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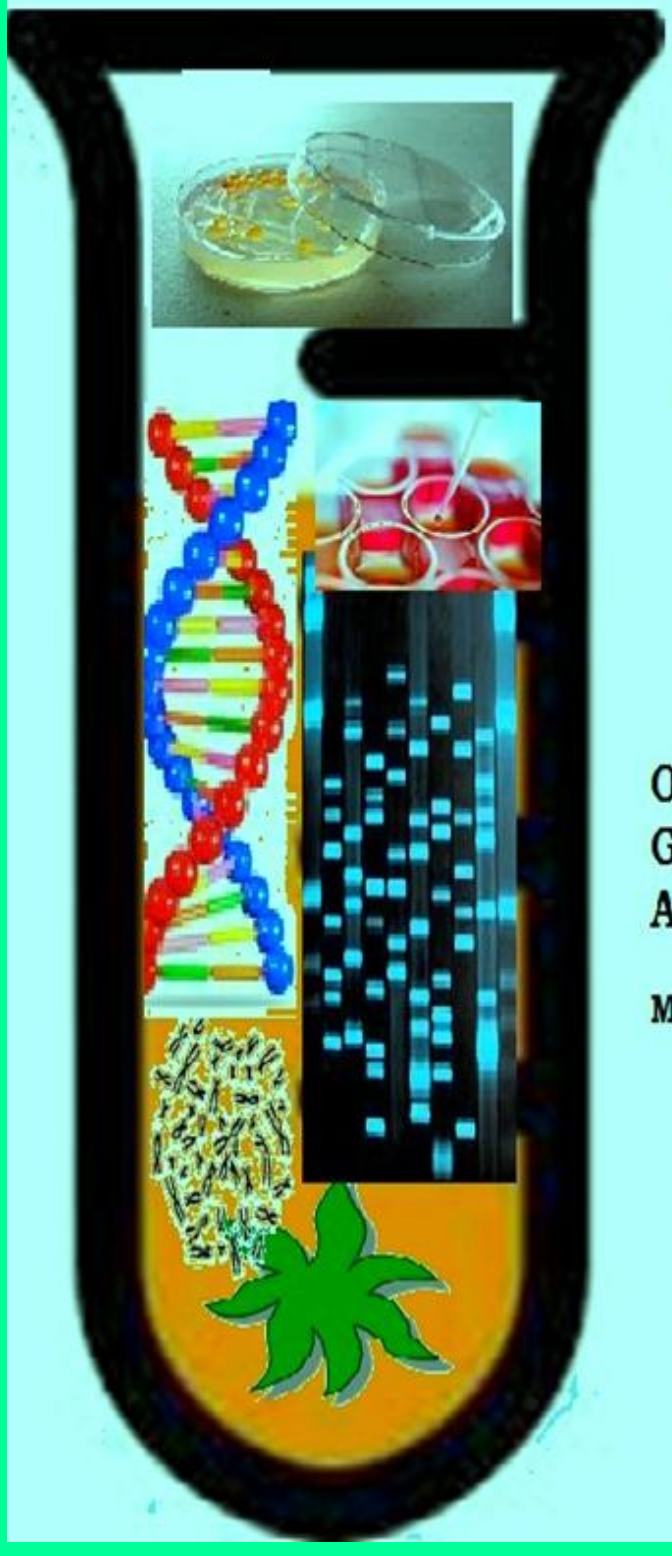

GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT

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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, isolation of antibiotics from moulds or other micro-organisms 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 micro-organisms 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, animals and 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 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.

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 which 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.

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'.

4. PROVISIONS COVERED

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

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

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

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

IV. 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,

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

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

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

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

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

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

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

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

5. 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.

6. 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.

7. 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.

7.1. 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.

(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.**

7.2. 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.

7.3. **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.

ILLUSTRATIVE 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.

8. 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.

ILLUSTRATIVE 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.

ILLUSTRATIVE EXAMPLE 1:

Claim: An improved process for the production of galactooligosaccharides (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.

ILLUSTRATIVE 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 37^{O}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.

ILLUSTRATIVE 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 C-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.

ILLUSTRATIVE 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.

9. 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.

ILLUSTRATIVE 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.

ILLUSTRATIVE 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.

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.

10. 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.

11. 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.

ILLUSTRATIVE 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.

ILLUSTRATIVE 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 perivitelline 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 perivitelline 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.

ILLUSTRATIVE EXAMPLE 3:

Claim: An isolated peptide that is structural equivalent of a cupredoxin or cytochrome that can inhibit parasitemia 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 natives 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 proteins, which is not patentable as per Section 3 (c) of the Act.

12. 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.

ILLUSTRATIVE 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.

ILLUSTRATIVE EXAMPLE:

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 Zn^{2+} 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.

13. 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.

ILLUSTRATIVE EXAMPLE:

Claim: A composition of innovative combination of dormant spore of naturally occurring *Paecilomyces 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.

14. 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.

ILLUSTRATIVE 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.

15. 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 injectables, 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 estrus 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.

ILLUSTRATIVE 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.

16. 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.

ILLUSTRATIVE 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.

ILLUSTRATIVE 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.

17. 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.**

ILLUSTRATIVE 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 mechanical leaning 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.

ILLUSTRATIVE 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.

18. 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 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.

ILLUSTRATIVE EXAMPLE:

Claim: Serum of pigeon possessing the anti-paralysis activity.

Analysis: The use of pigeon serum for the treatment of paralysis (as it possess 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 Ethnomedicine, 2006, 2:46, see entire document especially Table I), which discloses the use of pigeon blood for treating paralysis.

19. 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 claim(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 & Bruning 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.

ILLUSTRATIVE 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.

19.1. 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:

ILLUSTRATIVE 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.*

ILLUSTRATIVE 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 hetero-cycles 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 hetero-cycles 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*.

20. 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.

21. 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.

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