradation. Furthermore, the opportunity for cultural survival is a basic human right. The traditional knowledge is facing a problem of bio-piracy.

The act of Piracy is unauthorized publication or reproduction of another person’s work or material. When someone indulges in piracy, the accused is using someone’s else’s work illegally or without taking any permission. Biopiracy is the appropriation of another’s knowledge of use of biological resources. Of late, the major issue involving biopiracy is the exploitation of patent biological resources or knowledge of farmers and

traditional communities and indigenous tribes by many organizations and multinational companies. The innovations and discovery of the pharmaceutical and agricultural researches are not new as to qualify as invention as they are based on centuries of knowledge of the traditional societies.

Adult vs. Embryonic Stem Cells

Advantages of Adult Stem Cells

Both lines of stem cells have an enormous therapeutic potential. While embryonic stem cells offer the potential for wider therapeutic applications, adult stem cells avoid the ethical issues roused by embryonic stem cell research. Therefore, many stem cell therapies are currently being tested using adult stem cells. Additionally, adult stem cells offer the potential for autologous stem cell donation, which may help to avoid issues of immune rejection in certain situations.

It is also known that upon injection into mice with compromised immune systems, undifferentiated embryonic stem cells elicit the formation of a benign tumor called a teratoma. This tumor formation causes scientists to doubt the therapeutic applicability of embryonic stem cells. It is not yet known whether similar results are observed with adult stem cells [17].

Advantages of Embryonic Stem Cells

The advantages of embryonic stem cells is that they offer one cell source for multiple indications. They provide the potential for a wider variety of applications than do adult stem cells. Additionally, they theoretically have the possibility of being immuno-privileged, due to their highly undifferentiated state. A privileged immune status would remove one of the main barriers of stem cell therapies, as self rejection is one stem cell therapy's main complications [17]. The idea that embryonic stem cells can be immune privilaged, must be viewed skeptically, however, as this theory has not yet been proven.

Another advantage of embryonic stem cells, is that they appear to be immortal in vitro, while adult and differentiated stem cells cannot be cultured indefinitely in the lab. Once differentiated, these stem cells seem to die off like typical tissue cells.

Example of Biopiracy

• Patenting of Neem (Azadirachta indica)
The people of India in a variety of ways have used neem, since time immemorial. Indians have shared the knowledge of the properties of the neem with the entire world. Pirating this knowledge, the USDA and an American MNC W.R. Grace in the early 90s sought a patent (No. 0426257 B) from the European Patent Office (EPO) on the "method for controlling on plants by the aid of hydrophobic extracted neem oil." The patenting of the fungicidal properties of Neem was an example of biopiracy.
• Patenting of Basmati
Basmati is a long-grained, aromatic variety of rice indigenous to the Indian subcontinent. In 1997 the US Patent and Trademark Office (USPTO) granted a patent (No. 5663484) to a Texas based American company Rice Tec Inc for "Basmati rice line and grains". The patent application was based on 20 very broad claims on having "invented" the said rice. Due to people's movement against rice Tec in March 2001 the UPSTO has rejected all but three of the claims.
• Rice Biopiracy
Syngenta is a biotech company that tried to grab the precious collections of 22,972 varieties of paddy, India's rice diversity, from India's rice bowl, Chattisgarh in India. Syngenta has signed a MoU with the Indira Gandhi Agricultural University (IGAU) for access to Dr. Richharia's priceless collection of rice diversity. Dr. Richharia is the ex-director of Central Rice Research Institute (CRRI), Cuttack and is known as the rice sage of India who has done pioneering work in this field.

• Biopiracy of African Super-sweet Berries

A west African plant, Pentadiplandra brazzeana is a source of a protein called Brazzein which is 2000 times sweeter than sugar. Natives have used Brazzein as a low calorie sweetener for centuries. Sometime back the gene encoding brazzein was isolated, sequenced and patented in USA. It is proposed to transfer the brazzein gene into maize and express it in maize kernels. These kernels will then be used for the extraction of brazzein. This development could have serious implications for countries exporting large quantities of sugar.

What were some of the ethical, legal, and social implications addressed by the Human Genome Project?

The Ethical, Legal, and Social Implications (ELSI) program was founded in 1990 as an integral part of the Human Genome Project. The mission of the ELSI program was to identify and address issues raised by genomic research that would affect individuals, families, and society. A percentage of the Human Genome Project budget at the National Institutes of Health and the U.S. Department of Energy was devoted to ELSI research.

The ELSI program focused on the possible consequences of genomic research in four main areas:

- Privacy and fairness in the use of genetic information, including the potential for genetic discrimination in employment and insurance.
- The integration of new genetic technologies, such as genetic testing, into the practice of clinical medicine.
- Ethical issues surrounding the design and conduct of genetic research with people, including the process of informed consent.
- The education of healthcare professionals, policy makers, students, and the public about genetics and the complex issues that result from genomic research.

The Human Genome Project began in 1990, as part of a collaborative movement by the scientific community to better understand our own genetic makeup. The U.S Department of Energy and the National Institutes of Health coordinate this original 15-year plan, which are parts of the National Human Genome Research Institute. The major goals cited by these institutes is as follows:
Identify all the estimated 100,000 genes in the human genome.
Map the three billion chemical bases that make up human DNA.
Store this mapped information in databases worldwide.
Develop even better tools for sequencing and analysis.
Address the many ethical, legal and social issues that come with this project.
The debate over the importance of a Human Genome Project can be cleared up by looking at what the human genome actually is, and why knowing its DNA sequence can be beneficial to the scientific and the human community. The human genome is made up of about three billion base pairs, which contain about 100,000 genes. The 100,000 genes in the 46 human chromosomes only account for a small total of the DNA in our genome. Approximately 10 percent of our DNA make up these genes in our genome, these genes are what is actually encoded for and used by our body to make vital proteins needed for everyday life. The remaining 90 percent of our three billion base pairs are repeated sequences between genes that do not encode for any particular product. These repeated sequences account for the reason why 99 percent of any humans DNA is identical to another human's (1). With this knowledge many people believe it is not worth the time or money to sequence the entire human genome when only a small percent is used to encode for proteins. However, by sequencing the whole genome researchers will no longer have to do a needle in the haystack type of search for small genes, like the one found on chromosome four that is responsible for Huntington's disease (4). Also, knowing the complete human DNA sequence will allow scientists to determine the role and importance of the repeated DNA, non-protein encoding, sequences in our body.

The Human Genome Project has brought to light the importance of single nucleotide polymorphism's (SNPs), which occur every 100 to 300 bases (1). A single nucleotide variation in the DNA sequence can have a major impact on how humans react to bacteria, viruses and drug therapy. Mapping of these SNPs will allow scientists to associate multiple genes with diseases like cancer and diabetes. Current methods of linking multiple genes to a certain disease is very time consuming and difficult. Scientists hope that mapping SNPs will allow them to explain why certain diseases are linked to certain genes.

The Human Genome Project not only affects the scientific world but also the business world. The desire of companies to sequence parts of the human genome ahead of the U.S. Department of Energy and the National Institutes of Health has led to a multitude of company mergers and partnerships. From 1993 to 1996 companies alliances increased six times the normal rate, and in 1997 alone U.S. biotech companies saw their capitol raise eight folds from these mergers. The race to sequence the human genome by the private sector can be seen by looking at the number of patent requests received by the U.S. patent office. In 1991, the U.S. patent and Trademark Office received around 4000 patent proposals for sequence data, and in 1996 that number climbed to 500,000 (3). The increased number of biotechnology companies trying to patent DNA sequences has only harmed the Human Genome Project. Many long court cases have drawn attention and money away from research to court battles involving arguments on what material should and shouldn't be patented. Clearly the use of patented sequences could bring millions of dollars to biotech companies. By owning the rights to a specific gene sequence linked to cancer, a biotech company would have a huge advantage in discovering new cancer drugs and treatments. With these massive company mergers and the race to patent as many possible useful sequences, by these newly formed companies, the original intent of the Human Genome Project has been lost. The original intent of the Human Genome Project was not to start a massive global race to sequence and patent as many genes as possible for company profit, but rather to provide a free public database for companies to use for the common good of everyone.

One alarming discover came on May 9, 1998 when the Institute for Genomic Research and the Perkin Elmer Corporation announced that they would be teaming up to sequence the human genome (2). This announcement prompted the National Human Genome Research Institute to award $60.5 million to seven companies to help sequence the genome, so that the entire sequence does not become involved in a big patent battle. These races to sequence as much of the human genome before the National Human Genome Research Institute has forced extra federal money to be spent on the project. This push by the private sector to sequence the human genome has sparked the development of new sequencing machines and computers which, has allowed the project completion date to be changed from 2005 to 2003. The National Human Genome Research Institute has debated over whether or not they should do a rough draft of the human genome by 2001, or if they should continue with the original plan of sequencing the entire genome with no more than one base error per ten thousand bases (1). The intent of this idea is to ensure that the National Human Genome Research Institute is the first to complete the Human Genome Project. One new sequencing technique now being used is the whole genome shotgun technique (2). Instead of sequencing the genome by making bacteria clones that carry a 150,000 base human DNA sequence, which is cut and pieced back together by overlapping, the shotgun technique simply chops the genome into small pieces and a computer reads the DNA sequence. The shotgun technique has come under fire for being less than accurate, by genomic mapping standards. Commonly for genome mapping each piece of DNA is cut with different overlapping stretches ten times to ensure accurate sequencing. For the rough draft of the human genome the DNA bases are only checked four to six times, which may not catch all sequencing errors. The National Human Genome Research Institutes plan is now to in fact to do a rough draft of the genome by 2001, using the shotgun method, but also to have one-third of the genome sequenced with only one base error per ten thousand bases by the end of 2001. The complete, error free, genome should then be finished by 2003 and made free to the public via a worldwide web database.