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GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY PATENT APPLICATIONS

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BIOTECHNOLOGY

THE FUTURE OF HUMANITY

CONTENTS

INTRODUCTION

Biotechnology is the use of biological systems found in organisms or the use of the living organisms themselves to make technological advances and adapt those technologies to various fields. This term is very broad and includes the use of traditional or conventional breeding, as well as more modern techniques such as genetic engineering.

American Chemical Society defines biotechnology as the application of biological organisms, systems, or processes by various industries to learning about the science of life and the improvement of the value of materials and organisms such as pharmaceuticals, crops, and livestock. Per the European Federation of Biotechnology, biotechnology is the integration of natural science and organisms, cells, parts thereof, and molecular analogues for products and services.

Biotechnology is the basis for numerous processes for the production of food and feed, pharmaceuticals, chemical products and energy sources. It is also the technology that prepares raw biological materials and systems (cells and their components) for use in such processes.

History of biotechnology can be divided into 3 phases: ancient, classical and modern biotechnology. Ancient Biotechnology involves using living organisms in the production of food and medicine. It dates back several thousand years to when people inadvertently discovered the usefulness of one-celled organisms like yeasts and bacteria. The ancient Egyptians, for example, used yeast to brew beer and to bake bread, in Egypt at ca. 4000 b.c.

Classical Biotechnology existed from 1800 to almost the middle of the twentieth century. The age-old fermentation process for producing alcohol, isolation of antibiotics from molds or other micro-organisms are only a few examples of classical biotechnology.

Modern biotechnology is a term adopted by international convention to refer to biotechnological techniques for the manipulation of genetic material and the fusion of cells beyond normal breeding barriers. It is used to distinguish newer applications of biotechnology. It was upgraded by using genetic engineering. The new era of modern biotechnology came through the discovery of genes made of DNA. Modern biotechnology is expected to lead to important breakthroughs in many fields, such as health, food, energy, and the environment.

A biological patent is a patent on an invention in the field of biology that by law allows the patent holder to exclude others from making, using, selling, or importing the protected invention for a limited period of time. Biotechnological inventions are applied in a wide range of fields including: agriculture, agro-industry, fertilizers, the food industry, diagnostics, zootechnics, semi-conductors, pharmaceuticals, the refuse industry, fuels, chemistry, etc.

The Egyptian patent system allows biotechnology patent protection to be obtained for products and processes. In the context of bioscience inventions, patents are often granted for products such as polypeptides, chimeric/humanized antibodies, monoclonal antibodies and amino acid sequences that do not exist in nature, genetically modified microorganisms, biofertilizer,biopesticide,culture, vaccines and pharmaceuticals; and methods such as methods of producing product, methods of isolation of microorganisms from culture medium, methods of mutation, processes for making monoclonal antibodies, etc.

This guide provides guidance on how to construe claims commonly encountered in applications for biotechnological inventions and help examiners to assess the patentability of biotechnological inventions and determine whether a claimed invention is novel, inventive or has industrial application.

BIOTECHNOLOGY PATENT APPLICATION FORMAT

01. >> ABSTRACT

The abstract of a biotechnology patent application is a short summary (100 words or fewer) that communicates a short description of the invention written by the applicant(s). The abstract enables the patent office and the public to quickly determine the content of the patent. Although the "abstract shall not be used for interpreting the scope of the claims,".

02. >> BACKGROUND OF THE INVENTION

- Typically drafted for an Examiner
- Selected Prior art in the field is discussed to emphasize differences with the current invention.

03. >> PROBLEMS AND FAILURE OF THE PRIOR ART

- It compares selected art in the field with the current invention and explains the needs for the current invention.
- Discusses problem(s) associated with the prior art.

04. >> THE NEW TOPICS IN THE INVENTION

Distinct from the abstract and summarizes the scope of the invention i.e. independent claims.
- Meant to discuss the invention (i.e., the claims) rather than the disclosure as a whole.
- The advantages of the invention or explain show it solves problems existing in the art.

05. >> DETAILED DESCRIPTION OF THE INVENTION

The detailed description of the invention is the most substantial section of the patent. It is made up of two sections: the first section explains the invention and how to practice it; Second section: specific examples of the invention how to practice the invention i.e. Enablement and Best Mode Examples

06. >> EXPLOITATION METHOD

It mentions the best way in which the invention is exploited in the field of biotechnology and industry.

07. >> CLAIMS

- Claims drafting is one of the most important element of patent application.

- It is an art as well as science: it is important to ensure that the scope of protection is adequately mentioned and scientific knowledge of what is to be protected should be known.

Each claim must be written as a single sentence. A claim is presented in two parts, the preamble and the body, with a transition word or phrase between them.

• The preamble is an introductory statement that names the subject of the claim. For example, the preamble of claim 1. is: "A method for making a genetically modified plant."

• The body of the claim describes the elements or steps that compose the claimed subject. In claim 1, the body of the claim consists of the steps of "stably transforming ..." and "regenerating ..."

• The transition words or phrases between the preamble and the body of the claim indicate whether the claim encompasses at least the listed elements or steps or whether the claim encompasses only the listed elements or steps. The transition word comprising means "including the following elements but not excluding others. "

Furthermore, there are two kinds of claims: independent and dependent.

Independent claim : stands alone
- includes all the necessary limitations
- does not depend on or include limitations from any other claim.

Dependent claim : refers back to another claimor claims
- Further limits another claim or claims
- includes all the limitations of the claim incorporated by reference

08. >> FIGURES

Any graphs (for example, illustrating experimental data from the examples) are included in separate sheet after the claims in the figure section, while the technical drawings are included at the end of the patent description.

09. >> SEQUENCE LISTING

For the invention including nucleic acid and/or amino acid ,sequence listing must be submitted by computer readable form (CRF).

10. >> DEPOSIT (MICROORGANISMS) :

Where the invention involves micro-organisms, the applicant shall disclose the identity of such organisms and deposit a live culture thereof with the authority designated in the Regulations.

CHAPTER I
GLOSSARY

ADULT STEM CELLS: are undifferentiated cells, found throughout the body after development, that multiply by cell division to replenish dying cells and regenerate damaged tissues.

ANTIBODY STRUCTURE: Antibodies are immune system-related proteins called immunoglobulins. Each antibody consists of four polypeptides– two heavy chains and two light chains joined to form a "Y" shaped molecule. The Antibodies are divided into five major classes, IgM, IgG, IgA, IgD, and IgE, based on their constant region structure and immune function.

ANTIBODY: The term encompasses the various forms of antibody structures including but not being limited to whole antibodies and antibody fragments.

ANTIGEN: Any substance (or molecule) capable of inducing a specific immune response. Antigens include a wide variety of plant and microorganism components or toxins.

ANTIGEN-BINDING PORTION OF AN ANTIBODY: The term "antigen-binding portion of an antibody" refers to the amino acid residues of an antibody which are responsible for antigen-binding. The antigen-binding portion of an antibody comprises amino acid residues from the "complementary determining regions" or "CDRs".

AUTOIMMUNE DISEASE: Any disease caused by the immune system's erroneous and destructive actions on the body's own tissues, such as thyroiditis, myocarditis, glomerulonephritis, and lupus erythematosus.

BACTERIA: Most common group of microbes. Essential to life; many reside naturally in the body. Cause disease when a person is compromised.

B-CELLS (OR B-LYMPHOCYTES): Thymus-independent, bursa-equivalent lymphocytes produced by bone marrow to populate all lymphoid organs and tissues. They are capable of producing antibodies and maturing into plasma

cells. B-cells express antibody on their surfaces that can respond to foreign protein, polysaccharide, and lipid antigens in soluble form.

CODING SEQUENCES "CDS": The portion of gene that is transcribed into mRNA & translated into protein is known as coding sequences.

CYTOKINES: Small peptide molecules released by a variety of cells. Acting in the nature of hormones, apocrines, and/or paracrines, they allow intercellular communication and stimulate a diverse variety of responses by target cells. Cytokines include, but are not limited to, interleukins, interferons, and colony stimulating factors.

CYTOTOXIC T CELL: (also known as TC, cytotoxic T lymphocyte, CTL, T-killer cell, cytolytic T cell, CD8+ T-cell or killer T cell) is a T lymphocyte (a type of white blood cell) that kills cancer cells, cells that are infected (particularly with viruses), or cells that are damaged in other ways.

DEOXYRIBONUCLEIC ACID (DNA): Deoxyribonucleic acid, or DNA, is a molecule that contains the instructions an organism needs to develop, live and reproduce. These instructions are found inside every cell, and are passed down from parents to their children.

DISSOCIATION CONSTANT (Kd): Dissociation constant (Kd) indicates the strength of binding between A (antibody) and B (antigen) in terms of how easy it is to separate the complex AB. The smaller Kd, the stronger the binding between A and B. stronger the affinity of the antibody.

DORMANT SPORES: If a spore is faced with unfavourable conditions, such as lack of nutrients, low temperature, an unfavourable pH or the presence of an inhibitor (for example, on a surface of a plant), the spore remains dormant and delays germination.

EPITOPE: The term "epitope" includes any polypeptide determinant capable of specific binding to an antibody. An epitope is a region of an antigen that is bound by an antibody.

FUNGUS: is any member of the group of eukaryotic organisms that includes microorganisms such as yeasts and molds, as well as the more familiar mushrooms. These organisms are classified as a kingdom, separately from the other eukaryotic kingdoms, those being Plantae, Animalia, Protozoa, and Chromista.

GENOME: is the complete set of genetic information in an organism. It provides all of the information the organism requires to function. In living organisms, the genome is stored in long molecules of DNA called chromosomes.

GRAM NEGATIVE BACTERIA: Bacteria which appear red/pink following a staining process.

GRAM POSITIVE BACTERIA: Bacteria which retain a purple color when subjected to a staining process.

HALF MAXIMAL INHIBITORY CONCENTRATION, IC50: The half maximal inhibitory concentration (IC50) is a measure of the potency of a substance in inhibiting a specific biological or biochemical function.

HUMAN LEUKOCYTE ANTIGEN (HLA) SYSTEM: is an important part of the immune system and is controlled by genes located on chromosome 6. It encodes cell surface molecules specialized to present antigenic peptides to the T-cell receptor (TCR) on T cells.

HYBRID SEED: In agriculture and gardening, hybrid seed is produced by cross-pollinated plants. Hybrid seed production is predominant in modern agriculture and home gardening.

IMMUNITY: High protective resistance to a disease threat that is produced by the immune system or by some other nonspecific protective mechanism.

IMMUNIZATION: is the process by which an individual's immune system becomes fortified against an agent (known as the immunogen).

IMMUNOGLOBULIN: An antibody of one of several types (IgA, IgD, IgE, IgG, IgM).

INFLAMMATION: The body's response to infection. Signs/symptoms': redness, heat, swelling (edema), pain, pus.

INTERLEUKIN: Cytokine that permits communication among white blood cells and other tissues.

ISOLATED NUCLEIC ACID: An "isolated" nucleic acid refers to a nucleic acid molecule that has been separated from a component of its natural environment. An isolated nucleic acid includes a nucleic acid molecule contained in cells that ordinarily contain the nucleic acid molecule, but the nucleic acid molecule is present extra chromosomally or at a chromosomal location that is different from its natural chromosomal location.

LURIA-BERTANI (LB) BROTH: is the most widely used medium for the growth of bacteria.

MAJOR HISTOCOMPATIBILITY COMPLEX (MHC): group of genes that code for proteins found on the surfaces of cells that help the immune system recognize foreign substances.

MEMORY CELLS: Lymphocytes that have previously responded to a specific antigenic stimulus. They survive for exceedingly long periods and can respond rapidly to the same antigen.

MONOCLONAL ANTIBODIES: The terms monoclonal antibody (mAb or moAb) are antibodies that are made by identical immune cells that are all clones of a unique parent cell. Monoclonal antibodies can have monovalent affinity, in that they bind to the same epitope.

MULTIPLICATION OF THE BACTERIA: Under optimum conditions, bacteria are capable of multiplying indefinitely at a very rapid rate, so that their numbers may double every 20 min or so.

NEUTRALIZING ANTIBODY: A neutralizing antibody (NAb) is an antibody that defends a cell from an antigen or infectious body by neutralizing any effect it has biologically. An example of a neutralizing antibody is diphtheria antitoxin, which can neutralize the biological effects of diphtheria toxin.

ONCOFETAL ANTIGEN IMMATURE LAMININ RECEPTOR (OFA/iLR): is a multifunctional protein expressed by various tumors, including breast, lung, ovary and prostate carcinoma as well as lymphoma. OFA-iLR has been implicated in tumor invasiveness, metastasis and growth.

PARASITEMIA: is the quantitative content of parasites in the blood. It is used as a measurement of parasite load in the organism and an indication of the degree of an active parasitic infection.

PLASMID: is a small, circular, double-stranded DNA molecule that is distinct from a cell's chromosomal DNA. Plasmids naturally exist in bacterial cells, and they also occur in some eukaryotes. Often, the genes carried in plasmids provide bacteria with genetic advantages, such as antibiotic resistance.

PROLIFERATION ASSAY: is an assay that can be used to determine whether or not cells are triggered to divide after exposure to a specific stimulus, or to assess differences between cell populations in their ability to divide in

response to the same stimulus.

SPORE: is a reproductive cell capable of developing into a new individual without fusion with another reproductive cell. Spores are agents of asexual reproduction, they are produced by bacteria, fungi, algae, and plants.

T-CELLS (OR T-LYMPHOCYTES): Thymus gland-dependent lymphocytes responsible for the development and maintenance of cell-mediated immunity. T-cells recognize only short peptide sequences on intracellular protein antigens expressed on cell surface membranes; T-cells may exert a helper, suppressor, or effector function.

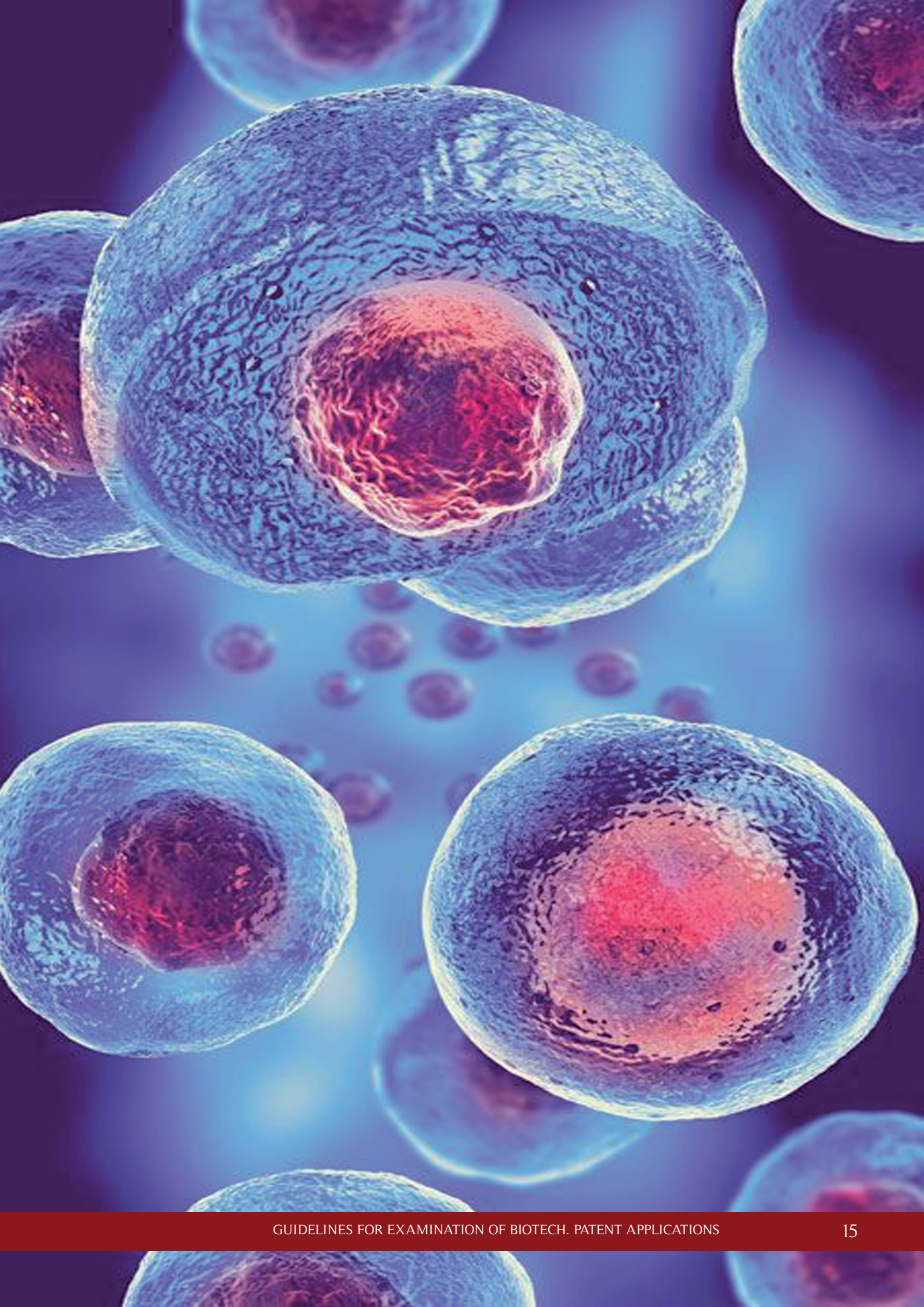
T HELPER CELLS (Th CELLS):are a type of T cell that play an important role in the immune system, particularly in the adaptive immune system.

THE HUMANIZATION PROCESS: The process of "humanization" is usually applied to monoclonal antibodies developed for administration to humans (for example, antibodies developed as anti-cancer drugs). Humanization can be necessary when the process of developing a specific antibody involves generation in a non-human immune system (such as that in mice). The protein sequences of antibodies produced in this way are partially distinct from homologous antibodies occurring naturally in humans, and are therefore potentially immunogenic when administered to human patients.

TOXIN: Poisons released by microorganisms.

VECTOR: The term "vector," as used herein, refers to a nucleic acid molecule capable of propagating another nucleic acid to which it is linked. The term includes the vector as a self-replicating nucleic acid structure as well as the vector incorporated into the genome of a host cell into which it has been introduced. Certain vectors are capable of directing the expression of nucleic acids to which they are operatively linked. Such vectors are referred to herein as "expression vectors".

VIRUS: Small, simple structured "particle" reliant of its host for survival.



CHAPTER II

UNITY

Article (12) of Egyptian Patent Law:

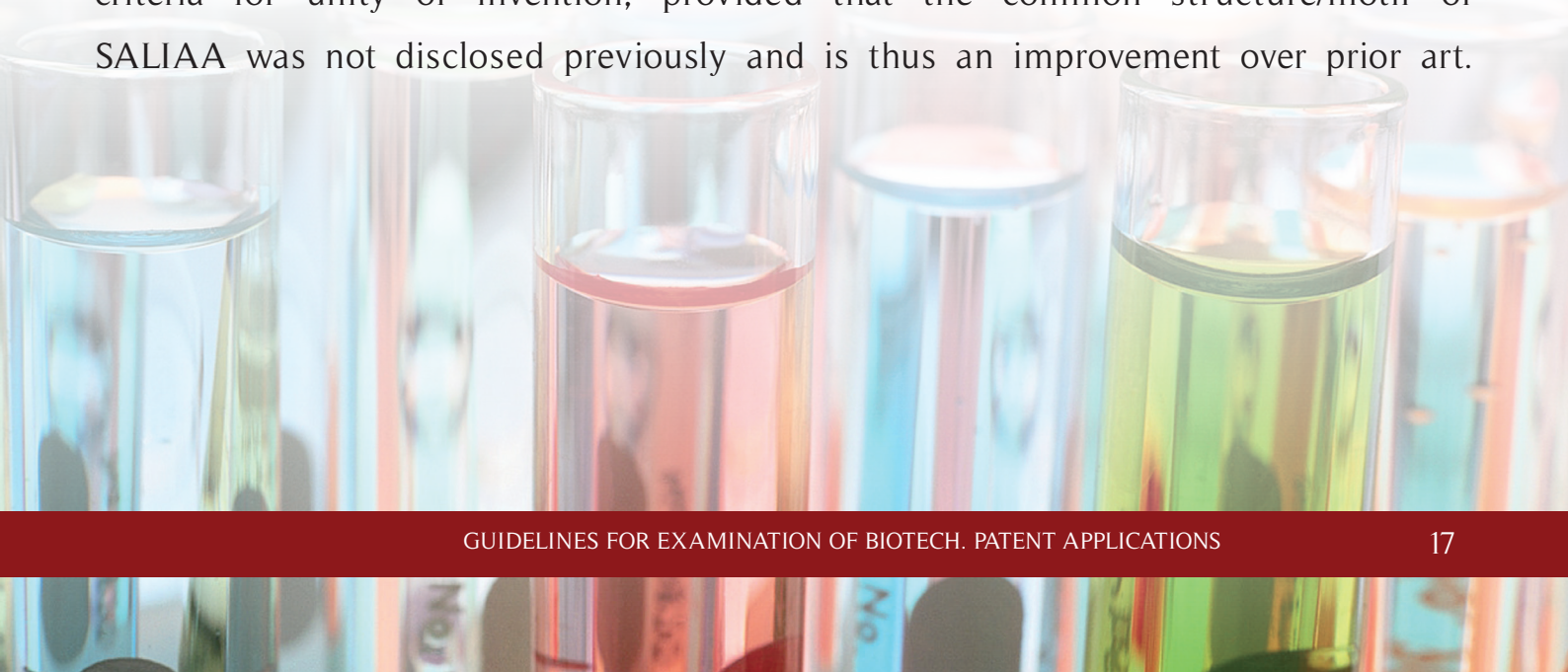
The patent application shall be filed by the inventor or his successor in title with the Patent Office, in accordance with the terms and conditions prescribed by the Regulations. An application may not contain more than one invention. A group of inventions so linked as to form an integrated inventive concept shall be considered as one invention.

Egyptian Patent Law demands that the application shall relate to one invention only or to a group of inventions so linked as to form single general inventive concept. Article (12) demands that this requirement shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

For instance, when a plurality of known proteins, A, B, C, and D are newly identified as recombinant fusion proteins for producing milk proteins in plants, those proteins cannot be claimed in one application even though they have the same use as recombinant fusion proteins for producing milk proteins in plants unless special technical features contributing to their use are based on common structural or functional characteristics of those proteins.

In one example, the new specifications describe an invention claiming an isolated antibody which binds an epitope on human Cadherin-17 comprising a heavy chain variable region comprising an amino acid sequence set forth in a SEQ ID NO: selected from the group consisting of 1, 2, 3, 4 and 5 and a light chain variable region comprising an amino acid sequence set forth in a SEQ ID NO: selected from the group consisting of 6, 7, 8, 9 and 10 and there are no sequence homologies or structural similarities among the above claimed antibodies, the only common technical feature shared by the claimed antibodies is the function of binding an epitope on human Cadherin-17. Since that function was already known in the art, the claimed peptides fail to meet the unity requirement.

In another example, the revised specifications state that "polypeptides capable of increasing abiotic stress tolerance wherein the polypeptides are at least one selected from the group of PATVSALIAALGYADNF, ADSALIAAEEWTGFL, KPVLIDGSALIAAPNTM, and TQWSYYRESALIAAGFG" could meet the criteria for unity of invention, provided that the common structure/motif of SALIAA was not disclosed previously and is thus an improvement over prior art.



CASE STUDY

>> An application discloses:

Claim 1: A method for producing a transgenic herbicide tolerance plant by integrating a dsRNA into the genome of plant cell, wherein said dsRNA confers herbicide tolerance in plant.
Claim 2: The method for producing a transgenic plant, according to the previous claim, wherein the dsRNA is miRNA with nucleotide sequences selected from the group consisting of SEQ ID NO: n1, SEQ ID NO: n2, SEQ ID NO: n3, SEQ ID NO: n4 and SEQ ID NO: n5.

>> There are no sequence homologies among miRNA nucleotide sequences, that confer herbicide tolerance for plant.

Material: D1

>> Analysis of the prior art:

D1 discloses a transgenic plant comprising, into the genome of said plant, a heterogenous RNA molecule with SEQ ID NO: n9, wherein said dsRNA molecule confers herbicide tolerance in plant.

>> Analysis of the Unity Requirements:

The common technical inventive concept of the miRNA nucleotide sequences mentioned in the claims shares single special technical feature which is all miRNA nucleotide sequences confer herbicide tolerance for plant, but in view of D1, this special technical feature is neither distinguished nor different from the miRNA nucleotide sequences of the prior art (i.e. the present application fails to make a contribution over the prior art), so there is no single general inventive links the group inventions, so the claims lacks unity.

CHAPTER III

NOVELTY

Article (1) of Egyptian Patent Law:

A patent shall be granted, in accordance with the provisions of this Law, to any industrially applicable invention, which is new, involves an inventive step, whether connected with new industrial products, new industrial processes, or a new application of known industrial processes.
The patent is also granted, independently, for any modification, improvement or addition to a previously patented invention, which meets the criteria of being new, inventive and industrially applicable, as stated in the preceding paragraph; in which case the patent shall be granted, under the provisions of this Law, to the owner of the modification, improvement or addition.

Novelty is requirement for a patent claim to be patentable. In contrast, if an invention was known to the public before filing a patent application, or before its date of priority, if the priority of an earlier patent application is claimed, the invention is not considered new and therefore not patentable.

To assess the novelty of an invention, a search through what is called the prior art is usually performed, the term "art" referring to the relevant technical field. A prior art search is generally performed with a view to proving that the invention is "not new" or old. No search can possibly cover every single publication or use on earth, and therefore cannot prove that an invention is "new". A prior art search may for instance be performed using a keyword search of large patent databases, scientific papers and publications, and on any web search engine. However, it is impossible to guarantee the novelty of an invention, even once a patent has been granted, since some little known publication may have disclosed the claimed invention.

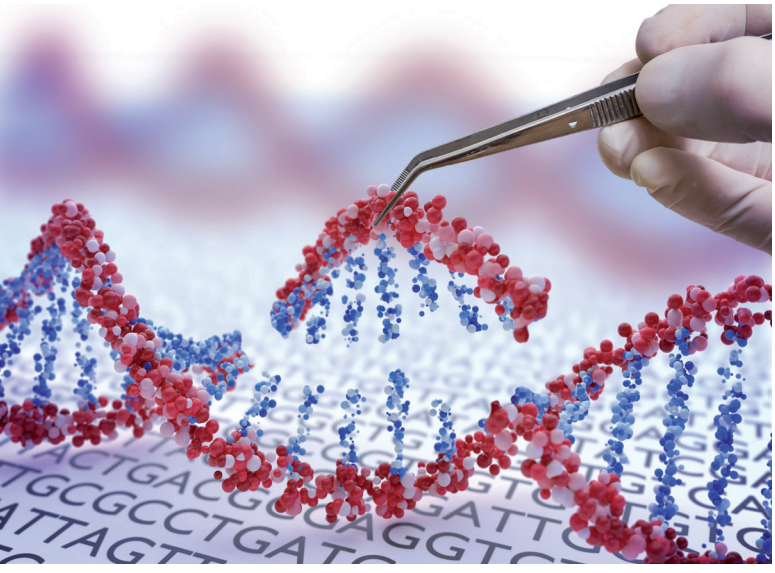
PRODUCT-BY-PROCESS CLAIMS

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:

The human nerve growth factor (b-NGF) producedby genetic engineering techniques is almost the same as that isolated from human placental tissue. Using product-by-process to claim engineering b-NGF thus was rejected by the patent examiner.

On the other hand, a product claim of erythropoietin (EPO) using recombinant DNA technology was also challenged to be anticipated by old EPO isolated from human urine. However, the patent specification indicated that recombinant EPO had a higher molecular weight and different charge than urinary EPO due to differences in carbohydrate composition. Therefore, recombinant EPO is not anticipated by the urine EPO.



GENERIC DISCLOSURE AND SPECIFIC EXAMPLES

In considering novelty, it should be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific that disclosure, e.g. a disclosure of fibrinogen takes away the novelty of blood protein as a generic concept, but not the novelty of any blood protein other than fibrinogen.

IMPLICIT DISCLOSURE

It is normally required that the features of the claim under consideration are explicitly disclosed, for example in an earlier publication. However, the teaching implicit in a document can be taken into account.

Practice

Sometimes, claimed sequences are qualified by their activity. An earlier disclosure of the same sequence but without any indication of its activity

would prima facie constitute a novelty anticipation of the claimed sequence. The assumption must be that the earlier sequence inherently possesses the activity of the later sequence. Here it should be noted that although there is a requirement that an earlier description must be enabling, there is no requirement that the skilled worker should be able to determine the activity of the earlier sequence from the earlier disclosure if the claim merely seeks to protect the sequence.

The same assumption can be applied to polypeptides when claimed by their tertiary structure if the same polypeptide previously has been isolated from the same source, with the same function, and with approximately the same molecular weight; it can be assumed that the earlier polypeptide has the same tertiary structure as the claimed polypeptide. However, a claim to a crystallized form of a known polypeptide may be novel if the prior art does not disclose crystals of the polypeptide or methods of making the crystals.

Whilst it could be argued that it is implicit that the sequence of a protein, which by name and function is identical to the polypeptide claimed, would also be identical in sequence, it could also be argued that due to the extent of variation between peptide sequences of the same family the sequence may differ significantly. Therefore, a document should not be cited under novelty unless it is certain that only one unique form of a particular polypeptide exists. If this certainly does not exist, then a document should only be cited under novelty if the peptide sequence is explicitly disclosed.

A claim to an isolated and purified molecule which comprises the binding pocket of a known protein, which is defined by structural coordinates, is not considered to be novel as the isolated known protein would inherently comprise this binding pocket. However, an isolated polypeptide consisting of the binding pocket, and which is demonstrated to retain the binding and signalling activity of the protein may be novel if no such

isolated polypeptide fragment is known in the prior art.

SEQUENCE CLAIMS

A claim to a polypeptide 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 polypeptide has not been previously determined. A claim to a specific fragment of polypeptide may be considered to be novel.

A prior disclosure of the same sequence as the claimed sequence, even without any indication of its activity, 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 polypeptide from a prior art does not exactly match with the claimed sequence of polypeptide, then the subject-matter of such claims cannot be said to be anticipated by the prior art sequence.

>> CASE STUDY

An isolated antibody, wherein the antibody comprises a light chain comprising SEQ ID NO: 44 and a heavy chain comprising SEQ ID NO: 40.

Prior art, D1 discloses:

An antibody that interacts with or binds to human nerve growth factor (NGF) and neutralizes the function of NGF thereby, said anti- NGF antibody comprises a heavy chain as set forth in SEQ ID NO: 40 and light chain set forth in SEQ ID NO: 44.

Claim analysis

In view of D1, the sequences of the heavy and the light chains of the antibody mentioned in D1 have 100% identity with those of the antibody of the present invention, as well as, the antibody of D1 has the same effect and activity and performs the same function as the antibody of the present invention, so the antibody is not novel according to Article (1) of Egyptian Patent Law.

COMBINATION/COMPOSITION CLAIMS

Quite often, the claims of combination of products of biotechnology escape the question of novelty and are dealt under the inventive step. However, sometimes it may happen that the combination has already fallen in the public domain and hence, to be dealt under novelty.

>> CASE STUDY:

Claim: A composition useful against the thyroid hormone, comprising anti-thyroid hormone antibodies together with acceptable preservatives and stabilizers, wherein the antibodies are recombinant monoclonal antibodies.

Prior art discloses a composition useful against the thyroid hormone comprising antibodies which are recombinant monoclonal antibodies, physiologically acceptable carrier and other additives and adjuvants. The prior art further discloses recombinant monoclonal antibodies with 100% sequences identity with those of the antibodies claimed in the present invention.

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

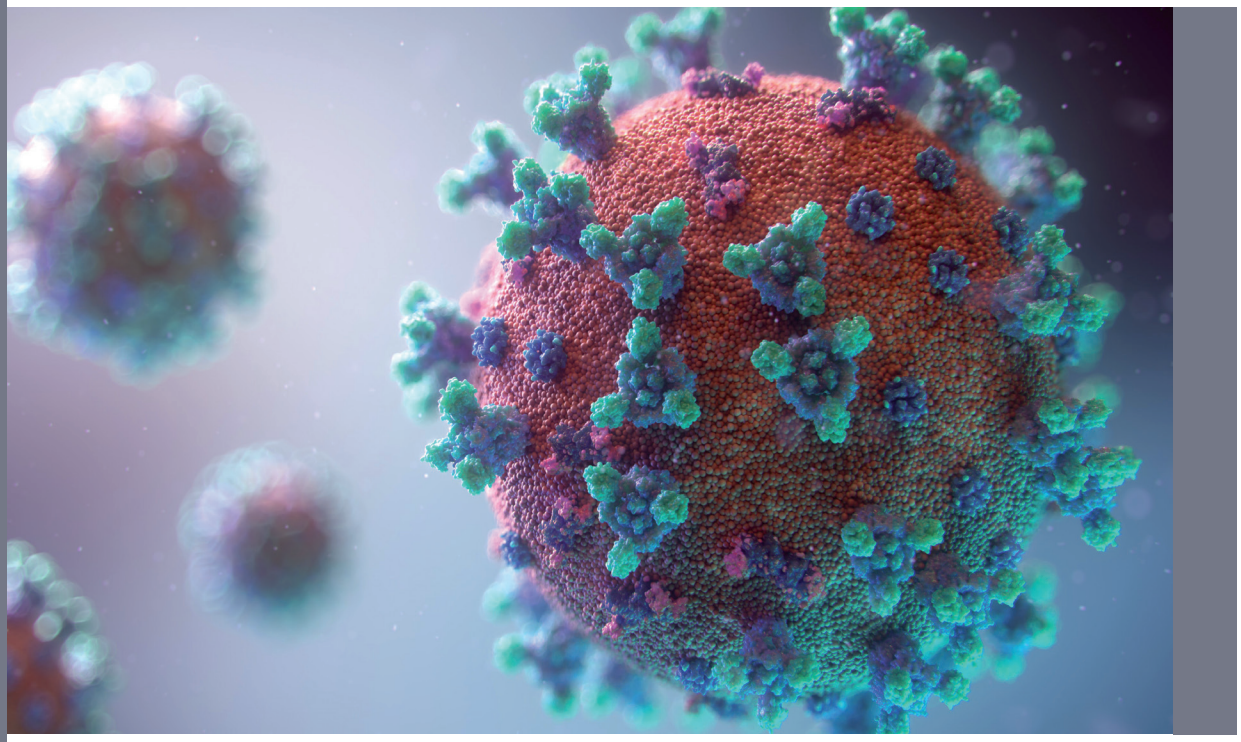
CHAPTER IV
INVENTIVE STEP

A claimed invention is considered to involve an inventive step if, having regard to the prior art, it is not obvious to a person skilled in the art. A person skilled in the art is a hypothetical person having ordinary skill in the art, who is aware of common general knowledge in the art at the relevant date, and has access to everything in the prior art.

The claimed invention is obvious if the person skilled in the art on the relevant date would have been motivated or prompted to realize the claimed invention by substituting, combining, or modifying one or more of those items of prior art with a reasonable likelihood of success.

CASE STUDY

If the claimed invention relates to a polypeptide having mutation(s) in a known sequence of polypeptide, which does not result in an unexpected property whatsoever, then the claimed subject-matter lacks inventive step.



Claim:

Notch-binding agents and Notch antagonists and methods of using the agents and/or antagonists for treating diseases such as cancer. The present application provides antibodies that specifically bind to a non-ligand binding region of the extracellular domain of one or more human Notch receptor, such as Notch2 and/or Notch3, and inhibit tumor growth. The present application further provides methods of treating cancer, the methods comprising administering a therapeutically effective amount of an antibody that specifically binds to a non-ligand binding region of the extracellular domain of a human Notch receptor protein and inhibits tumor growth.

Prior art, D1 discloses:

An isolated antibody that specifically binds to a non-ligand binding region of an extracellular domain of a human

NOTCH receptor and inhibits growth of tumor cells.

- The antibody specifically binds to a non-ligand binding region of the extracellular domain of NOTCH2.
- The antibody specifically binds to a non-ligand binding region of the extracellular domain of at least two Notch receptor family members.

Prior art, D2 discloses:

An isolated antibody that specifically binds to a non-ligand binding region of an extracellular domain of a human NOTCH receptor and inhibits growth of tumor cells.

In view of novelty

The present antibody is novel according to Article (1) of Egyptian Patent Law, because the prior art does not teach an antibody that specifically binds to a non-ligand binding region of the extracellular domain of one or more human Notch receptor, such as Notch2 and/or Notch3, comprising the VH and VL sequences as mentioned in the present invention and inhibit tumor growth.

In view of Inventive step

The referenced document negatively affects the inventive step of such claim. The difference between the claim and the documents resides in the antibody sequences, but neither the description nor the claim contains an explanation of the feature and the unexpected technical impact on the antibody and its activity and affectivity in binding the notch receptors and inhibiting tumor growth over that mentioned in the prior art (as disclosed in the specification), Such a difference in change did not constitute 'unexpected property' and hence, the subject-matter is held to be obvious and is not inventive.

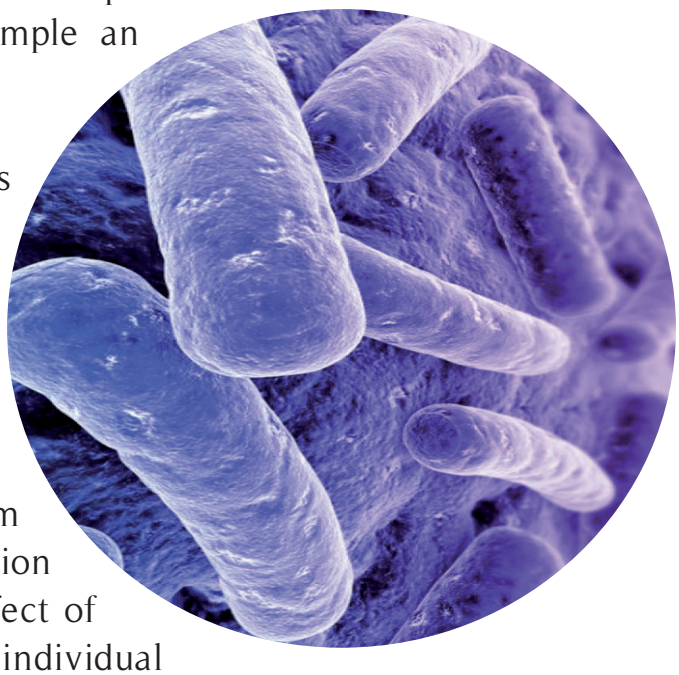
>> MERE ADMIXTURE RESULTING ONLY IN AGGREGATION OF THE PROPERTIES OR A METHOD OF MAKING SUCH MERE ADMIXTURE <<

It is a well-accepted principle of Patent Law that mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together has some working interrelation producing a new or improved result, then there is patentable subject matter in the idea of the working inter relations brought about by the collocation of the integers.

A mere juxtaposition of features already known before the priority date which have been arbitrarily chosen from among a number of different combinations which could be chosen was not a patentable invention.

CASE STUDY:

Claim: A combination of a bacterial host cell and a yeast host cell engineered to produce a first metabolic product, for example a carbohydrate, and to convert the first metabolic product into a second metabolic product, for example an alcohol.



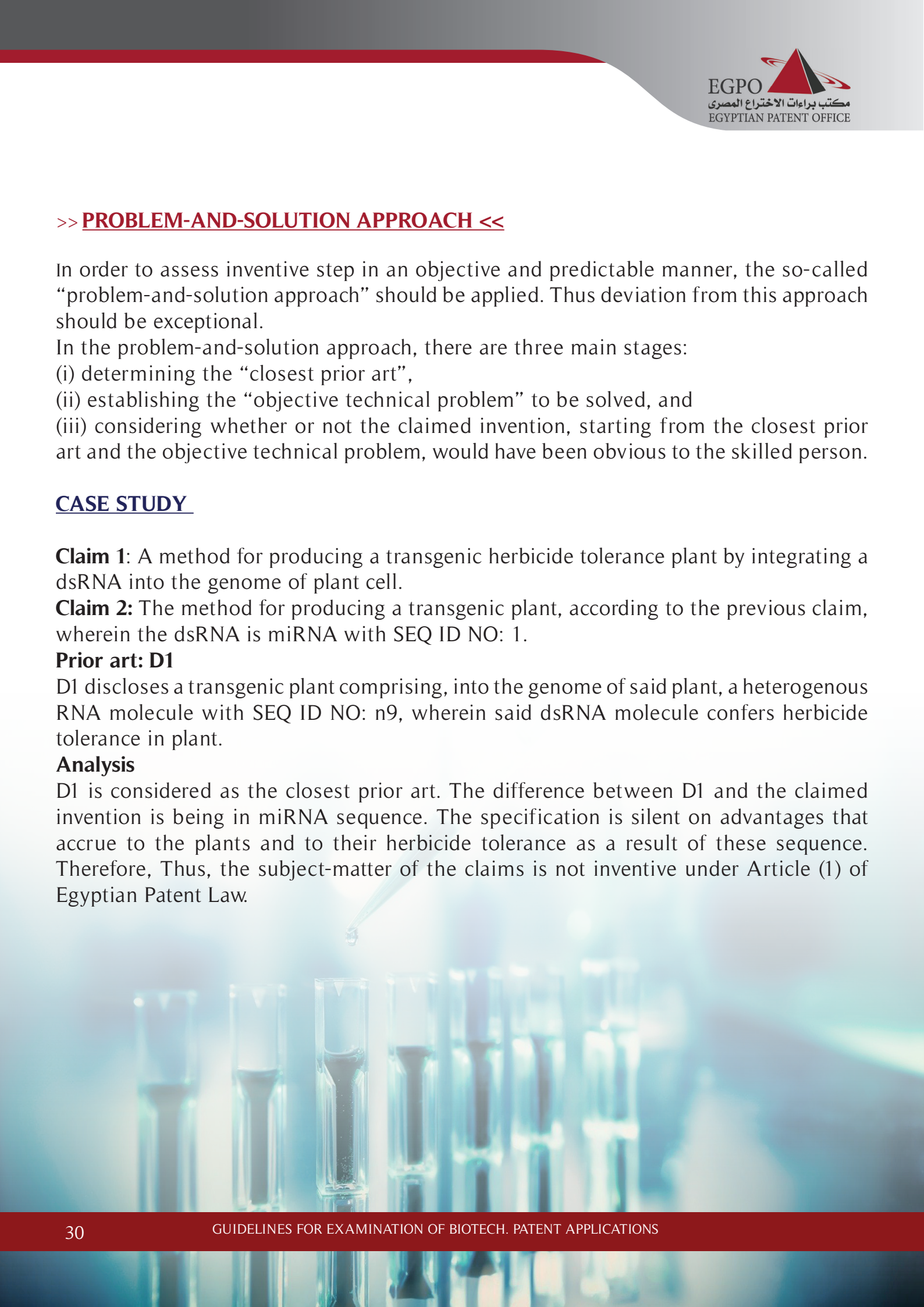
Analysis: The subject-matter of claim falls within the scope of Article (1) of Egyptian Patent Law. Upon examination, it is found that the claim is directed to a combination of two bacterial and yeast host cells. The said two host cells used in the alleged invention are known for their producing of first metabolic products and converting them to second metabolic products. 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 doesnot involve an inventive step under Article (1) of Egyptian Patent Law.

>> PROBLEM-AND-SOLUTION APPROACH <<

In order to assess inventive step in an objective and predictable manner, the so-called "problem-and-solution approach" should be applied. Thus deviation from this approach should be exceptional.
In the problem-and-solution approach, there are three main stages:
(i) determining the "closest prior art",
(ii) establishing the "objective technical problem" to be solved, and
(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

CASE STUDY

Claim 1: A method for producing a transgenic herbicide tolerance plant by integrating a dsRNA into the genome of plant cell.
Claim 2: The method for producing a transgenic plant, according to the previous claim, wherein the dsRNA is miRNA with SEQ ID NO: 1.
Prior art: D1
D1 discloses a transgenic plant comprising, into the genome of said plant, a heterogenous RNA molecule with SEQ ID NO: n9, wherein said dsRNA molecule confers herbicide tolerance in plant.
Analysis
D1 is considered as the closest prior art. The difference between D1 and the claimed invention is being in miRNA sequence. The specification is silent on advantages that accrue to the plants and to their herbicide tolerance as a result of these sequence. Therefore, Thus, the subject-matter of the claims is not inventive under Article (1) of Egyptian Patent Law.



CHAPTER V

INDUSTRIAL APPLICABILITY

As Article (1) of Egyptian Patent Law, 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".

Industrial applicability or industrial application is a patentability requirement according to which a patent can only be granted for an invention which is susceptible of industrial application, i.e. for an invention which can be made or used in some kind of industry.

Industrial applicability in the technical sense requires that the invention should be useful, which means that patent will not be granted if, at the date of filing, the application fails to indicate the issue to which the invention will be applied. The description should indicate explicitly the way in which the invention is capable of exploitation in industry, if this is not obvious from the description or from the nature of the invention. The expression "capable of exploitation in industry" means the same as "susceptible of industrial application"

CASE STUDY 1:

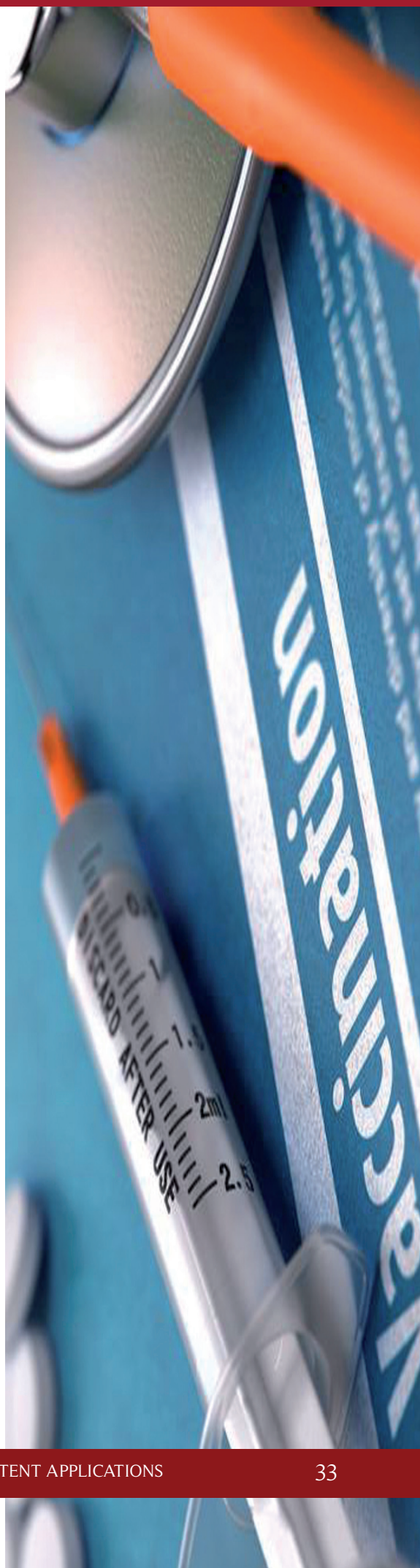
>> **Claim:** A polypeptide in substantially isolated form comprising a contiguous sequence of at least 10 amino acids encoded by the genome of hepatitis C virus (HCV) and comprising an antigenic determinant, wherein HCV is characterized by: (i) a positive stranded RNA genome; (ii) said genome comprising an open reading frame (ORF) encoding a polyprotein; and (iii) said polyprotein comprising an amino acid sequence having at least 40% homology to the 859 amino acid sequence X.

Upon examination it was found that the above claim was sufficiently enabled and its use was properly established in the specification. Therefore, claim 1 was allowable.

>> Another claim of the specification read as "A polypeptide in substantially isolated form whose sequence is shown in any one of SEQ IDs 1, 3 to 32, 36, 46 and 47, or whose sequence is encoded in a polynucleotide selectively hybridisable with the polynucleotide as shown in any one of SEQ IDs 1, 332, 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 (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.



CASE STUDY 2:

Claim: method of monitoring serum uric acid during pegylated uricase therapy

Analysis: the claim involving the protection of monitoring methods is not protected in the field of Egyptian patents for the following reasons:

An invention is a solution to a technical problem, whether it is a device, an industrial method, a compound or an industrial product, or any improvement of the aforementioned, according to the Intellectual Property Protection Law No. 82 of 2002 Article 1, It is noted that the monitoring method to be protected is not a method that leads to access to a product or compound, nor is it a method that can be applied in the industry to obtain the industrial product, but it is a method that can be applied in hospitals or in laboratories to track the effect of the drug (monitoring) and know the patient's ability to respond to it. These methods do not fall under Article 1 of the Egyptian Patent Law Law.

The lack of any industrial application for one aspect of an invention can have implications for other aspects of that invention. For example, if the one aspect of the invention is a receptor, the absence of any industrial application for the receptor would mean that an agonist to the receptor would also not be capable of industrial application. Similarly, a method of identifying agonists to the receptor would not be industrial applicable. On the other hand, if the specification established, for example by in vivo or in vitro data, that the receptor had some relevance to (for example) :The treatment of obesity, the receptor and agonists would all be capable of industrial application.

CHAPTER VI

PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS ACCORDING TO EGYPTIAN PATENT LAW 82, 2002

Exceptions of patentability under Egyptian Patent Law Article (2) items

Item (1): Inventions whose exploitation is likely to be contrary to public order or morality, or prejudicial to the environment, human, animal or plant life and health.

Item (2): Discoveries, scientific theories, mathematical methods, programs and schemes.

Item (3): Diagnostic, therapeutic and surgical methods for humans and animals.

Item (4): Plants and animals, regardless of their rarity or peculiarity, and essentially biological processes for the production of plants or animals, other than microorganisms, non-biological and microbiological processes for the production of plants or animals.

Item (5): Organs, tissues, living cells, natural biological substances, nucleic acid and genome.

What is not patentable:

- Newly invented and transgenic plants and animals.
- A process for the production of plants or animals is essentially biological.
- The discovery of a biological material cannot constitute patentable inventions.
- Naturally isolated or genetically engineered DNA, RNA, nucleic acid, gene or partial sequence thereof.
- Any naturally occuring microorganism.
- Isolated organs, tissues, or living cells (including all types of stem cells) which isolated from their natural environment or genetically engineered.

What is patentable:

- Genetically engineered microorganisms.
- Biological materials (e.g. antibodies, peptides or proteins) which are produced by means of recombinant technology process.
- Microbiological process for the production of plants or animals.
- A process by which a biological material is produced, processed or isolated.
- A product consisting of or containing many active ingredients among which a natural biological material.

>> EXAMPLES OF NONPATENTABLE BIOTECHNOLOGY INVENTION UNDER EGYPTIAN PATENT LAW <ARTICLE (2) <<

1. Inventions whose exploitation is prejudicial to the environment, human, animal or plant life and health.

According to Article (2) of the Egyptian Patent Law, the invention whose exploitation is prejudicial to the environment, human, animal or plant life and health is not patentable.

CASE STUDY 1:

Claim: A method to differentiate pluripotent stem cells, wherein the cells are Embryonic stem cells.

Analysis: The subject-matter of claim falls within the scope of item (1) - Article (2) of Egyptian Patent Law. Said differentiation method to be achieved, either requires a new use of human embryos, or presupposes a destructive use of human embryos. Even if the application mentioned that the method avoids the embryonic destruction and only single cell biopsy has been done. It is not guaranteed that the sample taken for biopsy will not affect the stages of fetal development and lead to the possibility of its deformation and the birth of unhealthy children, so this method is not patentable.

2. Scientific Principles or Abstract Theory or Discovery of Living Things or Non-Living Substances

According to Article (2) of the Egyptian Patent Law, the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature is not a patentable invention. Products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature, are not patentable subject-matter. However, processes of isolation of these products can be patented.

CASE STUDY 1:

Claim: *Lactobacillus sp.* comprising a gene responsible for the production of lactic acid as SEQ ID NO: 1 (deposition No. XXXXXX).

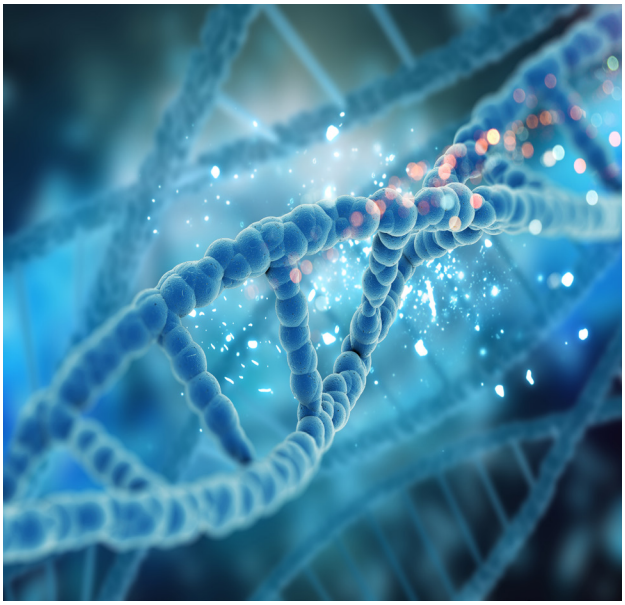
Analysis: The subject-matter of claim falls within the scope of item (2) - Article (2) of Egyptian Patent Law, as it attempts to claim an isolated Lactobacillus sp. (i.e. a living substance) occurring in nature (as disclosed in the specification). Thus, what is claimed in the claim is treated as a discovery of a living thing occurring in nature and hence, not patentable.

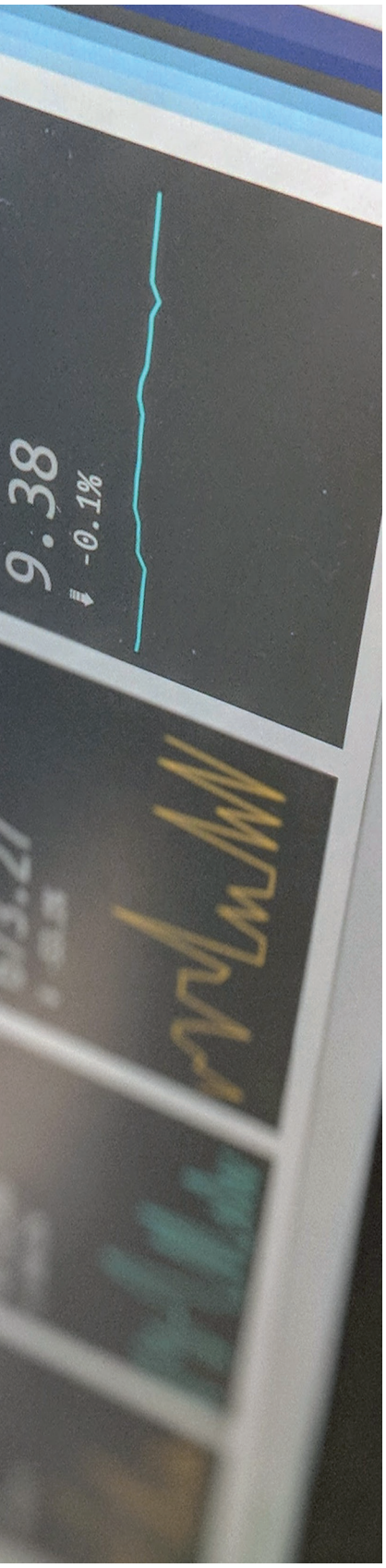
3. Organs, tissues, living cells, natural biological substances, nucleic acid and genome Are Not Patentable Subject Matter

CASE STUDY 1:

Claims: The method for introducting/ integrating a dsRNA into the genome of plant cell for improving a feature in said plant.

Analysis: The subject-matter of claim falls within the scope of item (5) - Article (2) of Egyptian Patent Law. Both the description and the claimed did not protect new or non-traditional steps of the method of introducting a dsRNA into the genome of plant cell (as disclosed in the specification), but the new and innovative resides in the dsRNA itself, which is not patentable, so the method is excluded from the patentability because the dsRNA is implicity protected in this way.





4. Mathematical or Business Method or A Computer Programme Per Se or Algorithms.

According to Item (2) – Article (2) of Egyptian Patent Law, a mathematical or business method or a computer programme per se or algorithms are not patentable inventions. Bio-informatics is a relatively young science and has emerged from thecombination of information technology and biotechnology. Thus, the determination of patentability of inventions relating to bioinformatics requires special attention vis-a-vis exclusions under (2) – Article (2) of Egyptian Patent Law.

CASE STUDY 1:

Claim: A data processing method, wherein a first chemical substance is a compound; a second chemical substance is nucleic acid, protein or a complex thereof; a first characteristic amount is expressed as a vector comprised of more than one type of chemical substance information of the first chemical substance; a second characteristic amount is expressed as a vector comprised of more than one type of biological information of the second chemical substance; and the first characteristic amount and the second characteristic amount are map-transformed using a multivariate analysis technique or a mechanical leaning method so as to increase a correlation between first space expressing the first characteristic amount and second space expressing the second characteristic amount.

Analysis: The claimed invention is considered as a mathematical method or computer program per se in so far as that it relates to data processing of certain technical parameters of chemical and biological substances, but does not lead to any product whatsoever. Various references to chemical and biological substances therein are only to the meaning of data itself and do not relate to any technical implementation details for carrying out the methods. Hence, the subject-matter of claim falls within the scope of statutorily non-patentable inventions under Item (2) – Article (2) of Egyptian Patent Law.

CHAPTER VII

SUFFICIENCY OF DISCLOSURE, CLARITY & SUPPORT OF THE CLAIMS

Article (13) of Egyptian Patent Law

The patent application shall be accompanied by a detailed description of the invention, including a full statement of the subject matter and of the best way to enable a person of expertise to execute it, and of each product or method for which protection is sought.

Article (13) of Egyptian Patent Law requires that the disclosure should be sufficient often overlaps with the requirement that the claims be supported by the description since both are concerned with the relationship between the extent of the disclosure and the scope of the claims. Thus, if a claim is unduly broad and speculative having regard to what has been disclosed, it might be difficult to decide whether the objection should be that the disclosure is incomplete, or that the claim is not supported by the description. Objection in these circumstances before grant should, as a matter of general practice, be made on the ground of lack of support.

The description shall also include in a clear manner the new elements for which the applicant seeks protection accompanied, where necessary, by an illustrative drawing of the invention.

The claims must be clear "in themselves when being read with the normal skills, but not including any knowledge derived from the description of the patent application . In other words, the wording of a claim must be clear in itself.

As mentioned above, a claim must define the matter for which the protection is sought in terms of the technical features of the invention. These technical features need not necessarily be structural however; they may also be functional. Structural features may for example consist in a nail, a screw or a rivet, whereas functional features define the suitability for performing certain functions, such as for example fastening means.

The scope of the claims must also not be "broader than is justified by the extent of the description and also the contribution to the art". "This requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified.

Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner.

Where the invention involves micro-organisms, the applicant shall disclose the identity of such organisms and deposit a live culture thereof with the authority designated in the Regulations.

The complete specification must describe "an embodiment" of the invention claimed in each of the claims and the description must be sufficient to enable those in the industry concerned to carry it into effect without their making further inventions "and the description must be fair, i.e. it must not be unnecessarily difficult to follow".

An insufficient complete specification cannot become sufficient because of general developments in the state of the art after the filing date. The relevant date for complying with the requirement for sufficiency is the date of complete specification. In other words, a complete

specification should provide enough information to allow a person skilled in the art to carry out substantially all that which falls within the ambit of what is claimed.

Analogues or variants of polynucleotides or polypeptide sequences, in the form of additions, substitutions or deletions, could extend to an almost infinite number of variants. In such cases, the claim should be restricted to variants sharing a common specific activity with each other that are disclosed in the specification. The said activity disclosed should not be predictable in nature.

CASE STUDY 1:

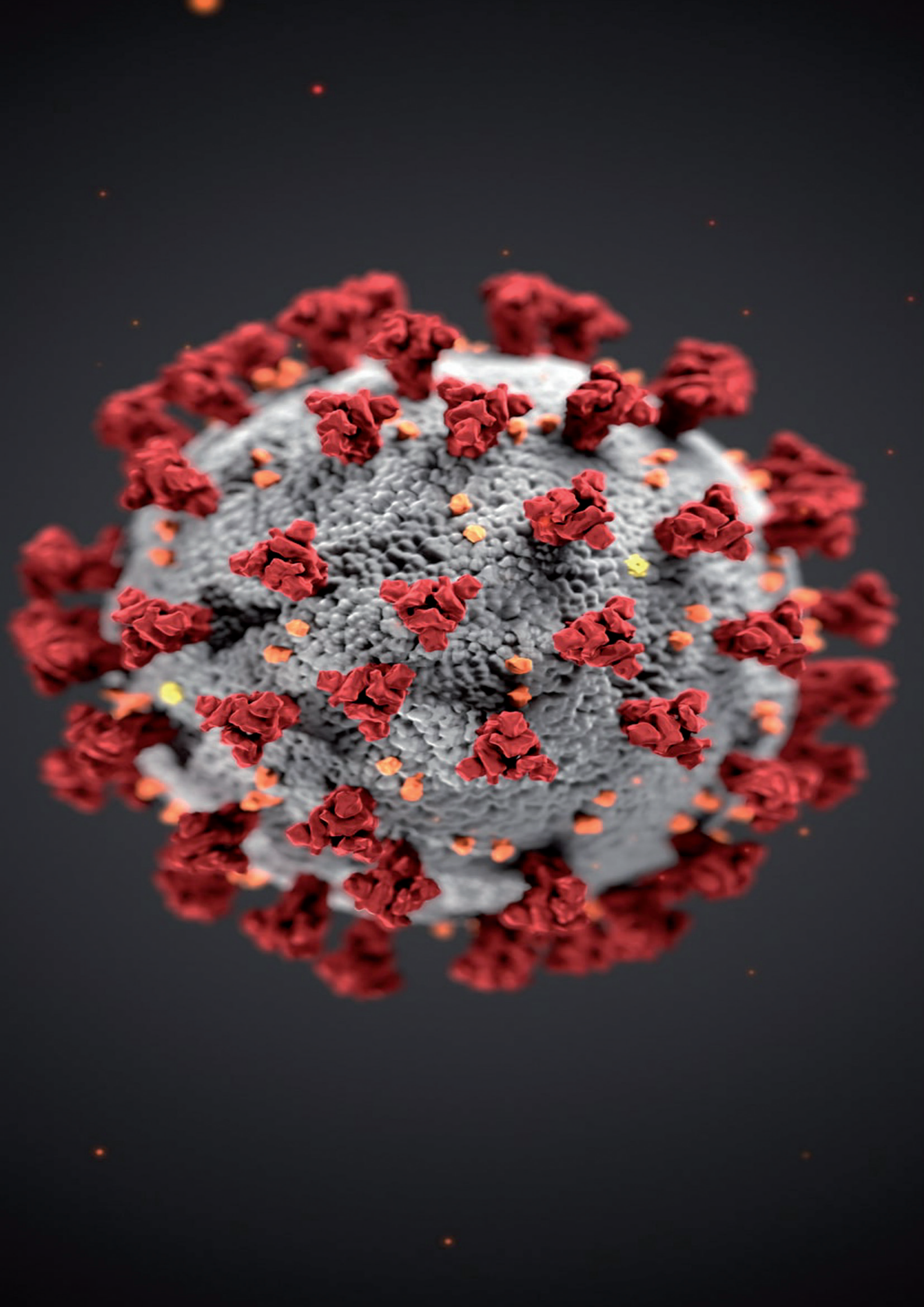
Claim: A method comprising: (i) contacting polypeptide X with a compound to be screened and determining whether the compound affects the activity of the polypeptide and (ii) formulating any active compound into a pharmaceutical composition.

Analysis: Any method that merely screens existing materials does not give rise to products and claims resulting from such methods 'reach through' to as yet unidentified materials. In the absence of any knowledge of any relationship, either from the specification or from common general knowledge, the skilled person would not know how to produce and use the compounds. It would require an undue burden of experimentation to screen undefined compounds for the desired activity. There will also be a lack of support where the function of the compounds identified is not specified.

CASE STUDY 2:

Claim: An antibody produced by the hybridoma deposited with ATTC deposit no. xxxxxxxx.

Analysis: The claim in this formulation are technically unacceptable due to the lack of clarity according to article (13) of Egyptian Patent Law, as no person skilled in the field can know the amino acid sequences of the antibody, specially its CDRs, by the deposition no. of the hybridoma.



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