Draft Guidelines

for Examination of Patent Applications

in the Field of Biotechnology

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भारत सरकार

वाणिज्य और उद्योग मंत्रालय

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DRAFT GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS IN THE FIELD OF BIOTECHNOLOGY

1. INTRODUCTION

Biotechnology is a discipline that utilizes biological systems and organisms to develop products and processes beneficial to society. It is generally categorized into classical and modern biotechnology. The advent of modern biotechnology began in the late 1970s with the emergence of genetic engineering. This innovation has led to the creation of valuable products such as human insulin, human growth factors, and monoclonal antibodies.

The biotechnological inventions therefore include products and/or processes of genetic 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. Notable developments include the creation of transgenic plants and animals, which offer significant improvements in agriculture, food security, and medical research. For instance, genetically modified (GM) crops have been engineered for enhanced resistance to pests, diseases, and environmental stresses, while also boosting nutritional content. Moreover, the isolation of human genes for the purpose of producing therapeutic proteins has revolutionized medicine, with biopharmaceuticals such as insulin, growth hormones, and monoclonal antibodies being produced in engineered organisms, particularly, bacteria and mammalian cell lines.

Beyond these applications, recent developments in gene editing technologies like CRISPR-Cas9 have raised the potential for precise modifications at the DNA level, offering unparalleled opportunities in gene therapy, personalized medicine, and disease eradication. However, these advances also raise critical ethical, environmental, and safety concerns- especially regarding gene editing in animals, including humans; ecological impacts of GM organisms; and the potential for unintended consequences. As these technologies continue to evolve, ongoing discussions about their regulation, safety protocols, and broader societal implications will be crucial to ensure their responsible and legally compliant use.

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 patenting of biotechnological inventions which are of serious concern to the users of the patent system such as novelty, obviousness, industrial applicability, sufficiency 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 (as amended). Thus, the guidelines are intended to help the Examiners and Controllers of the Patent Office so as to achieve uniformity and consistency.

2. BRIEF HISTORY OF PATENTING OF BIOTECHNOLOGICAL INVENTIONS 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. 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*[1]*'*, 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

[1] Dimminaco AG v. Controller of Patents and Designs [AID NO.1 OF 2001]

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 improved or restored the former conditions of the vendible item, or preserved and prevented the deterioration of a 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, wherein biochemical, biotechnological and microbiological processes were included within the scope of chemical processes for the grant of patents. 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 the deposition of the biological material and its reference in the patent application in cases where the invention relates to a biological material that cannot be sufficiently described and is not available to the public. The Patents Act, 1970 was further 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 ACT COMPLIANCE BY THE APPLICANT

The Biological Diversity Act, 2002 as amended in 2023 (hereinafter referred to as the 'BD Act') provides a mechanism for conservation of biological diversity, the sustainable use of its components, and the 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 of India and traditional knowledge associated thereto, the BD Act requires that access to the biological resources of India is subject to equitable benefit sharing through the approval of National Biodiversity Authority (hereinafter referred to as 'NBA'). Section 6 of the BD Act prescribes that obtaining IPRs from the utilization of biological resources from India is subject to the approval of, or registration with, the NBA, as the case may be.

To facilitate this access and benefit sharing, and in order to prevent any unauthorized use of the biological resources of India, in 2002 suitable amendments were made in Section 10 (4) of the Patents Act, 1970 (as amended), wherein disclosure of the source and geographical origin of the biological material was made mandatory in application for patent when the said material is used in an invention. In addition, a declaration was inserted in Form 1 of the Patents Rules, 2003 (as amended) through the 2005 amendment, requiring the applicant to state: *"The invention as disclosed in the specification uses biological material from India, and the necessary permission from the competent authority shall be submitted by me/us before the grant of the patent to me/us."* Further, non-disclosure or wrongful disclosure of source and geographical origin of biological materials is a ground of opposition u/s 25(1)(j) and 25(2)(j) of the Patents Act. Therefore, compliance related to the BD Act and those related to disclosure of the source and geographical origin constitutes an essential element of patent 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' (revised from time to time).

When applications are put in order for grant, an intimation letter is sent to the applicant, informing them to comply with requirement of declaration given in Form 1 [Para 12(iii)] and to submit the approval or certificate of registration from the competent authority in respect of the use of biological material obtained from India.

4. RELEVANT PROVISIONS WHILE EXAMINING BIOTECHNOLOGY APPLICATIONS

The following sections of the Patents Act, 1970 (as amended) are emphasized in the context of examination of patent applications in biotechnology and allied fields:

Part A- Patentability Criteria

1. Section 2(1)(j): Novelty
2. Section 2(1)(ja): Inventive step
3. Section 2(1)(ac): Industrial applicability of products and/or processes.

Part B- Non Patentable subject matter

4. 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.
5. 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.
6. 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.
7. 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.
8. Section 3(h): a method of agriculture and horticulture.
9. 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.

10. 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.
11. Section 3(k): a mathematical or business method or a computer programme *per se* or algorithms.
12. 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.

Part C: Section 10 requirements

13. Section 10(4)(a)-(d): Sufficiency of disclosure and the best method of performing the invention and scope of claims.
14. Section 10(5): Unity of invention and clarity, succinctness and support of the claims.

5. CLAIMS RELATED TO 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 on claims related to biotechnological inventions which are usually filed in patent applications of the relevant fields.

These patent applications often cover the following subject matters:

a. **Nucleic Acids:** Gene sequences, recombinant DNA/RNA, synthetic nucleotides, and genetic constructs.
b. **Proteins and Polypeptides:** Novel sequences, enzymes, variants, antibodies, antibody-drug conjugates (ADCs), and therapeutic proteins.
c. **Vectors and Constructs:** Plasmids, gene cassettes, viral vectors, and libraries.
d. **Cells and Organisms:** Host cells, micro-organisms, stem cells, transgenic cells and genetically modified organisms (GMO).
e. **Pharmaceuticals and Vaccines:** Biopharmaceutical compositions, vaccines, biologics, and nucleic acid-based therapeutics (e.g., siRNA, CRISPR-based).
f. **Diagnostics:** Kits, methods, and tests for detecting genes, proteins, mutations, diseases, or other biomarkers.
g. **Microbial and Biochemical Processes:** Bioremediation, fermentation, enzyme-mediated synthesis, and bio-industrial applications.

h. **Tissue Engineering and Bio-printing:** Bio-printing technologies, scaffolds, and methods for tissue regeneration and artificial organ production (e.g., bio-artificial kidneys, livers, heart valves).
i. **Bioinformatics:** Metabolomics, NGS, computational genomics etc.
j. **Advanced Technologies:** Gene editing (CRISPR, TALENs), synthetic biology, RNA interference, etc.

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(3) of the Patents Rules, 2003 (as amended), the same shall be filed in electronic form. To facilitate the processing of patent applications, the sequence listings should be filed in computer readable (WIPO Standard ST. 26) 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, UniProt, FASTA, etc.

The Examiner's report must mandatorily disclose the search string or query used during the prior art search.

Part A : Patentability Criteria

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 9, Para 09.03.02) 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.

Section 2(1)(l) of the Act further defines "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.

Accordingly, 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 or used in the country or elsewhere in the world 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. Also, any patent application filed in India that is published at a later date but has an earlier filing or priority date than a subsequently filed application, and claims the same subject matter as the subsequent application, shall be considered as prior art (i.e., prior claiming) for the subsequently filed application.

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 obtained by the method according to claim X.
(b) A transgenic micro-organism obtained by the method of…. 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 evidence is provided showing that the modifications in the processes result in products which are distinct with regard to their properties over the products known in the prior art. Such technical evidence may vary from case to case.

In the matter of VIFOR (International) Limited & anr Vs MSN Laboratories Pvt Ltd & anr[2], the Division Bench of the Hon'ble High Court of Delhi on 07th Feb 2024 explained the principles governing **product-by-process claims**. At paragraphs 127 and 128, the Hon'ble Court stated:

> *"127… a product-by-process claim would be accepted and accorded statutory protection, only if the product itself be novel. Irrespective of the language in which such a claim may be couched, it is necessary that such a patent application speak*

[2] VIFOR (International) Limited & anr Vs MSN Laboratories Pvt Ltd & anr, [(FAO (OS) (COMM) Nos. 159-161/2023)]

of a novel product. It is this foundational precept on which product-by-process claims are tested. This is evident when the guidelines urge us to bear in mind that novelty of a process does not necessarily mean that the product itself represents an invention…". "…a product is not rendered novel merely by virtue of the fact that it is produced by a new process. This since if novelty is claimed only in respect of a process, it would be treated and granted as a process patent…"

"128… It is thus manifest that for a patent application founded on a product-by-process claim being granted; it is imperative that it relate to an inventive and novel product notwithstanding the invention having been explained in process terms. The aforesaid discussion leads us to the irresistible conclusion that even in the case of product-by-process claims, it is the novelty of the product which must be established shorn of the process terms that may accompany such a claim…"

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 as novel if it is not anticipated; however, it must also satisfy the criteria of **inventive step, industrial applicability, and non-patentability provisions under 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 COMPOSITION CLAIMS

Quite often, the claims of composition of products of biotechnology escape the question of novelty and are dealt with 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.

Biotech / IE-1 (Illustrative Example -1):

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 also discloses a process for preparing egg yolk antibodies by employing steps of immunization of a chicken with a diphtheria antigen and antibodies purification.

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 9, 09.03.03) 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 an inventive-step if it involves (a) technical advance as compared to existing knowledge or (b) having economic significance; or (c) both; and (d) that makes the invention not-obvious to a person skilled in the art.

To demonstrate an inventive step, the claimed invention must not be something that a person skilled in the relevant field could easily deduce, even by combining existing knowledge from prior art. It must show a technical improvement or economic significance or both that is not obvious based on what is already known.

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.

Biotech / IE-2:

Claim: An isolated DNA sequence encoding a mature human IL-3 protein with a proline residue at position 8 of the mature polypeptide, wherein said protein possesses bone marrow proliferation-inducing activity in a human bone marrow proliferation assay.

Prior Art Disclosure: The prior art discloses a similar IL-3 protein, however, at position 8, the corresponding residue is serine instead of proline in the claimed invention.

Analysis: .The prior art discloses an IL-3 protein differing from the claimed protein only in that the amino acid residue at position 8 is serine rather than proline. A single amino acid substitution (serine to proline at position 8) does not necessarily alter the function or biological

activity of the protein unless the change occurs in a critical functional region. The applicant failed to provide experimental evidence demonstrating that the proline substitution resulted in any unexpected technical effect or significant improvement in chemical or biological properties compared to the prior art. In the absence of unexpected advantages or a surprising technical effect, the claimed subject matter appears to be an obvious modification for a person skilled in the art. Thus, the inventive step cannot be acknowledged.

Biotech / IE-3:

Claim: An improved process for the production of galacto-oligosaccharides (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 galacto-oligosaccharides solution.

Prior art disclosure: 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.* consumes glucose, a 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 leads to high yield & purity of GOS. Thus, the claimed subject-matter lacks inventive step.

Biotech / IE-4:

Claim: A humanized anti-CD19 chimeric antigen receptor (CAR) polypeptide comprising:

(a) a single-chain variable fragment (scFv) with a humanized anti-CD19 binding domain, including heavy chain framework regions (HFR1, HFR2, HFR3, HFR4) of sequences X, Y, and light chain framework regions (LFR1, LFR2, LFR3, LFR4) of sequences A, B;

(b) a hinge region comprising sequence C;

(c) a trans-membrane domain comprising sequence D or E;

(d) a cytoplasmic domain comprising a human 4-1BB co-stimulatory domain of sequence F and a CD3ζ signalling domain of sequence G;
wherein the CAR comprises Sequence H.

Prior Art Disclosure:

D1 discloses a humanized anti-CD19 CAR comprising a single-chain antibody (scFv) against CD19, a hinge region, a trans-membrane domain, and a cytoplasmic domain, including a 4-1BB co-stimulatory domain and a CD3ζ signalling domain. It further describes nucleotide sequences encoding the CAR, a vector for T-cell transduction, and pharmaceutical compositions containing the CAR-T cells. Additionally, D1 describes a method of treating diseases associated with CD19 expression by administering CAR-T cells to a mammal.

D2 discloses CAR-T cell therapies targeting various tumor-associated antigens, including CD19, CD20, CD22, and others. It describes CAR constructs incorporating antigen-binding domains derived from bi-specific or dual-affinity antibodies, as well as methods for treating cancer using such CAR-T cells.

Analysis: D1 is the closest prior art as it discloses a humanized anti-CD19 CAR comprising a single-chain antibody (scFv), a hinge region, a trans-membrane domain, and a cytoplasmic domain with a 4-1BB co-stimulatory domain and a CD3ζ signalling domain.

The claimed CAR polypeptide differs from D1 by incorporating a specific set of framework regions and optimized structural elements. The technical effect of these modifications is supported by experimental evidence in the specification, demonstrating that T cells expressing the claimed CAR exhibit a significantly improved cytokine profile compared to those expressing the CAR of D1. Additionally, the specification provides data showing that T cells engineered with the claimed CAR result in enhanced tumor size reduction upon administration, further highlighting the functional advantages of the structural modifications.

D2, which focuses on bi-specific antibody-based CAR constructs, does not suggest or provide motivation for the skilled person to implement the claimed modifications. The unexpected improvements in cytokine response and tumor reduction, supported by experimental data, establish an inventive step of the claimed CAR polypeptide over D1 and D2.

Biotech / IE-5:

Claim: A method for the removal of plasmids from live, multiplying plasmid-containing bacteria using sub-micronic silver particles comprising the following steps: (a) preparing a suspension of silver particles; (b) estimating the minimum inhibitory concentration (MIC) of silver particles for the target bacteria; (c) adding, in a reaction vessel, the first suspension and a growth medium of the bacteria to obtain a second suspension, wherein the concentration of silver particles in the second suspension is lower than the Minimum Inhibitory Concentration (MIC) determined in step (b) ("sub-MIC concentration"); (d) culturing the bacteria in a medium with a sub-MIC concentration of silver particles; (e) allowing bacterial multiplication under favourable conditions for 12–48 hours to obtain subsequent generations of the bacteria; and (f) testing the bacterial generations for absence of plasmids to obtain a generation of plasmid free bacteria.

Prior art disclosure: The prior art describes a method for investigating the antimicrobial effects of silver nanoparticles on *E. coli*, a representative model for Gram-negative bacteria. The disclosed teachings include: (a) the preparation and characterization of silver nanoparticles; (b) the culturing of *E. coli* in LB medium supplemented with varying concentrations (10–100 $\mu g/cm^3$) of silver nanoparticles; (c) the evaluation of bacterial growth rates and cellular changes using optical density (OD) measurements and transmission electron microscopy (TEM); (d) the observation of bacterial membrane damage, leading to increased permeability and leakage of intracellular substances; and (e) the accumulation of silver nanoparticles within bacterial membranes, resulting in structural changes and cell lysis. The prior art 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. It teaches that a membrane with such morphology exhibits a significant increase in permeability, which leads to leaking of intracellular substances.

Analysis: The prior art discloses all key aspects of the claimed invention, including the selection of *E. coli*, preparation and use of silver nanoparticles, and their effects on bacterial growth and membrane permeability. While it does not explicitly mention plasmid removal, it establishes that silver nanoparticles increase membrane permeability, leading to intracellular leakage, which may include plasmids. A skilled person would reasonably expect this effect to facilitate plasmid removal. Additionally, the use of sub-MIC concentrations to sustain bacterial viability does not present a non-obvious or surprising technical advancement beyond routine optimization. Since the core mechanism is already taught by prior art, the claimed method constitutes an obvious extension and therefore, lacks an inventive step.

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, then the claimed subject-matter lacks inventive step.

Biotech / IE-6:

Claim: Pro-insulin having a C-peptide encompassing only two amino acids selected from Arg-Lys, Lys-Lys and Lys-Arg*.

(*Human Pro-insulin comprises 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 is considered obvious in view of existing disclosures of Pro-insulin variants with short C-peptides. 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'. Therefore, the claim lacks an inventive step.

Biotech / IE-7:

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 revoke 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 are already established, either explicitly or implicitly.

In the context of 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 its practical application is disclosed. 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.

In the matter of Cipla Ltd. v. F.Hoffmann-La Roche Ltd. & Anr. (2015)[3], the Division Bench of the Hon'ble Delhi High Court on 27th Nov, 2015, analyzed the term "Industrial Application" in the Section 2(1)(ac) of the Act. At paragraph 42, the Hon'ble Court stated:

> *42. Section 2(1)(ac) stipulates that an invention [as defined in Section 2(1)(j)] is capable of being made or used in an industry'- thereby necessitating that an invention must have commercial use or manifestation. Further, even though an alleged invention may not be a final product, the same will be patentable only if it has some commercial viability. Thus, it is not the product which is the focus of attention but the actual physical substance created which has the potential of a commercial manifestation. Section 2(1)(ac) is clearly connected with Section 48 as it deals with "made" or "used" as also "new product" [through Section 2(1)(j) by using the term "invention"] which are all used in Section 48.*

Biotech / IE-8:

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.

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[3] Cipla Ltd. v. F.Hoffmann-La Roche Ltd. & Anr. [RFA(OS) 92/2012 and RFA(OS) 103/2012]

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.

Biotech / IE-9:

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 aV28 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.

Part B: Non-Patentable subject matter

10. **SECTION 3(b)**

According to Section 3(b) of the Act *"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"* is not a patentable invention.

Biotechnology deals with living biological 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-à-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 germline 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 e.g. A method for deriving pluripotent stem cells from human embryos.

Biotech / IE-10:

Claim: A method for differentiating human totipotent embryonic cells into specific tissue types for therapeutic applications, wherein the method involves culturing totipotent cells obtained from a human embryo under specific conditions that lead to the destruction of the embryo.

Analysis: The subject matter is not patentable under Section 3(b) of the Act, as the claimed method involves the destruction of human embryos. Human embryos represent the earliest stage of human life, and their destruction raises serious ethical and moral concerns. The primary use or commercial exploitation of such a method would be contrary to morality and the commercial exploitation of human embryos could cause serious harm to human life and health. Therefore, the claim is not patentable.

Biotech / IE-11

Claim: A method for editing the genome of human embryos using CRISPR-Cas9 technology to enhance intelligence and physical abilities, wherein the method involves germline editing.

Analysis: The subject matter is not patentable under Section 3(b) of the Act, as germline editing of human embryos is contrary to the public order and morality.

Biotech / IE-12

Claim: A genetically modified peptide based herbicide spray designed for pest control purposes that kills insect pests including pollinating insects.

Analysis: The subject matter is not patentable under Section 3(b) of the Act, as the claimed invention poses a significant risk to ecosystems by harming pollinators critical for maintaining biodiversity and food production. The commercial exploitation of such technology could result in long-term environmental damage and threaten global food security. Therefore, the claim is not patentable.

11. **SECTION 3(c)**

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 subject matter.

Accordingly, 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 patentable subject to fulfilling the requirements of Section 2 (1)(j) of the Act.

In the matter of Immunas Pharma, Inc. vs. Assistant Controller of Patents[4], the Hon'ble Madras High Court on 06th March, 2024 analyzed the scope of the term "discovery" in the Section 3(c) of the Act. At paragraph 13, the Hon'ble Court stated:

> *"…the noun "discovery" in the third limb is intended to apply both to living things and non-living substances occurring in nature. This is a pointer, albeit not conclusive, that the adjective "mere" does not extend to this limb as otherwise even a "living thing" could fall outside the scope of patent exclusion if there is something more than mere discovery…"*
>
> *"…that the qualifier "mere" is confined to the nearest reasonable referent "discovery of a scientific principle" and does not extend to "the discovery of any living thing or non-living substance occurring in nature…"*

[4] Immunas Pharma, Inc. vs. Assistant Controller of Patents [(T) CMA (PT) No. 118 of 2023]

Biotech / IE-13:

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.

Biotech / IE-14:

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.

Biotech / IE-15:

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 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 are found in their natives states. Thus, the subject-matter of claim is considered to be isolated non-living substance 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.

Biotech / IE-16:

Claim: An isolated lipase enzyme having a sequence identity of at least 90% with SEQ. ID. X

Analysis: As per the description, lipase with detergent activity is isolated from a naturally occurring microorganism. No recombinant enzymes are identified in the description of the application. Thus, the lipase enzyme as claimed is considered a non-living substance isolated from nature. Thus, the subject matter is not patentable under section 3(c) of the Act.

12. **SECTION 3(d)**

According to Section 3(d) of the Act *"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" is not a patentable subject matter.

Section 3(d) of the Act requires that any modifications in the already existing substance in the prior art are not patentable unless the improved property/efficacy of the modified substance is established.

Efficacy:

The landmark judgment in the matter of ***Novartis AG v. Union of India & Others***[5] primarily dealt with the patentability of pharmaceutical substances. However, its reasoning holds broader significance and offers interpretive guidance in the context of biotechnological inventions as well as inventions related to biopharmaceuticals, biosimilars, vaccines etc.

Notably, the Hon'ble Supreme Court at paragraph 180 provided the following interpretation of the term 'efficacy' under Section 3(d) of the Patents Act:

> *"180… 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....".*

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[5] *Novartis AG v. Union of India & Others* [CIVIL APPEAL Nos. 2706-2716 OF 2013]

Bio-availability and Therapeutic efficacy:

The issue of bioavailability and its relationship with therapeutic efficacy was addressed **in the matter of Natco Pharma Ltd. vs. Novartis AG and Anr.**[6] The Division Bench of the Hon'ble Delhi High Court, on 24th April, 2024, at paragraphs 84 and 86 made the following observations:

> *"84…Bioavailability is one of the pharmacokinetic parameters and not a direct measure of therapeutic efficacy...."*
>
> *"86…Enhanced bioavailability is not synonymous with higher therapeutic efficacy. As noted above, in Novartis v. UoI, the Supreme Court had – without going into the question whether increased bioavailability by itself would lead to an enhancement of therapeutic efficacy, expressly held that, if such a claim is made, the same would require to be established by research and data…".*

Efficacy of Non-therapeutic Enzyme Variants:

In the matter of Novozymes vs. Assistant Controller of Patents & Designs[7]**,** The Hon'ble Madras High Court on 20th September, 2023, examined the issue of patentability of enzyme variants. At paragraph 18, the Hon'ble Court stated:

> *"18…the appellant may claim that the phytase variants for which it seeks a patent are new forms of a known substance. Even so, the appellant would not be entitled to a patent unless the appellant passes the filter of "result in the enhancement of known efficacy of that substance" prescribed in the substantive provision de hors the Explanation. …"*

With regard to the analysis of enhancement of efficacy compared to a known substance, at paragraph 23, the Hon'ble Court stated:

> *"23…Given that Section 3(d) applies to new forms of a range of known substances, even by way of guidelines, it may not be possible to fix a numerical value or percentage of enhancement that applies across the board, and this appears to be the position taken by the Patent Office in its guidelines. The only workable solution appears to be for the patent applicant concerned to establish that there is reasonable enhancement of efficacy to the satisfaction of the Controller of Patents,*

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[6] Natco Pharma Ltd. vs. Novartis AG and Anr.[FAO(OS) (COMM) 178/2021 and CM Nos.46299/2021, 46300/2021, 46301/2021, 46302/2021, 19118/2022, 19119/2022 and 30850/2022]

[7] Novozymes vs. Assistant Controller of Patents & Designs [(T) CMA (PT) No. 33 of 2023]

and reasonable enhancement may be defined as enhancement that is material from an improvement of efficacy perspective …" ***[emphasis added].***

Requirement for Specificity in Section 3(d) Objection:

In the matter of DS Biopharma Limited vs. The Controller of Patents and Designs[8], the Hon'ble Delhi High Court on 30th August, 2022, at paragraph 14 stated that:

"14…For the purposes of a Section 3(d) objection, the one specific ***known substance is to be identified*** *and the manner in which the claimed compounds are 'new forms' ought to be mentioned by the Patent Office, even if not in detail but at least in a brief manner…"* ***[Emphasis added]***

Biotech / IE-17:

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.

Biotech / IE-18:

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.

Biotech / IE-19:

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[8] DS Biopharma Limited vs. The Controller of Patents and Designs [C.A. (COMM.IPD-PAT) 6/2021 & I.A. 12828/2021]

Claim: An Angiotensin-I-converting enzyme 2 (ACE2) inhibitor of the formula: N-(2-Aminoethyl)-1-aziridineethanamine for treating -SARS-COV2 (COVID19) infection, wherein the ACE2 inhibitor alleviates symptoms and signs of SARS-COV2 (COVID19) infection.

Prior art: The ACE2 inhibitor, N-(2-Aminoethyl)-1-aziridineethanamine for the treatment of SARS-COV infection.

Analysis: The ACE2 inhibitor of the claim is characterized for treatment of SARS- COV2 (COVID19) infection. This is considered to fall within the ambit of section 3(d) of the Act, as being a mere discovery of any new property or new use of a known substance.

13. **SECTION 3(e)**

According to Section 3(e) of the Act *"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"* is not a patentable subject matter. This means that if a claimed invention is merely a combination of ingredients without showing any synergistic effect beyond the sum of the individual properties, it is not considered as patentable subject matter.

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.

In the matter of Novozymes vs. Assistant Controller of Patents & Designs[9], Hon'ble Madras High Court on 20th September, 2023, at paragraphs 27 and 28 stated that:

> *"27…On examining the text of Section 3(e) and, indeed even by placing such text in context, I find that there is nothing therein that limits its application to a composition claim formed by the aggregation of known ingredients. By way of context, I notice that the adjective "known" is used as a qualifier in the following clauses of Section 3: Section 3(d)["known substance"]; Section 3(f) ["known devices"]; and Section 3(p)["known properties of traditionally known component or components"], but is conspicuous by its absence in Section 3(e)…".*
>
> *"28...Section 3(e) does not appear to be limited in its application to independent claims. Instead, the object and purpose, as gleaned from text and context, appears to be to exclude from patent-eligibility any composition claim for a substance that merely exhibits the aggregate properties of its constituents…."*

Biotech / IE-20:

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[9] Novozymes vs. Assistant Controller of Patents & Designs [(T) CMA (PT) No. 33 of 2023]

Claim: A composition of an innovative combination of dormant spores 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.

Biotech / IE-21:

Claim: A composition comprising: at least four isolated proteins, comprising a first protein comprising an amino acid sequence comprising at least 80% identity with SEQ ID NO:1, a second protein comprising an amino acid sequence comprising at least 80% identity with SEQ ID NO: 2, a third protein comprising an amino acid sequence comprising at least 80% identity with SEQ ID NO: 3, and a fourth protein comprising an amino acid sequence comprising at least 80% identity with SEQ ID NO: 4; a pharmaceutically acceptable carrier; and an adjuvant.

Analysis: The composition claimed is said to include 4 different proteins along with carrier and adjuvant. The specification is silent on advantages of a combinative effect of the 4 proteins over the sum of their individual effects which are already known. Thus, the subject-matter of the claim is not patentable under Section 3 (e) of the Act .

14. **SECTION 3(h)**

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.

In the matter of Mitsui Chemicals Inc vs Controller Of Patents, Hon'ble Delhi High Court on 23rd February, 2024[10], at paragraph 15 stated that:

> *.....The Court emphasizes the necessity for a more nuanced and detailed analysis of the claimed invention. This analysis must scrutinize whether it genuinely constitutes a 'method of agriculture' or embodies an innovative technical solution to agricultural challenges that might not fall within the*

[10] Mitsui Chemicals Inc vs Controller Of Patents [C.A.(COMM.IPD-PAT) 196/2022]

exclusions of Section 3(h) of the Act. Crucial to this assessment is a clear distinction between purely agricultural methods and those with technical or scientific foundation addressing agricultural problems.....

In the matter of BASE SE (OA/7/2019/PT/KOL) V. Deputy Controller Of Patents and Designs, Hon'ble Calcutta High Court (IPDPTA/3/2023) on 16th september, 2025[11], at paragraph 15 stated that:

.....section 3(h) of the Patents Act, 1970, excludes from patentability "a method of agriculture or horticulture."This provision reflects the legislative intent to preserve traditional and essential public-interest activities such as farming and gardening from being monopolized through exclusive rights. In such circumstances, unless the claimedinvention is directly and integrally connected to traditional agricultural activities, it cannot be excluded under this clause. There is a need to distinguish between biological processes and human-invented, technicalprocesses which points towards a narrow interpretation of section 3(h).....

Biotech / IE-22:

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.

Biotech / IE-23:

Claim: The method of increasing corn hybrid seed production in a field comprising the steps of: (a) growing male and female parent corn plants in pollinating proximity; (b) treating the male parent plants with a Gibberellin application of phytohormone GA3 to increase the height of male plant and thereby enhancing pollination success; and quantifying hybrid seed production.

Analysis: The claimed method of selectively applying gibberellins in male parent crops to increase the pollination success in large scale hybrid seed production of crops is a widely used agricultural practice in different parts of the world. Hence, the claim falls within the scope of Section 3(h) of the Act.

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[11] BASE SE (OA/7/2019/PT/KOL) V. Deputy Controller Of Patents and Designs [IPDPTA/3/2023]

Biotech / IE-24:

Claim: A method for conserving water and controlling weed growth in cultivated soil, comprising removing Pistia (water lettuce) from water bodies, draining excess moisture, and spreading it over agricultural land to form a mulch layer that suppresses weeds, retains soil moisture, and enhances soil fertility.

Analysis: The invention presents a sustainable agricultural method aimed at improving water conservation and controlling weed growth by utilizing *Pistia* (water lettuce). This method involves the removal of *Pistia* from water bodies, followed by its spread over cultivated soil. The dense, mat-like structure of *Pistia* helps reduce water evaporation, conserving soil moisture and minimizing the need for irrigation, thereby supporting water-saving practices in farming. Additionally, its coverage inhibits the growth of weeds by blocking sunlight, reducing competition for resources and minimizing the need for chemical herbicides or manual weeding. This approach not only provides an environmentally friendly solution to managing invasive *Pistia* species but also promotes soil health by contributing organic matter as the plant decomposes. By addressing both water conservation and weed control, this method supports sustainable agricultural and horticultural practices. Hence, the method is considered not patentable as being a method of agriculture or horticulture.

15. **SECTION 3(i)**

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 a patentable subject matter.

In the context of Section 3(i), the Manual of Patent Office Practice & Procedure (Chapter 09.03.05.08) 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.
(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 animals 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 a few 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 of pathological conditions and further includes methods of abortion, induction of labour, control of estrous 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 instruments or apparatus. Also, the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable.

In the matter of **The Chinese University of Hong Kong vs. Assistant Controller of Patents**[12], the Hon'ble Madras High Court on 12th October, 2023, examined the scope of Section 3(i) of the Act. The Hon'ble Court analyzed various provisions of Section 3(i) and at paragraph 23, it stated that:

> *"23...A human being may be treated for a disease or disorder or condition by administering medicines, performing surgery or by administering therapy involving medicines or other forms of treatment such as radiation or a combination thereof. If such treatment is administered in order to cure the human being of a disease, it is curative. On the other hand, if medicine or vaccination is administered to prevent a human being from developing a disease or to prevent a more severe manifestation of such disease, it is prophylactic. The common thread running through the following categories - medicinal, surgical, curative, prophylactic and therapeutic - is that they are clearly methods of treatment of human beings."*

With respect to interpretation of the Term **'Diagnostic'**, at paragraphs 24 and 25, the Hon'ble Court stated that:

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[12] The Chinese University of Hong Kong vs. Assistant Controller of Patents [CMA (PT) No.1 of 2023, C.M.P. No.13206 of 2023 & W.P. No.7666 of 2023 & W.M.P. Nos.7828 & 7832 of 2023]

"24…The odd one out, as indicated above, is 'diagnostic'. Diagnosis, in the context of medical science, is a method of identifying the existence or non-existence of a disease or disorder or condition and/or the site, extent, severity or other aspects thereof. Undoubtedly, such identification per se cannot be construed as a form of treatment. Consequently, the expression "any process for the diagnostic treatment of human beings" does not make complete sense unlike in the case of the forms of treatment dealt with in Section 3(i) and discussed in the preceding paragraph…"

"25…When viewed in context, i.e. in association with "forms of treatment", I conclude that the word "diagnostic" should be limited to diagnostic processes that disclose pathology for the treatment of human beings…"

Scope of *In vivo* and *In vitro* Diagnosis: Regarding the scope of *in vivo* and *in vitro* diagnostic methods, at paragraph 26, the Hon'ble Court stated:

"26…As is evident from the language of Section 3(i), there is no indication therein that the word "diagnostic" should be confined to in vivo diagnosis…"

Examination and Analysis of Claims: In relation to the analysis of claims for determining the patentability of the subject matter, the Hon'ble Court, at paragraphs 41, 42, 46, and 50, observed that:

"41…the standard I propose is to examine the claims, in the context of the complete specification, to determine whether it specifies a process for making a diagnosis for treatment. Such determination should be made by assuming that a person(s) skilled in the art, including a medical doctor, examines the claims and complete specification. If it is concluded that a diagnosis for treatment may be made, even if such diagnosis is not definitive, it would be patent ineligible, whereas, if diagnosis for treatment cannot be made, it would be patent eligible…."

"42…I am of the view that the embodiments of a claimed invention are relevant only for the purpose of ascertaining whether the process of the claimed invention per se points to a diagnosis for treatment. If such process does not uncover pathology for any reason, it would not be diagnostic for purposes of Section 3(i)…"

"46… What is determinative, therefore, of whether a process is diagnostic is to ask the question whether the process is inherently and per se capable of identifying the disease, disorder or condition for treatment of the person…"

"46…If the person(s) skilled in the art would not be in a position to diagnose the disease, disorder or condition, as the case may be, on the basis of the process

because the process is not designed to diagnose diseases, disorders or conditions, such process, whether labelled as screening or anything else, would not qualify as diagnostic for purposes of Section 3(i)…"

"50…Although the claims delimit the scope and ambit of the monopoly claim, the embodiments set out in the complete specification can and should be examined to assess whether the process is per se diagnostic…"

Screening of Asymptomatic Persons under Section 3(i):

"44… In my view, if a screening test is capable of identifying the existence or non-existence of a disease, disorder or condition and/or the site, extent, severity or other aspects thereof for treatment of human beings, irrespective of whether the person concerned is symptomatic or asymptomatic, such screening test would qualify as a diagnostic test…"

Further, in the matter of ***Sequenom Inc. & Anr. v. The Controller of Patents***[13] (paragraph 79)**,** ***EMD Millipore Corporation v. Assistant Controller of Patents and Designs***[14] (paragraph 65), and ***Natera Inc. & Anr. vs. Assistant Controller of Patents & Designs***[15](Paragraph 79***)*** decided on 9th October 2025, the Hon'ble Delhi High Court interpreted the key features of **Section 3(i)** of the Patents Act as follows:

"the salient points for interpretation of Section 3(i) of the Act may be summarised as under:

(i) ***Products*** *used for diagnosis or therapeutic purposes, including* ***kits, equipment, machines, and physical products,*** *which satisfy the conditions of patentability* ***do not fall within the scope of exclusions under Section 3(i) of the Act*** *and would hence be patentable.*

(ii) A perusal of the various terminologies used in Section 3(i) of the Act shows that the exclusions are meant ***for processes which are employed by medical practitioners, para-medical personnel, nurses, etc****. The interpretation of key terms in Section 3(i) of the Act in the context of other provisions of the Act would be as under:*

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[13] Sequenom Inc. & Anr. v. The Controller of Patents [C.A.(COMM.IPD-PAT) 13/2022 & 448/2022]

[14] EMD Millipore Corporation v. Assistant Controller of Patents and Designs, [C.A.(COMM.IPD-PAT) 7/2021]

[15] Natera Inc. & Anr. vs. Assistant Controller of Patents & Designs [C.A.(COMM.IPD-PAT) 16/2023]

(a) ***'Medicinal process'*** *would mean processes which are used for administration of medicines such as a* ***process for oral administration, a process for administration through intravenous therapy, a process for administration of medicine through topical, transdermal or subcutaneous routes or a process through insertion of the medicine****, etc. but* ***would not include medicinal products, medicines, medical devices, or even patentable product by process inventions.***

(b) 'Surgical process' means a process of performing surgery. However, surgical tools, surgical implements including surgical methods using novel tools and implements would all be patentable. For example, ***the manner of conducting a colonoscopy or heart transplant surgeries, including the method for sutures or the manner of creating an incision****, etc., which are commonly used by surgeons* ***would not be patentable****. However, a* ***novel product*** *such as an innovative scalpel used in conducting the surgery* ***would be patentable.***

*(c) 'Curative process' - this terminology is quite ambiguous and vague, considering the various other terms and expressions used in Section 3(i) of the Act. Curative means "****treatments and therapies aimed at eliminating a disease, injury, or illness to restore a person's health to its prior state"****. Thus, a process adopted by a medical practitioner for curing or healing a disease would not be patentable, but tools and products or novel patentable methods used for the same would not be excluded.*

(d) 'Prophylactic process' means a process for prevention of disease, for example, a ***process of administering a vaccine or a process of conducting cancer screening, blood test etc****.,* ***would not*** *be patentable. However,* ***preventive tools, preventive products or preventive mechanisms*** *which qualify the test of patentability* ***would not be excluded.***

(e) 'Diagnostic process' - The ***manner in which diagnosis is performed would not be patentable****, for example, the manner of checking blood pressure using different tools, the manner of doing a swab test, the process of checking glucose levels, etc., would not be patentable. However,* ***diagnostic products, diagnostic tools, diagnostic devices are patentable*** *so long as they satisfy the test of patentability and they do not unfairly monopolize processes of diagnosis which are to be generally used by medical practitioners, nurses*

etc. ***It is also clear that Section 3(i) does not make any distinction between in vivo or in vitro processes.***

*(iii)***Tools** *which could be used for the purpose of diagnosis would also not be covered by the exclusion and* ***would be patentable****. However,* ***if tools only consist of software-based tools, which utilize data for the purpose of diagnosis, they would have to be examined under Section 3(k) of the Act for further technical effect and for satisfying the conditions for patentability.*** *In addition, it would have to be checked if these tools or processes by themselves give results which are capable of clear interpretation as to the existence or non-existence of a medical condition.*

(iv)The phrase ***"to render them free of disease or to increase their economic value"*** *qualifies* ***only treatment of animals*** *and not of human beings;*

(v) Mere identification of the ***regimen for the use of certain medicines*** *in a particular manner or frequency or form* ***would be excluded from patentability.***

*(vi)***Methods of treatment of plants** *are* ***not covered by Section 3(i) of the Act*** *and would be patentable so long as the test of Section 3(j) of the Act is satisfied."[emphasis added]*

Furthermore, in the matter of *Sequenom Inc. & Anr. v. The Controller of Patents*[16], the Hon'ble Court stated that:

"102. In the opinion of this Court, when the language of the Section 3(i) of the Act uses the word diagnostic, the same would include positive and negative diagnosis. The persons who are eliminated from undergoing further confirmation tests in respect of any medical condition, genetic abnormality etc., shows that there is a tangible result achieved by the method/ test which is being performed. It would defeat the purpose of Section 3(i) of the Act, if a test is held to be patentable merely because the test does not confirm the presence of a particular medical condition, although it does eliminate the need for further examination in respect of that medical condition."

16 Sequenom Inc. & Anr. v. The Controller of Patents [C.A.(COMM.IPD-PAT) 13/2022 & 448/2022]

Additionally in *Natera Inc. & Anr. v. Assistant Controller of Patents & Designs*[17], the Hon'ble Delhi High Court defined the term **"diagnosis"** and observed that:

> *"93…The term 'diagnosis' itself would mean the process of obtaining a result as to whether any particular medical condition exists or not as also the stage thereof, if any. It cannot be accepted that only those methods which **finally confirm** the presence of a particular illness, disease or medical condition would be a diagnostic method. In view of the discussion hereinabove on interpretation of diagnostic methods, where the result of performing a method would **initially confirm** the absence of a particular illness, disease, genetic defect, medical condition etc., or negation of the same in an individual, the said method would also fall within the scope of diagnosis - irrespective of the said method being performed as an in vivo or invitro test…"*

Applicability of Section 3(i) to Combination/Composition Claims

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.

Biotech / IE-25:

Claim: A method of treating a patient suffering from cancer with a combination of Gemcitabine and P1446A, comprising monitoring the progression or recession of cancer by detecting the gene signatures of oncogenic and tumor suppressor pathways, wherein the gene signatures are indicative of therapeutic response or resistance to the treatment.

Analysis: The subject-matter of claim is directed to a treatment regimen of a patient suffering from cancer, which is statutorily barred from the patentability under Section 3(i) of the Act, as being a method of treatment. Hence, the subject-matter of claim is not patentable.

Biotech / IE-26:

Claim: A method for diagnosing early-stage pancreatic cancer in a human subject, comprising the steps of:

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[17] Natera Inc. & Anr. vs. Assistant Controller of Patents & Designs [C.A.(COMM.IPD-PAT) 16/2023]

(a) obtaining a blood sample from the subject;

(b) detecting the expression level of biomarker X (SEQ ID NO:1) using a quantitative PCR assay;

(c) comparing the detected expression level with a reference level indicative of healthy individuals;

(d) diagnosing the subject as having early-stage pancreatic cancer if the expression level of biomarker X is at least 3-fold higher than the reference level.

Analysis: The subject matter of the claim attracts the provisions of Section 3(i) of the Patents Act, 1970 (as amended), as it pertains to a method for the diagnosis of a disease in human beings. Specifically, the claimed method involves detecting the expression level of biomarker X and comparing it with a reference value indicative of healthy or diseased individuals, thereby constituting a diagnostic process carried out on the human body.

16. SECTION 3 (j)

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 a patentable subject matter.

Although micro-organisms are excluded from the 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(s) occurring in nature, are patentable subject matter under the Act.

Claims relating to essential biological processes of growing plants, germination of seeds, or development stages of plants and animals shall be objected under Section 3 (j) of the Act.

In the matter of **BTS Research International Pty Ltd (SR/55/2020/PT/KOL) Vs. The Controller General of Patents & Designs, Mumbai & Ors. (IPDPTA 56 OF 2023)**, the Hon'ble Calcuta High Court on 03rd April, 2025[18], examined the scope of "*essentially biological process",* Section 3(h) of the Act, it stated that:

> *14. A process is "essentially biological" if it consists entirely of natural phenomena such as of crossing or the like. The crucial question is how much of human intervention is necessary for a process which involves biological steps not to be classified as an essentially biological process? This can only be judged*

[18] **BTS Research International Pty Ltd [IPDPTA 56 OF 2023]**

on the basis of the essence of the invention after taking into account the totality of human intervention and its impact on the result achieved [Plant Bioscience/Broccoli, T 83/05 (2007) OJ EPO 644; G 2/07 (2012) OJ EPO 130 (EBA); Plant Bioscience/Broccoli II, T 83/05 (2014) OJ EPO A39; G 2/13 (2016) OJ EPO A28 (EBA)]. Hence, while each step of an invention might be characterized as biological, the arrangement of steps as a whole should also represent an essential modification of a known biological process. In order to fall within the category of "essentially biological", what requires to be ascertained is the extent to which a process should be non-biological before it loses the status of "essentially biological". The overall degree of human intervention in the process has to be taken into consideration. As such, the totality of human intervention and its impact or the results achieved is what is required to be determined. Thus, an invention has to be judged as a whole. (Sakata Seed Corporation vs. The Controller of Patents and Design, Order dated 19.7.2024 in CMA (PT) No.30/2023, Madras High Court, Speaking Roses International Inc. vs Controller-General of Patents & Ors MANU/MH/0194/2007 and Monsanto Technology LLC vs The Controller of Patents & Designs & Anr. 2013 SCC Online IPAB 106).

Biotech / IE-27:

Claim: A genetically modified rice plant comprising an inserted transgene of sequence ID 1 encoding a drought-responsive transcription factor, wherein the plant exhibits enhanced drought tolerance compared to wild-type rice.

Analysis: The claim is for a genetically modified rice plant, which is a plant in whole or in part. Even though the plant is genetically engineered, it remains excluded from patentability regardless of the method of modification. The insertion of a transgene does not change its exclusion status under Section 3(j).

Such subject matter may be protectable under the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act and not under the Patents Act 1970.

Biotech / IE-28:

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)

According to Section 3(k) of the Act, *"a mathematical or business method or a computer programme per se or algorithms"* is not a patentable subject matter.

Bio-informatics 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.

Biotech / IE-29:

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 learning method so as to increase a correlation between first space expressing the first characteristic amount and second space expressing the second characteristic amount.

Analysis: The claimed invention pertains to a data processing method that employs mathematical modeling and machine learning techniques to establish correlations between chemical and biological data. The method predominantly comprises computational steps such as vector transformation and multivariate analysis, without demonstrating any specific technical application or producing a tangible product. As the claimed subject matter is limited to software-based simulations and algorithmic processes, and lacks a technical contribution, it falls within the scope of a computer program per se or an algorithm. Accordingly, the claim is objected under Section 3(k) of the Patents Act, as it is not considered patentable subject matter in India.

Biotech / IE-30:

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 computer-assisted method involving algorithmic or computational steps for compound design 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)

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 invention.

In the matter of ***The Zero Brand Zone Pvt. Ltd. and others Vs Controller of Patents and others***[19]**,** the Hon'ble High Court of Madras on 05th July, 2024, at paragraphs 10 and 11 observed that:

> *"10…it is evident that the object and purpose of inserting clause (p) was to prevent the creation of a monopoly over traditional knowledge, including by aggregating the known properties of traditionally known components. It should also be noticed that the expression "traditional knowledge" is not qualified by the words "per se", unlike the expression "computer programme per se" in Section 3(k). It should, however, also be noticed that the exclusion is not intended to completely shut out inventions that draw on traditional knowledge provided the patent applicant is able to establish that the product or process can no longer be described as being, in effect, traditional knowledge…"*

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[19] The Zero Brand Zone Pvt. Ltd. and others Vs Controller of Patents and others [(T) CMA (PT) No.146 of 2023]

"11…In the Patents Act, Section 3(p) provides defensive protection of traditional knowledge by excluding inventions which are "in effect" traditional knowledge from patent eligibility. The term "in effect" in the provision ensures that there is no circumvention of the prohibition by concealing the usage of traditionally known components or their properties in a claimed invention…"

For the examination of TK related subject matters, separate guidelines have already been issued by the Office of CGPDTM.

Biotech / IE-31:

Claim: A serum derived from a pigeon, wherein the serum possesses anti-paralysis activity.

Analysis: The use of pigeon serum for the treatment of paralysis (as it possesses anti-paralytic activity) is a traditional knowledge in India. It is clearly evident from prior art, 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, (Table I), which discloses the use of pigeon blood for treating paralysis.

Part C: Section 10 requirements

19. SUFFICIENCY OF DISCLOSURE, CLARITY & SUPPORT OF THE CLAIMS

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 the 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 of 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 said to be 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 the matter of **Raj Praksh vs Mangatram Chowdhury**[20], following **Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruninga Corporation etc. Vs. Unichem Laboratories and Ors**.[21], the Hon'ble Court stated that:

> *"16…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…".*

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[20] Raj Praksh v Mangatram Chowdhury [AIR 1978 Del 1]

[21] Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruninga Corporation etc. Vs. Unichem Laboratories and Ors. [AIR 1969 Bom 255]

In the matter of **The Regents of The University Of California Vs Controller General Of Patents, Designs &Trademarks & Anr. [C.A.(COMM.IPD-PAT) 143/2022**[22]] on 05.02.2024, Hon'ble Delhi High Court at para 10 and 22 observed that

> *"10… It is, therefore, evident that amendments to the original application can be made only by way of the following: -*
>
> 1. *Disclaimer; or*
> 2. *Correction; or*
> 3. *Explanation.*
>
> *Additionally, the proposed amendments are tested against the following parameters:*
>
> 4. *Amendment should serve the purpose of incorporation of actual facts;*
> 5. *Effect of the amendment should not allow matter not in substance, disclosed originally or shown in the specification;*
> 6. *Amended claim of the specification should fall within the scope of the original claim of the specification…"*

> *"22…Thus, in the opinion of this Court, the amendments serve only as an explanation to the original claims, amount to incorporation of actual facts, and do not disclose any matter which was not originally disclosed in the claims of specification filed before the amendment…"*

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

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[22] The Regents of The University of California Vs Controller General of Patents, Designs &Trademarks & Anr. [C.A. COMM.IPD-PAT 143/2022]

conditions are not specifically disclosed and if the skilled person needs to perform undue experimentation to achieve the desired result.

Where the specification discloses the use of biological material, the source and geographical origin of such material shall be disclosed to meet the enablement requirement as per Section 10(4)(d)(ii) of the Act.

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.

Biotech / IE-32:

Claim: A method comprising: (i) contacting polypeptide X with a test compound and determining whether the compound modulates the activity of the polypeptide X; and (ii) formulating a compound that has been identified as modulating the activity of polypeptide X into a pharmaceutical composition.

Analysis: Any method that merely screens undefined compounds does not lead to a specific result or product. Claims resulting from such methods are perceived 'reach through' claims extending to unidentified materials. In the absence of any knowledge of any relationship between the polypeptide X, its therapeutic application and the screened compounds, either from the specification or from common general knowledge, a person with average skill and average knowledge in the art would not know how to produce and use these 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 in step (i) is not specified.

Biotech / IE-33:

Claim: An antigen-binding molecule comprising:

(b) a first antibody variable region capable of binding to a first antigen and a second antigen, but not simultaneously, wherein one of the first and second antigens is a T-cell receptor-associated molecule and the other is a non-T-cell receptor molecule expressed on an immune cell; said first antibody variable region comprising a heavy chain variable domain (VH) with CDR3 having a sequence at least 80% identical to the sequence XYZ;

(c) a second antibody variable region capable of binding to a third antigen distinct from the first and second antigens, wherein the third antigen is a tumor-associated antigen;

wherein the antibody variable regions comprise a light chain variable domain (VL) and a heavy chain variable domain (VH), and wherein the binding specificity to the second antigen is introduced via amino acid substitutions or insertions within the complementarity-

determining regions (CDRs) or framework regions (FRs) of the heavy or light chain variable domains at structurally relevant positions for antigen binding.

Analysis: The claim lacks sufficient disclosure for a skilled person to reproduce the invention without undue experimentation, as it broadly defines an antigen-binding molecule without providing concrete examples demonstrating how the numerous possible combinations, substitutions, or insertions confer selective binding to antigens. While it specifies that the first antibody variable region includes a CDR3 sequence with at least 80% identity to XYZ, the description fails to provide experimental data substantiating that all antibodies within this sequence identity range exhibit significant antigen-binding activity. Additionally, while the claim states that binding specificity to the second antigen is introduced via substitutions or insertions in the CDRs or FRs, it does not specify the exact amino acid changes, their impact on binding affinity, or whether all modifications within the claimed positions produce a functional antibody. The broad and undefined nature of the terms "T-cell receptor-associated molecule" "non-T-cell receptor molecule expressed on an immune cell" and "tumor-associated antigen" further obscures the claim's scope, making it unclear which antigens are encompassed. Without detailed sequence information, structural guidance, or experimental validation, a person with average skill and average knowledge in the art would be required to undertake excessive trial and error, rendering the invention non-enabling under sufficiency requirements.

Biotech / IE-34:

Claim: A method for evaluating a biological sample, the method comprising:

i. obtaining a biological sample from a patient,
ii. extracting biomarker data from the sample,
iii. processing the biomarker data using at least one machine learning model, wherein the processing includes feature extraction using a first neural network,
iv. classification of biomarkers using a second neural network, and
v. generating an output, wherein the output is compared against reference data to determine a clinical outcome.

Analysis: The claim refers broadly to "at least one machine learning model" and multiple neural networks (NNs) for feature extraction, classification, and output generation. However, the description does not specify the type of neural networks used, the architecture of these networks, the training methodology, and preferable Machine learning model architectures. In the absence of necessary guidance in the complete specification, a person with average skill and average knowledge in the field would face an undue burden in implementing the method without extensive experimentation.

20. 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 the 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.

Divisional Application in context to plurality of Invention

Moreover, a patent applicant may file one or more further applications if the application does not satisfy the requirements of unity of invention under the provision of Section 16 of Patent Act. Please refer to chapter 06.01 of Manual for Patent Office Practice and Procedures.

In the matter of Syngenta Limited Vs Controller of Patents C.A.(COMM.IPD-PAT) 471/2022, dated 13th October 2023[23], Para 18 of the Divisional bench of Delhi High Court Order noted that;

> *"Section 16(1) in unambiguous terms enables the filing of a further application in respect of an invention, provided it is disclosed in the provisional or complete specification already filed. As the learned Judge rightly observes there appears to be no justification to restrict the filing of a Divisional Application only to a situation where the plurality of inventions is found in the claims. The significance of the provision using the expression "disclosed in the provisional or complete specification" can neither be ignored nor discarded."*

Further, Para 32 of the said Court Order hold that;

> *"...a Divisional Application moved in terms of Section 16 of the Act would be maintainable provided the plurality of inventions is disclosed in the provisional or*

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[23] Syngenta Limited Vs Controller of Patents [C.A.(COMM.IPD-PAT) 471/2022 Syngenta Limited Vs Controller of Patents [C.A.(COMM.IPD-PAT) 471/2022]

complete specification that may have been filed. We are further of the considered opinion that Section 16 does not suggest or conceive of a distinction between the contingency of a Divisional Application when C.A.(COMM.IPD-PAT) 471/2022 moved by the applicant of its own motion or where it comes to be made to remedy an objection raised by the Controller. In either of those situations, the plurality of inventions would have to be tested based upon the disclosures made in either the provisional or complete specification."

Examples of *a priori* determination of prior art is given as herein below:

Biotech / IE-35: *A PRIORI* DETERMINATION OF UNITY OF INVENTION:

Claims:

1. A DNA construct for improved expression of a heterologous or homologous polypeptide comprising: (a) isolated DNA sequence of (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*.

Biotech / IE-36: *A POSTERIORI* DETERMINATION OF UNITY OF INVENTION:

Claims:

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 under section 10 (5) of the Act:

Group I: Claim 1 drawn to 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.

Group II: Claim 2 drawn to 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.

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 and 2 failed to meet the requirements of Section 10(5) of the Act. Consequently, the application may be objected to for lacking unity *a posteriori*.

21. DEPOSITION OF BIOLOGICAL MATERIAL

If the invention mentions a biological material in the specification, which is not available to the public and is not described in such a way as to satisfy the requirements of clauses (a) and (b) of the Section 10(4)(d)(ii) of the Act such material shall be deposited with an International Depository Authority (IDA) recognized 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 in the specification including the name, address of the depository institute and the date and number of the deposit.

Depository Authorities:

The International Depository Authorities in India under the Budapest Treaty are:

1. **Microbial Type Culture Collection and Gene Bank (MTCC)**
   Institute of Microbial Technology (IMTECH), CSIR-Institute of Microbial Technology, Sector 39-A, Chandigarh - 160036, India.
   Website- https://mtccindia.res.in/

2. **Microbial Culture Collection (MCC)**
   National Centre for Cell Science (NCCS), Savitribai Phule Pune University Campus, Ganeshkhind, Pune - 411007, Maharashtra, India.
   Website: http://www.nccs.res.in

3. **National Agriculturally Important Microbial Culture Collection (NAIMCC)**
   ICAR-National Bureau of Agriculturally Important Microorganisms Kushmaur, Mau Nath Bhanjan - 275103, Uttar Pradesh, India.
   Website: https://nbaim.icar.gov.in

Reference to IDA under the Budapest Treaty under Section 10(4) should be read with Section 2(1)(aba) of the Act.

Disclaimer

1) The guidelines set out above 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 shall prevail. The Guidelines are dynamic and the Patent Office will update the same as and when required.

2) The Case Laws as mentioned in the guidelines are for interpretation pertaining to relevant Sections of The Patent Act, 1970 and purely dynamic in nature.

[End of document]