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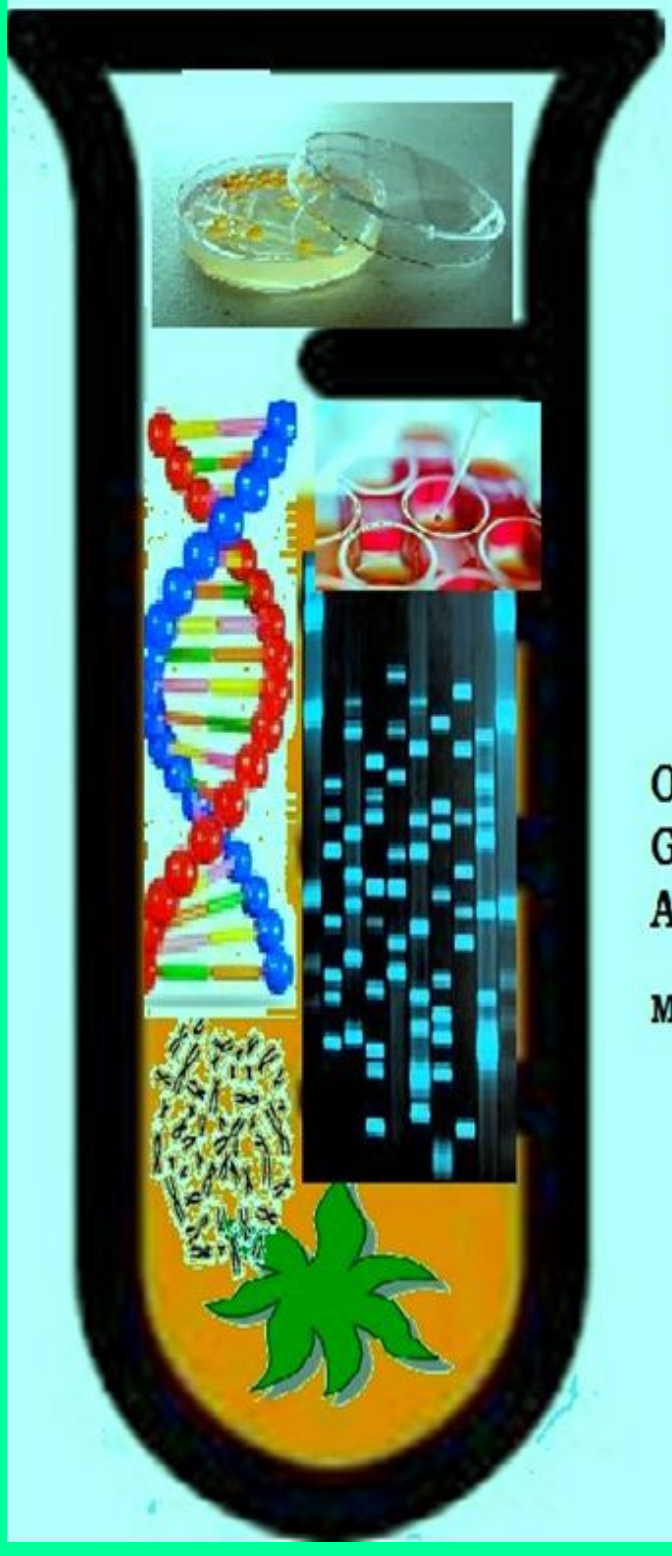

GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT

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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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Guidelines for Examination of Computer Related Inventions (CRIs)

INTELLECTUAL PROPERTY INDIA

OFFICE OF THE CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADE MARKS

2017

Contents

1. Introduction

1.1 Information Technology has gained special significance in the past two decades. It has emerged as a vital tool for scientific development. The term "Information Technology" encompasses the whole gamut of inputting, storing, retrieving, transmitting and managing data through the use of computers and various other networks, hardware, software, electronics and telecommunication equipment. Industry has witnessed rapid growth due to the computerization of activities which were hitherto carried out manually or mechanically. The advent of the internet and the World Wide Web (www) coupled with the exponential growth of processing and storage power has led to capabilities previously unheard of. The core elements in the application of Information Technology are computers and their peripherals. Computer Related Inventions (CRIs) comprises inventions which involve the use of computers, computer networks or other programmable apparatus and include such inventions having one or more features of which are realized wholly or partially by means of a computer programme or programmes.

1.2 Creators of knowledge in the domain of Computer Related Inventions (CRIs) have consistently endeavored for appropriate protection of their IPRs. The patent regimes have to cope up with the challenges of processing of patent applications related to computer related inventions and other related technologies. Major patent offices across the world are confronted with the issue of patentability of CRIs. They have developed examination guidelines/ manuals for examination of patent applications from these areas of technology so as to achieve uniform examination practices.

1.3 The aim of this document is to provide guidelines for the examination of patent applications in the field of CRIs by the Indian Patent Office so as to further foster uniformity and consistency in the examination of such applications. The objective of this document is to bring out clarity in terms of exclusions expected under section 3(k) so that eligible applications of patents relating to CRIs can be examined speedily.

1.4 The guidelines discuss various provisions relating to the patentability of computer related inventions. The procedure to be adopted by the Patent Office while examining such applications and the jurisprudence that has evolved in this field has also been discussed. Various examples and case laws relating to Computer Related Inventions (CRIs) have also been incorporated for better understanding of the issues involved from the perspective of the Patent Office.

1.5 However, these guidelines do not constitute rule making. In case of any conflict between these guidelines and the provisions of the Patents Act, 1970 or the Rules made there under, the said provisions of the Act and Rules will prevail over these guidelines. The guidelines are subject to revision from time to time based on interpretations by Courts of law, statutory amendments and valuable inputs from the stakeholders.

2. Legal Provisions relating to CRIs

2.1 The Patents (Amendment) Act 2002 (No. 38 of 2002) came into effect on 20th May, 2003. It amended the definition of invention[1] under section 2(1)(j) as *"Invention" means a new product or process involving an inventive step and capable of industrial application;*

and as per section 2(1)(ja)[2] *"inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;*

Further, section 2(1)(ac)[3] states that "*"capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;"*

Section 2 (1) (l)[4] defines "new invention" in The Indian Patents Act, 1970 as follows:

"New invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art;

[1] *Definition of Invention u/s 2(1)(j) under The Patents Act 1970 , after 2002 Amendments*

[2] *Definition of 'Inventive Step' under The Patents Act 1970, after 2005 amendments*

[3] *Definition of 'Capable of Industrial Application' under The Patents Act 1970*

[4] *Definition of 'New Invention' under The Patents Act 1970, after 2005 amendments*

2.2 The Patents (Amendment) Act, 2002 also introduced explicit exclusions from patentability under section 3 for Computer Related Inventions (CRIs) as under:

(k) a mathematical or business method or a computer programme per se or algorithms;
(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
(m) a mere scheme or rule or method of performing mental act or method of playing game;
(n) a presentation of information;

(o) topography of integrated circuits;

3. Terms/Definitions

The terms/definitions often used while dealing with computer related inventions are summarised hereunder. The terms which are defined in any of the Indian statutes have been construed accordingly and those which have not been given any statutory definition are normally construed in accordance with their use and ordinary dictionary meaning.

3.1 Algorithm

The term "algorithm" is not defined in Indian statutes and hence, for interpretation of this term, the general dictionary meaning is being used.

The Oxford Advanced Learners Dictionary defines 'algorithm' as "*a set of rules that must be followed when solving a particular problem* ".

3.2 Computer

The term "computer" is defined in The Information Technology Act, 2000 (No. 21 of 2000) as "*any electronic, magnetic, optical or other high-speed data processing device or system which performs logical, arithmetic, and memory functions by manipulations of electronic, magnetic or optical impulses, and includes all input, output, processing, storage, computer software, or communication facilities which are connected or related to the computer in a computer system or computer network*."

3.3 Computer Network

The term "computer network" is defined in The Information Technology Act, 2000 (No. 21 of 2000) as "*the interconnection of one or more computers through -*

(i) the use of satellite, microwave, terrestrial line or other communication media; and

(ii) terminals or a complex consisting of two or more interconnected computers whether or not the interconnection is continuously maintained;"

3.4 Computer Programme

The term computer programme has been defined in the Copyright Act 1957 under Section 2(ffc) as "*computer programme" means a set of instructions expressed in words, codes, schemes or in any other form, including a machine readable medium, capable of causing a computer to perform a particular task or achieve a particular result;'*

3.5 Computer System

The term "computer system" is defined in The Information Technology Act, 2000 (No. 21 of 2000) as "*a device or collection of devices, including input and output support devices and excluding calculators which are not programmable and capable of being used in conjunction with external files, which contain computer programmes, electronic instructions, input data and output data, that performs logic, arithmetic, data storage and retrieval, communication control and other functions;"*

3.6 Data

The term "data" is defined in the Information Technology Act, 2000 (No. 21 of 2000) as "*a representation of information, knowledge, facts, concepts or instructions which are being prepared or have been prepared in a formalised manner, and is intended to be processed, is being processed or has been processed in a computer system or computer network, and may be in any form (including computer printouts, magnetic or optical storage media, punched cards, punched tapes) or stored internally in the memory of the computer;*"

3.7 Firmware

The term "firmware" is not defined in Indian statutes and hence, for interpretation of this term, the general dictionary meaning is being used.

The Oxford Advanced Learners Dictionary defines "firmware" as "*a type of computer software that is stored in such a way that it cannot be changed or lost*"

3.8 Function

The term "function" is defined in the Information Technology Act, 2000 (No. 21 of 2000) as "*"function", in relation to a computer, includes logic, control arithmetical process, deletion, storage and retrieval and communication or telecommunication from or within a computer."*

3.9 Hardware

The term "hardware" is not defined in Indian statutes and hence, for interpretation of this term, the general dictionary meaning is being used. The Oxford Advanced Learners Dictionary defines "hardware" as "*the physical and electronic parts of a computer, rather than the instructions it follows*".

3.10 Information

The term "information" is defined in The Information Technology Act, 2000 (No. 21 of 2000) as "*information" includes data, message, text, images, sound, voice, codes, computer programmes, software and databases or micro film or computer generated micro fiche.*"

3.11 Manual

The term "Manual" as hereafter appears means "Manual of Patent Office Practice and Procedure" issued by CGPDTM, as may be amended from time to time, unless there is anything repugnant in the subject or context.

3.12 Per se

The term "per se" is not defined in Indian statutes including the Patents Act, 1970 and hence, for interpretation of this term, the general dictionary meaning is being used.

The general dictionary meaning of "per se" is "'*by itself" or "in itself" or "as such" or "intrinsically"* - to show that you are referring to something on its own, rather than in connection with other things.

3.13 Software

The term "software" is not defined in Indian statutes and hence, for interpretation of this term, the general dictionary meaning is being used. The Oxford Advanced Learners Dictionary defines "software" as "*the programs, etc. used to operate a computer*".

4. Examination Procedure

The examination procedure of patent applications relating to CRIs is the same as that for other inventions to the extent of consideration of novelty, inventive step, industrial applicability and sufficiency of disclosure etc. The determination that the subject matter relates to one of the excluded categories requires greater skill on the part of the examiner and these guidelines focus more on this aspect.

4.1 Novelty

Novelty is the foremost requirement to determine the patentability of any invention. No invention can be held patentable if the subject matter as described and claimed was disclosed before the date of filing, or before the date of priority, as the case may be. The determination of novelty in respect of CRIs is no different from any other field of invention.

The novelty criterion is judged under various provisions of the Patents Act and Rules made thereunder and also based on the procedures laid out in chapter 08.03.02 of the Manual.

4.2 Inventive step

Inventive step is decided in accordance with the provisions of section 2(1)(ja) of the Indian Patents Act, 1970. The determination of inventive step with regard to CRIs is carried out in like manner as in other categories of inventions.

> As per 2(1)(ja), "inventive step" means a *feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art*;

Hon'ble Supreme Court of India on inventive step: In Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd[5] it was held that "*The expression "does not involve any inventive step" used in Section 26(1) (a) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. The one suggested by Salmond L. J. in Rado v. John Tye & Son Ltd. is apposite. It is: "Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known."*

"Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under:"Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopaedia Britannica; ibid). To put it in another form: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned ?"[6]

[5] *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444)*

[6] *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444)*

In the F.Hoffman la Roche v Cipla[7] case the Hon'ble Delhi High Court had observed that the obviousness test is what is laid down in Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444) [8]and that "*Such observations made in the foreign judgments are not the guiding factors in the true sense of the term as to what qualities that person skilled in the art should possess. The reading of the said qualities would mean qualifying the said statement and the test laid down by the Supreme Court*."

Hon'ble High Court further added "*From the bare reading of the afore quoted observations of Supreme Court, it is manifest that the Hon'ble Supreme Court has laid down the test for the purposes of ascertaining as to what constitutes an inventive step which is to be seen from the standpoint of technological advancement as well as obviousness to a person who is skilled in the art. It is to be emphasized that what is required to be seen is that the invention should not be obvious to the person skilled in art. These are exactly the wordings of New Patents Act, 2005 u/s Section 2(ja) as seen above. Therefore, the same cannot be read to mean that there has to exist other qualities in the said person like unimaginary nature of the person or any other kind of person having distinct qualities…….. Normal and grammatical meaning of the said person who is skilled in art would presuppose that the said person would have the knowledge and the skill in the said field of art and will not be unknown to a particular field of art and it is from that angle one has to see that if the said document which is prior patent if placed in the hands of the said person skilled in art whether he will be able to work upon the same in the workshop and achieve the desired result leading to patent which is under challenge. If the answer comes in affirmative, then certainly the said invention under challenge is anticipated by the prior art or in other words, obvious to the person skilled in art as a mere workshop result and otherwise it is not. The said view propounded by Hon'ble Supreme Court in Biswanath Prasad (supra) holds the field till date and has been followed from time to time by this Court till recently without any variance….. Therefore, it is proper and legally warranted to apply the same very test for testing the patent; be it any kind of patent. It would be improper to import any further doctrinal approach by making the test modified or qualified what has been laid down by the Hon'ble Supreme Court in of Biswanath Prasad (supra).*"

[7] *F. Hoffmann-La Roche Ltd vs Cipla Ltd., Mumbai Central, ... on 7 September, 2012*

[8] *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444)*

The "obviousness" must be strictly and objectively judged[9]. While determining inventive step, it is important to look at the invention as a whole. It must be ensured that inventive step must be a feature which is not an excluded subject itself. Otherwise, the patentee by citing economic significance or technical advance in relation to any of the excluded subjects can insist upon grant of patent thereto. Therefore, this technical advance comparison should be done with the subject matter of invention and it should be found it is not related to any of the excluded subjects.[10]

Accordingly, the following points need to be objectively judged to ascertain whether, looking at the invention as a whole, the invention does have inventive step or not:

1. Identify the "person skilled in the art", i.e competent craftsman or engineer as distinguished from a mere artisan;

2. Identify the relevant common general knowledge of that person at the priority date;

3. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

4. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

5. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?

4.3 Industrial Applicability:

In patent law, industrial applicability or industrial application is a patentability requirement according to which a patent can only be granted for an invention

[9] *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444)*

[10] *IPAB in Yahoo Inc. (Formerly Overture Service Inc.) v. Assistant Controller of Patents and Designs & Rediff.com India Limited (OA/22/2010/PT/CH dated 8th December, 2011)*

which is capable of industrial application, i.e. for an invention which can be made or used in some kind of industry.

It has been defined in section 2(1)(ac) of Indian Patents Act, 1970 as follows:

> *"capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;*

The requirement of workability and usefulness are both connected to the requirement of industrial applicability. If an invention is not workable, it means that it is also not industrially applicable. The patent specification must disclose a practical application and industrial use for the claimed invention wherein a concrete benefit must be derivable directly from the description coupled with common general knowledge. Mere speculative use or vague and speculative indication of possible objective will not suffice.

4.4 Sufficiency of Disclosure:

Grant of patents is *quid pro quo*[11] to disclosure. It is for the disclosure of invention by the applicant that the patent rights are granted to him for a limited period of time, if all criteria of patentability is fulfilled. The Patents Act, 1970 requires the applicant to specify 'what' is the invention and 'how' to perform it. The invention shall be described fully and particularly to satisfy the 'what' requirement and further the best method of performing the invention known to the applicant to satisfy the 'how' requirement. The complete specification should therefore disclose the invention completely to meet the requirement of the Patents Act and should also enable a person skilled in the art to work the invention without any assistance of the patentee or any further experimentation. The description must be unambiguous, clear, correct and accurate. It must not contain any statements which may mislead the person skilled in the art to whom the specification is addressed. While the requirements of sufficiency of disclosure is considered generally in all fields of invention; in cases of patent application concerning computer related inventions (CRIs), these requirements are considered as fulfilled if the specification addresses the following:

[11] "something for something" or "this for that" in Latin

4.4.1 Fully and particularly (What):

1. If the patent application relates to apparatus/system/device i.e. hardware based inventions, each and every feature of the invention shall be described with suitable illustrative drawings. If the invention relates to 'method', the necessary sequence of steps shall clearly be described so as to distinguish the invention from the prior art with the help of the flowcharts and other information required to perform the invention together with their modes/means of implementation.

2. The working relationship of different components together with connectivity shall be described.

3. The desired result/output or the outcome of the invention as envisaged in the specification and of any intermediate applicable components/steps shall be clearly described.

4.4.2 Best Method of performing the invention (How):

The best mode of performing and/or use of the invention shall be described with suitable illustrations. The specification should not limit the description of the invention only to its functionality rather it should specifically and clearly describe the implementation of the invention.

4.4.3 Claims:

1. The claims should clearly define the scope of the invention and should take care of unity of invention requirements as defined under section 10(5) of the Patents Act, 1970.
2. The claim(s) of a complete specification should be clear and succinct and should be fairly based on the matter disclosed in the specification.
3. The claims in the field of Computer related inventions need to be construed to ascertain the substance of the claim without wholly relying on the forms and types of the claims.

4.4.4 Form and substance:

The sub-section 3(k) excludes a mathematical or business method or a computer programme *per se* or algorithms from patentability. While the

judgment of mathematical methods or business methods is comparatively easier, it is the computer programme per se or algorithms related inventions that require careful consideration of the examiner. Computer programmes are often claimed in the form of method claims or system claims with some 'means' indicating the functions of flow charts or process steps. The algorithm related claims are even wider than the computer programmes claimed by themselves as a single algorithm can be implemented through different programmes in different computer languages. If, in substance, claims in any form such as method/process, apparatus/system/device, computer program product/ computer readable medium belong to the said excluded categories, they would not be patentable.

Even when the issue is related to hardware/software relation, the expression of the functionality as a 'method' is to be judged on its substance. It is well-established that, in patentability cases, the focus should be on the underlying substance of the invention, not the particular form in which it is claimed. The Patents Act clearly excludes computer programmes per se and the exclusion should not be allowed to be avoided merely by camouflaging the substance of the claim by its wording.

4.4.5 Means plus Function:

The claims concerning CRIs are often phrased in means for performing some function such as means for converting digital to analog signal etc. These types of claims are termed as means +function format. The 'means' mentioned in the claims shall clearly be defined with the help of physical constructional features and their reference numerals to enhance the intelligibility of the claims. The claims in means plus function form shall not be allowed if the structural features of those means are not disclosed in the specification.

Further, if the specification supports performing the invention solely by the computer program then in that case means plus function claims shall be rejected as these means are nothing but computer programme per se.

Where no structural features of those means are disclosed in the specification and specification supports performing the invention solely

by the software then in that case means in the "means plus function" claims are nothing but software.

4.5 Determination of excluded subject matter relating to CRIs:

Since patents are granted to inventions, whether products or processes, in all fields of technology, it is important to ascertain from the nature of the claimed Computer-related invention whether it is of a technical nature involving technical advancement as compared to the existing knowledge or having economic significance or both, and is not subject to exclusion under Section 3 of the Patents Act.

The sub-section 3(k) excludes mathematical methods or business methods or computer programme per se or algorithms from patentability. Computer programmes are often claimed in the form of algorithms as method claims or system claims with some 'means' indicating the functions of flow charts or process steps. It is well-established that, while establishing patentability, the focus should be on the underlying substance of the invention and not on the particular form in which it is claimed.

What is important is to judge the substance of claims taking whole of the claim together. If any claim in any form such as method/process, apparatus/system/device, computer program product/ computer readable medium falls under the said excluded categories, such a claim would not be patentable. However, if in substance, the claim, taken as whole, does not fall in any of the excluded categories, the patent should not be denied.

Hence, along with determining the merit of invention as envisaged under Sections 2(1) (j), (ja) and (ac), the examiner should also determine whether or not they are patentable inventions under Section 3 of the Act.

4.5.1 Claims directed as "Mathematical Method": Mathematical methods are a particular example of the principle that purely abstract or intellectual methods are not patentable. Mathematical methods like method of calculation, formulation of equations, finding square roots, cube roots and all other similar acts of mental skill are therefore, not patentable. Similarly mere manipulations of abstract idea or solving purely mathematical problem/equations without specifying a practical application also attract the exclusion under this category.

However, mere presence of a mathematical formula in a claim, to clearly specify the scope of protection being sought in an invention, may not necessarily render it to be a "mathematical method" claim. Also, such exclusions may not apply to inventions that include mathematical formulae and resulting in systems for encoding, reducing noise in communications/ electrical/electronic systems or encrypting/ decrypting electronic communications.

4.5.2 Claims directed as "Business Method": The term 'Business Methods' involves whole gamut of activities in a commercial or industrial enterprise relating to transaction of goods or services. The claims drafted not directly as "business methods" but apparently with some unspecified means are held non-patentable. However, if the claimed subject matter specifies an apparatus and/or a technical process for carrying out the invention even partly, the claims shall be examined as a whole. When a claim is "business methods" in substance, it is not to be considered a patentable subject matter.

However, mere presence of the words such as "enterprise", "business", "business rules", "supply-chain", "order", "sales", "transactions", "commerce", "payment" etc. in the claims may not lead to conclusion of an invention being just a "Business Method", but if the subject matter is essentially about carrying out business/ trade/ financial activity/ transaction and/or a method of buying/selling goods through web (e.g. providing web service functionality), the same should be treated as business method and shall not be patentable.

4.5.3 Claims directed as "Algorithm": Algorithms in all forms including but not limited to, a set of rules or procedures or any sequence of steps or any method expressed by way of a finite list of defined instructions, whether for solving a problem or otherwise, and whether employing a logical, arithmetical or computational method, recursive or otherwise, are excluded from patentability.

4.5.4 Claims directed as "Computer Programme *per se*": Claims which are directed towards computer programs per se are excluded from patentability, like,

(i) Claims directed at computer programmes/ set of instructions/ Routines and/or Sub-routines.

(ii) Claims directed at "computer programme products" / "Storage Medium having instructions" / "Database" / "Computer Memory with instruction" stored in a computer readable medium.

The legislative intent to attach suffix *per se* to computer programme is evident by the following view expressed by the Joint Parliamentary Committee while introducing Patents (Amendments) Act, 2002:

> *"In the new proposed clause (k) the words "per se" have been inserted. This change has been proposed because sometimes the computer programme may include certain other things, ancillary thereto or developed thereon. The intention here is not to reject them for grant of patent if they are inventions. However, the computer programmes as such are not intended to be granted patent. This amendment has been proposed to clarify the purpose."* [12]

4.5.5 *A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions*

The above criterion is to be judged as per the procedures as laid out in chapter 08.03.05.11 of the Manual.

4.5.6 A mere scheme or rule or method of performing mental act(s) or a method of playing game(s)

The above criterion is to be judged as per the procedures as laid out in chapter 08.03.05.12 of the Manual.

4.5.7 Presentation of information

The above criterion is to be judged as per the procedures as laid out in chapter 08.03.05.13 of the Manual.

[12] *Report of the Joint Committee presented to the Rajya Sabha on 19th December, 2001 and laid on the table of Lok Sabha on 19th December 2001*

4.5.8 Topography of integrated circuits

The above criterion is to be judged as per the procedures as laid out in chapter 08.03.05.14 of the Manual.

5. Replacement of Provisions of Manual

Chapter 08.03.05.10 of the Manual, containing provisions pertaining to section 3(k) of the Patents Act, 1970 shall stand deleted with coming into force of these Guidelines for examination of CRIs.

6. Applicability of Guidelines:

These Guidelines shall be applicable with immediate effect.

--END OF DOCUMENT--

सत्यमेव जयते

Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals

INTELLECTUAL PROPERTY INDIA
Patents | Designs | Trademarks
Geographical Indications

Office of the Controller General of Patents, Designs and Trademarks

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1. Development of pharmaceutical patenting in India

1.1 Pharmaceutical patenting is an extremely important aspect of India's Patent system. At the time of Independence, India's patent regime was governed by the Patents and Designs Act, 1911, which had provisions both for product and process patents. It was felt that there was a need for a change in the existing patent law since it had not helped in the promotion of scientific research and industrialization in the country.

1.2 Immediately after independence, a Committee headed by Justice (Dr) Bakshi Tek Chand, a retired judge of the Lahore High Court, was constituted to undertake a comprehensive review of the working of the 1911 Act (1948-50). The Committee submitted its interim report on August 4, 1949 and the final report in 1950 making recommendations for prevention of misuse or abuse of patent rights in India. The Committee also recounted that the Patent Act should contain a clear indication that food and medicine and surgical and curative devices were to be made available to the public at the cheapest price while giving reasonable compensation to the patentee. Based on the recommendations of the Committee, amendments were made in the Patents and Designs Act, 1911, first in 1950 (by Act XXXII of 1950) in relation to working of inventions, including compulsory licensing and revocation of patents, and then in 1952, (by Act LXX of 1952) to provide for compulsory license for food and medicines, insecticide, germicide or fungicide, and for the process for producing substance or any invention relating to surgical or curative devices.

1.3 Subsequent to that, another Committee under Justice Ayyanger (1957-59) was constituted. Justice Ayyangar's report specially discussed (a) patents for chemical inventions and (b) patents for inventions relating to food and medicine. After thoroughly examining the contemporary law of patents governing inventions on chemical substances of different countries, the Committee recommended that only process claims be allowed. For foods and medicines, the Committee recommended that inventions related to foods and medicines including insecticides and fungicides should not be patentable as such and processes for their productions should alone be patentable.

1.4 On the basis of these reports and other deliberations, the Patents Act 1970 was enacted and came into force from 1972. The Patents Act 1970 allowed process patents for drugs, foods and products of chemical reactions but no product patents were allowed for inventions related to such substances [erstwhile Section 5 of the Patents Act 1970]. The definition of Drugs included pesticides and insecticides. Also, the term of patents, for processes related to drugs and foods, was reduced to a maximum of seven years as opposed to fourteen years for the general category patents. During the period 1970-1994, the Indian pharmaceutical industry became nearly self-sufficient and one of the largest exporters of generic medicines. A large number of developing countries depend upon the supply of cheaper generic medicines from India.

1.5 The 1990s marked the beginning of a new era in the world economy. From the Uruguay round of General Agreement on Tariffs and Trade, emerged the World Trade Organization (WTO), which also integrated IPR laws in international trade in a

comprehensive manner. The WTO agreement, of which India is a signatory, came into force from 01.01.1995. TRIPs (Trade Related Aspects of Intellectual Properties) agreement (Annexure 1C of the WTO agreement) under Article 27, required introduction of both product and process patenting in all fields of technology including drugs, foods, products of chemical reactions and micro-organisms.

1.6 To introduce product patents, TRIPs, under Article 65, allowed a ten years transition period for developing countries which did not have product patenting. However, for such developing countries like India, an interim measure was required to be adopted for pharmaceutical and agrochemical product related applications. Article 70.8 of TRIPS stipulated that such countries were required to introduce mail-box provisions for receiving applications claiming products in the relevant field. Also Article 70.9 mandated that Exclusive Marketing Rights (EMR) were to be made available for such applications subject to certain conditions for a term of five years from the date of grant of such rights or till the grant or rejection of patents claiming such products.

1.7 Accordingly, after the WTO agreement, the Patents Act 1970 was amended in a phased manner in 1999, 2002 and 2005 in conformity with the TRIPs agreement.

1.8 In 1999, mail-box and EMR provisions were introduced in India with a retrospective effect from 01.01.1995. Erstwhile Section 5 of the Patents Act 1970 was bifurcated to create a new Section 5(2) (mail-box provision) to receive applications claiming pharmaceuticals and agrochemicals product and a new chapter IVA was introduced to deal with EMR applications.

1.9 By the 2002 amendments, the term of all patents was uniformly made twenty years.

1.10 After the introduction of product patenting in 2005, mail-box and EMR provisions [Section 5 and Chapter IVA of the Patents Act 1970] were deleted and consequently product patents have been made available for inventions related to pharmaceuticals, agrochemicals, foods and products of chemical reactions since 01.01.2005.

1.11 While introducing the amendments, utmost care was taken to protect the public health and nutrition. Also, provisions for both pre and post-grant oppositions were engrafted in the Patents Act.

1.12 Other than the WTO agreement, India is signatory to various international agreements which, *inter alia*, have bearing on patenting in pharmaceuticals. These include Paris Convention (since 1998), Patent Cooperation Treaty (since 1998) and Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (since 2001), Convention on Biological Diversity (since 1992). The amendments of the Patents Act 1970 were also calibrated to recognize India's accession to these treaties.

1.13 In the wake of the public health crisis afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, the ministerial conference of WTO adopted 'The Doha declaration on TRIPS and Public Health' (2001). The Doha declaration provided a mechanism for compulsory licensing to supply medicines to countries with insufficient or no-manufacturing

capacities. The declaration also explicitly stressed that the TRIPs Agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all. Consequently, a provision (Section 92A) was introduced in the Patents Act for Compulsory Licensing for the purpose of export of pharmaceuticals products to any country having insufficient or no manufacturing capacity.

1.14 Convention of Biological Diversity (CBD) acknowledged the sovereign right of the nations on their genetic resources and mandated that the access to the genetic resources and any intellectual property derived therefrom should be subject to the benefit sharing accrued from such access. The CBD also warranted that the member states should protect their traditional and indigenous knowledge.

1.15 In consequence of the CBD, India passed the Biological Diversity Act, 2002 which provides a mechanism for access to the genetic resources and benefit sharing accrued therefrom. Section 6 of the Biological Diversity 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 was used in an invention.

1.16 Pharmaceutical patenting in India is of utmost concern not only to the people of India, but also for the world community as India has emerged as "the pharmacy of the world". While traversing the history of the development of the legislation related to pharmaceuticals, Honorable Supreme Court referred to a letter written by the HIV/AIDS Director of the WHO, dated December 17, 2004, to the then Minister of Health and Family Welfare, Government of India. A part of the said letter is quoted herein below:

"As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to anti-retrovirals, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines".

1.17 Pharmaceutical patenting in India is therefore, an extremely important and sensitive issue since, while a bad patent is a burden to society, good patents are also essential for promoting innovation and technological development in the country. Quality, consistency and uniformity of examination and grant of patents thereafter are, therefore, the top most priority concerns for the Patent Office. In order to achieve these targets the Patent Office is continuously upgrading its internal resources. Apart from updating its physical resources like revamping its internal work modules or its public interfaces, the Office, in an attempt to bring in quality, consistency and uniformity, has introduced guidelines for examination in certain key areas like traditional knowledge and biotechnology. Further, many of the issues related to the

product patenting in the field of pharmaceuticals are now becoming clear through the decisions of the Courts. Therefore, there is a need to develop guidelines for examination of pharmaceutical patents, incorporating the analysis of the Courts, with the objective that the guidelines will help improve the examination standard and will introduce harmonious practice amongst the technical Officers of the system.

2. Scope of the present guidelines

The guidelines as set out below are supplemental to the practices and procedures followed by the Patent Office as published in the 'Manual of Patent Office Practice and Procedure', "Guidelines For Examination of Biotechnology Applications" and the "Guidelines For Processing of Patent Applications Relating to Traditional Knowledge and Biological Material". The present guidelines are prepared with the objective that the Guidelines will help the Examiners and the Controllers of the Patent Office in achieving consistently uniform standards of patent examination and grant. The guidelines set out below contain, where feasible, certain illustrations. These illustrations are not intended to exhaust the manner in which the relevant guidelines are to be applied in practice. Examiners are requested to examine applications on a case-to-case basis, without being prejudiced by the specific illustrations being provided herein. In case of any conflict between these Guidelines and the Patents Act, 1970 and the Rules made thereunder, the provisions of the Act and Rules will prevail. The Guidelines are dynamic and Patent Office will update the same as and when required.

3. Provisions covered

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

Section 2 (1) (j): "invention" means a new product or process involving an inventive step and capable of industrial application;

Section 2(1)(j)(a): "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

Section 2(1)((ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;

Section 3 specifies that the following are not patentable inventions within the meaning of the Act:

(i) **Section 3 (b):** an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(ii) **Section 3 (c):** 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;

(iii) Section 3 (d): the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

(iv) Section 3 (e): a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(v) Section 3 (i): 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.

(vi) 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 for production or propagation of plants and animals;

(vii) Section 3 (p): an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

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

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

4. Claims of Pharmaceutical Inventions

4.1 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 and other patentability criteria, a preliminary reference is made hereunder on claims of pharmaceuticals and allied inventions which are usually filed in patent applications of the relevant fields.

4.2 Generally, applications pertaining to pharmaceutical and allied subject-matters comprise the claims relating to the following subject matters, but not limited to:

I. ***Product claims:***

i. Pharmaceutical product:

a. *New Chemical Entities;*
b. *Formulations/Compositions;*
c. *Combinations/ dosage/dose*;
d. *New forms of known substance* such as*:*
salts, ethers and esters; polymorphs; solvates, including hydrates; clathrates; stereoisomers; enantiomers; metabolites and pro-drugs; conjugates; pure forms; particle size; isomers and mixtures thereof; complexes; derivatives of known substances; and

ii. Kits;
iii. Product-by-process.

II. Claims for p*rocess/method of manufacturing;*

III. Claims related to n*ew property*, *new use of known substance or* u*se claims, including second indications*;

IV. Claims for m*ethod of treatment and/or diagnosis of human beings and animals;*

V. Claims related to s*election inventions (relating to product and process)*

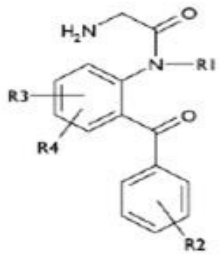
The Guidelines have been designed In such a manner that the explanations given with regard to the separate concepts such as novelty, inventive step, industrial use etc would be applicable generally to all the types of claims given above but where there seems to be a requirement of additional clarification or a different approach, an attempt has been made to explain it separately under the same conceptual head in the context of the pertinent provisions of law.

Markush claims

Often broad ("generic") patent claims are drafted covering a family of a large number (sometimes thousands or millions) of possible compounds. The so-called 'Markush claims' refer to a chemical structure with plurality of functionally equivalent chemical groups in one or more parts of the compound. The Markush claims are drafted to obtain a wide scope of protection encompassing a large number of compounds whose properties might not have been tested, but only theoretically inferred from the equivalence with other compounds within the claim. Quite often the Markush claims generate confusions regarding the novelty, non-obviousness and industrial applicability of a group of compounds covered within the said Markush formula. Also, the Markush claims may invoke the questions of sufficiency and plurality of distinct group of inventions surrounding such claims.

Illustrative example:

Claim 1: The compounds of the general formula:



Wherein, R1 is selected from phenyl, pyridyl, thiazolyl, thioalkyl, alkoxyl and methyl; R2-R4 are methyl, tolyl or phenyl the compounds are used as a pharmaceutical for increasing the oxygen intaking capability of blood.

While examining above said Markush claims, the complete specification should be critically examined whether: (i) it discloses best representatives, as known to the applicant, of the possible embodiments;(ii) such embodiments share a common use or property; (iii) such possible embodiments share common structure; (iv) physical and/ or chemical properties of best representatives of such embodiments known to the applicant are disclosed; (v) test conducted for the representatives of such embodiments known to the applicant is provided; (vi) in case of product claims at least one process for preparing the compounds has been disclosed enabling the whole scope of the invention.

Moreover, if any one of (i) to (vi) are not met such a Markush claims may be objected depending upon the circumstances of the application so examined under 'Unity of invention' and insufficiency of disclosure suitably. Compounds can be said to have a common structure where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

5. Prior Art Search

5.1 While conducting a prior art search, the Examiner should design/frame a comprehensive search strategy by combining various search parameters including key words, IPC, compound searches, etc. and thorough search should be carried out in patent as well as non-patent databases.

5.2 The compounds can be searched and identified from the various databases by using several methods[1]:

a) Molecular formula and structural formula searching;

b) Name searching using IUPAC nomenclature;

c) Compound searching using CAS Registry Numbers;

d) Generic name searching (INN); and

e) Search using International Patent Classification (IPC).

5.3 It is to be noted that quite often the claims of the pharmaceutical compounds involve derivatives of known compounds having established pharmaceutical activities. Also, it has been observed that such pharmaceutical substances have already been assigned generic names (International Non-Proprietary Names, INN). When the patent specification under examination disclose such INNs, the examiner should search the prior art on the basis of such INNs as well.

5.4 In case it is found that the applicant claims the second use/indication in the form of a product claim of an already known pharmaceutical compound/new form of a known substance or compound, the examiner should follow the same methodology and ask the applicant to inform the INN of the said pharmaceutical substance. If the applicant does not inform the INN even on the request, the examiner should try to find out the INN and use the same in the search strategy.

6. What is an invention: Section 2 (1) (j)

6.1 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. From the plain reading of section 2(1)(j), it is amply clear that only products and/or processes for making pharmaceutical compounds are considered to be inventions under the said clause. Sometimes, it is observed that applicants file claims in the following manner:

1) Use of compounds in the treatment of ----------

2) A product or a substance (which is known) for the treatment of new disease (which is nothing but use/application claim).

[1]Page 32 of Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries, Published by United Nations Development Programme304 E 45th Street New York, NY 10017, USA ,www.undp.org

The above two categories of claims are not to be considered as inventions, since the claimed subject matter neither pertains to product nor to process. Further, an objection with regard to Section 3(i) and Section 3(d) would be invoked.

6.2 Also, it may be noted that sometimes such claimed inventions relate to the second use of already known compounds which have fallen in the public domain. Necessary care may be exercised to examine those cases in the light of Section 2(1)(j) and Section 3. Further, it should be borne in mind that finding the new property of an already known substance does not make the substance novel and/or inventive.

Illustrative example: In an Order, Hon'ble Intellectual Property Appellate Board (IPAB) rejected one such application. The application initially claimed the use of known Fumaric acid derivatives for a second medical indication. The examiner raised objections on two counts i.e. claims are not allowable under section 2(1)(j) in that the claims relate neither to product nor process and the compounds of the invention were admittedly known[2].Facing the objections the claims were amended to product claims, but the question of lacking in novelty was maintained. The Controller refused the application on the ground of lacking in novelty. Later, the IPAB upheld the decision of the Controller.

7. Assessment of Novelty:

7.1 **Section 2 (1)(l)** of the Act states that '"new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art'. For the purpose of ascertaining the novelty during the examination, the prior art is to be construed as prescribed under Section 2 (1)(l) and 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.

7.2 **Documents:** It should be noted that while assessing novelty (as distinct from inventive step), it is generally not permitted to combine separate items of prior art together. It is also not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested or essentially linked to one another. If a Markush formula covers innumerable compounds and if some of the compounds fall within one prior art and certain other compounds fall within another prior art, in such cases all these prior art documents are to be cited. A generic disclosure in the prior art may not necessarily take away the novelty of a specific disclosure. A specific disclosure in the prior art takes away the novelty of a generic disclosure.

[2] In FUMAPHARM AG vs THE CONTROLLER OF PATENTS & DESIGNS, OA/6/2009/PT/KOL and Miscellaneous Petition No. 34/2011 in OA/6/2009/PT/KOL, ORDER (No. 73 of 2013)[2]

7.3 Relevant date of a prior document: According to Section 2 (1) (w) of the Act, "priority date" has the meaning assigned to it by Section 11. In determining novelty, a prior document should be read as it would have been read by a person skilled in the art on the relevant date of the document. 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 in public domain. For anticipation, such publication must be before the date of priority of the claim under consideration. 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. The prior art document must be enabling i.e. there should be a clear and unmistakable direction for the invention in the prior art.

7.4 **Implicit disclosure:** The lack of novelty must normally be clearly apparent from the explicit teaching of the prior art. However, since the prior art is read through the eyes of the person skilled in the art, the *implicit* features of a document may also be taken into account for determining novelty. Thus, if the person skilled in the art would read a disclosure as including a particular feature without it being specifically mentioned, it would be considered an implicit feature of that disclosure and lack of novelty may be implicit in the sense that, in carrying out the teaching of the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. Therefore, if the said prior art discloses the claimed subject-matter in such implicit manner that it leaves no doubt in the mind of examiner as to the content of the prior art and the practical effect of its teaching, an objection regarding lack of novelty should be raised.

7.5 **Inherent anticipation:** Sometimes the prior art may inherently disclose the subject matter of an invention. In one case before the IPAB, it was held that " patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. The prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating prior art. It is not necessary that inherent anticipation requires that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. But it is necessary that the result is a necessary consequence of what was deliberately intended in the invention"[3].

[3][paragraph 58 of the decision of the IPAB in Enercon (India) Limited vs Aloys Wobben ORA/6/2009/PT/CH ,ORDER (No. 18 of 2013)].

7.6 Illustrative examples for determination of novelty

Example 1:

The claimed invention relates to a class of heterocyclic compounds of Formula I which are used as mGluR1 enhancers. Prior art disclosed compounds with following general formula II having similar biological properties.

Following substituents are selected from list of substituents disclosed in prior art to claim compound of formula I;

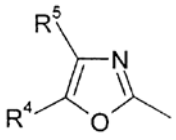
*R^1 is **hydrogen**;*

*R^2, $R^{2'}$ **hydrogen** or **halogen (as R^3 and $R^{3'}$ of present invention)**;*

*X is **O**;*

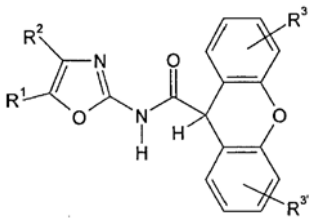
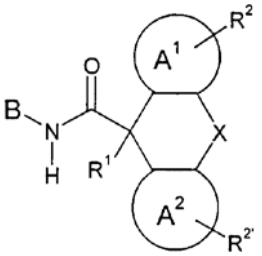
*A^1, A^2 is **phenyl;***

B is 4,5-substitued oxazole

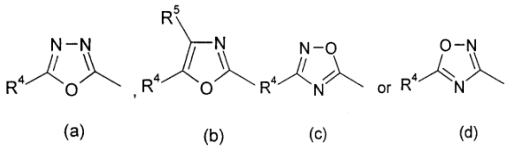


(b)

where *R^4 and R^5**(as R^1 and R^2 of present invention)** is **hydrogen** or **trifluoromethyl**, with the proviso that at least one of R^4 or R^5 has to be hydrogen.*

Present Invention	**Prior Art**
1. Compounds of general formula  Formula I	1. A compound of general formula  Formula II
one of R1 and R2 signifies trifluoromethyl, and the other one signifies hydrogen;	Wherein
R3, R 3' signify, independently from each other, hydrogen or halogen;	R1 signifies hydrogen or lower alkyl;
as well as pharmaceutically acceptable salts thereof.	R2, R2' signify, independently from each other, hydrogen, lower alkyl, lower alkoxy, halogen or trifluoromethyl;
	X signifies O, S or two hydrogen atoms not forming a bridge;
	A1, A2 signify, independently from each other,phenyl or a 6-membered heterocycle

B is a group of formula



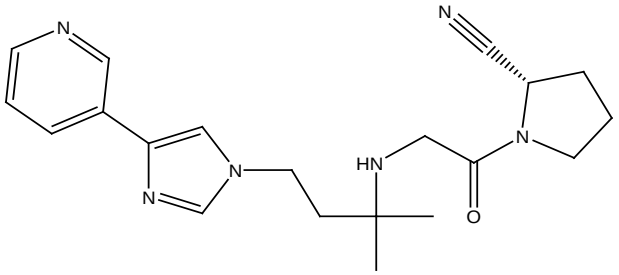
R4 and R5 signifies hydrogen, lower alkyl, lower alkoxy, cyclohexyl, lower alkyl¬ -cyclohexyl or trifluoromethyl, with the proviso that at least one of R4 or R5 has to be hydrogen; as well as their pharmaceutically acceptable salts.

R4 and R5 signifies hydrogen, lower alkyl, lower alkoxy, cyclohexyl, lower alkyl¬ -cyclohexyl or trifluoromethyl, with the proviso that at least one of R4 or R5 has to be hydrogen; as well as their pharmaceutically acceptable salts.

Analysis: It may be noted that the compound of the present invention as well as prior art compound is represented by Markush formulae. It is to be checked from the prior art, whether compounds disclosed specifically in the prior art are of such structure so that they can unambiguously take away the novelty of the compound(s) in question. If the compounds of prior art disclosed specifically do not take away the novelty of the compounds in question, then the generic disclosure in the prior art may still be cited for the purpose of inventive step.

Example 2:

The invention relates to the fumarate salt of (2S)-1-{[1,1-Dimethyl-3-(4-(pyridin-3-yl))-imidazol-1-yl)-propylamino]-acetyl}-pyrrolidine-2-carbonitrile useful for the treatment of diabetes mellitus, having the structure



Prior art specifically discloses methanesulfonic acid salt of (2S)-1-{[1,1-Dimethyl-3-(4-pyridin-3-yl-imidazol-1-yl)-propylamino]-acetyl}-pyrrolidine-2-carbonitrile.
Further, it discloses "many pharmaceutically acceptable salts" of the said compound and also mentions many salt forming acids, among which fumaric acid was

mentioned as one of the pharmaceutically acceptable salt forming acid. However, it does not specifically disclose the fumaric acid salt.

Analysis: The subject-matter of the claimed invention claiming fumaric acid salt of a compound (2S)-1-{[1,1-Dimethyl-3-(4-pyridin-3-yl-imidazol-1-yl)-propylamino]-acetyl}-pyrrolidine-2-carbonitrile, the implicit disclosure of prior art anticipates the novelty of claimed subject-matter.

7.7 Combination/Composition Claims

Quite often, the claims of combination of pharmaceutical products 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, should be dealt under novelty also.

7.8 Illustrative Examples for determination of novelty for combination/composition claims:

Example 1:

Claimed invention relates to a composition for enhancing corneal healing said composition comprising vitamin A and a sterile buffer administered to the eye.

Prior art discloses the use of the eye-drops to rewet contact lenses, wherein said eye-drops comprising Vitamin A , the sterile buffer and other exciepients.

Analysis: The claim lacks novelty, as being anticipated by the said prior art, which discloses all the features of claimed composition useful for enhancing corneal healing.

Thus, the claimed subject matter lacks novelty.

Example 2:

Claim: A pharmaceutical formulation comprising a substantially clear aqueous solution characterized in that it has a viscosity of less than 10 mPa.s and contains 3.5 to 5% w/v of 1,3-bis(2-carboxychromon-5-yloxy)-propan-2-ol, or a pharmaceutically acceptable salt thereof as active ingredient, glycerol, and ions of metals of groups IA, IB, IIB and IVB of the periodic table or transition metals having the concentration of the ions less than 20 ppm.

The prior art (D1) describes a pharmaceutical formulation comprising an aqueous solution containing 2% w/v of 1,3-bis(2-carboxychromon-5-yloxy)-propan-2-ol sodium salt (sodium cromoglycate) as active ingredient and glycerol and method of preparing the same. Further, D1 indicates that the concentration of sodium cromoglycate may be from 0.1% w/v to 10% w/v and that it is preferred that the concentration of sodium cromoglycate be less than 5% w/v.

D1 does not mention expressis verbis that this pharmaceutical formulation is a substantially clear aqueous solution which has a viscosity of less than 10 mPa.s and that the concentration in the formulation of ions of metals of groups IA, IB, IIB and IVB

of the periodic table or of transition metals is less than 20 ppm. However, these features were not distinguishing features over D1. There was a clear-cut similarity of the method of preparation of the pharmaceutical formulation according to application under question with that of D1, there was no reason to expect a different viscosity or a different metal content in the two formulations. Accordingly, the question was whether the range of 3.5 w/v to 5% w/v of sodium cromoglycate, could be regarded as novel over the disclosure of D1. D1 indicates that the concentration of sodium cromoglycate may be from 0.1% w/v to 10% w/v and that it is preferred that the concentration of sodium cromoglycate be less than 5% w/v.

Analysis: The skilled person will inevitably read the value of 5% w/v for the concentration of sodium cromoglycate. Accordingly, the claimed range of 3.5% w/v to 5% w/v is anticipated.

7.9 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. In a product-by-process claim, by using only process terms, the applicant seeks rights to a product, not a process. The IPAB held in ORDER No. 200/2012 "…….product-by-process claims must also define a novel and unobvious product, and that its patentability cannot depend on the novelty and unobviousness of the process limitations alone. Therefore, the patentability of a product by process claim is based on the product itself if it does not depend on the method of production. In other words, if the product-by-process claim is the same as or obvious from a prior product, the claim is un-patentable even if the prior art product was made by a different process. Accordingly the product by process claim must define a novel and un-obvious product and the patentability in such claim cannot depend on the novelty and un-obviousness of the process limitation alone"[4].

Therefore, in product-by-process claims, the applicant has to show that the product defined in process terms, is not anticipated or rendered obvious by any prior art product. In other words the product must qualify for novelty and inventive step irrespective of the novelty or inventive step of the process.

[4] The Research Foundation Of State University Of New York Vs Assistant Controller Of Patents [OA/11/2009/PT/DEL (ORDER No. 200/2012)]

7.10 Illustrative Examples for determination of novelty for Product-by-process claims:

Example 1:

The patent application relates to "Ceramic based nanoparticles for entrapping therapeutic agents for photodynamic therapy and method of using the same". The specification disclosed, in one embodiment, that the invention provided a method for the synthesis of photosensitizer dye/drug doped silica-based nanoparticles (diameter ~30 nm), by controlled alkaline hydrolysis of a ceramic material [such as triethoxyvinylsilane (VTES)] in micellar media and in another embodiment, the photosensitive drug/dye used was 2-devinyl-2-(1-hexyloxyethyl) pyropheophorbide (HPPH), an effective photosensitizer.

Claims 1 to 6 were for method of preparing ceramic nanoparticles loaded with drugs and claims 7 to 13 being composition claims.

Claims 1 and 7 are reproduced below:-

1. A method of preparing ceramic nanoparticles loaded with one or more photosensitive drugs comprising the steps of:

a) preparing micelles entrapping the photosensitive drugs;

b) adding alkoxyorganosilane to the micelles to form complexes of silica and the micelles;

c) subjecting the complexes of silica and micelles to alkaline hydrolysis to precipitate silica nanoparticles in which the photosensitive drug, molecules are entrapped; and

d) isolating the precipitated nanoparticles by dialysis

7. A composition comprising ceramic nanoparticles in which one or more photosensitive drugs are entrapped by a method comprising; the steps of:

a) preparing micelles entrapping the photosensitive drugs;

b) adding alkoxyorganosilane to the micelles to form complexes of silica and the micelles ;

c) subjecting the complexes of silica and micelles to alkaline hydrolysis to precipitate silica nanoparticles in which the photosensitive drug, molecules are entrapped; and

d) isolating the precipitated nanoparticles by dialysis

Prior art (D1) is directed to use of photoluminescent nanoparticles for photodynamic therapy to address the problem of application of light of a suitable wavelength to a photodynamic drug (PDT). The solution suggested in D1 was the use of Light-Emitting nanoparticles to be administered in addition to PDT in order to activate the drug. It is taught that the Light Emitting Nanoparticles absorb light from the light source and re-

emit lights at a different wavelength, which is suitable to activate the PDT drug in the vicinity of Light Emitting Nanoparticles. Thus, the role of nanoparticles is to absorb the light from a light source and re-emit the light of different wavelength to activate the PDT drug. To achieve this purpose, firstly, a PDT drug is to be administered; thereupon nanoparticles are administered and thereafter light source become active. The time gap between administration of PDT drug and administration of nanoparticles has been highlighted in the specification. The Controller refused the application on the ground of lacking in novelty.

Analysis of IPAB: IPAB found that D1 did not teach or formally suggested a method of synthesizing ceramic based nanoparticles entrapped with photosensitive drugs where the method involve steps restricted in claim 1. Thus, the method claims could be allowed. However, regarding the product-by- process claims, the IPAB was of the opinion that in the present case the PDT drug is same but only the carriers are different. Difference between prior art composition and claimed composition is in the use of non-bio-gradable carrier. In the prior art, the carrier is polyacrylamide non-

degradable nanoparticles but in the claimed invention the carrier is ceramic based, which is also non-bio-degradable. The composition claimed has known constituents and beyond understanding to have any enhanced effect. The composition claims were refused by the IPAB.

Example 2:
Claim: Compound C obtained by a process X

Prior art (D1) teaches the same compound C with same characteristics. However, in D1 the compound C was prepared by process Y.

Analysis:
As the compound C is already identified in D1, it lacks novelty despite the fact that it has been prepared by a different method.

8. ASSESSMENT OF INVENTIVE STEP:

8.1 An invention should possess an inventive step in order to be eligible for patent protection. As per the section 2(1)(j)(a) of Patents Act, an invention will have inventive step if the invention is (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. Further, 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).

8.2 The invention that creates the product must have a feature that involves technical advance as compared to the existing knowledge or having economic significance or both and this feature should be such as to make the invention not obvious to a person skilled in the art[5].

8.3 Prior art for determining inventive step constitutes any "state of knowledge existing before the priority date of the claim under consideration." In other words, inventive step is determined vis-à-vis any matter published in any document anywhere in the world or any use before the priority date of the claim. Unlike the novelty, mosaicing of prior art documents is permissible in the context of inventive step.

8.4 In the case of Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries (AIR 1982 SC 1444), Hon'ble Supreme Court observed on inventive step as :

"The expression "does not involve any inventive step" used in Section 26(1) (a) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. The one suggested by Salmond L. J. in Rado v. John Tye & Son Ltd. is apposite. It is: "Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known (AIR 1982 SC 1444)"paragraph no.25.

"Whether an alleged invention involves novelty and an 'inventive step', is a mixed question of law and fact, depending largely on the circumstances of the case. Although no absolute test uniformly applicable in all circumstances can be devised, certain broad criteria can be indicated. Whether the "manner of manufacture" patented, was publicly known, used and practised in the country before or at the date of the patent ? If the answer to this question is 'yes', it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention which would disqualify the grant of a patent can be by word of mouth or by publication through books or other media. "If the public once becomes possessed of an invention", says Hindmarch on Patents (quoted with approval by Fry L. J. in Humpherson v. Syer, "by any means whatsoever, no subsequent patent for it can be granted either to the true or first inventor himself or any other person; for the public cannot be deprived of the right to use the invention..... the public already possessing everything that he could give (AIR 1982 SC 1444)"Paragraph 24.

[5]SC in Novartis vs Union of India, SUPREME COURT OF INDIA Civil Appeal Nos. 2706-2716 of 2013 (Arising out of SLP (C) Nos. 20539-20549 of 2009)paragraph 89

8.5 "Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under: "Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopaedia Britannica; ibid paragraph 26). To put it in another form: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned ?" [Halsbury, 3rd Edn, Vol. 29, p. 42 referred to by Vimadalal J. of Bombay High Court in Farbwrke Hoechst & B. Corporation v. Unichem Laboratories](AIR 1969 BOM 255)"(AIR 1982 SC 1444) paragraph 26.

8.6 **Skilled person:** The meaning of a person skilled in the art is extremely important in the context of inventive step analysis. This hypothetical person is presumed to know all the prior arts as on that date, even non-patent prior art available to public. He has knowledge of the technical advancement as on that date, and the skill to perform experiments with the knowledge of state of the art[6]. He is not a dullard and has certain modicum of creativity[7]. The IPAB has made a distinction between the person skilled in the art (the obviousness person) and the person who has average skill (enablement man)[8].

IPAB, further clarified in Enercon vs alloys Wobbens (order no.123/2013, paragraph 30) "We do not intend to visualize a person who has super skills, but we do not think we should make this person skilled in the art to be incapable of carrying out anything but basic instructions". Choosing a better alternative/substitute from the known alternative from the prior art to obtain the known results would not go beyond what may be normally expected from person skilled in the art.

8.7 Hindsight analysis: The 'obviousness' has to be strictly and objectively judged[9]. To judge obviousness objectively, the skilled person needs to eliminate the hindsight analysis. The prior art needs to be judged on the date of priority of the application and not at a later date.

[6] Please see decision of IPAB in Fresenius Kabi Oncology Limited vs Glaxo Group Limited, ORA/22/2011/PT/KOL AND M.P. NO.140/2012 IN ORA/22/2011/PT/KOL, ORDER (No.161 of 2013) [Paragraph 52], quoting therein IPAB Order No.128 of 2013 in ORA/08/2009/PT/CH AND Miscellaneous Petition Nos. 7/2010, 31/2010, 51/2011, 86/2012, 142/2012 & 143/2012 in ORA/08/2009/PT/CH Enercon (India) Limited vs. Aloys Wobben, on the basis of Judgment of Delhi High Court in F. Hoffmann-La Roche Ltd, vs Cipla Ltd, CS (OS) No.89/2008 and C.C. 52/2008,

[7] IPAB in In Sankalp Rehabilitation Trust vs Hoffman–Roche [OA/8/2009/PT/CH) Oder No. 250/2012]

[8] in Enercon, vs Aloys Wobben, [ORA/08/2009/PT/CH] (Order No. 123 of 2013) [Paragraph 30]

[9] Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries, *op.cit*

8.8 [10]**Reasonable expectation of success:** With respect to what is obvious, it must be borne in mind that "the mere existence in the prior arts, of each of the elements in the invention, will not *ipso facto* mean obviousness **For after all most inventions are built with prior known puzzle-pieces.** There must be a coherent thread leading from the prior arts to the invention, the tracing of the thread must be an act which follows obviously". This "coherent thread leading from the prior art to the obviousness" or in other words, "the reasonable expectation of success embedded in the prior art which motivates the skilled person to reach to the invention, is the most crucial determining factor in ascertaining inventive step". Obviousness cannot be avoided simply by showing of some degree of unpredictability in the art so long as there was a reasonable probability of success [11]. Obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success[12].

In the matter of pharmaceutical inventions structural and functional similarity of the product provides this motivation to combine the teachings of the prior arts. A surprising effect, synergistic outcome of the combinations, prior art prejudice etc. usually demonstrates the non-obvious nature of the invention. However, it is reiterated that choosing a better alternative/substitute from the known alternative from the prior art to obtain the known results would not go beyond what may be normally expected from person skilled in the art. Thus, when the solution is from a limited number of identified predictable solutions, which is obvious to try, even the demonstration of surprising effects etc. do not provide any answer to the obviousness.

8.9 Method for objectively analysing the inventive step:

a) Identify the inventive concept of the claim in question

b) Identify the "person skilled in the art",

c) Identify the relevant common general knowledge of the person skilled in the art at the priority date;

d) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim;

e) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?

[10] IPAB in Enercon vs Aloys Wobben [ORA/08/2009/PT/CH,Oder No. 123 of 2013] [Paragraph 43]

[11] IPAB in M/s. BECTON DICKINSON AND COMPANY vs CONTROLLER OF PATENTS & DESIGNS, [OA/7/2008/PT/DEL) [280-2012], [Paragraph 32]

[12]IPAB in Ajanta Pharma Limited vs Allergan Inc., ORA/20/2011/PT/KOL, ORDER (No.172 of 2013) [Paragraph 93]

8.10 Illustrative examples for assessment of inventive step:

Example 1:

Invention: Compound represented by the formula Py-B3, **in** wh**ich Py stan**ds for a specific pyrazolone skeleton and B stands for ethyl. The compounds of the invention possess analgesic properties.

Prior Art: Closest prior art describes Py-B3, wherein B stands for methyl. The compound of the prior art was not known to possess any therapeutic activity**.**

Analysis:

Step 1: identifying the inventive concept embodied in the patent: the inventive concept is Py-B3, B stands for ethyl; where the compounds of invention possess analgesic properties

Step 2: Imputing to a person of ordinary skill having ordinary creativity what was common general knowledge in the art at the priority date:

This test requires two activities, namely, identifying the skilled person and the common general knowledge.

Skilled person: In this case the skilled person is a medicinal chemist or may be a composite team of an organic chemist and a pharmacologist.

Common general knowledge: The skilled person has a thorough knowledge of the state of the art related to the organic chemistry of pyrazolones and also a thorough knowledge of the state of the art of the compounds or classes of compounds having analgesic activity. The knowledge must be of the date of the priority of the patent application in question, and not later than that. That is, the person must not consider any document published subsequent to the date of priority.

Step 3: Identifying the differences if any between the matter cited and the alleged invention; the difference between the prior art and the invention is the replacement of three methyl substituents at the annular positions and the pharmaceutical activity of the resultant compound**.**

Step 4: Deciding whether those differences, viewed without any knowledge of the alleged invention constituted steps which would have been obvious to the skilled man or whether they required any degree of invention: (or whether there was reasonable expectation of success or coherent thread leading from the prior art)

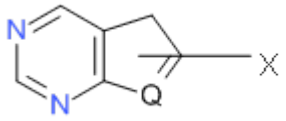
The prior art compound, although structurally very close, does not provide any clue to the skilled person that the resultant compounds with a very nominal change would be successful as a pharmaceutical product. Changing from methyl to ethyl would have been obvious to the skilled person but the said change would not suggest achieving any pharmacological property of the modified compound. In other words there was no coherent thread leading from the prior art to arrive to the invention. Alternatively, it may be said that there was no prior art motivation.

Conclusion: The invention is therefore non-obvious.

Example 2

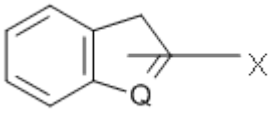
Invention: Selective COX-II inhibitor NSAIDs represented by the formula Hy-X**.** Hy represents a complex heterocyclic structure, whereas X represents substituents.

Background: Cyclooxygenase I and II play vital roles in pharmacological activities of NSAIDS. Early NSAIDS are known to cause gastric irritations and life threatening ulcers. Selective COX II inhibitors, developed later, are shown to inhibit gastric secretions and thereby proved to be a better choice as NSAID. The object of the invention is to provide a class of COX II inhibitors.

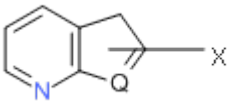


Q stands for S and O

Prior Art: D1 teaches compounds with following structures:



D2 teaches compounds with following structures:



Both the compounds of D1 and D2 are non-steroidal anti-inflammatory drugs and have disadvantage of gastric acid secretions. D2 is known to display higher level of gastric acid secretion as compared to D1.

Analysis:

Step 1: Identifying the inventive concept embodied in the patent: the inventive concept is the replacement of an annular C atom in the left hand aromatic ring with the resultant finding of a class of selective COX II inhibitor with analgesic properties.

Step 2: Imputing to a person of ordinary skill having ordinary creativity what was common general knowledge in the art at the priority date:

Skilled person: In this case the skilled person is a medicinal chemist or may be a composite team of an organic chemist and a pharmacologist.

Common general knowledge: The skilled person has a thorough knowledge of the state of the art related to the organic chemistry of heterocyclic compounds and also a thorough knowledge of the state of the art of the compounds or classes of compounds having analgesic activity. The knowledge must be of the date of the priority of the patent application in question, and not later than that. That is, the person must not consider any document published subsequent to the date of priority.

Step 3: Identifying the differences if any between the matter cited and the alleged invention; the difference between the prior art and the invention is the replacement of C atom at the annular position as said above and the pharmaceutical activity of the resultant compound.

Step 4: deciding whether those differences, viewed without any knowledge of the alleged invention constituted steps which would have been obvious to the skilled man or whether they required any degree of invention: (or whether there was reasonable expectation of success or coherent thread leading from the prior art)

In the instant case, the invention required two successive changes in the annular positions if viewed from D1. However, after reaching to D2 and after finding that the resultant compound does not display any selective COX II inhibiting properties, the skilled person would not feel motivated to make any further change in D2 to reach to the compound of the present invention. In other language the prior art teaches away from the invention.

Conclusion: The invention is therefore non-obvious.

Example 3

Invention: Besylate salt of a compound A (A-B) with blood pressure lowering properties.

Background: Conversion of A-M to A-B significantly improves the processability in the manufacturing of the drug, and improves its stability, while the pharmacological property of A-B remains same as that of A-M.

Prior Art:

D1: The closest prior art D1 teaches Maleate (A-M) salt of compound A having same physiological properties.

D2: D2 shows a list of 53 pharmacologically acceptable anions as salt forming candidates from the list of drug approval authorities. However, the most commonly used anion is hydrochloride, whereas besylate is used for 0.25% of the approved drugs. Other than hydrochloride, which was used in approximately 43% of approved drugs, almost all other salts could be categorized as “seldom used.” 40 out of 53 anions were used in less than 1% of drugs and 23 out of 53 were used in 0.25% or less of drugs.

D3: Prior art D3 shows that besylate salts impart excellent stability and other properties.

Analysis:

Step 1: Identifying the inventive concept embodied in the patent: besylate salt of a compound A with better processability.

Step 2: Imputing to a person of ordinary skill having ordinary creativity what was common general knowledge in the art at the priority date:

Skilled person and common general knowledge: the skilled person is either a medicinal chemist or a composite team comprising a medicinal chemist and a pharmacologist. The skilled person has a common general knowledge, has a thorough understanding of processability of drugs. He is capable of undertaking experiments within a limited area and is capable of choosing a better alternative/substitute from the known alternative from the prior art to obtain the known results. He is aware of both D1 , D2 and D3.

Step 3: Identifying the differences if any between the matter cited and the alleged invention; the difference is the replacement of maleate anion with besylate anion as salt forming agent**.**

Step 4: deciding whether those differences, viewed without any knowledge of the alleged invention constituted steps which would have been obvious to the skilled man or whether they required any degree of invention: In the present case, the person skilled in the art had to try from a list of 53 anions. He would not have been dissuaded by the fact that besylate is used for 0.25% of the approved drugs as he had knowledge that other anions were also used rarely. Rather D3 would have motivated him to undertake the trials from within this set of 53 anions particularly keeping in view the better properties of the besylate salts. Considering that the besylate salts would have been obvious to try and having reasonable expectation of success he would go for such alterations.

Conclusion: The invention is therefore obvious.

The inventive step in the subsequent examples has been analysed by following the steps as prescribed above.

Example 4:

The claimed invention relates to a process for the preparation of Compound C by treating Compound A and Compound B in the presence of platinum catalyst. All the features of the invention are disclosed in the prior art except the platinum as a catalyst explicitly, but it was mentioned as noble metal catalysts.

Analysis: Prior art generically disclosed platinum as noble element which is also an equivalent element used in the art for similar purposes and obvious to the skilled person. Therefore, it is application of known feature in the prior art into claimed invention in an obvious way.

Example 5:

The claimed invention relates to monoester of a known diol compound for treating cancer diseases using amino acids selected from lysine, valine, leucine and the like, as an esterifying agent. Due to poor oral bioavailability, the diol was unable to use as oral delivery system. To improve the oral bioavailability one of the hydroxyl group in the diol was converted into a monoester using said amino acids.

Prior art disclosed monoalcohol with similar structure having poor oral bioavailability was converted into an ester using amino acids selected from lysine, valine, leucine and the like, as an esterifying agent, which exhibit improved oral bioavailability in the treatment of cancer diseases. Amino acid used in the prior art as well as in the claimed invention is lysine.

Prior Art	**Claimed Invention**
$R\text{-}CH_2\text{-}OH$ ↓ $R\text{-}CH_2\text{-}OR'$ R' is lysine, valine, leucine and the like	$HO\text{–}CH_2\text{-}R\text{-}CH_2\text{-}OH$ ↓ $HO\text{–}CH_2\text{-}R\text{-}CH_2\text{-}OR'$ R' is lysine, valine, leucine and the like

Analysis: Object of the claimed invention was to provide a solution to overcome the poor oral bioavailability of diol, when administered as oral delivery system. One of the alcohol groups in the diol was converted into ester using lysine for improving the oral bioavailability of the diol.

Prior art addressed poor oral bioavailability for substantially similar structure of monoalcohol. The problem was solved by converting the monoalcohol into ester using lysine as an esterifying agent. Therefore a person skilled in the art can be motivated with teachings of the prior art to use the amino acid for improving the oral bioavailability by converting diol into monoester ester of diol to solve similar kind of problem. Therefore there is no technical advancement involved in the claimed invention.

Example 6:

A pharmaceutical composition comprising first active agent in an amount from about 2 mg to about 4 mg corresponding to a daily dosage and second active agent in an amount from about 0.01 mg to about 0.05 mg corresponding to a daily dosage together with one or more pharmaceutically acceptable carriers or excipients. The composition consists of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days.

The first active agent present in the composition is in micronized form or sprayed from a solution onto particles of an inert carrier.

D1: The first and second active agents together with combination of those agents are known in the art. D2: Micronisation for poorly soluble similar drugs is also known in the art for improved drug delivery.

Analysis: Micronized form of first active agent is novel aspect in the present composition. Dose and dosage regimen of first and second active agents in combination and micronisation for poorly soluble similar type of drugs are known in the art. Therefore, it is obvious to a person skilled in the art to convert poorly soluble active ingredient into micronized form for improved drug delivery. Further, changing the particle size is mere modification in the physical form of the active agent for improved and anticipated effect and therefore the claimed invention is obvious.

9. Industrial applicabilitys

9.1 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. The patent specification must disclose a practical application and industrial use for the claimed invention wherein a concrete benefit must be derivable directly from the description coupled with common general knowledge. Mere speculative use or vague and speculative indication of possible objective will not suffice.

9.2 Illustrative examples for industrial applicability:

Example 1:

Invention: Synthetic analogues of a steroid. The steroids possess certain medicinal properties. However, the compounds of the invention, as asserted, are subjects of serious investigation, being the analogue of compounds known for medicinal properties.

Analysis: The claimed compounds are not patentable as they lack any credible and specific utility. A mere scientific interest does not make something eligible for patentability.

Example 2:

Invention: The application comprises three sets of claims:

1. A compound of formula A
2. A compound of formula B

3. A process of making A and B, wherein, C and D are reacted at m to n degree centigrade, in an aprotic solvent Y, the said aprotic solvent being selected from a, b, c, d, e and subsequently distilled and purified to isolate A from B

The specification describes the use of compound of formula A as having certain pharmaceutical applications. However, the specification does not disclose any use of the compound of formula B.

Analysis: Claim 2 is not allowable in so far that the compound is not shown to possess any utility. Just because it is a by-product of a reaction for the preparation of the compound of formula A, does not make it a patentable subject matter.

10. **Inventions not patentable:**

10.1 **Section 3 (b):** Inventions contrary to morality or which cause serious prejudice to human, animal or plant life or health or environment are not patentable. Any invention, the primary or intended use or commercial exploitation of which is against the public order or morality or is capable of causing serious damage to the human, animal or plant life or cause damage to the environment or public health is not allowable under this section. Since an invention is a reward to the owner of an invention in the form of monopoly, such rewards are not justified from the public policy angle, if they are prejudicial to the public interest.

10.2 **Section 3(c):** Scientific principles or abstract theory or discovery of living things or non-living substances are not patentable inventions. Section 3 (c) of the Act, excludes 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 from the scope of patentability. Compounds which are isolated from nature are not patentable subject-matter. However, processes of isolation of these compounds can be considered subject to requirements of Section 2 (1) (j) of the Act.

10.3 Illustrative examples for section 3(c):

Example 1:

Claim: A compound for cardiac disorder related activity, wherein the compound is obtained from the cerebrospinal fluid of horseshoe crab, Tachypleusgigas.

Analysis: The subject-matter is not patentable under Section 3 (c) of the Act, because the application attempts to claim a compound, which is isolated from cerebrospinal fluid of embryos of horseshoe crab, Tachypleusgigas(i.e. a compound which is non-living substance occurring in nature). As per Section 3 (c) of the Act, a non-living substance occurring in nature is statutorily non-patentable subject-matter.

Example 2:

Invention: An extract of *Calotrophis gigantea* containing cardiac glycosides having antineoplastic effect, which exhibit *in vitro* cytotoxic activity on human carcinoma cell line without exhibiting cytotoxicity on a normal human cell line, wherein the extract is effective against human lung carcinoma cell line A549 and human colon adenocarcinoma cell line COL0205 without showing cytotoxicity on a normal human cell line W138.

Analysis: The claimed extract of *C. gigantea* containing cardiac glycosidesis statutorily excluded from patentability under Section 3 (c) of the Act, as being directed to a discovery of non-living substance occurring in nature.

10.4 **Section 3(d) :** The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus is not a patentable invention unless such known process results in a new product or employs at least one new reactant.

Explanation:- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

10.5 In the context of the pharmaceutical inventions, Section 3(d) deserves special attention. Section 3(d) stipulates that an incremental invention, based upon an already known substance, having established medicinal activity shall be deemed to be treated as a same substance, and shall fall foul of patentability, if the invention in question fails to demonstrate significantly improved therapeutic efficacy with respect to that known compound. After analysing the legislative history of Section 3(d), the Hon'ble Supreme Court commented, "We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds"[13].

[13]SC in Novartis AG Vs. Union of India (UOI) and Ors, op.cit, MANU/SC/0281/2013,Paragraph 103

10.6 While interpreting what is “efficacy”, the Hon’ble Supreme Court in the Novartis case held that in the context of the pharmaceutical patenting the “efficacy” should be understood as “therapeutic efficacy”.[14] **In Paragraph 180 of the order it was held:** What is “efficacy”? Efficacy means “the ability to produce a desired or intended result”. Hence, the test of efficacy in the context of Section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be “therapeutic efficacy”. ……It may be noted that the text added to Section 3(d) by the 2005 amendment lays down the condition of “enhancement of the known efficacy”. Further, the explanation requires the derivative of “differ significantly in properties with regard to efficacy”. What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy. While dealing with the explanation as provided in Section 3(d) it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to “therapeutic efficacy”, are expressly excluded from patentability. Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy[15].

[14]“Efficacy means “the ability to produce a desired or intended result”. Hence, the test of efficacy in the context of section 3(d) would bedifferent, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be “therapeutic efficacy”.[ibid, Paragraph 180]

[15]Ibid, paragraph 181

10.7 Also, the Supreme Court explained what would mean a "new product" in the context of Section 3(d): "……the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind". However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation"[16].

10.8 According to the Supreme Court, whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data[17].

"The position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model. Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention", it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act".

10.9 However, it is important to note that Supreme Court has clarified further that the test of Section 3(d) of the Act does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances[18].

Para 191 of the Judgment mentions "We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment".

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[16] *Ibid*, paragraph 192

[17] *ibid*[Paragraph 189]

[18] "We have held that the subject product, ……does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d)bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment". [*ibid*, Paragraph 191].

10.10 The term "combination" as appearing in Section 3(d) has been explained by IPAB as "The combination mentioned in the Explanation can only mean a combination of two or more of the derivatives mentioned in the Explanation or combination of one or more of the derivatives with the known substance which may result in a significant difference with regard to the efficacy"[19].

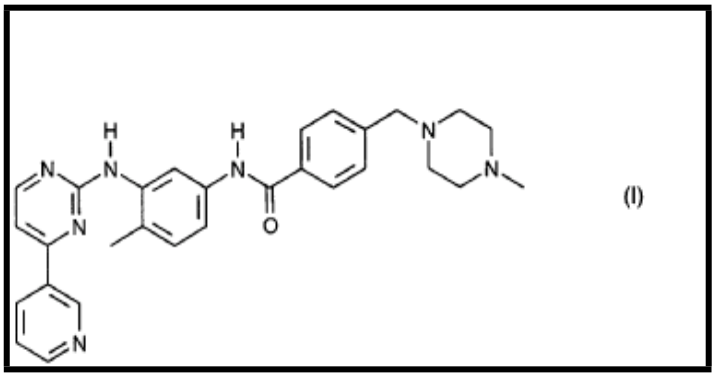
10.11 Illustrative examples for section 3(d):

Example 1:

The invention relates to a β-crystalline form of methanesulfonic acid addition salt of imatinib and processes for the preparation thereof. The application was filed with the title: Crystal Modification of A N-phenyl-2-pyrimidineamine Derivative, Processes for Its Manufacture And Its Use. The substance claimed was a medi*cine* f**or the treatm**ent of chronic myeloid leukemia (CML).

The specification asserts that the claimed β-form has (i) more beneficial flow properties: (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate. No experimental data related to efficacy is provided in the specification for β-crystalline form imatinib mesylate or imatinib mesylate.

Claims: A form of the methanesulfonic acid addition salt of a compound of formula comprising crystals of the β-modification.



A number of pre-grant oppositions were filed. The application for patent was refused under Section 25(1) on the ground that the invention was

- anticipated by US Patent no: 5521184 (Zimmerman Patent, disclosing Imatinib and salts), "Nature Medicine' of May 1996, and the Patent term extension certificate for the 1993 patent issued by the USPTO which specifically mentions imatinib mesylate as the product;
- obvious vis-à-vis US 5521184
- not allowable u/s 3(d): Applicant fails to prove enhanced efficacy (thirty percent bioavailability was held not meeting the requirement of "therapeutic efficacy").

[19]Ajantha Pharma Limited Vs Allergan Inc. and Others,ORA/21/2011/PT/KOL of Order no. 173 of 2013, Paragraph 84

Decision of Supreme Court: After several rounds of litigations in different forums, the matter reached before the Supreme Court.

It was argued on behalf of the appellant that

There is certainly no mention of polymorphism or crystalline structure in the Zimmermann patent. The relevant crystalline form of the salt that was synthesized needed to be invented. There was no way of predicting that the beta crystalline form of Imatinib Mesylate would possess the characteristics that would make it orally administrable to humans without going through the inventive steps.

It was further argued that the Zimmermann patent only described, at most, how to prepare Imatinib free base, and that this free base would have anti-tumour properties with respect to the BCR ABLkinase.

Thus, arriving at the beta-crystalline form of Imatinib Mesylate for a viable treatment of Chronic Myeloid Leukemia required further invention – not one but two, starting from Imatinib in free base form, (formation of mesylate and then beeta crystalline thereof).

The Court mainly focussed its analysis on
(1) whether imatinib mesylate was already known, and then
(2) if it is a known substance, it must meet the criteria of enhanced efficacy as in Section 3(d).
The Court after analysing the documents held that, "Imatinib Mesylate is all there in the Zimmermann patent. It is a known substance from the Zimmermann patent"[20]. After finding that Imatinib Mesylate is a known substance from the Zimmermann patent itself……its pharmacological properties are also known in the Zimmermann patent and in the article published in the Cancer Research journal (Cancer Research, January 1996)[21]. "The subject product , that is beta crystalline form of Imatinib Mesylate, is thus clearly a new form of a known substance, i.e., Imatinib Mesylate, of which the efficacy was well known. It, therefore, fully attracts section 3(d) and must be shown to satisfy the substantive provision and the explanation appended to it"[22]. "It is noted, in the earlier part of judgment, that the patent application submitted by the appellant contains a clear and unambiguous averment that all the therapeutic qualities of beta crystalline form of Imatinib Mesylate are also possessed by Imatinib in free base….."[Paragraph 162]

"..the appellant was obliged to show the enhanced efficacy of the beta crystalline form of Imatinib Mesylate over Imatinib Mesylate (non-crystalline).There is, however, no material in the subject application or in the supporting affidavits to make any comparison of efficacy, or even solubility, between the beta crystalline form of Imatinib Mesylate and Imatinib Mesylate" (non-crystalline). [Paragraph 171]

[20] *Ibid,* [paragraph 131]

[21] *ibid*, [paragraph 157].

[22] *ibid*[Paragraph 161]

On the question of bio-availability the Court held that"…….the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research dataIn this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model"[23].

The Court, therefore rejected the appeal.

Example 2 :

In yet another case, No.162 of 2013 in Fresenius Kabi Oncology Limited vs . Glaxo Group Limited, the IPAB determined the issue of Section 3(d).

Claimed compound: A quinazoline derivative having anticancer activity.

Prior Arts: two prior arts were cited by opponent. The respondent admitted the prior arts, but argued that the compound as claimed was a new chemical entity.

Decision of IPAB[24]: While rejecting the argument of Section 3(d) IPAB held that "It is true that it is the patentee who must prove the enhanced therapeutic efficacy of his invention.

But in a revocation the applicant must plead and prove that it is hit by S.3(d) and that it has the same therapeutic efficacy as the known substance. Then the respondent will counter it either by proving that it is not a derivative of a known substance or by proving that though it is only a new form of a known substance he has shown that it has enhanced therapeutic efficacy. In the present case, there are no such pleadings. It is not enough to plead that because Ex1 and 2 are admitted prior arts, this is only a new form of those compounds. That is vague. It is only when the pleadings show how the invention is one kind of a derivative of known substance the patentee will have to explain how the grant of patent is justified because of the enhancement of therapeutic efficacy. In this case the pleadings are not adequate. We hold that the S.3(d) ground has not been proved".

[23] *Ibid [Paragraph 189].*

[24] Fresenius Kabi Oncology Limited vs . Glaxo Group Limited ORA/17/2012/PT/KOL, Order No.162 of 2013, paragraph 56.

10.12 Section 3 (e): Mere Admixture Resulting only in Aggregation of The Properties Or A Method Of Making Such Mere Admixture

10.13 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.

10.14 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.

10.15 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.

10.16 Claims related to compositions obtained by mere admixture resulting in aggregation of the properties of the individual components are not patentable under section 3(e) of Act. However, in a composition if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features.

10.17 : Illustrative examples for section 3(e):

Example 1:

Claim: A composition of Paracetamol (Antipyretic) and Ibubrufen (analgesic)] to control pain and inflammation.

Analysis: The compounds used in the alleged invention are known for their activity. The application is silent on a combinative effect of these two compounds over the sum of their individual effects. Thus, the claimed subject-matter is non-patentable under Section 3 (e) of the Act.

Example 2:

Invention : A pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastro-enteric tolerance in unit doses form which contained imidazole salicylate as the active ingredient in the amount of 100-600 mg and an inert carrier was claimed .

The active compound imidazole salicylate and carriers are known in the art. Thus the claimed composition is merely an aggregation of the ingredients involved, wherein the carrier is not playing any role in enhancing the activity of imidazole salicylate.

10.18 Section 3 (i): Method Of Treatment

10.19 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. Under this section, the Manual of Patent Office Practice & Procedure states that the followings are excluded from patentability:

(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.

10.20 In the field of pharmaceuticals, it is noticed that method of treatments are often claimed in the guise of composition claims. Sometimes, such claims are converted to product claims during examination procedure. Such amendments shall be examined as

per Section 57 read with section 59 of the Act.

10.21 ILLUSTRATIVE EXAMPLE:

Claim 1: A method of treating cancer in a subject, the said method comprising administering simultaneously or sequentially a combination of Gemcitabine and P276-00 or the combination of Gemcitabine and P1446A, wherein the said cancer is selected from a group comprising of pancreatic cancer, lung cancer, colorectal carcinoma and head and neck cancer.

Analysis: The claimed subject-matter falls within the scope of statutorily non-patentable inventions under Section 3 (i) of the Act, as being directed to a method of treatment of human beings or animals.

10.22 **Section 3(j) and 3(p):** To avoid unnecessary repetition, relevant sections of the "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS" and "GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL" are hereby incorporated by reference.

10.23 According to Section 3(j), plants or animals including its parts like seeds etc. are not patentable subject matter. The only exception to this rule is micro-organisms. From the conjoint reading of Section 3(c) and 3(j), the micro-organisms,which occur in nature are not patentable subject matter. Accordingly, only genetically modified micro-organisms qualify for patentability. In the GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT, Section 3(j) has been discussed with specific examples. According to Section 3(p) of the Act, an invention which, in effect, is a traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components is not a patentable subject matter. "GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL" already issued by the Office discusses in details, the manner in which cases related to traditional knowledge may be handled. However, in the following, an example related to Section 3(p) is given:

10.24 Illustrative Example for Section 3(p):

Claim: A method of treating an inflammatory bowel disease (IBD) in a subject in need thereof, comprising administering to the subject an effective amount of an extract of Andrographis paniculata, wherein said extract contains andrographolide, 14-deoxy-andrographolide, 14-deoxy-11, 12-dehydrogen-andrographolide and neoandrographolide.

Analysis: The claimed subject-matter falls within the scope of statutorily non-patentable inventions under Section 3 (p) of the Act, as being directed a traditional knowledge in effect. This is clearly evident from an article published in the Journal of Natural Medicine (Kakrani et al., "Traditional treatment of gastro-intestinal tract disorders in Kutch District, Gujarat State, India", Journal of Natural Medicine, Vol. 2/1(2002), pages 71-75). The cited article describes traditionally known treatments of gastro-intestinal tract disorders in Kutch district of Gujarat. In this article, 41 species of 37 genera belonging to 22 families are reported along with plant parts used for the

medicinal treatments, including Andrographis paniculata and its medical indication. Thus, the claimed subject-matter, in effect, is traditional knowledge and non-patentable under Section 3 (p).

10.25 Illustrative Example for Section 3(j):

Claim 1: A pharmaceutical composition comprising an antigen-presenting cell that expresses a polypeptide comprising at least an immunogenic portion of a breast tumor protein, or a variant thereof in combination with a pharmaceutically acceptable carrier or excipient, wherein the antigen presenting cell is a dendritic cell or a macrophage.

Analysis: Although claim 1 is directed to a pharmaceutical composition, it should be objected under Section 3 (j) of the Act, since the composition essentially contain an antigen-presenting cell as an active ingredient and carriers or excipients are obvious features with the cell while in the composition.

11. Sufficiency of description, clarity and support of the claims:

11.1 According to Section 10 (4) (a) and (b) of the Act, the complete specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed and it should also disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection. As per Section 10(c), every complete specification should end with a claim or a set of claims defining the scope of invention. Section 10(5) prescribes that the claims should be clear, succinct and fairly based on the description. Also, the claims must relate to a group of inventions linked so as to form a single inventive concept. For convenience, unity of invention has been discussed below, under separate head.

11.2 Sufficiency of disclosure with respect to biological material and deposits: 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.

11.3 In Para 17 of "GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL", it is directed that "if the source and geographical origin of the biological material used in the invention is not disclosed in the specification, an objection shall be raised thereof in conformity with section 10 (4) (a) & (b) of the Patents Act." Therefore, the same is incorporated herein by reference and also, applicable in the present guidelines. Thus, while accessing the sufficiency of

disclosure, non-disclosure of the source and geographical origin of the biological materials used in the invention would be treated as insufficiency of disclosure as per the requirement of Section 10 (4) (ii) (D) of the Act. Nevertheless, in Para 20 of above said guidelines, it also directed that "On the other hand, if the declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India and should clearly specify the country of source and geographical origin of the same." Therefore, while processing the patent application in which the above declaration is cancelled out by the Applicant, as directed, necessary amendment shall be sought for. 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.

11.4 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 "e.g., claiming many compounds without proper support in the examples 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".[25]

11.5 Sufficient disclosure of the invention in the patent specification is the consideration for which a patent is granted. While assessing the sufficiency of disclosure, it must be ensured that the best method for performing the invention known to the applicant is 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 application of inventive ingenuity.

[25] Raj Praksh v Mangatram Chowdhury (AIR 1978 Del 1 at 9) following Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning a Corporation etc. Vs. Unichem Laboratories and Ors".(AIR1969Bom255)

11.6 It may be noted that the IPAB has distinguished the person skilled in the art involved in assessing "Inventive step" and "Enablement". In one case (please see the discussion under Inventive Step) the IPAB observed: The Act makes a distinction between the person skilled in the art (the obviousness person) and the person who has average skill (enablement man)"[26] .In the opinion of the IPAB, in the context of enablement, the person to whom the complete specifications are addressed is a person "who has average skill and average knowledge." The description in the specification should contain at least one example or more than one example, covering the full breadth of the invention as claimed, which enable(s) the person skilled in the art to carry out the invention. If the invention is related to product per se, description shall be supported with examples for all the compounds claimed or at least all the genus of the compounds claimed. Method for preparation and experimental data relating to properties of representatives of each embodiments claimed shall be incorporated in the description, which enable a person having ordinary skilled in the art can make use of the invention without undue burden.

11.7 Non-technical terms, like trademarks etc. should be discouraged and the applicant should be asked to replace them with equivalent technical terms.

11.8 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. Specific and substantial use of the invention along with any test conducted and results obtained for such an effect shall be disclosed at that time of filing. In case, application claimed substance, composition or combination, detailed report pertaining to the test, such as in vitro or in vivo, conducted and experimental results with inference of such a test shall be provided in the description. Test parameters, choice of testing method, mode of drug delivery, results obtained with explanation and inference shall be provided. If more than one genus or pharmacological use claimed in an application, relevant test for the best representatives of such genus and their pharmacological use shall be incorporated in the description.

11.9 It is not necessary to describe in the claims to a specification, processes by which a new chemical compound is discovered, when they are part of the common knowledge available to those skilled in the science who can, after reading them, refer to the technical literature on the subject for the purpose of carrying them into effect[27].

[26] Enercon, vs Aloys Wobben ORDER No. 123 of 2013. "….In fact it is clear that in the context of enablement, the person to whom the complete specifications are addressed is a person "who has average skill and average knowledge." Neither of these attributes has been assigned by the Act to the person to whom the invention should be non-obvious. We are not called upon in this case to decide the person who is enabled. We are only pointing out to the difference in the words used in the Act. We do not intend to visualize a person who has super skills, but we do not think we should make this person skilled in the art to be incapable of carrying out anything but basic instructions. The Act makes a distinction between the person skilled in the art (the obviousness person) and the person who has average skill (enablement man)". [Paragraph 30].

[27] Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning a Corporation etc. vs Unichem Laboratories and Ors, AIR1969Bom255, (1974)76BOMLR130

11.10 While examining the claims with respect to clarity and support as required under section 10 (5) of the Act, due consideration should be given to the provisions of section 10 (4) (a) and (b) as these requirements are complementary to each other.

11.11 Clarity and support of claims: As mentioned in connection with the type of claims, it was mentioned that in the pharmaceutical applications, claims are often filed as "Use of…". Such wordings in the claims are not permissible in that a claim should relate either to a product or to a process.

11.12 A claim may be lacking in support, if it is not fairly based on the description. Claims may be drafted in non-definitive terms and the scope of claim is often unreasonably broader than the description and enablement of the specification. Claims may embrace non-definitive terms like "comprising", "including", etc. to indicate certain components of the invention. Similarly terms like "near to", "approximately" may lead to confusion about the scope of the invention. Such terms or any other terms , should be closely examined vis-à-vis the support in the description and the scope of protection sought for ensuring the definitiveness of the claims.

11.13 Functional claims, i.e. claims where the substances are defined in terms of their physiological properties/results to be achieved, should be discouraged, as such claims not only lead to confusion regarding the scope of the invention, all most all the times, they are much wider in scope and are inconsistent with descriptions.

11.14 In pharmaceutical patenting, the claims are often drafted in terms of Markush formula. Special care should be given to search and examine such claims. Claims with Markush formulas may cover innumerable compounds and may be overbroad, thus leading to conclusion of inconsistency between description and claims. Also, such formulas can lead to the question of plurality of distinct inventions. Compounds represented by different alternatives should have a technical interrelation ship.

11.15 Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity; AND

(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR

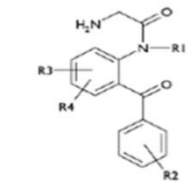
(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The claims of a specification may be said to be linked with a single inventive concept, if they are co-related to reach other by a common thread. For example, the specification may contain a claim for (1) a drug (2) intermediates (3) process of making the compound of claim (1) and (2). However, the intermediates shall be allowed provided they are new and non-obvious and the specification does not disclose any other use of the said intermediates.

11.16 Illustrative examples for sufficiency of disclosure and support:

Example 1:

The alleged invention claims a compound of the following formula



Wherein, R1 is selected from phenyl, pyridyl, thiazolyl, thioalkyl, alkoxyl and methyl; R2-R4 are methyl, tolyl or phenyl, pyridyl… the compounds are used as a pharmaceutical for increasing the oxygen intaking capability of blood.

Description: the specification embraces innumerable compounds covering formula as above. The examples however are restricted to the limitation that R1 is always phenyl, e.g. :

R1	R2	R3	R4
phenyl	tolyl	Phenyl	Methyl
phenyl	tolyl	Pyridyl	Tolyl
phenyl	pyridyl	Methyl	Tolyl

In all examples, the definition of R1 is restricted to Phenyl. The claim is much broader than what has been described and enabled and is therefore lacking in support. It may be noted that sufficiency and support are two different criteria and serve two distinct purposes, despite that they are supplemental to each other. In the example given, the examiner can raise a question of sufficiency also.

Example 2:

An H2 receptor antagonist of formula I

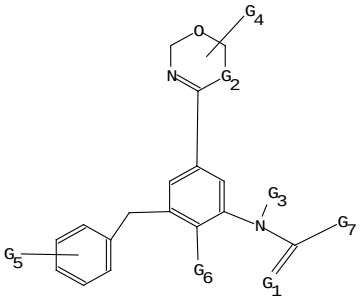
Formula I is depicted as A-Z.

A comprises substituted imidazoles and Z comprises substituted benzimidazoles.

At the first place, the term ‘Comprises’ or ‘substituted’ are open ended terms and there remains every likelihood that the majority of the compounds claimed would not serve the purpose of the alleged invention. As in above, the examples are limited to only few substituents and do not enable (which is not possible also) other classes of substituents. An objection of insufficiency and support may be raised against such claims and descriptions.

Example 3:

Invention: Discloses a compound of formula 1 having insecticidal property.



G1 represents oxygen or sulphur,

G2 represents oxygen, amino, aminoformyl or aminoacetyl,

G3 represents hydrogen, amino, hydroxyl or represents C1-C6-alkyl, CrC6-alkenyl, C2- C6-alkynyl or C3-C6-cycloalkyl,

G4 independently of one another represent C1-C6-alkyl, C2-C6-alkenyl, C2-C6-alkynyl, C3-C6-cycloalkyl,

n represents 0 to 4,

G5 represents hydrogen, halogen, cyano, nitro, C1-C4-alkyl, C1-C4-haloalkyl, C2-C6-alkenyl, CrC6-haloalkenyl, C2-C6-alkynyl, C1-C4-alkoxy, C1-C4-haloalkoxy,

G6 represents C1-C6-alkyl, C3-C6-cycloalkyl, C1-C6-haloalkyl, C1-C6-halocycloalkyl, C2-C6-alkenyl, C2-C6-haloalkenyl, C2-C6-alkynyl, C2-C6-haloalkynyl, C1-C4-alkoxy,

G7 represents a 5- or 6-membered heteroaromatic ring optionally mono- or polysubstituted

The specification and working examples provides support only for compound of formula I-1 and process for preparing the same.

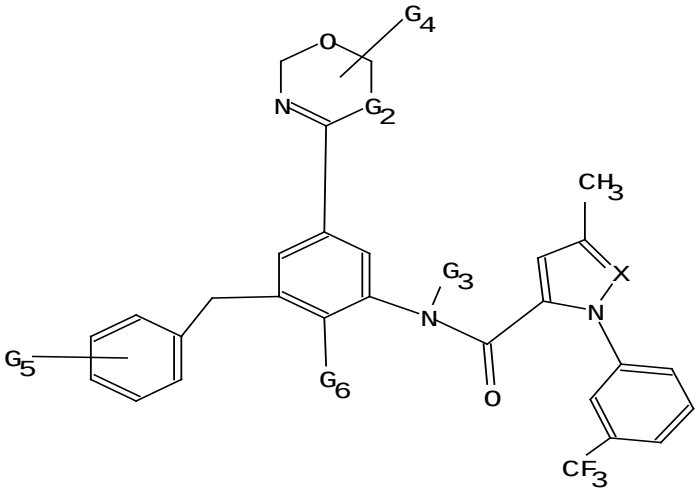
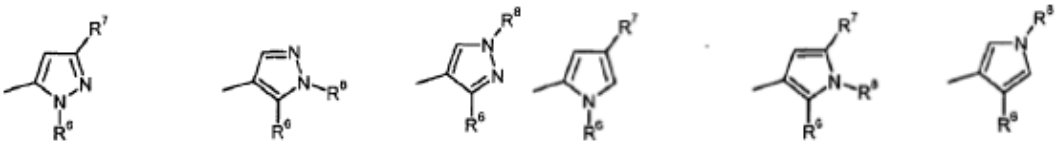


Figure I-1

Where
G1 of Formula I is oxygen
G2 is oxygen, amino, G3 for hydrogen,
n of Formula I is 0,
G4 is absent
G5 is hydrogen, Cl, Br and I
G6 CH3 or Cl
Nitro or C3-c6- Trialkylsilylethynylated is available.
G7 for a pyrazole - or Pyrrole

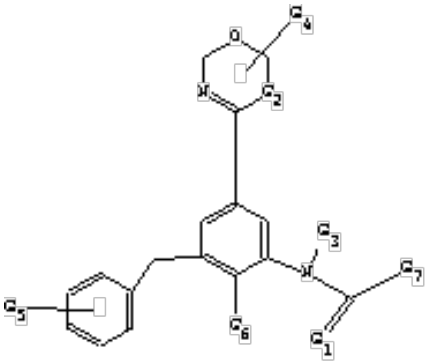


R6 is chloropyridine
R7 is Cl, Br or CF3
R8 is H

Although the applicant claims that the compound has insecticidal property the claimed activity has not been demonstrated.

Claim:

An insecticidal compound of formula 1



Wherein
G1 represents oxygen or sulphur,
G2 represents oxygen, amino, aminoformyl or aminoacetyl,
G3 represents hydrogen, amino, hydroxyl or represents C1-C6-alkyl, CrC6-alkenyl, C2-C6-alkynyl or C3-C6-cycloalkyl,
G4 independently of one another represent C1-C6-alkyl, C2-C6-alkenyl, C2-C6-alkynyl, C3-C6-cycloalkyl,
n represents 0 to 4,
G5 represents hydrogen, halogen, cyano, nitro, C1-C4-alkyl, C1-C4-haloalkyl, C2-C6-alkenyl, CrC6-haloalkenyl, C2-C6-alkynyl, C1-C4-alkoxy, C1-C4-haloalkoxy,
G6 represents C1-C6-alkyl, C3-C6-cycloalkyl, C1-C6-haloalkyl, C1-C6-halocycloalkyl, C2-C6-alkenyl, C2-C6-haloalkenyl, C2-C6-alkynyl, C2-C6-haloalkynyl, C1-C4-alkoxy,

G7 represents a 5- or 6-membered heteroaromatic ring optionally mono- or polysubstituted.

Analysis:

In the present case the disclosure in the description is not considered sufficient for the entire scope of the subject matter claimed specifically where G1 represents sulphur.

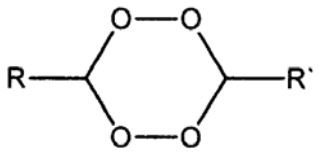
Even though the description sufficiently discloses the compounds where G1 represents oxygen there is a lack of evidence demonstrating the use (insecticidal) of the claimed compound.

Hence can be objected under section 10(4)(a).

As compounds where G1 represents sulphur and the process for preparing the same are not disclosed the specification is not considered enabled for the entire scope of the claims and can be objected under section 10(4)(b).

Example 4:

Description: The invention relates to a the compound represented by general formula I. and a pharmaceutical composition comprising the compound represented by the formula (I) a salt thereof, a solvate thereof, or a prodrug thereof; in combination with other drugs. Compound represented by general formula I is useful in the treatment of cancer.



I

R and R' are selected from Mono, di, tri, poly substituted aromatic, heteroaromatic, cyclic, acyclic, polycyclic groups.

The working examples provides support only for the following compounds and process for preparing them along with the assay to show anti cancer activity.

3,6-Bis-(ethyl)-[1,2,4,5]tetroxane

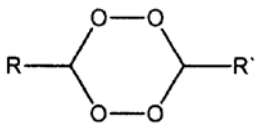
3,6-Bis-(methyl propyl)-[1,2,4,5]tetroxane

3,6-Bis-(tert-butyl-methyl)-[1,2,4,5]tetroxane

3-(Methoxy-methyl)-6-methyl-[1,2,4,5]tetroxane

Claim:

Compound of formula I



I

R and R' are substituted acyclic/aromatic/heteroaromatic/cyclic/ polycyclic groups

Analysis: The complete specification must describe each embodiment of the invention claimed and the description must be sufficient to enable a person skilled in the art to carry out substantially all that which falls within the ambit of what is claimed without undue experimentation.

There is no support for compounds where R and R' are Mono, di, tri, poly substituted aromatic, heteroaromatic, cyclic or polycyclic groups. To prepare compounds where R and R' are Mono, di, tri, poly substituted aromatic,. Heteroaromatic, cyclic or polycyclic groups and to find the claimed biological activity involves undue experimentation.

Hence the subject matter of claim 1 where R and R' are Mono, di, tri, poly substituted aromatic, heteroaromatic, cyclic or polycyclic lacks groups lacks support.

12. UNITY OF INVENTION

12.1 The requirement of unity of invention is provides by the following provision in the Patent Act and Manual of Patent Office Practice and Procedure. As referred above, the provisions of section 10(5) of Patent 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.

12.2 The MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, at 05.03.16 requires that there may be more than one independent claim in a single application if the claims fall under a single inventive concept. In the Manual, it has been advised "While there is no restriction as to the number of claims, including independent claims, it is advisable to limit the number of claims, as well as the number of independent claims in a single application so that the claims are all of cognate character and are linked so as to form a single inventive concept. If claims relate to a plurality of distinct inventions, it may be objected on ground of lack of unity of invention".

12.3 In other words when there is a group of inventions in a specification they should be linked by a single concept or there should be a technical relationship among the claimed inventions, which makes the inventive contribution over the prior art. To fulfil the requirement of unity of invention each claim of a complete specification should share a single common technical relationship which is inventive. The single common technical relationship which is inventive is called the "special technical feature". This determination should be done on the content of the claims supported by the description in the light of the prior art.

12.4 In the field pharmaceuticals patent applications may sometimes claim, huge number of chemical compounds by Markush structures, chemical compounds as intermediate and final products, compositions comprising different chemical components, processes for their manufacture, their uses or applications, even devices

or apparatus used for carrying out specific processes are usually claimed in a single application. Sometimes it becomes complicated to handle search and examination of such combinations of different categories of claims and variable dependency of claims. Interpreting such claims whether claims claimed in the application relate to a single invention or a group of inventions linked so as to form a single inventive concept or lack unity.

12.5 Illustrative example of a priori determination of unity of invention:

Example 1:

Claims

1) An antibiotic of formula I for treatment of staphylococcal infection.

2) A steroid of formula A for treatment of staphylococcal infection.

3) A bioactive compound of formula X for treatment of staphylococcal infection.

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 they relate to structurally different products. As antibiotic of formula I, steroid of formula A and bioactive compound of formula X do not share any common structural feature, which could serve as a unifying feature. Each of these claims has to be considered as a separate invention and said to lack unity a priori.

12.6 Illustrative Example of A Posteriori Determination Of Unity Of Invention:

Claims

1. A combination, comprising sulphonamide compound X and a taxane and its use in treatment of cancer.

2. A combination, comprising sulphonamide compound X and a vinca alkaloid derivative or analogue thereof and its use in treatment of cancer

Prior art: Use of Sulphonamide compound X in treatment of cancer.

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.

Group 1: claim 1: A combination, comprising sulphonamide compound X and a taxane

Group 2: claim 2: A combination, comprising sulphonamide compound X and a Vinca alkaloid derivative or analogue thereof .They are not so linked as to form a single general inventive concept in view of the following:

The special technical feature should be an essential structural part common to all of the embodiments of the claimed invention (and responsible for the inventive effect), and which is absent in the prior art that provide the same solution. Upon prior art search, it is found that use of Sulphonamide compound X in treatment of cancer is already known in the prior art. Taxane, and vinca alkaloid derivative are structurally different from each other. The only common component is the sulphonamide

compound X which is already known as an anticancer agent. Hence here it is considers that a common technical link in the above mentioned groups is not inventive. The above mentioned groups lack common feature which could be regarded as the special technical feature providing unity to the application. Consequently, the application may be objected for lacking unity a posteriori.

12.7 Combinations of Different Categories of Claims

Illustrative examples showing combinations of different categories of claims

Example 1:

Claim 1: A compound of formula I

Claim 2: A method of preparing the compound of formula I.

Claim 3: Compound of formula I for use as a fungicide.

Unity exists between claims 1, 2 and 3as the special technical feature is compound of formula I.

Example 2

Claim 1: A process of manufacture of compound of formula I comprising steps A and B.

Claim 2: Apparatus specifically designed for step A.

Claim 3: Apparatus specifically designed for step B.

Unity exists between claims 1 and 2 or between claims 1 and 3. Claims 2 and 3 lack unity since there exists no common special technical feature between the two claims.

Example 3

Claim 1: A compound of formula I

Claim 2: A process of manufacture of compound of formula I comprising step A.

Claim 2: Apparatus specifically designed for step A.

Unity exists between claims 1, 2 and 3 as the special technical feature is compound of formula I. The process should essentially result in compound of formula I and contribution over the prior art of the apparatus specifically designed for step A should correspond to the inventive feature of the process of claim 2. However, if the compound of formula I is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

12.8 Unity of invention in Markush claims

12.9 In Markush claims the unity of invention shall be considered to be met when the alternatives claimed are of a similar nature. The Markush group of alternative chemical compounds, can be regarded as being of a similar nature is subjected to the fulfillment of the following conditions:

a)They have a common property or activity,

b) All of the alternatives have a common structure, which is a significant structural element shared by all of the alternatives (it includes compounds that share a common chemical structure which occupies a large portion of their structures, or compounds that have in common only a small portion of their structures, which constitutes a structurally distinctive portion in view of the prior art, and is essential to the common property or activity),

12.10 Illustrative example showing unity of invention in Markush claims

Example 1:

A compound A of formula:

R1-R2-R3

wherein R1 is indolyl moiety and R2-R3 are methyl, benzyl, or phenyl. The compounds are useful as pharmaceutical for treatment of asthma.

In this case the compound A has a significant structural element that is shared by all of the alternatives and all the claimed compounds possess the same activity. Thus all the claimed compounds possess unity.

Example 2

The claim relates compound

R1-R2-R3

Wherein R1 is a heterocyclic moiety comprising diverse molecular species and R2-R3 are methyl, benzyl, or phenyl. The molecular variations of R1 encompass huge number of moieties which cannot be structurally linked and cannot be said to fall within single inventive concept.

12.11 Unity of invention in Intermediate and Final Product

12.12 The term "intermediate" includes intermediate and starting products which have the ability to be used in a process to produce the final product through a physical or chemical change in which the identity of the intermediate is lost. The fulfilment of the requirement of unity of invention between intermediate and final product, is subjected to the fulfilment of the following conditions:

a) the intermediate and final product should have the same essential structural element, i.e. the basic chemical structure of the intermediate and the final product are the same, or the chemical structure of the intermediate and final product are technically closely interrelated, with the intermediate incorporating an essential structural element into the final product,

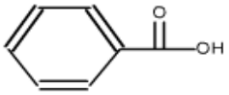
and

b) technically interrelated, also meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all sharing the same essential structural element.

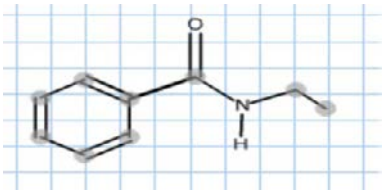
12.13 **Illustrative example for Unity of invention in Intermediate and Final Product**

Example 1:

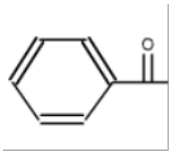
Claim 1: (intermediate)



Claim 2: (final product)



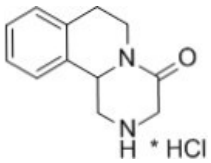
The chemical structures of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:



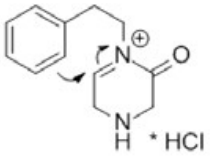
Therefore, unity exists between claims 1 and 2.

Illustrative example 2

Claim 1: I (final product)



Claim 2: II (intermediate)



Compound (II) is described as an intermediate to make (I). The closure mechanism is one well known in the art. Though the basic structures of compound (I) (final product) and compound (II) (intermediate) differ considerably, compound (II) is an open ring precursor to compound (I). Both compounds share a common essential structural element therefore considered to be technically closely interrelated.

This example therefore satisfies the requirement for unity of invention.

12.14 To satisfy unity of invention between intermediate and final products when any one or both the structures are not known, there should be sufficient evidence to conclude that the intermediate and final products are technically closely interrelated such as the intermediate contains the same essential element as the final product or incorporates an essential element into the final product.

12.15 Different intermediate products used in different processes for the preparation of the final product, satisfy unity of invention provided that they have the same essential structural element.

12.16 To satisfy unity of invention the intermediate and final products should not be separated, in the process by an intermediate which is not new.

12.17 Different intermediates for different structural parts of the final product, do not satisfy unity of invention.

12.18 To satisfy unity of invention where the intermediate and final products are families of compounds, each intermediate compound should correspond to a compound claimed in the family of the final products.

12.19 Where unity of invention is recognized the fact that, the intermediates also exhibit other properties or activities should not affect the unity of invention.

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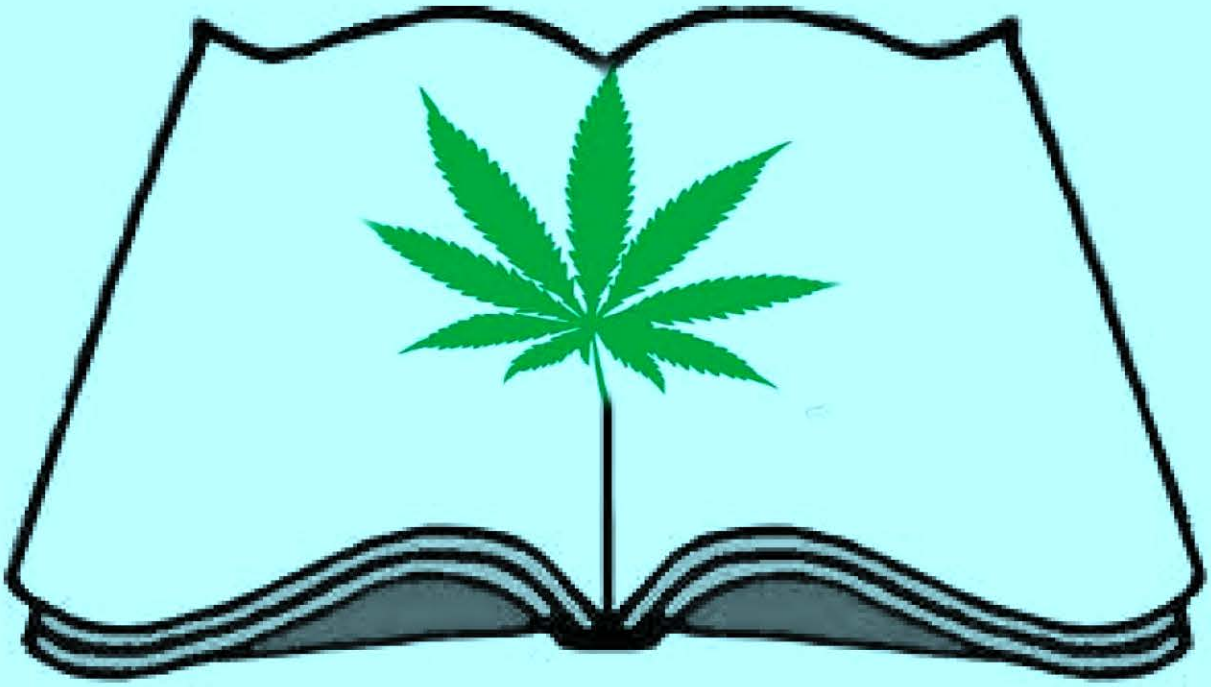
सत्यमेव जयते

Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material



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Office of the Controller General of Patents, Designs & Trademarks

GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL

It has been reported that the Indian Patent Office is granting patents on the use of traditional knowledge (TK) of India, particularly relating to the Ayurveda, Unani and Siddha systems of medicine, etc and patents have been granted on inventions related to biological resources obtained from India without taking adequate care to observe the mandate of law. This is inspite of the fact that other international patent offices are denying/objecting to the grant of such patents on the basis of prior art evidence retrieved from the Traditional Knowledge Digital Library (TKDL).

2. India has played a pivotal role in the decade old efforts of developing countries on the global platform for bringing the protection of traditional knowledge at the centre stage of the International Intellectual Property System. These efforts have resulted *inter alia* in setting up of an Inter-Governmental Committee (IGC) on Intellectual Property, Traditional Knowledge, Genetic Resources and Folklore by WIPO and the Doha Ministerial Declaration of the year 2001 wherein it was decided to establish a relationship between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) on the issue of Access to Genetic Resources and the fair and equitable sharing of the benefits arising from their utilization. Further, India has been able to conclude TKDL Access (Non-Disclosure) Agreements with several international patent offices including USPTO, EPO, JPO etc. Consequently, many patent applications concerning India's traditional knowledge have either been cancelled or withdrawn or claims have been amended in several international patent offices. Negotiations are also under way for establishing an international legally binding instrument on protection of TK.

3. Indian law has adequate provisions for the protection of TK and Biological Resources. Traditional knowledge, by its very definition, is in the public domain and hence, any application for patent relating to TK does not qualify as an invention under section 2 (1) (j) of the Patents Act, 1970, which defines that "invention means a new product or process involving an inventive step and capable of industrial application". Further, under section 3(e) of the Patents Act "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable. The Indian Patents Act also has a unique provision under Section 3 (p), wherein "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 an invention and hence, not patentable, within the meaning of the Patents Act. Additionally, sections 3 (b), (c), (d), (f), (h), (i) and (j) are of relevance with respect to the patent applications related to TK and/or biological material.

4. On the issue of Biological resources, section 6 (1) of the Biological Diversity Act, 2002 provides very clearly that "no person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or

information on a biological resource obtained from India without obtaining the previous approval of National Biodiversity Authority before making such application; provided that, if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent[1] by the patent authority concerned; provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof. The Indian Patent Law complements this provision of the Biological Diversity Act, 2002 by making it mandatory for the applicant of a patent to submit a declaration under Form-1 (Application for Grant of Patent) of the Patent Rules 2003 to the effect that "the invention as disclosed in the specification uses the biological material from India and the necessary permission from the Competent Authority shall be submitted by me/us before the grant of patent to me/us." The Biological Diversity Act, 2002 has a penal provision in this regard under section 55 (1) which provides that "whoever contravenes or attempts to contravene or abets the contravention of the provisions of the section 3 or section 4 or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both."

5. Moreover, applications for patents based on TK and/or biological material contravening the provisions of law can be refused under section 15 or in pre-grant opposition under clauses (d), (f) and (k) of Section 25 (1) and granted patents can be revoked in post-grant opposition under clauses (d), (f) and (k) of Section 25 (2) of the Patents Act, 1970. Non-disclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification also forms a ground for pre- and post- grant opposition under clause (j) of Sections 25 (1) and 25 (2) respectively of the Patents Act, 1970.

6. In view of the above facts and the sensitivity and importance of the issue, it is imperative that due care and diligence be exercised while processing patent applications relating to TK and/or biological materials and in post-grant proceedings thereto. Accordingly, the following guidelines are issued for strict compliance by all Examiners and Controllers:

Screening:

7. It should be ensured that all patent applications relating to Traditional Knowledge (TK) are correctly identified, screened and classified as "Traditional Knowledge" by RECS Section. The RECS in-charge should take due care that no case relating to TK is wrongly screened and classified. Additionally, the person in-charge of screening should accord appropriate IPC classification for such TK applications so that these applications can be properly routed for examination to the respective groups such as Chemistry, Pharmaceuticals, Agrochemicals, Biotechnology, Microbiology, Biochemistry, Food, Mechanical, etc. e.g., C07D, C07G5/00 (for Chemical), A61K, A61L (for Pharmaceuticals), A01N (for Agrochemcials), C12S, C12N, C07K4/00; 14/00 (for Biotechnology), C12N, C12P, C12Q (for Microbiology), C12F, C12G (for

[1] With effect from 01-01-2005, in the Patents Act, 1970, the process of grant of patent has been modified to replace acceptance and subsequent grant and sealing of patent by a process of grant of patent.

Biochemistry), A23C, A23L (for Food), B25F (for Mechanical), etc. The screening of an application as “Traditional Knowledge” is an administrative process for facilitating the examination and to indicate that the subject-matter of the application is important and has relevance in the context of traditionally known substances, articles or processes for preparing them or their use.

8. In the rare situation that the screening and/or classification by the RECS Section is not found to be appropriate in respect of applications relating to TK during allotment/examination, it should be immediately brought to the notice of the Group Leader by the concerned Examiner/Controller and re-screening and/or re-classification should be done by the Group Leader (GL) forthwith.

9. If an application is wrongly screened and classified as "Traditional Knowledge", only the Technical Head shall be competent for re-screening and/or re-classification of the same to any other screening field on the recommendation of the concerned Group Leader.

10. System Administrator should create separate screening fields in the Module namely, TK-Chemical, TK-Biotechnology and TK-Mechanical.

Allotment:

11. In the concerned Group, the Group Leader shall himself/herself act as the Controller for all applications related to TK. The Group Leader/Controller shall ensure that the provisions related to the protection of TK and/or biological material are fully complied with. The concerned Group Leader shall select one suitable Examiner from within his/her Group for dealing with all applications relating to TK. The concerned Group Leader/Controller and Examiner should endeavor to continuously upgrade their knowledge about TK and/or Biological Resources.

12. Any application/case already under process including pre-grant opposition relating to TK shall be re-allotted to the identified pair in the respective Group. Whenever any Examiner/Controller comes across a case related to TK, he/she shall bring to the notice of GL for re-allotment.

Examination:

13. In every case related to TK and/or biological material, the Examiner shall carry out a thorough search for anticipation in TKDL and/or other databases. If any citation is made from TKDL database, then copy of the citation (English translated) should be sent along with the examination report.

14. Assessment of Novelty and Inventive step:

The patents Act warrants that the subject-matter claimed in a patent application must be novel. The inventive step is another cardinal principle of patentability. Often it is said to be the final gate keeper of the patent system. While considering the traditional knowledge based inventions, the following guiding principles must be followed in assessing the novelty and inventive step:

Guiding Principle 1: If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge.

When the subject-matter of claims relate to extracts of plant materials containing undefined active ingredients, such claims cannot be said to be novel if the use of such plants or plant materials is pre-known as a part of teaching of TK. However, if the claims relate to alkaloids and/or active principles obtained from the plant materials and structures of the said alkaloids and/or active principles are characterized, which do not form the part of the prior art, such claims cannot be said to involve an inventive step, since the use of said plant materials and their therapeutic effects are known from the teaching of TK. Thus, the prior art motivates the person skilled in the art to isolate the individual ingredients such as alkaloids, flavonoids, phyto-steroids, etc.

Illustration 1: Patent application claims relate to an extract of Withania plant for the management of stress.

Prior art (TKDL): Discloses use of *Withania somnifera* roots and not Withania plant extract for the treatment of stress related disorders in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to an extract of Withania plant. Based on the prior art, it can be objected that the extract of *Withania somnifera* would be useful in treatment of chronic stress disorders such as insomnia, gastric ulcers, hyperacidity, restlessness and depression. Therefore, the subject-matter of claims is not considered as novel over the teaching of prior art obtained from TKDL.

Illustration 2: Patent application claims relate to an alkaloid, Chamaemeloside, derived from Roman or German chamomile for the treatment of Cancer, Diabetes mellitus, Arthritis, Acne vulgaris, Eczema and for wound healing.

Prior art (TKDL): Discloses use of German chamomile (from which Chamaemeloside is derived) in wound healing and for the treatment of cancer, diabetes mellitus, arthritis, acne vulgaris and eczema in Ayurveda and Unani systems of medicine. The prior art does not disclose the Chamaemeloside.

Analysis: The claims of alleged invention relate to Chamaemeloside derived from Roman or German chamomile. Based on the prior art, it can be objected that German or Roman chamomile (from which Chamaemeloside is derived) has already been used alone or in combination with other ingredients for afore-mentioned indications and therefore, the prior art

motivates the person skilled in the art to isolate and identify the active ingredient such as Chamaemeloside, which has the same therapeutic effects. Hence, the isolation and characterization of the same cannot be considered to involve an inventive step in the light of prior art obtained from TKDL.

Guiding Principle 2: Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.

Illustration 1: Patent application claims relate to a composition comprising of Calendula officinallis, Aloe vera and Centellae asiatica as healing agent and for treatment of wound.

Prior art (TKDL): Discloses independent use of Calendula officinallis, Aloe vera and Centellae asiatica for the treatment of wound and as a Cicatrizant/healing agent in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention were on a composition. Based on the prior art, it can be objected that the combination of these plants would be obvious for the treatment of skin diseases and healing of wounds. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disease is considered to be an obvious combination. It would normally be expected that such combinations of medicinal plants would be more effective than each of the medicinal plants when applied separately (additive effect).

Illustration 2: Patent application claims relate to a composition comprising Ginger, Radish, Celery and Black seed for enhancing male fertility.

Prior art (TKDL): Discloses independent use of Ginger, Radish, Celery and Black seed as Aphrodisiac and Spermatogenic in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to a composition. Though none of the prior arts disclose a composition comprising a combination of the four extracts as claimed in the present application, it can be objected from prior art documents that the use of the single ingredients ginger, radish, celery and black seed as aphrodisiac and/or spermatogenic is well-known in the prior art.

Guiding Principle 3: In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.

Illustration 1: Patent application claims relate to a combination of five constituents, one of these being a 1:2 watery extract of Cucumis melo containing catalase and superoxide dismutase; along with Pimiemta racemosa, Citrus aurantifolia, Coenzyme Q-10 and Pyridoxine Chlorhydrate for the treatment of vitiligo.

Prior art (TKDL): Discloses usefulness of only one of the constituents, watery extract of Cucumis melo for its anti-vitiligo property in the Unani system of medicine.

Analysis: The claim of alleged invention relates to a composition comprising five constituents and not on a single constituent, the watery extract Cucumis melo for its anti-vitiligo property. Based on said cited documents, it can be objected that if one ingredient here, Cucumis melo, was already known for the treatment of vitiligo, then it is necessarily expected that a combination comprising this known active ingredient must be effective for treating vitiligo as long as no surprising (superior) effect of the claimed combination vis-a-vis the already known product comprising Cucumis Melo, inventive merits can not be acknowledged.

Guiding Principle 4: Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive.

In case of inventions relating to selection of optimum or workable range of ingredients, this is to be borne in mind that the selection of a particular range of known ingredients is not inventive since the selection of optimum or workable range is well within the expectation of a person skilled in the art.

Illustration 1: Patent application claims relate to a formulation comprising at least two of the following: an extract of Pongamia pinnata (in the range of 2 to 20%), an extract of Lawsonia alba (in the range of 5 to 15%), an extract of Dhatura alba (in the range of 2 to 20%) and an extract of of Cocos nucifera (in the range of 20 to 60%) for the management of chronic ulcer, diabetes ulcer, and the management of bleeding in cuts and wounds.

Prior art (TKDL): Discloses use of said plants for the treatment of ulcer/wound in Ayurveda, Unani and Siddha systems of medicine.

Analysis: The claims of alleged invention relate to a composition comprising plant parts in a specified ratio. The claims can be objected as unpatentable in so far as the alleged invention is obvious over Agasthiyar (TKDL) which taught a composition of extracts of two of the claimed plants, Karanj and Heena formulated as oil for topical treatment of ulcers and wounds. Although cited art does not specifically teach adding the ingredients in the percentages claimed by the applicant, however the amount of specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

Guiding Principle 5: In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive.

Illustration 1: Patent application claims relate to an extract of Zingiber zerumbet (bitter ginger) for inflammation and also for allergic disorder like Asthma.

Prior art (TKDL): Discloses use of Zingiber zerumbet (bitter ginger) along with few other ingredients for the treatment of inflammation and Asthma in Unani system of medicine.

Analysis: The claims of alleged invention relate to an extract of Zingiber zerumbet. As per the prior art disclosure, the multi-component formulation comprising Zingiber zerumbet have the same therapeutic activity (i.e. anti-bronchial asthmatic), therefore it is not surprising that one single component namely Zingiber zerumbet taken out of them again would have the same

therapeutic activity. Hence, a person skilled in the art would have been motivated to arrive at the invention without exercise of inventive skills and thus, the claims of alleged invention can be objected for lacking in inventive step.

Guiding Principle 6: In case individual ingredients are already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).

Illustration 1: Patent application claims relate to a composition comprising of Calendula officinallis, Aloe vera and Centellae asiatica as healing agent and for treatment of wound.

Prior art (TKDL): Discloses use of said plants for the treatment of wound and as a Cicatrizant/healing agent in Ayurveda and Unani systems of medicine.

Analysis: The claim of alleged invention relates to a composition. In view of the prior art, the combination of these plants would be obvious for the treatment of skin diseases and healing of wounds. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disease is considered to be an obvious combination. It would normally be expected that such combinations of medicinal plants would be more effective than each of the medicinal plants when applied separately (additive effect).

Illustration 2: Patent application claims relate to a composition comprising of theanine (Tea) and a herb selected from Sankhapuspi, Satavari or a mixture thereof for the treatment of a disease (cold and/or influenza) related to reduced immunity.

Prior art (TKDL): Discloses independent use of said plants for the treatment of cold and influenza and as immuno-potentiator in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to a composition. In view of the prior art, the use of theanine comprised in tea and extracts thereof, for prevention and/or treatment of cold and/or influenza was known from popular medicine since ages. The immunoadjuvant/immunomodulatory potential of Asparagus racemosus (Satavari), aqueous exctracts/Evolulus alsinoides (Sankhapuspi) was also disclosed in prior art documents. Therefore, nothing inventive could be seen in the additional use of immunopotentiating herbs to treat these diseases. A combination of these plants would be obvious as an immuno-potentiator and for the treatment of common cold and a variety of other diseases.

15. While deciding the patentability of the claimed subject matter, the relevant clauses of section 3, particularly sections 3 (c), (e), (i), (j) and (p) of the Patents Act, for TK and/or biological material should be strictly followed.

16. The applications related to TK and/or biological material shall also be critically examined with respect to requirements of full and particular disclosure of the invention, its operation or

use and the method by which it is to be performed along with the best method of performing the invention by way of working examples known to the applicant in the complete specification as provided under Section 10 (4) (a) & (b) of the Patents Act,

17. If the source and geographical origin of the biological material used in the invention is not disclosed in the specification, an objection shall be raised thereof in conformity with section 10 (4) (a) & (b) of the Patents Act.

NBA permission:

18. In Form-1 of the Patent Rules 2003, the applicant is required to furnish a declaration "the invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us". This provision of declaration in paragraph 9 (in) of Form-1 came into force from 01-01-2005 and every application submitted thereafter should mandatorily have either the affirmative or cancelled out declaration. Where the applicant leaves the declaration unattended, the RECS section should insist upon a fresh Form-1 wherein it should be clearly indicated. If such omission is noted during any stage of processing of the application, the Examiner/Controller should raise an objection in this regard.

19. If the above declaration in Form-1 regarding the use of biological material from India is affirmative, the Examiner/Controller should raise the objection in the FER about the requirement of permission from NBA in the matter, if already not submitted. If the objection has not been raised in the FER, the same may be raised at any stage thereafter. In any case, the patent should not be granted unless the NBA permission is submitted by the applicant.

20. On the other hand, if the declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India and should clearly specify the country of source and geographical origin of the same.

21. Where the declaration in Form-1 is cancelled out but the disclosure in the specification is that the source and/or the origin of the biological material is from India, then NBA permission is required.

22. Therefore, no patent shall be granted without the necessary permission from the National Biodiversity Authority in cases where the invention uses biological material from India or the source and/or the origin of the biological material is from India as per the disclosure in the specification.

23. The directions given in circular No. 1 of 2012 by CGPDTM should be strictly followed, which is reproduced herein below:

It has been observed that during the examination of applications pertaining to the Biological materials diverse yardsticks are adopted by different Patent Officer/Controller as regards the exemption from obtaining permission from NBA in r/o the claimed biological resource in the present application. In view of this, the following directions are issued for strict compliance of the concerned Controllers and Examiners:

"Exemption to medicinal plants from the provisions of the Biological Diversity Act, 2002 given by the notification issued by the Ministry of Environment and forests Notification dated 26th October 2009 is available only if they are traded as commodities and the said provisions are very much applicable if the biological resources are used as ingredients for medicine. As such, any interpretation by the Controllers/Examiners of the Office of CGPDTM to see this as an exemption from the Biological Diversity Act would be wrong.

Controllers/Examiners are directed to ensure strict compliance with the aforesaid order and approval of NBA should be sought for any biological resources derived from India and used in an invention for which patent application is filed."

Publication of list of TK related patent applications:

24. The System Administrator shall publish the list of all pending patent applications related to TK, which are published under section 11 (A) of the Patents Act, in a separate link on the official website of CGPDTM. This list should be updated automatically on the website as per screening field in the module on real time basis. The list should display at least the following fields: application number, date of filing, title of the invention and name of applicant (indexed in the order of date of filing).

25. A list of patents granted on applications related to TK should also be published on the website for all such patents granted from 1st July 2012. This list should also be updated automatically on the website as per screening field in the module on real time basis. The list should display at least the following fields: application number, patent number, date of filing, date of grant, title of the invention and name of patentee (indexed in the order of date of grant).

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