

INVENTOR GUIDANCE NOTES

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SCOPE: This Inventor Guidance Notes provides information for scientists working in the area of Microbiology and explains what can and what cannot be patented.	DATE: 02 January 2012
TABLE OF CONTENTS: A. Summary B. Relevant legal extracts C. Interpretation of the law and explanations D. Examples and cases E. References	REVIEWER: Vinita V Panchanadikar Nitin S Tewari V. Premnath Srividya Ravi

A. SUMMARY:

Details	INDIA	USA	EUROPE
The Law:	The Patent Act, 1970	United States Code Title 35 – Patents	European Patent Convention
Patent Law protects what:	Microorganisms [except those discovered /found in nature]; Microbiological processes or products thereof	Microorganisms, plants & animals have all received patentable status in US provided there is considerable human intervention.	Inventions of microorganisms [microbiological processes or products thereof]
Micro-organisms means:	No definite meaning is given in The Patent Act/ TRIPs Agreement. [Various microscopic organisms, including algae, bacteria, fungi, protozoa and viruses may be considered as they come under the definition of microorganisms. Alternatively, an expansive definition of 'Microorganism' may include within its scope all 'biological materials' containing genetic information and capable of reproducing or being reproduced in a biological system.]	'Anything under the sun made by man is patentable' [Diamond v. Chakrabarty 44U.S. 303 1980]	Bacteria & yeasts, fungi, algae, protozoa & human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. (Case no. T 0356/93-334 dated 21-02-1995)
Test for patentability:	Inventive Step, Utility/Industrial applicability, Novelty, Considerable Human Intervention, Sufficiency of disclosure –deposition of the Biological matter at the International depository.	Novelty, Non obviousness, Industrial Application and considerable Human Intervention.	Considerable Human intervention i.e. Man-made life, Novelty, Non obviousness & Industrial Application.
Micro-organisms	✓ *	✓ *	✓ *
Microbiological processes	✓	✓	✓
Microbial products	✓	✓	✓
Eg Claims:	IN 228892 titled ALTERED STRAIN OF THE MODIFIED VACCINIA VIRUS ANKARA (MVA) claims: -A modified vaccine virus Ankara (MVA) adapted for growing in cells of a continuous cell line.... -A composition preferably a pharmaceutical composition, comprising the MVA and/or DNA of the MVA.... & -A vaccine of...	US 4259444 claims: -A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway... -The process in which a first energy-generating plasmid specifying a degradative pathway is transferred... - An inoculum for the degradation of a preselected substrate...	EP0906336B1 claims: -A biologically pure culture of the cyclosporin-producing microbe deposited as provisional accession number I-1714, Collection Nationale de Cultures de Microorganismes, Institut Pasteur.

✓ Patentable

* Not naturally occurring; inventions with considerable human intervention.

B. RELEVANT LEGAL EXTRACTS:

COUNTRY & LAW	LEGAL EXCERPTS
¹ INDIA [The Patents Act 1970]	<p>S3. What are not inventions</p> <p>(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</p> <p>(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</p>
² USA [35 USC]	<p>35 U.S.C. 101 Inventions patentable.</p> <p>Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent there for, subject to the conditions and requirements of this title.</p> <p>35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.</p> <p>(3) For purposes of paragraph (1), the term “biotechnological process” means-</p> <p>(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-</p> <p>(i) express an exogenous nucleotide sequence,</p> <p>(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or</p> <p>(iii) express a specific physiological characteristic not naturally associated with said organism;</p> <p>(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and</p> <p>(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B)</p>
³ EUROPE [EPC]	<p>Article 53</p> <p>Exceptions to patentability</p> <p>European patents shall not be granted in respect of:</p> <p>(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;</p> <p>(c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.</p>

C. INTERPRETATION OF THE LAW AND EXPLANATION:

INDIA:

Microorganisms, non-biological, and microbiological processes have been provided patent protection as per Article 27(3) (b) of TRIPS Agreement.

In compliance with TRIPS, sub-section 3j of the Patents Act 1970, allows patent rights for microorganisms, non-biological, and microbiological processes.

However, any discovered micro-organism from the nature is not patentable as the same is considered to be a mere discovery as per the provisions of the section 3(c) of the Indian Patent Act, 1970.

As Section 3 (C) prohibits patenting of any naturally occurring substance in nature, only those inventions having considerable amount of human intervention are patentable.

¹⁰Genetically Modified Microorganisms (GEMs) are patentable provided the invention results in enhancing the efficacy of the already existing strain of the Microorganism. For eg:

<p>Indian Patent IN 223392 titled MODIFIED FREE-LIVING MICROBES, VACCINE COMPOSITIONS AND METHODS OF USE THEREOF</p>	<p>Independent Claims:</p> <ul style="list-style-type: none"> -A vaccine comprising modified microbes, wherein the nucleic acid of the microbes has been modified by reaction with nucleic acid targeted compound that reacts directly with the nucleic acid so that the microbes are attenuated for proliferation, wherein the microbes are bacteria, protozoa, or fungi, and wherein the modified microbes express an antigen at a level sufficient for the vaccine to induce an immune response to the antigen in a host upon administration of the vaccine to the host. - Isolated professional antigen-presenting cells comprising modified microbes.... - A vaccine comprising the professional antigen-presenting cell...
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Other areas involving microorganisms like microbial products and processes thereof are also patentable in India.

¹²A synergistic composition containing the microorganism and a process using microorganisms to produce a substance can both be patented. For eg:

<p>Indian Patent 209517 titled PROBIOTICS FOR PET FOOD APPLICATIONS</p>	<p>Independent Claims:</p> <ul style="list-style-type: none"> - A pet food composition containing at least one novel isolated strain of lactic acid bacteria and / or a supernatant of its culture and / or metabolites thereof, associated with an ingestible support or a pharmaceutical matrix ... -The ingestible support or a pharmaceutical matrix... -The novel isolated strains of the composition.... -A dietary adjunct or a supplement...
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¹²The process of biosynthesis of a new microorganism is patentable as per the Act.

Attenuated microorganisms & their lyophilized end products are also patentable. For eg:

Indian Patent <u>233428</u> titled 'ATTENUATED STRAINS OF VIBRIO CHOLERAEE AND LYOPHILIZED VACCINES CONTAINING SAME'	Independent Claims: -Live attenuated strains of Vibrio cholerae for the manufacture of oral cholera vaccines.... - Live attenuated strains of Vibrio cholera..... & - Freeze dried formulation of live attenuated strains of Vibrio cholera....
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USA :

The US Patent system is liberal in granting patents to new microbiological inventions with proved utility and considerable human intervention.

For eg. ¹⁶A bacterium with digestive enzymes is not patentable as it is a mere discovery. However, genetically engineered bacterium with modifications that render it capable of breaking down crude oil into its basic components and being put to use in oil spills (Diamond v. Chakrabarty) is certainly patentable.

¹⁸ The U.S. Supreme Court ruled that a live microorganism is patentable in Diamond v. Chakrabarty in 1981. A landmark patent was granted to Chakrabarty for microorganisms having oil-splitting properties. This case formulated the criterion of human intervention for patenting microorganisms.

After Diamond v. Chakrabarty [44U.S. 303 1980], the settled position in U.S. is that microorganisms are patentable subject matter under the US Patent Code.

The Court made the classic statement that, "Anything under the sun made by man is patentable." This decision opened the door for patenting living organisms for the first time.

Many microorganisms, their products and processes thereof have been patented in US since then.

Thus, any invention which is Novel, Non obvious, has an Industrial Application and has considerable Human Intervention is patentable in USA.

EUROPE :

¹⁸The European Patent Convention provides for the grant of patent for inventions of microorganisms [Art 53(b) of EPC] though it failed to provide a definition for microorganisms.

Thus in Green Peace Ltd v. Plant Genetic System N.V. (Case no. T 0356/93-334 dated 21-02-1995), The Technical board of appeals of the European Patent Office has attempted a definition of microorganisms as: "Microorganisms include not only bacteria & yeasts, but also fungi, algae, protozoa & human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also contained to fall under these inventions."

Europe allows patenting of 'Man-Made' life forms in a similar manner as the US patent system. Thus for inventions to become patentable, they have to:

- Be man-made inventions
- Show considerable human intervention in case of modifications done to already existent microorganisms &
- Have novelty, inventive step and well defined industrial application.

D. EXAMPLES AND CASES:

INDIA :

Case Details:	Case History:	The Verdict:	The Consequences:
^{12,15} Dimminaco AG v. Controller of Patents and Designs, 2002	Dimminaco A.G., a Swiss company applied for patenting the process for preparation of a live vaccine for Bursitis, an infectious poultry disease. The invention involved a live (attenuated) vaccine to combat the disease. [Indian Patent Application No <u>136/CAL/98</u> titled Infectious Burisits Vaccine] Patent office rejected the patent on the basis that an inventive process must lead to manufacture of an article or a substance. Statutory definition of 'manufacture' did not include a process that resulted in a 'living organism' and hence the 'claim' did not fall within Section 2(1) (j) of the Patent Act, 1970.	The patenting of a process relating to manufacture of a product containing living organisms, was strictly considered not patentable in India until the year 2001. However, in year 2002, Kolkatta High Court held that, the dictionary meaning of 'manufacture' did not exclude from its purview the process of preparing a vendible commodity that contains a living organism.	The Calcutta High Court's decision in Dimminaco AG v. Controller of Patents and Designs, 2002 relating to patentability of biotechnological process with living end product is a milestone decision in Indian context. This was the first time in the history of the Indian patent system that the patenting of a process for the production of a product containing living organisms was considered legitimate.

Some of the microbiological inventions which have been granted Indian patents and their corresponding claims are summarized hereunder:

Patent No	Title	Types of Claims	Independent claims
IN <u>228892</u>	ALTERED STRAIN OF THE MODIFIED VACCINIA VIRUS ANKARA (MVA)	Product claim for a modified vaccine virus, Product claim for a pharmaceutical composition, & Product claim for a vaccine.	A modified vaccinia virus Ankara (MVA) adapted for growing in cells of a continuous cell line.... A composition preferably a pharmaceutical composition, comprising the MVA and/or DNA of the MVA.... & A vaccine of...
IN <u>226136</u>	RECOMBINANT MICROORGANISMS CAPABLE OF FERMENTING CELLOBIOSE	Product claim for a recombinant microorganism, Product claim for recombinant nucleic acid & Process claim for ethanol.	A recombinant microorganism which expresses pyruvate decarboxylase.... A recombinant nucleic acid molecule comprising.... A method for making ethanol....
IN <u>225709</u>	A PROKARYOTIC RECOMBINANT HOST CELL COMPRISING A HETEROLOGOUS REPLICATION INITIATION PROTEIN	Product claim for a prokaryotic recombinant host cell, Product claim for a plasmid, Process claims for their production & detection.	A prokaryotic recombinant host cell.... A method for producing a plasmid using a host cell.... A method for detecting a plasmid copy-up mutation.... A plasmid comprising a heterologous pir gene...

USA :

Case Details:	Case History:	The Verdict:	The Consequences:
<p>¹⁸Funk Brothers Seed Co v. Kalo Inoculant co. (33US 127(1948)).</p>	<p>In this case, patent was claimed over a mixture of different strains of bacteria, each of which was useful to inoculate the roots of different species of leguminous plants, assisting the plants in nitrogen fixation. Different species of root-nodule bacteria existed in nature and has been available separately in the market. Efforts were made to combine the different species of bacteria in a mixed culture suitable for inoculating a range of crops. But these attempts were failed because the different species inhibited each other's effectiveness in combination. The plaintiffs claim was for the discovery of strains of each species of root nodule bacteria that are not mutually inhibitive and in the combination of these strains is a single mixed-culture inoculant.</p>	<p>The supreme Court held the patent claim to be invalid on the ground that the patentee had not created any new bacteria. The court reasoned that the bacteria in the mixed culture serve the end nature originally provided and act quite independently of any effort of the patentee.</p>	<p>Most of the inventions became non-patentable as they are considered to be the product of nature. For a long time the 'Doctrine of Products of nature' barred patents for living matter.</p>
<p>^{11,17}Diamond v. Chakrabarty [44U.S. 303 1980]</p>	<p>In 1972, Anand Chakrabarty, a microbiologist, and a researcher in the General Electric Company, filed a patent application in relation to a bacterium that was intended to consume petroleum spills. He claimed that a bacterium from the genus Pseudomonas containing at least two stable energy-generating plasmids, each providing a separate hydrocarbon degradative pathway was a human-made, genetically engineered bacterium capable of breaking down multiple components of crude oil. It was asserted that because of this property, which is possessed by no naturally occurring bacteria, the invention could treat oil spills.</p> <p>Chakrabarty's patent claims were of three type's viz., process claims for the method of producing the bacteria; Claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and Claims to the bacteria themselves.</p> <p>The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. The decision rested on two grounds, 1. That micro-organisms are products of nature, and 2. That as living things they are not patentable subject matter.</p> <p>The Patent Office Board of Appeals reiterated the examiner's decision on the same grounds. The Court of Customs and Patent Appeals emphasized whether it constituted an invention made by human intervention.</p>	<p>In the courts view, the fact that Chakrabarty's bacterium was alive was without legal significance. In a landmark decision, the US Supreme Court reaffirmed that the bacterium was not a naturally occurring; rather it was Chakrabarty's invention. As a result of the Supreme Court's decision, the US biotechnology industry flourished and many US patents have been granted on human-made higher life forms such as transgenic mice, fish etc. Before the TRIPs come into existence, the US had allowed patenting of micro-organisms.</p>	<p>US Patent regime embraced a much more patent friendly approach post Chakrabarty's Patent case. The doctrine "Anything under the sun made by man is patentable" gave way to patenting of many more life forms.</p>

Patent No	Title	Types of Claims	Independent claims
Chakrabarty's Patent: US <u>4259444</u> :	MICROORGANISMS HAVING MULTIPLE COMPATIBLE DEGRADATIVE ENERGY-GENERATING PLASMIDS AND PREPARATION THEREOF	-Product claim for a genetically modified bacterium -Product claim for an inoculum -A process claim for the method of preparation of the recombinant bacterium.	-A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway. -An inoculum for the degradation of a preselected substrate comprising a complex or mixture of hydrocarbons, said inoculum consisting essentially of bacteria of the genus Pseudomonas at least some of which contain at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway. & -The process in which a first energy-generating plasmid specifying a degradative pathway is transferred by conjugation from a donor Pseudomonas bacterium to a recipient Pseudomonas bacterium containing at least one energy-generating plasmid that is incompatible with said first plasmid...
US <u>5589168</u>	PROBIOTIC	Product claims for a group of microorganisms, their viable and lyophilized forms and the bacterium itself.	-Organisms of Enterococcus faecium selected from the group consisting of strain NCIMB 40371 and IBS-alleviating mutants thereof -Organisms of claim 1 in viable form. -Organisms of claim 1 in lyophilized form. -Enterococcus faecium strain NCIMB 40371.

¹⁸In 1873, a US patent was granted to Louis Pasteur [Patent No.135245] for a microorganism used in the fermentation process to manufacture beer.

Many patents have also been granted on various types of Cheese, Probiotics etc i.e microbial products and their process of production.

EUROPE:

¹² In 1969 in Germany, a patent was claimed on a method for breeding doves with red plumage, German patent office rejected the patent on the ground that the method was not repeatable and the Supreme Court confirmed the same. It was the first case, which opened the door for patenting biotechnology inventions.

Further, in the early 1970s, the German Federal Supreme Court upheld patent protection for new micro-organisms if the inventor were to demonstrate a reproducible way for its generation. Later on it was held in T356/93 that micro-organisms are patentable as products of microbiological processes, and micro-organisms were defined as generally unicellular organisms with dimensions beneath the limits of vision, which can be propagated and manipulated in laboratory.

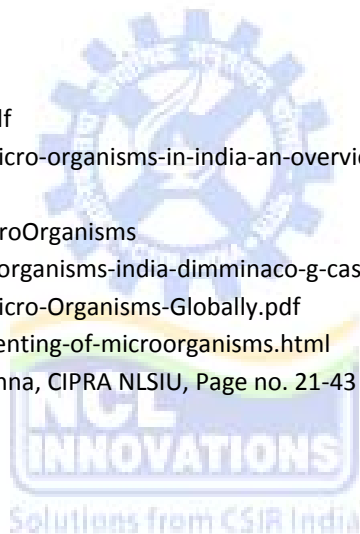
Patent No	Title	Types of Claims	Independent claims
EP <u>2343319</u>	GENETICALLY MODIFIED FOOD GRADE MICROORGANISM FOR TREATMENT OF INFLAMMATORY BOWEL DISEASE	Product claims for a gene construct, a protein construct, A Genetically modified organism, A pharmaceutical composition. Process claim for the method of producing the genetically modified microorganism	-A gene construct coding for a polypeptide..... -A protein construct encoded by a gene construct.... -A genetically modified microorganism produced from a GRAS microorganism..... -A method for producing a genetically modified microorganism... & -A pharmaceutical composition comprising a genetically modified microorganism....
EP 2021457	PROBIOTIC STRAIN AND ANTIMICROBIAL PEPTIDE	Product claim for An isolated peptide, A recombinant plasmid, A transformed microbial	-An isolated peptide selected from the group..... -A recombinant plasmid adapted for transformation of a microbial host cell.....

	DERIVED THEREFROM	<p>cell, a pure culture, A polymer, A probiotic composition, A primer, An isolated transporter peptide, & An isolated nucleotide sequence. Related Process claims.</p>	<ul style="list-style-type: none"> -A transformed microbial cell which includes a recombinant plasmid.... -A substantially pure culture of Enterococcus mundtii strain ST4SA..... -A process for the production of a peptide... -A method of treating a bacterial infection..... -Use of a therapeutically effective amount of the cultured Enterococcus mundtii strain.... -Use of a therapeutically effective amount of the antimicrobial peptide... -A substance or composition for use in a method of treating a bacterial infection.... -A method of inhibiting growth of bacterial species.... -A polymer having incorporated therein an antimicrobial quantity of the isolated peptide... -A probiotic composition including a therapeutically effective concentration... -A method of reducing the levels of pathogenic bacteria or.... -Use of a biologically pure culture of strain Enterococcus mundtii.... -A primer selected from the group consisting of SEQ. ID. NO. 1 to SEQ. ID. NO. 10... -An isolated transporter peptide from the bacterium Enterococcus mundtii... & -An isolated nucleotide sequence which codes for ST4SA immunity peptide of the bacterium Enterococcus mundtii.
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18. Biotechnology & Intellectual Property Rights, Dr.T Ramakrishna, CIPRA NLSIU, Page no. 21-43



Note: This IGN was finalized in the current form on 2nd Jan 2012. This is intended as a working document. Readers are requested to provide comments/suggestions & point to any errors (if any) so as to help improve this document. Comments may be sent to sv.kanitkar@ncl.res.in