Impact Factor 6.1

Journal of Cyber Security

ISSN:2096-1146

Scopus

DOI

Google Scholar

More Information
www.journalcybersecurity.com

Crossref doi Google Scholar scopus

Protection of Biotechnological Inventions under Intellectual Property Rights: A Review

Ashok Kumar[1], S.R. Singh[2], M.C. Yadav[3], Arvind Kumar[4], Vijay Kumar Yadav[5], Anupam Yadav[6], Alkesh Khakre[7], and Tanisha Jain[8]

1. *Professor & Dean Agriculture, JNCTPU, New Chouksey Nagar, Bhopal, India.*
2. *Principal Scientist, Indian Institute of Sugarcane Research (ICAR), Lucknow, U.P., India.*
3. *Principal Scientist, NBPGR (ICAR), Pusa Campus, New Delhi-110012, India.*
4. *Principal Scientist, ICAR Head Quarters, Pusa Campus, New Delhi -110012, India*
5. *Professor Genetics & Plant Breeding, CSAUA&T—Kanpur, U.P., India.*

6, 7, & 8. *Assistant Professor, Agriculture, JNCTPU, New Chouksey Nagar, Bhopal, India.*

****Corresponding Author:***

Prof. (Dr.) Ashok Kumar
Professor & Dean Agriculture, JNCTPU, New Chouksey Nagar, Bhopal (M.P.), India.
Mobile: 7819993411, 8273847446

Abstract

Intellectual property rights (IPRs) are the rights given to an individual or company that provide rights over the use of the IP for a period of time. Intellectual Property Rights (IPR) in biotechnology play a crucial role in fostering innovation, protecting investments, and ensuring ethical use of genetic resources. The current Intellectual Property Rights framework supports the commercialization of seed improvement, monoculture, and the patent protection of novel plant varieties, microorganisms, and genetically modified animals. As a consequence, our rich biogenetic diversity is irreversibly dissipating. However, we need to figure out how to create a methodology for elective choices that will achieve harmony between the official Intellectual Property (IP) structure and maintainable biodiversity components. The majority of the biotechnology sector's programmes in India are managed by the Department of Biotechnology. It is under the Ministry of Science and Technology. Its goals are to provide services in the fields of study, infrastructure, human resource development, biotechnology popularization, industry promotion, and establishment of centres of excellence. Implementation of practice biosafety regulations for genetically modified organisms, recombinant DNA products, and programmes is based on biotechnology for the good of society. This creates an information network for India's bioinformatics mission in the local, national, and worldwide scientific community.

Keywords: Intellectual property rights, agriculture, biotechnology, patent, society, transgenic

1. Introduction

Biotechnology exploits biological materials, living or non-living, and is broadly classified as classical and modern biotechnology. The age-old fermentation process for producing alcohol and the isolation of antibiotics from molds or other microorganisms are only a few examples of classical biotechnology. Modern biotechnology started with the gene-splicing technology, or genetic engineering, which developed in the late seventies of the last century. By using genetic engineering, many useful things like human insulin, human growth factors, monoclonal antibodies, etc. have been developed. The biotechnological inventions therefore include products and/or processes of gene engineering technologies, methods of producing organisms, methods of isolation of microorganisms from culture medium, methods of mutation, cultures, mutants, transformants, plasmids, processes for making monoclonal antibodies, cell lines for making monoclonal antibodies, etc. While on the one side, biotechnological inventions have resolved many problems and branched out to several fields, on the other side, they have invoked many debates.

The application of genetic engineering in plants and animals has resulted in exciting and yet debatable technological developments such as transgenic plants and animals and the isolation of human genes for using them to produce medicaments. Scientists across the world are using bioinformatics tools, ingenious techniques, and genomes of organisms to probe the mysteries of biological processes and the living world, thereby generating vast amounts of information which may provide the keys to new medical treatments, improved crops and so on. However, there are some issues relating to the patentability of biotechnological inventions, which are of serious concern to the users of Patent System such as novelty, obviousness, industrial applicability, extent of disclosure and clarity in claims. In addition, a few special issues have also evolved such as those relating to moral and ethical concerns, environmental safety, issues relating to patenting of ESTs (Expressed Sequence Tags) of partial gene sequences, cloning of farm animals, stem cells, gene diagnostics, etc. Thus, the patenting of inventions in the field of biotechnology poses challenges to the applicants for patents as well as to the Patent Office. Therefore, there is an urgent need to put in place Guidelines to establish uniform and consistent practices in the examination of patent applications in the field of biotechnology and allied subjects under the Patents Act, 1970. Thus, the guidelines are intended to help the examiners and controllers of the Patent Office so as to achieve uniformity and consistency. However, these guidelines do not constitute rule making. In case of any conflict between these guidelines and the provisions of the Patents Act, 1970 and the Patents

Rules, 2003, the said provisions of Act and Rules will prevail over these guidelines. The guidelines are subject to revision from time to time based on interpretations by a Court of Law, statutory amendments and valuable inputs from the stakeholders.

Fig 1: Patentability of Biotech Inventions

2. Brief history of patenting of biotechnology in India

Till 2002, as per the prevailing practice in the Patent Office, patents were not granted for inventions relating to (a) living entities of natural or artificial origin, (b) biological materials or other materials having replicating properties, (c) substances derived from such materials, and (d) any processes for the production of living substances/entities, including nucleic acids. However, patents could be granted for processes of producing non-living substances by chemical processes, bioconversion, and microbiological processes using micro-organisms or biological materials. For instance, claims for processes for the preparation of antibodies or proteins or vaccines consisting of non-living substances were allowable. In 2002, the Hon'ble Calcutta High Court, in its decision in 'Dimminaco AG v. Controller of Patents and Designs', opened the doors for the grant of patents to inventions where the final product of the claimed process contained living microorganisms. The court concluded that a new and useful art or process is an invention, and where the end product (even if it contains living organism) is a new article, the process leading to its manufacture is an invention. The Dimminaco case was related to a process for the preparation of a live vaccine for protecting poultry against Bursitis infection. The Controller of Patents had refused the application for grant of patent on the ground that the vaccine involved processing of certain microbial substances and contained gene sequence. The Controller had decided that the said claim was not patentable because the claimed process was only a natural process devoid of any manufacturing activity and the end-product contained living material. The Hon'ble High Court held that the word "manufacture" was not defined in the statute therefore, the dictionary meaning attributed to the word in the particular trade or business can be accepted if the end product is a commercial entity. The court further held that there was no statutory bar in the patent statute to accept a manner of manufacture as patentable even if the end product contained a living organism. The court asserted that one of the most common tests was the vendibility test. The said test would be satisfied if the invention resulted in the production of some vendible item or it improved or restored the former conditions of the vendible item or its effect was the preservation and prevention from deterioration of some vendible product. The court further stated that the vendible product meant something which could be passed on from one man to another upon transaction of purchase and sale. In other words, the product should be a commercial entity. The subsequent major step, which further opened the arena of grant of patents in the field of biotechnology, was in the year 2002 when the Patents Act, 1970 was amended by the Patents (Amendment) Act, 2002, where biochemical, biotechnological, and microbiological processes were included within the scope of chemical processes for the grant of patent. The definition of "invention" was also changed to "any new product or process involving an inventive step and capable of industrial application," thereby deleting the word "manner of manufacture" as mentioned in the earlier Act. India joined the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on 17th December 2001. Consequently, section 10 of the Act was amended in 2002 to provide for deposition of the biological material and its reference in the patent application in case the invention relates to a biological material that is not possible to be described in a sufficient manner and which is not available to the public. The Patents Act, 1970, was amended by the Patents (Amendment) Act, 2005 paving the way for the grant of product patents in any field of technology, including biotechnology, with certain exceptions keeping in view the national policy to protect the public interest. The Act, as amended, recognizes the International Depository Authorities (IDAs) under the Budapest Treaty.

3. Biodiversity related issues

The Biological Diversity Act, 2002 (hereinafter referred to as BD Act) provides a mechanism for access to the genetic resources and benefit sharing accrued therefrom. Section 6 of the BD Act came into force on 1st July 2004, and prescribes that obtaining IPRs from the utilization of biological resources in India is subject to the approval of the National Biodiversity Authority (hereinafter referred to as NBA). To facilitate this access and benefit sharing and in order to prevent any unauthorized use of the biological resources of India, in 2005 suitable amendments were made in Section 10 of the Patents Act, 1970, wherein disclosure of the source and geographical origin of the biological material was made mandatory in an application for patent when the said material is used in an invention. In addition, a declaration by the applicant regarding the required permission from the competent authority was inserted in Form 1 of the Patents Rules, 2003.

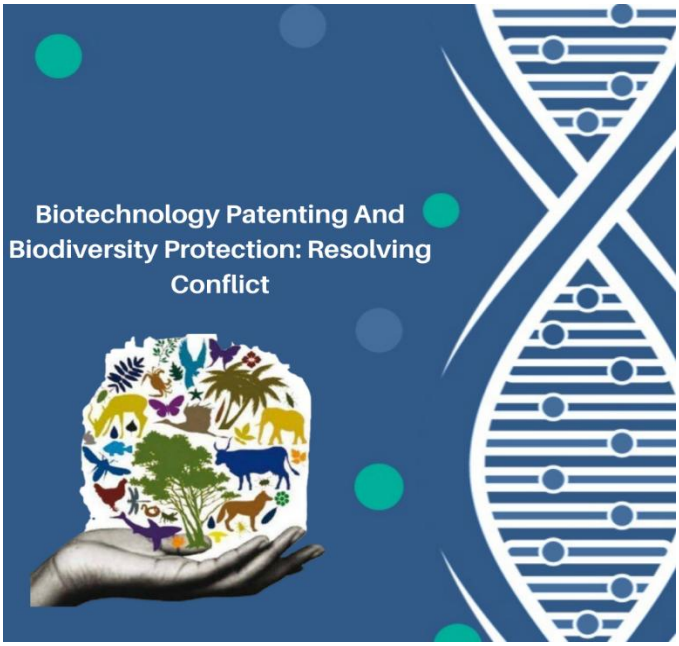


Fig 2: Biotechnology patenting and Biodiversity Protection

Therefore, the issues related to the BD Act and those related to mandatory disclosure of the source and geographical origin constitute an essential element of examination of biotechnology related subject matters. In view of the above background, the guidelines for the examination of patent applications in the field of biotechnology and allied subjects within the Patent Office have become essential in order to establish uniform and consistent practice. The guidelines as set out below are supplemental to the practices and procedures followed by Patent Office as published in the 'Manual of Patent Office Practice and Procedure'.

3.1. What Is Biotechnology Intellectual Property Rights?

Biotechnology intellectual property rights are the legal ownership of an interest in a patent, trademark or trade secret. This means that another company cannot use those assets without permission from 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.

3.2. Provisions covered

The following sections of the **Patents Act, 1970** are emphasised in the context of examination of applications in biotechnology and allied fields:

Section 2 (1) (j): Novelty, inventive step & industrial applicability of products or processes,

Section 3 (b): Inventions contrary to morality or which cause serious prejudice to human, animal or plant life or health or environment,

Section 3 (c): Discovery of any living thing or non-living substance occurring in nature,

Fig 3: Concept of Intellectual property Rights

Section 3 (d): Mere discovery of new form of known substance which does not result in enhancement of known efficacy or mere discovery of any new property or new use for a known substance,

Section 3 (e): Mere admixture resulting only in aggregation of the properties,

Section 3 (h): Method of agriculture and horticulture,

Section 3 (i): Method of treatment and diagnosis,

Section 3 (j): Plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species, and essentially biological processes,

Section 3 (k): Computer programs per se and algorithms, mathematical methods,

Section 3 (p): Inventions which are in effect traditional knowledge,

Section 10 (4): Sufficiency of disclosure and the best method of performing the invention, and

Section 10 (5): Unity of invention and clarity, succinctness and support of the claims.

4. Claims of biotechnological inventions

The details of wording of claims, clarity, support and sufficiency of the disclosure are discussed under appropriate headings. However, for better understanding of the issues related to novelty and inventive step, it is felt that we should begin with a preliminary discussion of claims of biotechnology related inventions which are usually filed in patent applications of the relevant fields. Usually the biotechnology applications comprise the claims relating to the following subject matters: (a) Polynucleotides or gene sequences (product and/or process), (b) Polypeptides or protein sequences (product and/or process), (c) Vectors (e.g., plasmids) (product and/or process), (d) Gene constructs or cassettes and gene libraries, (e) Host cells, microorganisms and stem cells (product and/or process), transgenic cells, (f) Plants and animals tissue culture (product

and/or process) (g) Pharmaceutical or vaccine compositions comprising microorganisms, proteins, polynucleotides (product and/or process), (h) Antibodies or antigen binding fragments thereof (monoclonal or polyclonal), (i) Diagnostic kits and tests, and (j) Diagnostic tests (products/process) such as a test for the detection of a mutation in a gene/protein which might be associated with a particular condition such as protein expression or a disease.

5. Prior art search

While conducting a prior art search, the Examiner should design a comprehensive search strategy by combining various search parameters including key words, IPC, sequences, etc. and thorough search should be carried out in patent as well as non-patent databases. If a patent application discloses sequence listing of nucleotides and/or amino acids as per Rule 9 (1) of the Patents Rules 2003, the same shall also be filed in electronic form. To facilitate the processing of patent applications, the sequence listings should be filed in computer readable format. The examiner should carry out the sequence search on the commercial databases available to the office and freely available databases using diverse search tools such as BLAST, FASTA, etc.

6. Novelty

In the case of biotechnological inventions, the assessment of novelty shall be carried out in the same manner as for other inventions. For the purpose of ascertaining novelty during the examination, the prior art is to be construed as prescribed under Section 13 (read with Sections 29 to 34) of the Act. The Manual of Patent Office Practice & Procedure has set out the guidelines for assessment of novelty of inventions (Chapter 8, Para 08.03.02) that may be referred to. According to Section 2 (1) (j) of the Act, an "invention" means a new product or process involving an inventive step and capable of industrial application. An invention will be patentable only if it is new in the light of prior art, or is not anticipated by prior art. The prior art includes all information and knowledge relating to the invention, which is available in any publication before the date of priority of the patent application. For the purpose of examination, an invention will not be new if it forms part of the prior art or has entered the public domain. For anticipation, such publication must be before the date of priority of the patent application. Also, any application for patent filed in India, but published after the date of filing of a subsequent application for patent in India claiming the same subject matter shall be treated as a prior art (i.e. prior claiming) to the said subsequent application provided that the previous application has earlier priority date.

6.1. Product-by-process claims

A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se, regardless of its method of production. Examples of 'Product-by-process' claims– (a) A polypeptide/compound which is the product of the method according to claim X

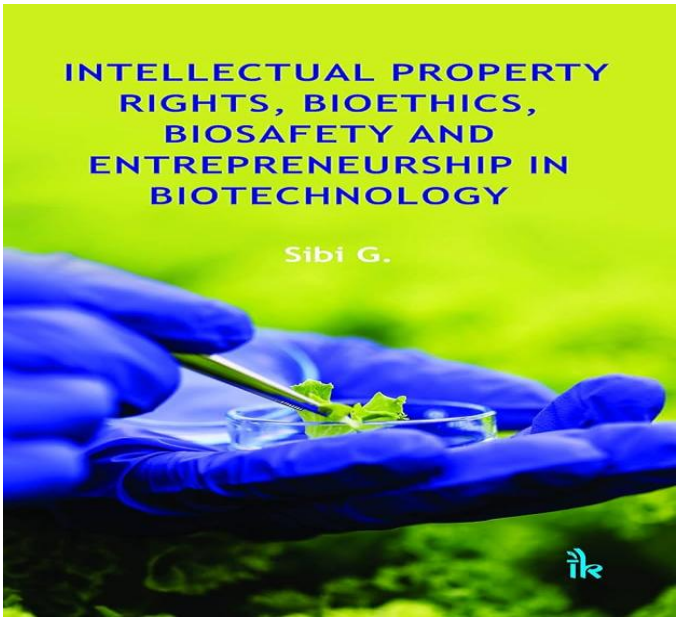


Fig 4: Biosafety of Biotechnology under IPR

(b) A transgenic microorganism obtained by the method characterized in that" (c) A plasmid obtained by the method of Such claims are admissible only if the products themselves fulfil the requirement of patentability over the prior art. The claimed products cannot be considered novel merely due to the novelty in the processes by which they are produced, but rather novelty can only be established, if technical evidences are provided showing that the modifications in the processes result in other products which are distinct with regard to their properties over the products known in the prior art. Such technical evidences may vary from case to case.

6.2. Sequence claims

A claim to a polynucleotide sequence that was available, e.g. as part of a library before the priority date, lacks novelty, even if activity or function of the said sequence of the polynucleotide has not been previously determined. A claim to a specific fragment of polynucleotide may be considered to be novel, but subject to fulfilment of the inventive step and non-patentability under relevant clauses of Section 3 of the Act. A prior disclosure of the same sequence as the claimed sequence, even without any indication of its activity, would prima facie constitute anticipation to the novelty of the claimed sequence. The reasoning is that the earlier sequence inherently possesses the activity of the claimed sequence. If any sequence of a polynucleotide/polypeptide from a prior art does not exactly match with the claimed sequence of polynucleotide/polypeptide, then the subject-matter of such claims cannot be said to be anticipated by the prior art sequence. However, such sequence of polynucleotide/polypeptide of the prior art would be relevant for deciding inventive step or non-patentability under relevant clauses of Section 3 of the Act.

Fig 5: Legal Protection under IPR

6.3. Combination/composition claims

Quite often, the claims of combination of products of biotechnology escape the question of novelty and are dealt under the inventive step or relevant clauses of Section 3 of the Act. However, sometimes it may happen that the combination has already fallen in the public domain and hence, to be dealt under novelty. **Example: Claim:** A composition useful against diphtheria toxin, comprising anti-diphtheria antibodies together with acceptable preservatives and stabilizers, wherein the antibodies are obtained from chicken egg yolk (IgY). Prior art discloses a composition useful against the diphtheria toxin comprising antibodies obtained from chicken egg yolk, physiologically acceptable carrier and other additives & adjuvants. The prior art further discloses a process for preparing egg yolk antibodies by employing the same steps right from an immunization of a chicken with a diphtheria antigen to antibodies purification as claimed in the present invention.

Analysis: The claim lacks novelty, as being anticipated by the said prior art which discloses all the features of claimed composition useful against the diphtheria toxin. Thus, the claimed subject matter lacks novelty.

6.4. Inventive step

The Manual of Patent Office Practice & Procedure has set out the guidelines for assessment of Inventive Step of inventions (Chapter 8, Para 08.03.03) that may be referred to. An invention should possess an inventive step in order to be eligible for patent protection. As per the Patents Act, an invention will have inventive step if the invention involves (a) technically advanced as compared to existing knowledge or (b) having economic significance or (c) both, and that makes the invention not-obvious to a person skilled in the art. **Example: Claim:** An isolated DNA sequence encoding a mature human IL-3 protein having a proline residue at position 8 of the mature polypeptide, said protein possessing bone marrow proliferation-inducing activity in a human bone marrow proliferation assay. Difference with prior art is that the claimed compound at position 8, there was a proline moiety whereas in the prior art compound in the same position there was a serine molecule**. Analysis:** Primate IL-3 are part of family proteins which are similar in their amino acid sequences, but are minor variants or point mutations of each other. A single variation in the amino acid sequence does not normally change the activity and function of the protein unless the single variation is in a critical region of the protein. The applicant could not provide any evidence that the protein coded by the claimed DNA was any different from that of the prior art in its chemical properties. Thus, the inventive step cannot be acknowledged. The claimed subject-matter would lack inventive step if it is obvious to a person skilled in the relevant art in view of a single prior art or a mosaic of the relevant prior art documents.

E**xample 1: Claim:** An improved process for the production of galacto oligo saccharides (GOS) of high yield and purity comprising the steps of: (i) isolating *Bullera singularis* and *Saccharomyces sp*. (ii) immobilizing the *B. Singularis* and *Saccharomyces sp;* (iii) hydrolysis of lactose by the immobilized microbial cells, said reaction being carried out until galactose content being at least 65 % and (iv) optionally concentrating the galactooligosaccharides solution. Prior Art: D1 discloses a process for the production of galacto-oligosaccharides from lactose using immobilized *B. singularis* cells. D1 does not explicitly teach the combined use of *B. Singularis* and Saccharomyces sp. in the production of galacto-oligosaccharides. D2 discloses the use of Saccharomyces sp. for the production of galacto-oligosaccharides from lactose. It further discloses that Saccharomyces sp. uses lactose as a carbon source & approximately it removes 92% of glucose from the GOS mixture by fermentation without losing the GOS content. **Analysis:** Since it is evident from D2 that Saccharomyces sp. consume glucose, one of ordinary person skilled in the art would be motivated to use Saccharomyces sp. in combination with *B. singularis* to solve the problem of separation of saccharides and also, reducing the competitive inhibition of beta-galactosidase enzyme by glucose, which leading to high yield & purity of GOS. Thus, the claimed subject-matter lacks inventive step.

Example 2: Claim: A culture independent method of removal of plasmids from live and multiplying plasmid containing bacteria comprising the following steps: (a) preparing an aqueous first suspension of sub-micronic silver particles; (b) estimating MIC (minimum inhibitory concentration) of the silver particles for the bacteria to determine the inhibitory concentration of the particles suspension for the bacteria; (c) adding in a reaction vessel, the first suspension and growth medium of the bacteria to obtain a second suspension containing sub-MIC concentration of silver particles; (d) introducing the bacteria in the reaction vessel under conditions favouring the multiplication of the bacteria, for 12 to 48 hrs., to obtain subsequent generations of the bacteria and (e) testing the bacterial generations for absence of plasmids to obtain a generation of plasmid free bacteria. Prior art discloses a method in which an antimicrobial activity of silver Nano-particles

against E. coli was investigated as a model for Gram-negative bacteria. Bacteriological tests were performed in LB medium on solid agar plates and in liquid systems supplemented with different concentrations of silver Nano-sized particles. To examine the effect of silver nanoparticles on Gram-negative bacteria, approximately 105 colony-forming units (CFU) of E. coli strain were cultured on LB agar plates supplemented with silver Nano-sized particles in the concentrations of 10 to 100 µg cm-3. Silver-free LB plates cultured under the same conditions were used as a control. The plates were incubated for 24 hours at 37O C. E. coli bacteria were grown in 100 cm3 of liquid LB medium supplemented with 10, 50, & 100 µg of these particles per cm3 of medium. Growth rates & bacterial concentrations were determined by measuring optical density (OD) at 600 nm each 30 min (OD of 0.1 corresponds to a concentration of 108 cells per cm3). The size and morphology of the silver nanoparticles were examined by transmission electron microscopy (TEM). The results confirmed that the treated E. coli cells were damaged, showing formation of "pits" in the cell wall of the bacteria, while the silver nanoparticles were found to accumulate in the bacterial membrane. A membrane with such morphology exhibits a significant increase in permeability, which leads to leaking of intracellular substances (that is admitted by the applicant on page 16, 3rd paragraph in the specification of the present invention). The TEM micrograph also shows coagulation of Nano-sized particles at the bacterial surface. Analysis: Prior art discloses each and every aspect of claimed invention right from the selection of E. coli strain, preparation of silver nanoparticles, culturing of the bacterial strain with different concentration of silver nanoparticles, conditions for bacterial growth and assessment of effect of silver nanoparticles on gram negative bacteria. Prior art does not explicitly teach removal of plasmid from bacteria; however, it teaches that the silver nanoparticles were responsible for significantly increasing the permeability of bacterial cell membrane that leads to leaking of intracellular substances (which may include plasmids) from E. coli. Thus, the teaching of cited art would motivate a person having ordinary skill in the art with reasonable expectation of success to provide an alternative method for removal of plasmids from plasmid containing bacteria in order to solve the problem faced with plasmid containing bacteria using varied concentration of silver nanoparticles, as these particles effectively increase bacterial cell membrane permeability leading to removal of intracellular substances, which may include plasmids. Thus, the claimed subject-matter lacks inventive step in view of prior art. If the claimed invention relates to a polynucleotide/polypeptide having mutation(s) in a known sequence of polynucleotide/polypeptide, which does not result in an unexpected property whatsoever, then the claimed subject-matter lacks inventive step.

Example 1: Claim: Pro-insulin having a C-peptide encompassing only two amino acids selected from Arg-Lys, Lys-Lys and Lys-Arg*. (*Human Pro-insulin is comprised of three chains, A, B and C, in the insulin the two chains are combined eliminating the third chain, i.e. the C–chain consisting of thirty amino acids). Prior art discloses natural Pro-insulin having 30 amino acids C-peptide, Pro-insulin with Peptide as short as two amino acids (Arg-Arg).

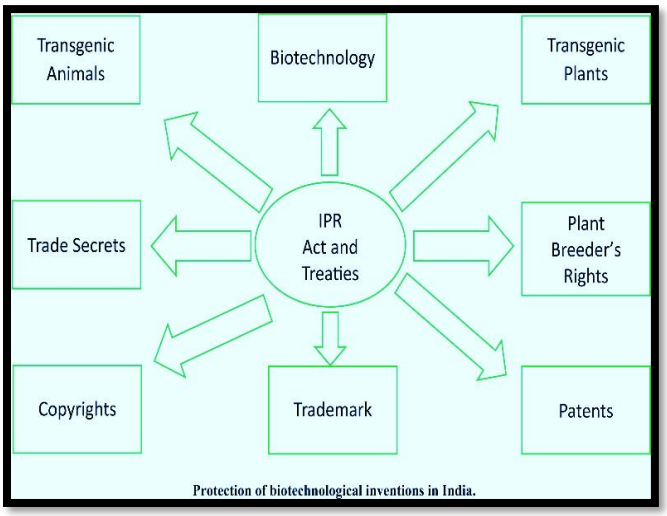
Analysis: The claim was held to be prima facie obvious. The applicant argued that the yield of claimed Pro-insulin having a C-peptide expressed in yeast is 1.6 to 2.0 mmol/l whereas the yield of the prior art Pro-insulin with a C-chain of Arg-Arg is only 1.0 mmol/l. Such a difference in change did not constitute 'unexpected property' and hence, the subject-matter is held to be obvious.

Example 2: Claim: A recombinant DNA sequence of SEQ ID NO: X encoding human interferon α2 polypeptide. Prior art discloses a nucleic acid sequence of SEQ ID NO: X1 encoding human interferon α1 polypeptide. **Analysis:** The claimed human interferon α2 is structurally close to the prior art's human interferon α1. However, the alleged invention can be held non-obvious, because of the fact that the claimed human interferon is thirty times more potent in its antiviral activity than its prior art analogue.

7. Industrial application

As per Section 2(1) (ac) of the Act, the expression "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry". Further, Section 64 (1) (g) of the Act provides that a patent is liable to be revoked if the invention is not useful. To be patentable an invention must be useful and capable of industrial application. The specification should disclose the usefulness and industrial applicability of an invention in a distinct and credible manner unless the usefulness and industrial applicability of the invention is already established, either in explicit or in implicit manner. In the context of the gene sequences, it may be said that whatever ingenuity is involved in discovering a gene sequence, one cannot have a patent for it or a protein encoded by it unless it is disclosed how it can be used. It is therefore necessary to consider whether the invention claimed has a useful purpose, and whether the specification identifies any practical way of using it. **Example 1: Claim:** A polypeptide in substantially isolated form comprising a contiguous sequence of at least 10 amino acids encoded by the genome of hepatitis C virus (HCV) and comprising an antigenic determinant, wherein HCV is characterized by: (i) a positive stranded RNA genome; (ii) said genome comprising an open reading frame (ORF) encoding a polyprotein; and (iii) said polyprotein comprising an amino acid sequence having at least 40% homology to the 859 amino acid sequence X. Upon examination it was found that the above claim was sufficiently enabled and its use was properly established in the

specification. Therefore, claim 1 was allowable. Another claim of the specification read as "A polypeptide in substantially isolated form whose sequence is shown in any one of SEQ IDs 1, 3 to 32, 36, 46 and 47, or whose sequence is encoded in a polynucleotide selectively hybridisable with the polynucleotide as shown in any one of SEQ IDs 1, 3-32, 36,46 or 47." Upon examination, it was seen that the said claim covered an almost vast number of polypeptides for which no use was established and the said claim therefore, was not allowable on the ground that it lacked industrial applicability. The use of claimed subject-matter (e.g. a gene or a protein) disclosed in the specification should not be merely speculative, rather the said use should be specific, substantial and credible for establishing industrial applicability of the claimed subject matter. **Example 2: Claim 1:** A V28 protein (V28) having a function as a receptor (of a kind known as 7TM). Claim 2: A method of verifying the function of a V28 protein as claimed in claim 1. **Analysis:** The function of V28 protein as a receptor was based on prediction upon various structural elements in the deduced amino acid sequence and homology to known 7TM receptors but the specification disclosed no ligand. The use of the invention is disclosed in the specification, which is however based on a proposed function of the V28 protein as a receptor that is not sufficiently disclosed in the specification. Thus, the use disclosed in the application is speculative, i.e. is not specific, substantial and credible and as such is not considered industrially applicable.



Protection of biotechnological inventions in India.

9.1. Fragments/ESTs

Fragments/ESTs (Expression Sequence Tag) are allowable if they in addition to other conditions satisfy the question of usefulness and industrial application. An EST whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered to have an industrial application. A credible, specific and substantial use of the EST should be disclosed, for example use as a probe to diagnose a specific disease.

8. Section 3 (b): inventions contrary to morality or which cause serious prejudice to human, animal or plant life or health or environment

Biotechnology deals with living subject matters and involves alteration of genomic materials of an organism. Such change may influence or may have a deep impact upon the environment or the human, animal or plant life or may involve serious questions about morality. Hence, adequate care should be taken while examining the inventions vis-a-vis their primary or intended use or commercial exploitation and it should be carefully dealt so that the subject-matter must not be contrary to public order, morality or causes serious prejudice to human, animal or plant life or health or to the environment. A few non limiting examples may further clarify the issues: (a) a process for cloning human beings or animals; (b) a process for modifying the germ line of human beings; (c) a process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or other benefit to man or animal, and also animals resulting from such process; (d) a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact; (e) uses of human embryos for commercial exploitation.

9. Section 3(c): scientific principles or abstract theory or discovery of living things or non-living substances

According to Section 3 (c) of the Act, the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature is not a patentable invention. Products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature, are not patentable subject-matter. However, processes of isolation of these products can be considered subject to requirements of Section 2 (1) (j) of the Act. **Example 1: Claim:** Bacillus sp. IN123 comprising rDNA (ribosomal DNA) sequence represented as SEQ ID NO: 1 (deposition No. XXXXXX). **Analysis:** The subject-matter of claim falls within the scope of Section 3 (c) of the Act, as it attempts to claim an isolated Bacillus sp. IN123 (i.e. a living substance) occurring in nature (i.e. from soil as disclosed in the specification). Thus, what is claimed in the claim is treated as a discovery of a living thing occurring in nature and hence, not patentable. **Example 2: Claim:** A novel agent for promoting cardiac development activity, said agent having SEQ ID NO: 1, wherein the agent is obtained from the per vitelline fluid of horseshoe crab, *Tachypleus gigas*. **Analysis:** The subject-matter is not patentable under Section 3 (c) of the Act, because the claim attempts to claim an agent, which is isolated from per vitelline fluid of embryos of horseshoe crab, Tachypleus gigas (i.e. a peptide which is non-living substance occurring in nature). As per Section 3 (c) of the Act, a non-living substance occurring in nature is not patentable subject-matter and thus, it is not

patentable. **Example 3: Claim:** An isolated peptide that is structural equivalent of a cupredoxin or cytochrome that can inhibit parasitaemia in malaria-infected red blood cells and intracellular replication of a malarial parasite in malaria-infected human red blood cells. **Analysis:** The subject-matter of claim falls within the scope of Section 3 (c) of the Act, because the disclosure does not clearly indicate what modifications/alterations/deletions are made in the wild-type peptides. In fact, the definition of a word "isolated" used in claims refers to materials, which are substantially or essentially free from components, which normally accompany the materials as they found in their native's states. Thus, the subject matter of claim is considered to be isolated non-living substances occurring in the nature and functional features for said isolated peptide is considered inherent to a cupredoxin or a cytochrome protein, which is not patentable as per Section 3 (c) of the Act.

10. Section 3(d): discovery of new form of known substance which does not result in enhancement of efficacy

Section 3 (d) of the Act requires that any minor modifications in the already existing substance in the prior art are not patentable unless the improved property/efficacy of the modified substance is established. **Example: Claim:** Pre-protein A being one of the factors which primarily control glucose metabolism in mammals having C-peptide, wherein said C-peptide comprises two amino acids selected from XY, YZ and ZX. **Analysis:** Prior art discloses modified protein A having C-peptide, wherein said C-peptide consists of amino acids XX. The applicant failed to demonstrate any therapeutic efficacy as a result of claimed modification over the prior art. Hence, the subject-matter of claim is not patentable under Section 3 (d) of the Act. The inventions relating to three-dimensional or crystal structure of a polypeptide attracts the provision of Section 3 (d) of the Act unless it is proved that such polypeptide differs significantly in the properties with regards to therapeutic efficacy. E**xample: Claim:** A crystal of a peptide consisting of SEQ ID NO: A, wherein said crystal comprises an asymmetric unit, said asymmetric unit comprises four molecules of said peptide per Zn2+ and further wherein the crystal belongs to space group X, Y, Z. **Analysis:** The amorphous forms of peptide of SEQ ID NO: A are known. The applicant failed to demonstrate any significant improvement in properties with regards to the therapeutic efficacy over the known amorphous peptide. Hence, it is not allowable under Section 3 (d) of the Act.

11. Section 3 (e): mere admixture resulting only in aggregation of the properties or a method of making such mere admixture

It is a well-accepted principle of Patent Law that mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together has some working interrelation producing a new or improved result, then there is patentable subject matter in the idea of the working inter relations brought about by the collocation of the integers. In Ram Pratap v Bhaba Atomic Research Centre (1976) IPLR 28 at 35, it was held that a mere juxtaposition of features already known before the priority date which have been arbitrarily chosen from among a number of different combinations which could be chosen was not a patentable invention. Section 3(e) of the Act reflects the legislative intent on the law of patenting of combination inventions in the field of chemical as well as biotechnological sciences. **Example: Claim:** A composition of innovative combination of dormant spore of naturally occurring Actinomyces lilacinus and Arthrobotrys sp. fungus with enzymes, fats and growth promoting molecules to control plant-parasitic nematodes. **Analysis:** The subject-matter of claim falls within the scope of Section 3 (e) of the Act. Upon examination, it is found that the claim is directed to a composition of two known fungal species. The said two species used in the alleged invention are known for their nematode bio-control activity. The specification is silent on advantages of a combinative effect of these two fungal species over the sum of their individual effects. Thus, the subject-matter of the claim is not patentable under Section 3 (e) of the Act.

12. Section 3 (h): method of agriculture and horticulture

According to Section 3 (h) of the Act, a method of agriculture or horticulture is not considered as patentable subject matter. While deciding patentability under Section 3 (h), conventional methods performed on actual open fields should be construed as method of agriculture/horticulture**. Example: Claim:** A method of growing leguminous plants as inter-cropping for improving fertility of soil by augmenting nitrogen content of the soil. **Analysis:** The subject-matter of the claim is agriculture method and hence, falls within the scope of Section 3 (h) of the Act.

13. Section 3 (i): method of treatment

According to Section 3 (i) of the Act, any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not an invention. In the context of Section 3 (i), the Manual of Patent Office Practice & Procedure states that this provision excludes from the patentability the followings: (a) Medicinal methods: As for example a process of administering medicines orally, or through injectable, or topically or through a dermal patch. (b) Surgical methods: As for example a stitch-free incision for cataract removal. (c) Curative methods: As for example a method of cleaning plaque from teeth. (d) Prophylactic methods: As for example a method of vaccination. (e) Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history

and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic. (f) Therapeutic methods: The term "therapy'' includes prevention as well as treatment or cure of disease. Therefore, the process relating to therapy may be considered as a method of treatment and as such not patentable. (g) Any method of treatment of animal to render them free of disease or to increase their economic value or that of their products. As for example, a method of treating sheep for increasing wool yield or a method of artificially inducing the body mass of poultry.

(h) Further examples of subject matters excluded under this provision are: any operation on the body, which requires the skill and knowledge of a surgeon and includes treatments such as cosmetic treatment, the termination of pregnancy, castration, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor, any therapy or diagnosis practiced on the human or animal body and further includes methods of abortion, induction of labour, control of oestrus or menstrual regulation. (i) Application of substances to the body for purely cosmetic purposes is not therapy. (j) Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable. Sometimes the claims are so drafted that a combination/composition of drugs in certain dosage forms is claimed, but the claimed subject-matter relates to application or administration of individual drugs in simultaneous, sequential or concomitant manner. In such cases, although the claims are directed to a combination/composition of drugs, but the claimed invention resides in the method of administration of individual drugs in the said manner and thus, it falls within the scope of section 3 (i) of the Act. **Example:** Claim: A method of monitoring drug response in a patient suffering from cancer treated with a combination of Gemcitabine and P1446A, comprising detection of a gene signature with at least two drug response markers, wherein the said drug response markers are selected from the group consisting of P21, REV3L, FGF5, PTK7, POLH, P27 and SSTR2. Analysis: The subject-matter of claim is directed to method of diagnosis of human beings or animals, which are statutorily barred from the patentability under Section 3 (i) of the Act. Hence, the subject-matter of claim is not patentable.

14. Section 3 (j): plants & animals in whole or any part, seeds, varieties, species other than microorganisms & essentially biological processes are not patentable subject matter

According to Section 3 (j) of the Act, plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable inventions. Although, microorganisms are excluded from non-patentability list, a conjoined reading with Section 3 (c) of the Act implies that only modified microorganisms, which do not constitute discovery of living thing occurring in nature, are patentable subject matter under the Act. Claims relating to essential biological processes of growing plants, germination of seeds, of development stages of plants and animals shall be objected under Section 3 (j) of the Act. **Example 1: Claims:** A therapeutic composition for treating an immune-related disorder in a mammalian subject, the composition comprises as an effective ingredient ex vivo educated autologous NK T cells capable of modulating Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells and optionally comprising pharmaceutically acceptable carrier, diluent, excipient and/or additive. Analysis: The claimed subject-matter falls within the scope of Section 3 (j) of the Act for claiming ex vivo educated autologous NK T cells in the form of therapeutic composition. Although the claim is directed to a composition, but there is nothing like a composition; in fact the educated autologous NK T cells alone would be treated as a final product, because other ingredients are kept as optional. Just by wording a claim as a composition claim comprising additional one or more routine ingredients (for example pharmaceutically acceptable carriers) has no effect on the final product and it does not exclude the claim from falling within the scope of Section 3 (j) of the Act. **Example 2: Claim:** A method of producing at least one of substantially pure hybrid seeds, plants and crops, comprising the steps of (i) producing a male parent which is male fertile, (ii) breeding the male parent with a female parent which is substantially male sterile, and (iii) harvesting seeds from the female parent which contain pure hybrid seeds. Analysis: The claimed method involves the step of cross breeding for producing pure hybrid seeds, plants and crops. Thus, it is an essentially biological process and not allowable under Section 3 (j) of the Act.

14. Section 3 (k): mathematical or business method or a computer programme per se or algorithms

According to Section 3 (k) of the Act, a mathematical or business method or a computer programme per se or algorithms are not patentable inventions. Bio-informatics is a relatively young science and has emerged from the combination of information technology and biotechnology. Thus, the determination of patentability of inventions relating to bioinformatics requires special attention vis-a-vis exclusions under Section 3 (k) of the Act. **Example 1: Claim:** A data processing method, wherein a first chemical substance is a compound; a second chemical substance is nucleic acid, protein or a complex thereof; a first characteristic amount is expressed as a vector comprised of more than one type of chemical substance information of the first chemical substance; a second

characteristic amount is expressed as a vector comprised of more than one type of biological information of the second chemical substance; and the first characteristic amount and the second characteristic amount are map-transformed using a multivariate analysis technique or a machine learning method so as to increase a correlation between first space expressing the first characteristic amount and second space expressing the second characteristic amount.

Analysis: The claimed invention is considered as a mathematical method or computer programme per se in so far as that it relates to data processing of certain technical parameters of chemical and biological substances, but does not lead to any product whatsoever. Various references to chemical and biological substances therein are only to the meaning of data itself and do not relate to any technical implementation details for carrying out the methods. Hence, the subject-matter of claim falls within the scope of statutorily non-patentable inventions under Section 3 (k) of the Act. **Example 2: Claim:** A computer-assisted method of generating a compound that inhibits the glutamine formation active site activity of a glutamine synthetase polypeptide, wherein said test compound is capable of inhibiting the interaction between an adenylated catalytic triad site of the glutamine formation active site and a γ-glutamyl phosphate intermediate, or of inhibiting the interaction between an de-adenylated catalytic triad site of the glutamine formation active site and a γ-glutamyl phosphate intermediate, the method comprising the steps of: (a) providing a three-dimensional structure of a glutamine formation active site of a glutamine synthetase polypeptide; and (b) designing, based on the three-dimensional structure, a test compound capable of inhibiting the interaction between the glutamine formation active site and a γ-glutamyl phosphate intermediate.

Analysis: The claimed method is considered as a mathematical method or computer programme per se as it relates to a method of designing the inhibitory compound based on three dimensional structures, but does not lead to a real product whatsoever. Thus, the subject-matter of claim falls within the scope of statutorily non-patentable inventions under Section 3 (k) of the Act.

15. Section 3(p): traditional knowledge related inventions

According to Section 3 (p) of the Act, an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components is not a patentable subject matter. For the examination of TK related subject matters, separate guidelines have already been issued by the Office of CGPDTM. **Example: Claim:** Serum of pigeon possessing the anti-paralysis activity. Analysis: The use of pigeon serum for the treatment of paralysis (as it possesses anti-paralytic activity) is a traditional knowledge in India or is an aggregation or duplication of known properties of traditionally known component. It is clearly evident from D1 (Mahawar et al., "Animals and their products utilized as medicines by the inhabitants surrounding the Ranthambhore National Park, India", Journal of Ethnobiology and Ethno medicine, 2006, 2:46, see entire document especially Table I), which discloses the use of pigeon blood for treating paralysis.

16. Sufficiency of disclosure, clarity & support of the claims & unity of inventions

Section 10 (4) of the Act requires that every complete specification shall fully and particularly describe the invention and its operation or its use and the method by which it is to be performed. Every specification shall also disclose the best method of performing the invention known to the applicant for which he is entitled to claim protection. A complete specification shall end with a set of claims(s) defining the scope of invention for which protection is sought. As per Section 10 (5) of the Act, the claim(s) shall be clear and succinct and shall be fairly based on the matter disclosed in the specification. The purpose of the disclosure and the claims are not same and yet mutually supportive. Whereas, the disclosure of the specification constitutes the essential component of the quid pro quo of the patent system, the claims notify the public the forbidden area. While assessing the sufficiency of disclosure, the examiner must be careful to ensure that at least one method for performing the invention must be described so that the whole subject-matter that is claimed in the claims, and not only a part of it, must be capable of being carried out by a skilled person in the relevant art without the burden of an undue amount of experimentation or the application of inventive ingenuity. If the skilled person, following the directions given in the specification has to find out something that is new in order to reproduce the invention, the disclosure is insufficient. Where the claims in an application are broad and indeterminate and of a speculative character, the claims will be treated as not supported by the description. If the specification discloses a listing of a wide range of unrelated diseases as potential future therapeutic or diagnostic targets of a claimed gene or the protein that it encodes, the claims of such gene are known as Claims having laundry list. It is possible that the gene may play an important role in the treatment of one or more of the listed diseases; it is unlikely that gene or its product will have a role in all of the diseases. Such claims are generally made when the activity of the protein has not been fully characterised, and therefore any potential uses of the protein are speculative. Even if the function of the polypeptide has been characterised, and its association with one type of disease has been ascertained, this is not enough to support the use of the polypeptide in the diagnosis or treatment of numerous other unrelated diseases. Therefore, if there is no evidence in the specification as filed that the gene or polypeptide is of therapeutic or diagnostic use in each different disease listed, then the specification is insufficient. When claims seek to protect things that are not identified by the applicant at the time of filing the application,

but that may be identified in the future by carrying out the applicant's process, such claims are not patentable on the ground of insufficiency of description.

Thus, the claims reach through to things, which are not yet identified by the applicant. In Raj Praksh v Mangatram Chowdhury AIR 1978 Del 1 at 9, it was observed following Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Burning a corporation etc. Vs. Unichem Laboratories and Ors"., AIR1969Bom255: the complete specification must describe "an embodiment" of the invention claimed in each of the claims and the description must be sufficient to enable those in the industry concerned to carry it into effect without their making further inventions "and the description must be fair, i.e. it must not be unnecessarily difficult to follow". An insufficient complete specification cannot become sufficient because of general developments in the state of the art after the filing date. The relevant date for complying with the requirement for sufficiency is the date of complete specification. In other words, a complete specification should provide enough information to allow a person skilled in the art to carry out substantially all that which falls within the ambit of what is claimed. Analogues or variants of polynucleotides or polypeptide sequences, in the form of additions, substitutions or deletions, could extend to an almost infinite number of variants. In such cases, the claim should be restricted to variants sharing a common specific activity with each other that are disclosed in the specification. The said activity disclosed should not be predictable in nature. When DNA sequences are claimed on the basis that they hybridise with a specifically identified probe and that they possess a certain activity, the claim will not be supported if the hybridisation conditions are not specifically disclosed and if the skilled person needs to perform an undue experimentation to achieve the desired result. Claims to antibodies that may have therapeutic or diagnostic potential are unsupported if a role for the target protein in a specific disease has not been identified and proved by sufficient data. **Example: Claim:** A method comprising: (i) contacting polypeptide X with a compound to be screened and determining whether the compound affects the activity of the polypeptide and (ii) formulating any active compound into a pharmaceutical composition. **Analysis:** Any method that merely screens existing materials does not give rise to products and claims resulting from such methods 'reach through' to as yet unidentified materials. In the absence of any knowledge of any relationship, either from the specification or from common general knowledge, the skilled person would not know how to produce and use the compounds. It would require an undue burden of experimentation to screen undefined compounds for the desired activity. There will also be a lack of support where the function of the compounds identified is not specified.

17. Unity of invention

According to Section 10 (5) of the Act, the claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept. In the field of gene technology, it is quite common for a patent application to claim, a large number of polynucleotide and polypeptide sequences. This raises problems at the various phases of the application such as publication stage, examination especially the searching stage. In particular, it is not always clear whether claimed sequences relate to a single invention, or to a group of inventions linked so as to form a single inventive concept. Lack of unity may be evident in an application in the following ways: `A priori', i.e., before consideration of prior art, if the claims falling in different groups do not share a same or corresponding technical feature. `A posteriori', i.e., after a search of the prior art, if the shared technical feature fails to make a contribution over the prior art. Examples of a priori determination of prior art is given as herein below:

17.1. Example of a priori determination of unity of invention:

1) A DNA construct for improved expression of a heterologous or homologous polypeptide comprising: (a) isolated DNA sequence (SEQ ID NO: A) or a portion thereof which retains promoter activity adapted for recombinant protein expression, (b) DNA sequence encoding the desired polypeptide such that said DNA sequence is in operative association with said promoter and is expressed under the control of the said promoter, wherein said isolated DNA sequence is a constitutive promoter for citrate synthase (citA) gene from filamentous fungi *Aspergillus niger*.

2) A DNA construct for improved expression of a heterologous or homologous polypeptide comprising: (a) a promoter sequence according to SEQ ID NO: B or a portion thereof which retains promoter activity, (b) DNA sequence encoding the desired polypeptide such that said DNA sequence is in operative association with said promoter and is expressed under the control of the said promoter.

3) A DNA construct for improved expression of a heterologous or homologous polypeptide comprising: (a) a promoter sequence according to SEQ ID NO: C or a portion thereof which retains promoter activity, (b) DNA sequence encoding the desired polypeptide such that said DNA sequence is in operative association with said promoter and is expressed under the control of the said promoter. Analysis: The subject-matter of claims 1-3 does not relate to a single invention, or to a group of inventions linked so as to form a single inventive concept as per Section 10 (5) of the Act. Thus, claims 1-3 contain following groups of inventions: Group-I: Claim 1 directed to a DNA construct for improved expression of a heterologous or homologous polypeptide comprising isolated DNA sequence (SEQ ID NO: A), Group-II: Claim 2 directed to a DNA construct for improved expression of a heterologous or homologous polypeptide comprising isolated DNA sequence

(SEQ ID B) and Group-III: Claim 3 directed to a DNA construct for improved expression of a heterologous or homologous polypeptide comprising isolated DNA sequence (SEQ ID NO: C). Upon examination, it is found that the DNA sequences as described SEQ ID NO: A, B & C do not share any common structural feature. Therefore, as there is no special technical feature, which could serve as basis for unifying the above-said groups of inventions, each of these groups has to be considered as a separate invention. Thus, these three groups are said to lack unity a priori.

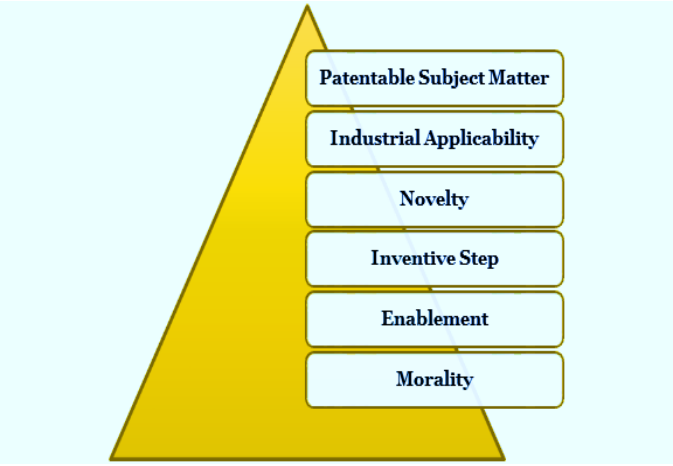


Fig 6: Patentability of Subject Matters

17.2. Example of a posteriori determination of unity of invention:

1) A composition comprising a combination of X and Protein Y to identify a gene for prostate cancer, wherein X is selected from a group of hetero-cycles as depicted in formula 1 [Formula 1 given] 2) A composition comprising a combination of X and Protein Z to identify a gene for prostate cancer, wherein X is selected from a group of hetero-cycles as claimed in claim 1. Analysis: Claims 1-2 contain the following inventions or group of inventions, which are not so linked as to form a single general inventive concept as required u/s 10 (5) of the Patents Act, 1970 (as amended): Group I: Claim 1 drawn to a composition comprising a combination of X and Protein Y to identify a gene for prostrate caner, wherein X is selected from a group of heterocycles as depicted in formula 1. Group II: Claim 2 drawn to a composition comprising a combination of X and Protein Z to identify a gene for prostrate caner, wherein X is selected from a group of heterocycles as claimed in claim 1. The above said groups are linked by the technical feature "X". Upon prior art search, it is found that "X" is already known in the prior art. Thus, this feature is not a special technical feature, because it does not constitute advancement over the prior art. The unity of invention is treated to be fulfilled only when there is a technical relationship among inventions involving one or more of the same or corresponding special technical features. Thus, claims 1 & 2 failed to meet the requirements of Section 10 (5) of the Act. Consequently, the application may be objected for lacking unity a posteriori.

18. Deposit of biological material

If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit. Depositary Authorities: Reference to IDA under the Budapest Treaty under Section 10 (4) should be read with Section 2 (1) (aba) of the Act.

19. Biodiversity related issues

It has been discussed in the beginning that biodiversity related matters play a vital role in the patentability of the biological substances. The Biological Diversity Act, 2002 provides mechanism for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. In order to prevent misappropriation of biological resources and traditional knowledge of India, the Biological Diversity Act requires that access to the biological resources of India is subject to the equitable benefit sharing through the approval of National Biodiversity Authority (NBA). No Intellectual Property Rights (IPRs), including patents based on research or information on biological resources obtained from India shall be granted without the approval of the NBA. The Patents Act provides interfaces with the process of obtaining patents and access to and benefits sharing from utilization of Indian biological resources. Thus, disclosure of the source and geographical origin of a biological material used in an application for a patent has been made mandatory as per Section 10 (4) of the Act. Also, Section 3 (p) of the Act prohibits patenting of any invention which, in effect, is traditional knowledge. With respect to the patenting of inventions related to traditional knowledge and biological material obtained from India, the instructions issued by the Controller General of Patents, Designs and Trademarks should be strictly followed.

20. International IP treaties Patent treaties

20.1. Budapest Treaty

The Budapest Treaty eliminates the need to deposit microorganisms in each country where patent protection is sought. Under the treaty, the deposit of a microorganism with an "international depositary authority" satisfies the deposit requirements of treaty members' national patent laws. An "international depositary authority" is capable of storing biological material and has established procedures that assure

compliance with the Budapest Treaty. Such procedures include requirements that the deposit will remain available for the life of the patent and that samples will be furnished only to those persons or entities entitled to receive them.

20.2. Hague Agreement

The Hague Agreement is an international registration system which offers the possibility of obtaining protection for up to 100 industrial designs in designated member countries and intergovernmental organizations (referred to as "Contracting Parties") by filing a single international application in a single language, either directly with the International Bureau of the World Intellectual Property Organization (WIPO) or indirectly through the office of the applicant's Contracting Party.

20.3. Patent Cooperation Treaty

Under this WIPO-administered treaty, nationals or residents of a contracting state file a single patent application, called an "international" application, with their national patent office or with WIPO as a receiving office. This automatically lodges the application for patent protection in all contracting parties of the **Patent Cooperation Treaty** (PCT). By simplifying patent application filing, the PCT assists innovators in obtaining patent protection throughout the world. It also encourages small businesses and individuals to seek patent protection abroad.

20.4. Patent Law Treaty

The Patent Law Treaty (PLT) harmonizes and streamlines formal procedures in respect of national and regional patents and patent applications, making the procedures and the global patent system more user friendly. To do so, the provisions of the PLT set forth a maximum set of requirements a party to the treaty may apply. It does not, however, harmonize substantive patent law. Rather, it makes it easier for patent applicants and patent owners to obtain and maintain patents throughout the world by simplifying and, to a significant degree, aligning formal requirements associated with patent applications and patents among global patent offices and jurisdictions.

20.5. UPOV

The International Convention for the Protection of New Varieties of Plants, or UPOV Convention, was adopted on December 2, 1961, following a diplomatic conference held in Paris, France. The UPOV Convention is administered by the International Union for the Protection of New Varieties of Plants (UPOV), an intergovernmental organization with headquarters in Geneva, Switzerland. The mission of UPOV is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.

20.6. Trademark treaties

Trademark Law Treaty

The Trademark Law Treaty simplifies and harmonizes trademark application and registration procedures by member states. It facilitates renewals, the recordation of assignments, name and address changes, and powers of attorney.

20.7. Singapore Law Treaty

The **Singapore Treaty on the Law of Trademark** modernizes the international trademark system by expanding protectable subject matter to include non-traditional marks, such as sensory marks, colour, position, and movement marks, among others.

20.8. Madrid Protocol

The **Madrid Protocol** is a filing or procedural treaty, not a substantive harmonization treaty. It was designed to provide a cost-effective, efficient, and centralized way for trademark owners—individuals and businesses—to obtain protection for their marks in multiple countries by filing one international application with the applicant's office of origin, in one language, with one set of fees, in one currency. Learn about the Madrid Protocol registration process.

20.9. Trade-related treaties and agreements

TRIPS

The Agreement on **Trade-Related Aspects of Intellectual Property Rights (TRIPS)** came into force in 1995, as part of the Agreement Establishing the World Trade Organization (WTO). TRIPS applies basic international trade principles to member states regarding intellectual property, including national treatment and most-favoured-nation treatment. TRIPS establishes minimum standards for the availability, scope, and use of seven forms of intellectual property: copyrights, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits, and undisclosed information (trade secrets). It spells out permissible limitations and exceptions in order to balance the interests of intellectual property with interests in other areas, such as public health and economic development. For the complete text of the TRIPS Agreement, as well as an explanation of its provisions, see the WTO website.

20.9. Other IP treaties

Berne Convention

The Berne Convention for the Protection of Literary and Artistic Works, adopted in 1886, is the world's oldest multilateral copyright convention. The treaty contains a series of substantive provisions that set forth the minimum protection to be granted to authors and their copyrighted works (e.g., it sets forth certain minimum exclusive rights that must be provided and a minimum term of protection). The Convention is based on the important principles of national treatment (which requires each Berne member to treat nationals of other members at least as well as it treats its own nationals) and "automatic" protection (i.e., copyright protection outside the country of origin must not be conditioned upon compliance with any legal formalities such as a registration system).

International Treaties on IPR

There are different subject matters of intellectual property like Patents, Copyright, Trademarks, Industrial design, Plant Varieties etc. Need for protection in these different subjects arose in different periods. These are reflected in different

treaties. Agreement on TRIPS, under the aegis of WTO, remains the most influential, comprehensive and inclusive of all. Other treaties are covered here for background information.

There are two main bodies – *World Intellectual Property Organization (WIPO) under UN which administers 1-7 treaties mentioned below. The 8th treaty is independent of any organization. Another relevant body is the World Trading Organization. 9th (or TRIPS) is administered by the WTO. The 10th treaty comes under UNESCO.*

Paris Convention for Industrial Property, 1883 – *Since it deals only with Industrial property, it covered only Patents and Trademarks. It was among the first treaties to recognize various principles of international trade like National Treatment, Right of Priority, Common rules etc. Bern convention for literary and artistic works, 1886 – It provided for a copyright system. It doesn't provide for any formality to claim protection. Protection is automatically accorded to any creation, provided work is original and other conditions under the treaty are fulfilled. It means that your work, if original, is already protected. You can claim that you have copyright.*

Madrid Agreement, 1881 *– Governs the international recognition of trademarks. Made international fillings easy and cheap.*

Patent cooperation treaty, 1970 – It was earlier not possible for an entity to claim protection in different countries by single application. This was made possible as it aimed for co-operation and it was open for all parties to the Paris convention.

Budapest Treaty of 1980 – *It made possible patenting for microorganisms. Claimant is required to deposit his invention on micro-organisms with an Authority – 'International depository of Micro-Organisms' under WIPO. He shall make all the adequate disclosures.*

Trademark Law Treaty, 1994 – *Harmonized administrative procedures and introduced 'service marks' in ambit of trade marks. Earlier trademarks were accorded only to goods.*

The Hague agreement concerning the International Deposit of 'Industrial Design' 1925 – *It created the International Design Bureau of WIPO.*

International Union for protection of new varieties of plants, 1961 – *This provides breeders and farmers the right to new plant varieties.*

Agreement on Trade Related Aspects of Intellectual Property – It is a landmark and most comprehensive treaty on Intellectual property. While earlier treaties' subject matters were specific, TRIPS deal with 8 kinds of property rights – Patents, Trademarks, trade dress, Copyrights, Industrial Designs, Plant Varieties, Integrated Circuits and layouts, and Geographical Indication. Further, almost all countries are party to TRIP. In earlier treaties only limited countries participated. It also provides an enforcement mechanism which was not available in WIPO treaties. It mandated all member countries to make their domestic laws compliant to TRIPS. India passed certain laws and amended others. India's IPR regime now stands fully compliant to TRIPS. For E.g. India amended patent law in 2005 to provide 'product' patent protection. Earlier protection was available only to 'processes.

TRIPS were the results of discussions held in the Uruguay round which led to the formation of WTO. This treaty is an offshoot of the General Agreement on Trade in Goods (GATT). This treaty provided a robust Dispute Resolution Mechanism and stringent penal provisions under auspices of WTO.

21. Indian Government Role in Biotechnology Sector The national science and technology policy of the government and the Vision Statement on Biotechnology has been issued by the Department of Biotechnology (DBT), New Delhi established under the Ministry of Science and Technology in 1986 was the major instrument of action to bring together most talents, material resources, and budgetary provisions. It began sponsoring research in molecular biology, agricultural and medical sciences, plant and animal tissue culture, bio fertilizers and bio pesticides, environment, human genetics, microbial technology, and bioprocess engineering, etc. The establishment of a number of world class bioscience research institutes and provision of large research grants to some existing universities helped in developing specialized centers of biotechnology. Besides DBT, the Department of Science & Technology (DST), also under the Ministry of S&T, sponsors research at universities working in the basic areas of life sciences in India (Ghose and Bisaria, 2000) [20]. This policy further aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, therapeutic and medical biotechnology, marine biotechnology, regenerative and genomic medicine, diagnostic tools, bioprocess engineering, nanotechnology, bioinformatics and computational biotechnology, clinical biotechnology, environment and intellectual property and patent law (Chawla, 2005; Manual of Patent Office Practice and Procedure, 2011) [14, 30].

21.1. Biotechnology Inventions Patents in India

The Indian Patent Office considers biotechnological inventions to be related to living entities of natural origin, such as animals, human beings including parts thereof, living entities of artificial origin, such as micro-organisms, vaccines, transgenic animals and plants, biological materials such as DNA, plasmids, genes, vector, tissues, cells, replicons, processes relating to living entities, processes relating to biological material, methods of treatment of human or animal body, biological processes or essentially biological processes. The following biotechnological inventions are not considered as patentable under Section 3 of the Indian Patent (Amendment) Act 2005

(Biotechnological Innovations Patent 2010). Living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organisms. Any process of manufacture or production relating to such living entities. Any method of treatment such as medicinal, surgical, curative, prophylactic diagnostic and therapeutic, of human beings or animals or other treatments of similar nature. Any living entity of artificial origin such as transgenic animals and plants, or any part thereof. Biological materials such as organs, tissues, cells, viruses and all the process of preparing them. Essentially biological processes for the production of plants and animals such as method of crossing or breeding (Guidelines for Examination of Biotechnology Applications for Patent, 2013).

21.2. Promoting Transfer of Agricultural Biotechnology to Developing Countries

Developing countries frequently lack the required IP management capacity and resources to perform product clearance analyses and evaluations that facilitate the legitimate import, use and/or export of technologically advanced products. Thus, to help transfer of appropriate agribiotech to developing countries, capacity building in IPR management is of vital importance from both the donor and the recipient side (Katherine Linton and MIHIR Torsekar, 2011). This can involve the following: Educate research staff and research administrators on the basic principles of IPR management. Use different patent databases as well as scientific databases as information sources. Remain aware of the complexity of germplasm issues. Stress the importance of good laboratory records. Document what comes in and goes out of the lab. Establish clear lines of responsibility for negotiating, reviewing and signing Material Transfer Agreements (MTAs) and licenses. Manage and organize licenses and MTAs and the various documents and correspondence associated with them Plant Breeder's Rights Plant breeder's rights (PBRs) are used to protect new varieties of plants by giving exclusive commercial rights for about 20-25 years to market a new variety or its reproductive material. The variety must be novel, distinct, uniform, and stable. This protection prevents anyone from growing or selling the variety without the owner's permission. Exceptions may be made, however, for both research and use of seed saved by a farmer for replanting (Binenbaum et al., 2000; Cohen and Paarlberg, 2002).

21.3. The Protection of New Varieties of Plants Convention

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) was signed in Paris in 1961 and enforced in 1968. It was revised in Geneva in 1972, 1978 and 1991. The 1978 Act was enforced in 1981, and the 1991 Act was enforced in April 1998. UPOV has 38 member states of which 29 are parties of 1978 Act and eight are parties of 1991 Act. UPOV provides a framework for intellectual property protection of plant varieties. These rights are most often referred to as plant variety rights or plant breeders' rights (PBRs). To be eligible for protection, the plant variety must be distinct, stable, and uniform in its relevant characteristics (UPOV, 1991), or homogeneous with regard to the particular feature of its sexual reproduction or vegetative propagation (UPOV, 1978); and novel, that is, have not been offered for sale or marketed, with the agreement of the breeder or his achievement or in title, in the source country, or for longer than a limited number of years in any other country (Wright and Parley, 2006; Das, 2011). UPOV (1978) defines the scope of protection as the breeder's right to prior authorisation for the following acts: the production for purposes of commercial marketing; the offering for sale; and the marketing of the reproductive or vegetative propagating material, as such, of the variety (Article 5). UPOV (1991) version extends the scope of the breeders' rights in two ways. Firstly, it increases the number of acts for which prior authorisation of the breeder is required so that these include production or reproduction; conditioning for the purpose of propagation; offering for sale; selling or marketing; exporting; importing; and stocking for the above purposes (Article 14). Secondly, such acts are not just in respect of the reproductive or vegetative propagating material as with the 1978 version, but also encompass harvested material obtained through the use of propagating material, and so-called "essentially derived" varieties (Dutfield, 2002; Das, 2011). The International Convention for the Protection of New Varieties of Plants (UPOV convention) is significant because it provides a legal mechanism for the protection of plant varieties developed by commercial plant breeders through the introduction of "plant breeders' rights." Plant breeders' rights are a hybrid form of intellectual property rights, which give the seed industry similar incentives to those offered by patents, without establishing a complete monopoly (Cullet and Raja, 2004). The knowledge relating to biological processes and biological material is not the inventions. Under the Trips Agreement, member countries may be excluded from patentability of plants and animals and essentially biological processes for the production of new plants and animals.

Meanwhile, member countries of the Trips Agreement are required to apply some form of protection to plant varieties either by patents or an effective sui generis system or combination of the two systems. The technology transfer is an important mechanism for stimulating the formation and growth of high-technology entrepreneurial start-ups, regional economic development for firms, research and development centers and universities. The commercialization of patent in agriculture biotechnology sector is nothing but the working patent for the industrial use, where the prerequisite of the patent gets fulfilled and the technology transfer rate shows the quality of research to grow a successful and high technology economy. Intellectual property issues go beyond the scope and levels of protection. Other relevant issues include enforcement

capacities, which are critical to manage the regulation and trade in genetically modified (GM) crop varieties. In addition, the "privatization of science" brings a new management challenge for research institutions, particularly in developing countries, as many are not well equipped to deal with proprietary knowledge. The lack of negotiating skills and the administrative and bureaucratic limitations of research institutions have an impact on their ability to acquire, negotiate, and protect IPRs, and often represent tangible barriers for accessing certain strategic technologies. Moreover, intellectual property policies are also necessarily linked to broader economic policies, such as the creation of the appropriate environment for direct foreign investment and greater participation by foreign firm in domestic markets. The technology transfer is a related issue of IPRs, which play vital role in the research and development in academic area and its goal is to facilitate the transfer of knowledge that could have direct economic value from research and development institutes to the industry. The genomic-centric biology by producing hybrid varieties is taking away the invention and innovation to commercial market. The discovery of Human Genome Sequence, Incyte, and Sequena shifted the new genomic framework with IPRs in reshaping the balance struck among the interests of biomedical researchers, private sector market participation and the public good (Ramasami, 2009).

21.4. Biodiversity

India has great commercial potential in agricultural biodiversity which could be sustainably exploited for socioeconomic development of the continent. Therefore, the commercialization of useful plants and animals remains a viable option for reducing poverty in India. India produces about 10% of total world agricultural production, yet it accounts for less than 1% of agricultural trade, due to agricultural protectionism (Sharma et al., 2003). In biotechnology, the microbial processes and plant varieties are granted patent protection in some developed countries such as the United States and Australia. The protection of new forms of life in particular has proved to be difficult and there are substantial variations among countries. This shift of patenting new forms of life has generated intense debate at regional, national and international flora. The critics of patenting of life forms have argued that it is inappropriate to use the patent system to reward scientific work in the field of biological resources and processes, as living organisms are qualitatively different from non-living materials. In addition, there are provisions needed for prior consent and sharing of benefits for indigenous and local com-munities that have historically safeguarded the resources. The negative impact of patents, as private rights, granted over genetic resources raises an alarm for many biodiversity-rich countries, sui generis system or by any combination thereof. The most widely used sui generis system for plant variety protection is the International Convention for the Protection of New Varieties of Plants (UPOV Convention). Even though plant variety protection developed separately from patent protection and is considered to be more appropriate for the particular nature and characteristics of agricultural innovation, higher levels of protection have raised similar concerns as those in the patent field. Revisions to the UPOV Convention, for example, have generally served to progressively strengthen plant breeders' rights (Ravishankar and Archak, 1999; Alston and Venner, 2002) [40, 2]. Ex situ conservation and sustainable development of technologies includes tissue culture, field-based propagation, protoplast fusion and cryopreservation. Common mechanisms for transferring technologies include joint Research and Development (R&D), the training of nationals in foreign universities and other institutions, and technology partnerships undertaken under biodiversity prospecting arrangements. The exception to patentability in Article 27.3(b) also gives rise for offering sui generis protection over plant varieties. This also provides that members must provide protection for plant varieties, either in the form of patents or an "effective sui generis system". The interpretation and application of these provisions on plant variety protection will have significant implications for the implementation of the CBD. The rights to information, allocated under the Trips Agreement, will have an impact on the benefits from the use of genetic resources being shared. For example, although a high proportion of in situ biodiversity and related traditional knowledge, innovations and practices, are found in developing countries, most patents relating to biological resources are granted for research under-taken in developed countries. Sui generis protection may, if appropriately defined, provide a tool for implementing the CBD's objectives, including access and benefit sharing, and technology transfer.

21.5. Medical Biotechnology

In India, the pharmaceutical industry is one of the first to reap the benefits of biotechnology. Human health biotechnology products account for about 60% of the domestic market, while bio-drugs, vaccines and diagnostics have significant market shares as well. Consequently, Indian pharmaceutical is beginning to harvest the benefits from enhanced IP protection of their products. An example is Ranbaxy's NDDS for Ciprofloxacin licensed to Bayer for $65 million plus royalties. Other Indian research-based companies have earned about $70 million from R&D milestone payments. CSIR has also earned revenues by licensing its patents to the industry. The Indian Patent Office received 15 applications for the grant of Executive Marketing Right (EMR). Of these, three have been allowed, four rejected and the remaining eight are pending. The Patent Office has become more open to the grant of EMR's. Novartis was the first company in India to be granted an EMR by the Indian patent Office for a blood cancer drug, GLIVEC. SmithKline Becham challenged the order in a writ petition before the Delhi High Court. This writ was dismissed for want

of territorial jurisdiction. However, Novartis won a stay from the Madras High Court restraining six drug companies from manufacturing and distributing Imatinib Mesylate – the active ingredient in Novartis' Glivec. The EMR provision is no longer in force from January 1, 2005. Medical biotechnology offers a good possibility for Indian industry to establish a strong pharmaceutical sector, a growing number of small and medium biotechnology companies, a large network of universities, research institutes and medical schools and low cost of product evaluation (Jayashree Watal, 2001; Rai, 2001; Rai and Eisenberg, 2003; Chawla, 2005; Rishabha Malviya, 2010).

22. Scope of Patentability

The scope of patentability therefore has an impact on safeguarding the investment and access that others will have to the invention. Indeed, because many developing countries do use these exceptions and also have problems with enforcing existing patents, many foreign investors feel they lack assurance for property rights in GM technologies that will be adequately protected. On the other hand, high levels of patent protection may result in food security and bio- safety; conserve biodiversity, and socio-economic problems. For example, there is considerable debate about the actual impact of patent protection on innovation and diffusion in agricultural biotechnology (International Centre for Trade and Sustainable Development, 2008). The patenting of many GM crops innovations by private companies and universities-particularly when an innovation is covered by multiple patents creates so-called "patent thickets" and veritable legal gridlocks for further research (Yamin, 2003). In this regard, patent protection mechanisms are not a new issue with respect to agricultural research, but now proprietary claims are not only increasing but are rapidly enveloping research tools. As many developing countries focus their R&D on marginal innovations and minor improvements in existing technologies, their efforts may be blocked by strong patent protection (Rangasamy and Elumalai, 2009). Patenting is still not cheap; hence patents are usually registered only in countries where a large return is to be expected from the commercial use of the patented subject matter. Country of manufacture or residence of competitors is additional criteria for filing. Patents applications on key biotechnologies are rarely filed in developing countries, except where major crops such as soyabean, canola and cotton are extensively planted, e.g. Argentina, Brazil, and China (Mayer, 2003). In addition, more extensive patent protection is also considered problematic for achieving the objectives of other international agreements, particularly the 1992 Convention on Biodiversity. The CBD recognized the sovereign right of States over their natural resources, including genetic resources. Access to such resources thus can only take place on the basis of prior informed consent and mutually agreed terms. In addition, there are provisions on the need for prior consent and sharing of benefits for indigenous and other local communities that have historically safeguarded the resources. The negative impact of patents, as private rights, granted over genetic resources is thus a cause of alarm for many biodiversity-rich countries (CBD, 1999; International Centre for Trade and Sustainable Development, 2008).

23. Biotechnology Companies in India

India is home to over 300 biotech companies with a total bioscience investment of more than $500 million. Though this is a small share of the global biotech market, the promise of the growth of the industry in India is significant. It is estimated that the domestic market for biotech products will grow tremendously and India may claim 8% of the world's biotechnology companies by 2010. The major players in the Indian Industry include: Biocon, Serum Institute of India, Panacea Biotech, Nicholas Piramal, GlaxoSmithKline, Abbott, Ranbaxy etc. The active role of Indian biotech companies has become visible through various efforts and final revenue generated by them. ABLE, the association of Biotechnology Led Enterprises, for example, is a forum of leading Indian biotechnology companies to generate a symbiotic interface between the industry, the government, academic and research bodies, and domestic and international investors. Recently, Serum Institute of India Ltd., has announced an investment of Rs.1200 crore at the inauguration of India's first biotech SEZ in Pune (Krattiger, 2002). In conclusion, India has sailed through the journey from a state of a total lack of IP awareness to the present state of proactive pursuit of IP in frontier areas of technology. Having unleashed India's IT potential in the recent past, the time has now come to harness the tremendous strengths and energies of the countries in the Biotechnology Sector. Moreover, IPs generated by the public sector can be considered assets that can be exchanged for private sector owned IPs or used as bargaining chips in technology transfer negotiations. Partnership between the private and public sectors in technology development through sharing of knowhow and IP can speed up technology transfer and acquisition on both sides.

24. Summary and Result:

Biotechnological research raises problems concerning the protection of intellectual property of innovations in this field, beyond the legal and ethical questions of patentability. Such problems arise because living organisms are able to reproduce themselves and patents may undermine the value of genetic resources and traditional knowledge. The interests of farmers and those of the developing countries are particularly concerned. Methods other than patents have to be found in order to achieve a balanced system for protecting both intellectual property and the common heritage of mankind. Progress in agriculture should benefit as many people as possible. The Assembly advocates new procedures that are transparent for all concerned and a biotechnological innovation protection system that will promote lasting world food security.

I. Draft recommendation

1. The Assembly recalls its Recommendation 1213 (1993) on developments in biotechnology and the consequences for agriculture.
2. It is aware that the patent system, as a system for the protection of intellectual property, is an integral part of market economy and therefore can be a driving force for innovation in many technological questions.
3. A guideline on patents legislation should help to develop criteria for granting patents continuously according to technological progress in favour of both the interests of the claiming party, as well as the interests of the public in regard to public order, morality and general aspects of state economy.
4. Living organisms are able to reproduce themselves even if they are patented and in view of this special quality of living organisms, the scope of a patent is difficult to define, which makes it nearly impossible to find a balance between private and public interests.
5. The Assembly deems it necessary to oblige scientists, as well as scientific research and development units working in the field of biotechnology, to conform with the Convention on Biological Diversity (Rio de Janeiro, 1992), guaranteeing both the principle of free scientific approach to world-wide genetic resources and the interests of developing countries in sharing the benefits of technological progress.
6. However, it is aware that for ethical reasons there are also severe reservations against patenting living organisms.
7. It considers that the issue of patenting living organisms could conflict with provisions of international treaties such as the Convention on Biological Diversity or the agreement on Trade Related Property Rights (Marrakech, 1994) of the World Trade Organization.
8. The Assembly has taken note that Directive 98/44/EEC on the legal protection of biotechnological inventions of 6 July 1998 (Bio-Patenting Directive of the European Community) was challenged at the European Court of Justice by the governments of the Netherlands and Italy, and that Norway is considering not implementing it.
9. The Assembly considers that monopolies granted by patent authorities may undermine the value of regional and world-wide genetic resources and of traditional knowledge in those countries that provide access to these resources.
10. It considers that the aim of sharing the benefits from the utilisation of genetic resources on this broader view does not necessarily require patent-holding but requires a balanced system for protecting both intellectual property and the "common heritage of mankind".
11. It also considers that the many outstanding questions regarding the patentability and the scope of protection of patents on living organisms in the agro-food sector must be solved swiftly taking into account all interests concerned, not least those of farmers and developing countries.
12. The Assembly therefore believes that neither plant, animal nor human derived genes, cells, tissues or organs can be considered as inventions nor be subject to monopolies granted by patents.
13. For these reasons, the Assembly recommends that the Committee of Ministers, in co-operation with the World Intellectual Property Organization, the Food and Agriculture Organization, the World Trade Organization and in accordance with the Convention on Biological Diversity (CBD):
    a) Study in detail all aspects linked to the protection of intellectual property in biotechnological innovations with a view to further improving international legislation in this field;
    b) Assess and review the effects of granting patents on a broad scope as regards the progress of research and development and the free market;
    c) Develop a code of conduct for scientists and scientific units working in the field of biotechnology which guarantees both free scientific approach to world-wide genetic resources and benefit-sharing with developing countries;
    d) Discuss a suitable system of protecting intellectual property in the field of biotechnology fitting the purposes of the CBD and meeting the needs of world-wide private as well as public interests.

II. Explanatory memorandum

1. Introduction

1. Developments in biotechnology and their impact on agriculture were debated by the Parliamentary Assembly of the Council of Europe in 1986 and 1993. Those discussions resulted in the adoption of Recommendation 1213 (1993), which deals with both the rich potential of biotechnology and its dangers and long-term effects on agriculture as a whole and the development of rural regions. With regard to protection of intellectual property in the sphere of biotechnological research, the Assembly at that time called on the member states and the European Union "to adopt a cautious policy with regard to the granting

of patents for biotechnological inventions and applications, so as to take due account of ethical considerations and environmental safety concerns".

2. In February 1995, the European Commission first proposed a draft directive on the legal protection of biotechnological inventions. After intense discussion and public criticism, this draft was adopted by the European Parliament, in revised form but basically unchanged, as Directive 98/44/EC. For the first time, plants, animals, cells and genes were explicitly classified as patentable.
3. As soon as the first draft of the directive was tabled by the Commission in 1995, members of the Parliamentary Assembly began to take an interest in the protection of intellectual property in the sphere of biotechnology. As a result, in May and October 1995, the Council of Europe held two hearings and in January 1996. The present report is based on that early draft and was made possible by the important preliminary efforts of Mr Scheer and Mr Szakal. It also relies on the experts' comments sought at the time by the rapporteurs.
4. Numerous new developments of direct or indirect relevance to the subject of the Council of Europe's draft recommendation have also had to be taken into account. Discussion of the scope and effects of protection of intellectual property in the sphere of biotechnological research has become more diversified in recent years and is no longer confined to legal and ethical questions of patentability.
5. In the meantime, the **European Patent Office (EPO)** has stopped issuing plant and animal patents for the time being, on the grounds that this is contrary to the European Patent Convention. A decision of principle is to be taken in 1999. The European Patent Convention may be amended and brought into line with the European Union Directive. In the USA, a court ruling is expected shortly on the patentability of plants. The **European Court of Justice (ECJ)** is expected to decide by the end of 1999 in the Dutch and Italian case against the European Union directive. Norway has also explained in detail that it will not apply the EU Directive, because it is incompatible with the object and purpose of the **Convention on Biological Diversity (CBD)**[1] and because the transformation of the Patent Directive into national legislation will constitute a major obstacle to countries' ability to implement the CBD through national and international measures, activities and co-operation. The CBD provides for appropriate involvement of the countries of origin in the utilisation of natural resources. There is currently controversial discussion of these provisions at many levels. The World Trade organisation (WTO) has also reopened discussion of commercial trademarks and patents, since 1999. Plan and animal patents are the main focus of these discussions.
6. Southern countries in particular have been critical of patenting natural resources, as have the Food and Agricultural Organisation (FAO) and the World Bank.
7. Most recently, in May 1999 at Oviedo (Spain), the Conference on Ethical Issues arising from the Application of Biotechnology drew attention to fundamental problems in relation to the protection of intellectual property in biotechnological innovations, ranging from human rights issues, through possible widening of the gap between the southern hemisphere and the industrial nations to the continuous blurring of boundaries in the use of biotechnological processes in medicine and agriculture (xenotransplantation, gene-pharming, drug-pharming).
8. Against the background of this dynamic development, the Council of Europe must endeavour in its Recommendation to do justice to the complexity of the subject. That is why the title of the introductory memorandum reads "Biotechnology and intellectual property".

2. General remarks on the protection of intellectual property by means of patents

1. The granting of patents is basically subject to the three criteria: novelty, inventiveness and industrial applicability. Patent law makes a strict distinction between discovery and invention. What distinguishes an invention from an innovation is the "spark of genius"; only then is a patent granted, whether for a product or a process.
2. Patent law is intended to afford the inventor protection against unauthorised claims on his intellectual feat and also to protect costly investment in research and development and the industrial application of research findings. At the same time, the public description of the technical novelty, including its manufacture and purpose, in a patent is intended to satisfy society's claim to comprehensive knowledge of all new inventions.
3. The effect of patents on economic development, innovation, research and development is complex. On the one hand, investment is stimulated by the prospect of an exclusive right to the use of an invention; on the other hand, patent law can also be used "defensively", i.e. to prevent competition and innovation through the monopoly it grants. For example, first "basic patents" can be applied for, and then "follow-up patents" which protect the operational field of a firm and so become the core of a competitive strategy. If a competitor has got in

first with his patent, he can be cut off from the further development of his invention by "a patent net". Examples of this were quoted in the European Patent Office's 1995 Annual Report.

4. In this way, patents can be used to construct worldwide systems of economic control that have little to do with a "free" market economy. Patents are used to protect export markets, to erect trade barriers, monopolise new technologies, as assets to trade in co-operation between firms and as a lever with which to stifle the economic development of competitors. Patents are often systematically used to shut out competition. Whole national economies, of developing countries for example, can be stifled because of market control exercised on the basis of patents. This can also be seen in the agricultural sector, which has become interesting from the patent point of view with the advent of biotechnology.
5. Patent law can sometimes cause the opposite of what it is intended to achieve. Instead of encouraging competition and innovation, it leads to the sealing off of markets and the protection of competition-free zones.
6. As patent law has developed, freelance inventors have lost in importance. Instead of them, the beneficiaries have been big rich concerns which have been able, through their research departments and production programme, by means of a network of patents, to turn themselves into technical development centres.
7. However, the importance of granting patents for products or processes, based on feats of invention, should not be underestimated. Without the guarantee of exclusive application rights, many developments might never have reached fruition.
8. Self-reproducing organisms make the problem of the applicability of exclusive rights, such as they are granted by patents, difficult, if not insoluble. This casts no doubt on the patent system as such, but along with the patent-law problem of determining "inventiveness" in self-reproducing organisms, it raises the question of whether patents are an appropriate means of protecting intellectual property in the sphere of biotechnology.

3. Innovation in the sphere of biotechnology and the question of protection of intellectual property by patents

1. The ability to reproduce is a characteristic feature of patented organisms in the sphere of biotechnology. Consequently, the manufacturing process means something quite different by comparison with other technologies. The question of defining the inventive activity, e.g. in the isolation of a gene or its insertion in another cell, when the techniques employed are those of the current state of the art, has repeatedly given rise to controversy.
2. The Council of Europe, realising that describing biotechnological feats as "inventions" confines discussion of intellectual property protection systems to questions of patent law, has tended to talk more generally of biotechnological innovations. This is intended to take into account the special importance to humanity of the diversity of genetic resources. This concept does not diminish the intrinsic value of plants and animals.
3. The application of patent law has proved particularly difficult in agriculture. Farmers and many small breeders possess neither the necessary knowledge nor the technical and financial resources to cope with this legal instrument. Furthermore, patents as such only protect novelty, while conservation of what exists goes economically unrewarded. This could have a lasting detrimental effect on the conservation of species diversity, because for example the patent system makes no provision for the breeder's exemption traditionally provided for in the protection of varieties.
4. Meanwhile, in biotechnology, the defensive aspect of patent law described above has gained the upper hand in many areas. Extensive patents could in some spheres give rise to a anti-innovative situation in medicine, agriculture and plant breeding.
5. Legislators have always seen a need for compromise between the interests of patent holders and society, because patents can have a negative effect for society. In some areas, patents have been prohibited on principle. For instance, human therapeutic and diagnostic methods cannot be patented. The European Patent Convention of 1977 excludes "essentially biological processes", "plant or animal varieties" and "discoveries" and requires conformity with "order public" and "morality". Corresponding provisions are to be found in WTO and NAFTA (North American Free Trade Area) rules, the latter using the same wording.
6. Despite this, European patents for plant and animal varieties were still granted until they were prohibited by a ruling of the EPO Board of Appeal in 1995.
7. Even human body cells and genes are being patented. At the EPO, over 2,000 human gene patents have been applied for; about 300 have already been granted. Worldwide, there are about 1,500 human gene patents. Of some 500 applications for animals, about a dozen have been granted. Over 1,000 patent applications have been filed for plants and of those over 100 granted.
8. By this means, not only actual fully researched industrial applications, but also potential applications are protected. This is in line with traditional patent practice, whereby not yet (completely) known applications can be protected. But patenting genes

opens entirely new horizons. Anyone holding a gene patent can control all possible applications of that gene. This applies to pharmaceutical applications and also to plant and animal breeding.

9. Patent claims in the biotechnological sphere, insofar as they concern genes capable of self-reproduction, can comprise the following:
    - All variations of the gene sequence,
    - Use for diagnostic and therapeutic purposes,
    - Production of vaccines,
    - All micro-organisms into which the gene can be transplanted,
    - All plants and plant varieties into which the gene can be transplanted,
    - All as yet unknown uses of the gene,
    - All proteins that can be produced using the gene and all uses of them, e.g. for medical purposes.
10. These possibilities of extensive patent claims based on biotechnological innovations are not without consequences for agriculture, especially in the species-rich developing countries.

4. Patents on genetic resources – effects on agriculture and the developing countries

1. Although the protection of intellectual property in the field of biotechnology, especially gene technology, has only been provided by patent law for a few years, serious unprecedented difficulties have come to light concerning the balance between public and private interests.
2. It is in the area of plant breeding that the clearest evidence has emerged of the great difficulty of weighing up legitimate claims for the protection of innovations on the one hand, and mankind's entitlement to free access to the genetic resources that make up humanity's common heritage on the other. In the meantime, there are now patented hybrid seeds that as a result of genetic modification have lost the ability to reproduce. This makes it not only legally, but biologically impossible to repeat the crop by self-seeding. Control of the seed market in southern countries is economically interesting also because in India, Asia, Africa and South America, up to 80% of the harvest is used for reshowing. Especially China and Brazil, but also Mexico, Morocco, India and Pakistan are regarded as important growth markets for commercial seed.
3. Not only plants, but also animals, insects and micro-organisms are systematically catalogued and analysed with a view to securing patents. Nor can it be ruled out that similar developments may occur in animal breeding and in the therapeutically and economically interesting combination of farming and pharmaceuticals (gene pharming e.g. of valuable proteins in the milk of transgenic animals).
4. Furthermore, cultural knowledge about the use of biological diversity, e.g. the use of medicinal plants or plant breeding, may also be affected.
5. Perhaps the best-known illustration is the case of the Neem tree, which was discussed at length at the Conference organised by the Council of Europe in May 1999 at Oviedo (Spain) on "ethical issues arising from the application of biotechnology". The substances contained in the tree, once technically isolated, can be patented. The tree's pre-existing uses for medicinal and pesticides purposes cannot be patented. Yet in India the Neem tree has for centuries played a key role in agriculture, in public health, medicine, cosmetics, in protecting domestic animals and in religious ceremonies. Its medical uses include tooth care, treatment of skin infections, parasites, and inflammations of the eyes and ears and much more besides. In India, the Neem tree is regarded as the "village dispensary". It is also used successfully in various ways to combat plant pests. For one of its main active substances, Azadirechtin, several patents have been granted in the USA and Europe. Critics point out that the use of substances from the Neem tree can in no way be regarded as an invention. In 1993 hundreds of thousands of farmers demonstrated against it.
6. One of the key problems in this respect is that only what has been isolated ("invented") in the laboratory can be patented. The collectively acquired knowledge of generations and the related innovations, e.g. in the use of medicinal plants, enjoys no protection. These patents shift the profit from the countries where they have hitherto been used, including economically, to the industrial nations. For the countries of origin, this can have additional direct effects: Because industry buys up the seeds of such plants, there is a risk that these may become scarce and more expensive for traditional use.
7. If the patenting of cultivated plants after genetic modification were to become standard procedure for protecting intellectual property in plant breeding, it would be only a matter of time before all cultivated plants of direct or indirect value as human food were patented. Attention was drawn to this and to the possible consequences, a breeding stoppage, by the European farming bodies (COPA Committee of Agricultural Organisations in the European Union) and COGECA (General Committee of Agricultural Co-operation in the European Union) in 1998. They

called for full acceptance of the breeders' exemption in the patent directive. "However, this legal European framework must be balanced so as to enable the industry to be fully involved in this development, thereby ensuring the maintenance of a certain number of medium-sized plant and animal breeding enterprises under competitive conditions. Therefore, COPA requests the introduction of the 'breeder's privilege' concept."

8. At the Conference of states parties to the CBD in Bratislava in May 1998, forthright criticism was made of the European Union's Patent Directive and in particular of the removal from the text, under pressure from industry, of reference to a legally binding rule of origin.
9. Worldwide, there are some 1,500 seed suppliers; already today 60% of the market is controlled by only 35 competitors. Of over 30 such firms active in gene technology in 1990, only 7 remained in 1997. Experts estimate that this concentration process will continue and the gap between North and South will grow. About 90% of patents granted in the Third World belong to firms whose headquarters are in the industrial states.
10. China, India, Brazil and others recently restricted access to their genetic resources (TIME, 30 November 1998, p 46). India, referring to the CBD, passed a specific Biodiversity Act prohibiting the unauthorised export of biological material and making the acquisition of inventor's rights subject to prior authorisation.
11. Meanwhile, the World Bank has urged the developing countries to defend their interests more strongly at the WTO's TRIPS negotiations[2]. It pointed out that the extension of patent protection carried a risk of "shifting bargaining power towards the producers of knowledge and increasing the knowledge gap" (Nature, Vol 395, 8 October 1998). Leading representatives of the World Bank publicly championed "serious dialogue between the public and the private sectors in order to ensure that there is adequate attention to the poor, and that the issue of proprietary science does not become a real threat. Proprietary science also could exacerbate the gap between the haves and have-nots, with the risk of creating a "scientific apartheid" in the next century. We have to design the system in a way that reflects the mutual interests of all." (Newsweek, 24 August 1998, p 52)

21. Conclusions:

1. The patent system as one system for the protection of intellectual property is an integral part of the market economy and can therefore be a driving force for innovation in many areas of technology. The problems caused by the application of patent laws to biotechnological innovations arise because living organisms are able to reproduce themselves even if they are patented. In regard to this special quality of living organisms the scope of a patent is difficult to define, which makes it nearly impossible to find a balance between public and private interests.
2. Monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of the traditional knowledge in those countries that provide access to biological resources. The many outstanding questions in regard to the patentability of living organisms in the agro-food sector and the extent of protection provided by such patents must be solved swiftly and with regard to all interests involved, not least those of farmers and of the developing countries. Furthermore, the patenting of living organisms could conflict with the provisions of international treaties such as the Convention on Biological Diversity (CBD) or the Trade Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organisation (WTO).
3. The aim of sharing benefits related to the utilisation of genetic resources has to be addressed in broader terms. Bearing in mind the many unsolved questions, it is clear that methods other than patents have to be found in order to achieve a balanced system for protecting both intellectual property and the common heritage of mankind.
4. The Council of Europe therefore advocates organising rights to exploit biological resources according to procedures that are transparent for all concerned. Allowance must be made for ethical or religious objections to particular applications or particular protection rights. All measures to enhance biological diversity should focus on conserving existing species diversity and natural habitats. Forms of knowledge and traditional methods which are not patentable (e.g. the use of medicinal plants in the tropical forest) must not be overridden by patent law.
5. The FAO recently agreed that "the responsibility for realising Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments. In accordance with their needs and priorities, each Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:
    (a) Protection of traditional knowledge relevant to plant genetic resources for food and agriculture,
    (b) The right to equitably participate in benefit-sharing arising for the utilisation of plant genetic resources for food and agriculture,

(c) The right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

6. Nothing in this article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." (FAO, Commission on Genetic Resources for Food and Agriculture. Report of the Contact group, Part V – Farmers' Rights. Article 15.2, 15.3, April 1999).
7. The FAO wishes to disseminate knowledge and use of biological diversity, support projects for preserving it, encourage technology transfer and help produce and market specific agricultural produce. The aim is not to satisfy individual claims, but to secure global systems for preserving and enhancing biological diversity. This supports cultural and economic areas in the exploitation of their traditional local resources and protects them against bio-colonialism. Corresponding provisions should now be introduced in the revision of the CBD.
8. These FAO ideas could also set an example for the "sui generis" systems for the protection of intellectual property in biotechnology now under discussion in the WTO.
9. Progress in agriculture should benefit as many people as possible. The Council of Europe advocates a biotechnological innovation protection system that will promote lasting world food security.

Further, every treaty under WTO is based some principle which are –

- ***National Treatment –*** *No foreign products, once they enter domestic territories, shall be discriminated against in any manner. This also applies to intellectual property. Members must accord similar treatment to foreign creations, as they do to domestic ones.*
- ***Most Favoured Nation –*** *If a member provides some privilege, favourable treatment or exemption to another country or group, then other members must get similar favourable treatment.*
- ***Right to priority treatment –*** *If a similar patent application has been filed in two different countries, then the prior applicant has the right to the patent.*
- ***Concept of Minimum Standards –*** *This treaty provides for a minimum level of protection that every member should provide to intellectual property. Members have discretion to provide more protection than minimum standards.*
- ***Universal Copyright Convention, 1952 –*** *This convention is administered by UNESCO. This exists simultaneously with the Bern Convention. This treaty provides for procedural formalities for filing and recognition of copyright. As Bern convention provides for an automatic route to copyright, this treaty has lost its relevance.*

KEY TAKEAWAYS

- *Intellectual property rights, as they pertain to the Biotechnology sector, concern the legal ownership and exclusive rights to patents, trademarks, and trade secrets.*
- *Just like with other industries, intellectual property rights allow biotech firms to establish ownership and protect their products from the threat of competitors.*
- *A company might own the patent to a specific drug and the exclusive right to market it under a certain name, for example, because it holds the intellectual property rights.*

Understanding Biotechnology Intellectual Property Rights

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 favour 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.

Biotechnology Intellectual Property Rights 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 Hoffmann-La 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 image are central components of business operations and strategic positioning. Some studies estimate that pharmaceutical companies spend as much as $30 billion on marketing annually to raise brand awareness for their drugs. 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.

25. Author Contributions

All the authors participated in the drafting the manuscript and discussion of all topics related to this perspective manuscript.

26. Conflict of Interest Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

27. Availability of data and material

All relevant data and material are presented in the Research Review Paper.

28. Funding

Not Applicable.

29. Consent for publication

Not applicable.

30. Ethics approval and consent to participate

Not applicable

31. References

1. Ahmed R, Segal I, Hassan H. Fermentation of dietary starch in humans. Am. J. Gastroenterol. 2000; 95:1017 1020.
2. Alston JM, Venner RJ. The effects of the US plant variety protection act on wheat genetic improvement. Res. Policy. 2002; 31:527-542.
3. Ashok K Chauhan. A Textbook of Molecular Biotechnology (I.K. International Pvt. Ltd), 2009. 4. Bagde US. A comparative study of Human rights in World constitutions. Aarati Book Company, Mumbai, 2007.
4. Bagde US, Prasad R, Varma A. Legal provisions for the protection of intellectual property rights in India. In: Relevance of intellectual property rights: Status and prospects edited by Dominic Keating, Abha Agnihotri, Ajit Varma I K International, Delhi (In Press), 2012.
5. Bent SA. Intellectual property rights in biotechnology worldwide. Stockton Press, New York, 1987.
6. Bhargava PM. Biotechnology in India: The beginnings. Biotechnol. J. 2009a; 4:313-318.
7. Bhargava PM. The social, moral, ethical, legal and political implications of today's biological technologies: An Indian point of view. Biotechnol. J. 2009b; 1:34-35.
8. Binenbaum E, Nottenburg C, Pardey PG, Wright BD, Zambrano P. South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops. International Food Policy Research Institute, Washington D.C, 2000. 10. Brink JA, Woodward BR, DaSilva EJ. Plant biotechnology: a tool or development in Africa. Elect. J. Biotechnol. 1998; 1(3):142-150.
9. Buzzini G. La theories des sources face au droit international general (Graduate Institute of International Studies), Geneva, 2001.
10. CBD. Article 19. Handling of biotechnology and distribution of its benefits, 1999. http://www.biodiv.org/chm/conv/art19.htm.
11. Chakrabarty AM. Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof. Assigned to GE Company, NY. US Patent. 1981; 4(259):444.
12. Chawla HS. Patenting of Biological Material and Biotechnology. Journal of Intellectual Property Rights, 2005, 44-5.
13. Cohen JI, Paarlberg R. Explaining restricted approval and availability of GM crops in developing countries. Agbiotechnet, 2002.
14. Cullet P, Raja J. Intellectual property rights and biodiversity management: The case of India. Global Environ. Politics. 2004; 4(1):97-114.
15. Daneshyar SA, Kohli K, Khar K Roop. Biotechnology and intellectual property. Sci. Res. Essay. 2006; 1(1):20-25. 18. Das S. Seeds and trees: An insight into agriculture, biotechnology and intellectual property rights. Int. J. Bus. Soc. Sci. 2011; 2:205-211.
16. Dutfield G. Trade, intellectual property and biogenetic resources: a guide to the international regulatory framework, Background Paper for the multi-stakeholder dialogue on trade, intellectual property and biological and genetic resources in Asia, International Centre for Trade and Sustainable Development (ICTSD), Geneva, April, 2002.
17. Ghose TK, Bisaria VS. Development of Biotechnology in India. Adv Biochem. Eng. Biotechnology. 2000; 68:87 124.
18. Guidelines for Examination of Biotechnology Application for Patent. Office of the Controller General of Patents. Designs and Trade Marks, 2013.
19. International Centre for Trade and Sustainable Development. A framework for policymaking on trade, agricultural biotechnology and sustainable development. International Centre for Trade and Sustainable Development, Geneva, Switzerland, 2008.
20. Janice M Mueller. Biotechnology Patenting in India: Will Bio-Generics Lead a 'Sunrise Industry' to Bio Innovation (No. 2, 2008 ed. University of Missouri Kansas City Law Review), 2008.
21. Jayshree Watal. Indian patent Law on Biotechnological Inventions, 79-83 (4th ed. Asia Pacific Biotech, 2001. 25. Katherine Linton, MIHIR Torsekar. Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China, Journal of International Economics and Commerce, 2011, 23-27.

22. Kershen DL. Biotechnology: an essay on the academy, cultural attitudes, and public policy. Ag Bio Forum. 1999; 2:137-146. 27. Kowalski SP, Ebora RV, Kryder RD, Potter RH. "Transgenic crops, biotechnology and ownership rights: What scientists need to know." The Plant Journal. 2002; 31(4):407-421.
23. Krattiger AF. "Public-private partnerships for efficient proprietary biotech management and transfer, and increased private sector investments. A briefings paper with six proposals commissioned by UNIDO." IP Strategy Today, 2002, 4-2002.
24. Laxmi T, Janaki Krishna PS, Pakki Reddy G. Changing paradigms in agricultural research-significance of end user involvement. Outlook Agric. 2007; 36(2):119-125.
25. Manual of Patent Office Practice and Procedure. Office of the Controller General of Patents. Designs and Trade Marks, 2011.
26. Mayer JE. Intellectual property rights and access to a biotech by developing countries. Ag Biotech Net, 2003; 5:1-5.
27. Moschini G. Intellectual property rights and the world trade organization: retrospect and prospects. In: Agricultural policy reform and the WTO, Anania G, Bohman M, Carter C, McCalla A (eds), Edward Elgar Publishing, Aldershot, UK., 2004.
28. Pardey PG, Wright BD, Nottenburg C. International Food Policy Research Institute 2000-2001 Annual Report, 2001.
29. Pray C, Oehmke JF, Naseem A. Innovation and dynamic efficiency in plant biotechnology: an introduction to the researchable issues. Ag Bio Forum. 2005; 8:52-63.
30. Rai A, Eisenberg R. 'Bayh-Dole Reform and the Progress of Biomedicine' 66 Law and Contemporary Problems, 2003, 289.
31. Rai A. 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust' 16 Berkeley Technology Law Journal 813 at 831, 2001.
32. Ramakrishna T. Innovation, Invention in Biotechnology and Intellectual Property Rights Law: Can India Catch the Bus (3rd Edition), 2008.
33. Ramasami T. Basic and applied research in India: Present and future. Biotechnol. J. 2009; 4:301-305.
34. Rangasamy N, Elumalai K. Market opportunities and challenges for agri-biotech products in India. Agric. Econ. Res. Rev. 2009; 22:471-481.
35. Ravishankar A, Archak S. Intellectual property rights and agricultural technology: interplay and implications for India. Econ. Polit, 2000, pp. 2446-2452.
36. Ravishankar A, Archak S. Searching for policy options: is COFAB a suitable alternative to UPOV?' Econ. Polit. Weekly. 1999; 34(52):3661-3667.
37. Richard GE, Matthew H. The role of biotechnology Intellectual Property Rights in the Bio economy of 2030. OECD International Futures programme, 2007, pp.1 11.
38. Rishabha Malviya. Biotechnological Innovations Patent: A Review 131-135 (2nd Edition, ISSN 0976 044X), 2010.
39. S Kameswaran. Intellectual property rights (IPRS) role in genetic engineering a review European Journal of Biotechnology and Bioscience, 2019, Volume 7; Issue 6; November 2019; Page No. 65-70
40. Sachin Chaturvedi, Dynaimcs of Biotechnology Research and Industry in India: Statistics, perspectives and Key Policy Issues, 35-62 (Organisation for Economic Cooperation and Development, 2006.
41. Saxena D, Flores S, Stotzky G. Transgenic plants: Insecticidal toxin in root exudates from Bt corn. Nature, 1999; 402:480.
42. Scott N, Chen H. Nanoscale science and engineering for agriculture and food systems. A report submitted to Cooperative State Research, Education and Extension Service, USDA, National Planning Workshop, Washington, 2003.
43. Seyed Jamal Hosseini, Somaeih Esmaeeli, Bahereh Ansari. Challenges in commercialization of nano and biotechnologies in agricultural sector of Iran. Afr. J. Biotechnology. 2011; 10(34):6516-6521.
44. Sharma M, Charak KS, Ramanaiah TV. Agricultural biotechnology research in India: Status and policies. Curr. Sci, 2003; 84:3.
45. Somerville C, Somerville S. Plant functional genomics. Science. 1999; 285:380-383.
46. Spielman DJ, Cohen J, Zambrano P. Will, A biotech applications reach marginalized farmers? Evidence from developing countries. Ag Bio Forum. 2006; 1:23 30.
47. The Convention on Biological Diversity (CBD) was signed on 5 June 1992 in Rio de Janeiro.
48. The Trade Related Intellectual Property Rights agreement (TRIPS) was signed on 15 April 1994 in Marrakech.
49. UPOV. (International Union for the Protection of New Varieties of Plants) (1968) (1972) (1978). (1991). International Conventions for the Protection of New Varieties of Plants. UPOV, Geneva, 1961.
50. Wheeler S. Factors influencing agricultural professionals' attitudes toward organic agriculture and biotechnology. Center for Regulation and Market Analysis, University of South Australia, 2005.
51. Wright BD, Parley PG. The evolving rights to intellectual property protection in the agricultural biosciences. Int. J Technol. Global. 2006; 2:12-29.
52. Yamin F. IPRs, biotechnology and food security. Foundation for International Environmental Law, 2003, pp. 1-58.