INVENTOR GUIDANCE NOTES

(While papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

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INVENTOR GUIDANCE NOTES

(White papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC: **AGRO-BIOTECHNOLOGY**	AUTHOR: **SNEHA KANITKAR** **A207, PAML** **National Chemical Laboratory** **Pune – 411008** **Phone: +91-20-2590-2757** **Email: sv.kanitkar@ncl.res.in**
IGN Number: **IGN-01**	VERSION: **04**
SCOPE: **This Inventor Guidance Notes provides information for scientists working in the area of plant/agro biotechnology and explains what can and what cannot be patented.** [Note that this Inventor Guidance Notes does not cover provisions under The Protection of Plant Varieties And Farmers' Rights Act, 2001]	DATE: **16th November 2011**
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A. SUMMARY:

INVENTIONS [PLANTS, GENES etc]	IN	US	EP
Asexually Reproduced distinct & new variety including: • Cultivated spores, • Mutants, • Hybrids, and • Newly found seedlings.	X	✓	X
Tuber propagated plant or a plant found in an uncultivated state	X	X	X
Biological processes of Plants	X	X	X
New varieties of plants	X	✓	X
Transgenic plants & seeds	X	✓	✓
Process of preparation of transgenic plants	✓	✓	✓
Individual plants and their descendants	X	✓	X
Particular plant traits	X	✓	X*
Plant parts	X	✓	X
Plant components (e.g. specific genes or chromosomes)	✓ +	✓	✓
Plant products (e.g. oils, pharmaceuticals)	✓	✓	✓
Plant culture cells	✓ **	✓	✓
Methods of cultivating Plant Cells	✓	✓	✓
Plant material used in industrial processes (e.g. cell lines used in cultivation methods),	✓	✓	✓
Reproductive material (e.g. seeds or cuttings),	X	✓	X
Hybrid plants & Seeds	X	✓	✓
Vectors and processes involved in the production of transgenic plants.	✓	✓	✓
Plant breeding methodologies,	X	✓	✓ *
Nucleotide & Amino Acid sequences	✓	✓	✓
SNP single nucleotide polymorphisms	✓	✓	✓
Genes & gene fragments(cDNA, EST etc)	✓ +	✓	✓
Protein Structures	✓	✓	✓ *
DNA Sequences & Gene constructs	✓ +	✓	✓

Note:

*There is some ambiguity for patenting of these inventions in EP.

**A cell line is patentable in India only if artificially produced.

+ Refer to the interpretation; as in light of S3j, this may become non-patentable.

B. RELEVANT LEGAL EXTRACTS

INDIA:

Section 3 , Indian Patent Act, 1970 [Non-Patentable inventions]

(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
(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
(h) a method of agriculture or horticulture;
(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.
(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

USA:

35 U.S.C. 101Inventions patentable.
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 thereof, subject to the conditions and requirements of this title.

35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.
(3)For purposes of paragraph (1), the term “biotechnological process” means-
(A)a process of genetically altering or otherwise inducing a single- or multi-celled organism to-
(i)express an exogenous nucleotide sequence,
(ii)inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
(iii)express a specific physiological characteristic not naturally associated with said organism;
(B)cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody;

35 U.S.C. 161Patents for plants.
Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent thereof, subject to the conditions and requirements of this title.
The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

35 U.S.C. 163Grant.
In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.
(Amended Oct. 27, 1998, Public Law 105-289, sec. 3, 112 Stat. 2781.)

EUROPE:

Art 53EPC
European patents shall not be granted in respect of:
(b) plant or animal varieties or essentially biological processes for the production of plants or animals

Rule 26(5) EPC
A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomenon such as crossing and selection.

C. INTERPRETATION OF THE LAW AND EXPLANATIONS

In general, raw products of nature are not patentable. DNA products usually become patentable when they have been isolated, purified, or modified to produce a unique form not found in nature.

INDIA:

Non-Patentable inventions:

1. Discovery of any living thing occurring in nature is not patentable subject matter in India.
2. Prohibited biotech subjects further include plant and animals in whole or any part thereof including seeds; varieties, species and essentially biological processes for production or propagation of plants and animals.
3. Genetically modified multi-cellular organisms including plants, animals, human beings and their parts are excluded from patentability in India.
4. Varieties of plants developed using modern plant breeding techniques cannot be patented as per the Indian patent law.
5. Transgenic plants are not patentable in India
6. Gene sequences, DNA sequences without function are non-patentable.

Patentable inventions:

1. Promoters, enhancers, individual exons
2. Expressed sequences as expressed sequence tags (ESTs) or cDNAs
3. Whole transcribed genes as cDNAs
4. Individual mutations known to cause disease,
5. Polymorphisms
6. Cloning vectors, formed from bacterial DNA
7. Expression vectors, also formed from bacterial DNA,
8. Isolated host cells transformed with expression vectors
9. Amino acid sequences (proteins) and the use of such proteins as medicines
10. Protein sequences of antibodies, which are used as markers [Transgenic plants offer an attractive method for large-scale production of antibodies for immunotherapy]
11. Nucleic acid probes, which are fragments of DNA that are used to locate particular parts of DNA sequences
12. Methods of identifying the existence of a DNA sequence or a mutation or deletion in an individual
13. Testing kits for detecting genetic mutations/ diagnostic kits

14. Whole genomes [only with established utility ; refer Indian Patent No.216295]
15. Microorganisms and microbiological processes are patentable subject matter.
16. Biological material such as recombinant DNA, plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention.
17. Gene sequences and DNA sequences having disclosed functions are considered patentable in India. Eg: Patents have been granted for DNA sequences from plants such as nutmeg, cinnamon, rubber, jojoba and cocoa.
18. Processes of extraction of active ingredients, product developments by using Medicinal & Aromatic Plants and usages of Medicinal & Aromatic Plants for new purposes are patentable subject matter.
19. In India, concerning patentability of transgenic plants some amendments have been made in the Indian Patents Act 1970. But these amendments seem to be more in favour of patenting process of producing transgenic plants rather than patenting of transgenic plant itself.
20. The mention of 'plants' has been omitted from section 3 (i) in the 2nd amendment of Patent act 1970. Since section 3 (i) addresses principally the 'process' of human/animal treatments, the amendment can be a priori interpreted as a possibility to grant patents for genetic modification process of plants.

[The portions covered under the provisions of The Protection of Plant Varieties And Farmers' Rights Act, 2001 are outside the scope of this Inventor Guidance Notes]

USA:

1. In the United States, any living organism that is the product of human intervention (such as by some breeding process or laboratory-based alteration) qualifies as a composition of matter, which is patentable (*Diamond v Chakrabarty* (1980) 447 US 303). As a result, plants are patentable subject matter (35 U.S.C. 101).

2. Furthermore, the United States has extended patent protection to plants produced by either sexual or asexual reproduction and to plant parts including seeds and tissue cultures (*Ex parte Hibberd* (1985) 227 USPQ 433).

3. Utility Patents cover *"inventions"* -- a machine, an article of manufacture, a method of doing something, a chemical or DNA sequence or the method of its use, products of genetic engineering, or improvements to any of these things.

4. Plant Patents may be granted to anyone who invents or discovers, and asexually reproduces, a new variety of certain kinds of plants. (Note that other kinds of plants, especially those altered by genetic engineering, may be protectable under utility patents).

5. New varieties of many asexually propagated plants are patentable, i.e. for example Apple trees and Rose bushes that are propagated by cutting pieces of the stem rather than by germinating seeds.

6. Tuber-propagated plants, such as potatoes, were exempted from patent coverage because the part of the plant used for asexual propagation was also the part used as food.

7. DNA sequences -typically isolated and purified, qualify as manufactures or compositions of matter under U.S. law. In other words, they are products of human ingenuity "having a distinctive name, character, [and] use". Hence they are patentable subject matter in the United States.

8. In order for DNA sequences to be distinguished from their naturally occurring counterparts, which cannot be patented, the patent application must state that the invention has been purified or isolated or is part of a recombinant molecule or is now part of a vector.

9. Genetically engineered plants, seeds & plant tissues are patentable. For eg. Patent No. US 5159135& EP 301749 cover all cotton & soybean seeds and plants which contain a recombinant gene construct i.e. are genetically engineered.

EUROPE:

Non-Patentable inventions:

1. So long as the characteristics of a plant resulting from a process of crossing and selection are solely the result of an essentially biological process, then a process for its production is excluded from patentability.
2. The use of technical steps to facilitate the crossing and selection process (such as the use of DNA markers) does not make the process patentable, so long as their use has no impact on the outcome of the biological process.
3. A process involving human intervention where the plant genome is modified by genetic engineering, where the GMO plant product is not solely the result of plant crossing and selection, is not patentable.
   [Explanation: In case of a GMO plant product wherein its attributes are NOT SOLELY because of the human efforts; i.e some natural phenomenon also plays a major role in getting the required characteristics of this GMO; it is not patentable. But if the end product was a result of sheer human intervention, it will be patentable invention (point #4 next page)]
4. A genetic modification of a specific plant variety is not patentable
5. Plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.
6. Plant traits per se are not patentable but gene sequences for modifying plant traits are.

Patentable inventions:

1. Technical steps or tools for plant breeding could, in themselves qualify as patentable inventions.

[Explanation: Although DNA markers are valuable tools for breeding, their use can neither be protected in a process for breeding a plant, nor are can they be protected as DNA sequences in a plant, if they are too short to be attributed any biological function. **]**

2. A genetic modification of a wider scope, wider than varieties concerning maybe a species or a higher taxonomic level may be patentable.

[Explanation: In Europe, individual plant varieties *per se* are not patentable. However, a plant which is characterized by a particular gene (as opposed to its whole genome) is not included in the definition of a plant variety and is therefore patentable. Transgenic plants are patentable if they are not restricted to a specific plant variety, but represent a broader plant grouping.]

3. Hybrid plants & seeds are patentable.

[Explanation: In decision T 320/87 of EPO, known as Lubrizol, The Board of appeal allowed claims related to patentability of hybrid plants & seeds.]

4. If a process for the production of plants includes at least one essential technical step which cannot be carried out without human intervention, and which has a decisive impact on the final result, the process is not an "essentially biological process".

[Explanation: The step of inserting the resistance-conferring DNA sequence into the plant genome was found to be such a decisive, human-directed step and claims to the process of producing the genetically transformed plants were found patentable.]

5. Claims to genetically modified plant cells and to a process for producing genetically modified plants are held to be patentable

[Explanation: The term "microorganism" includes plant cells as manipulated in vitro in a laboratory. They therefore concluded that genetic engineering processes carried out on plant cells may be defined as "microbiological processes" and that the product, namely the genetically modified plant cells and cultures thereof may be defined as "the products thereof".]

D. EXAMPLES AND CASES

INDIA:

P1: 232681 COTTON EVENT MON15985 AND COMPOSITIONS AND METHODS FOR DETECTION
The invention provides cotton plants, cotton tissues, and cotton seeds that include the MON15985 event, which confers resistance to Lepidopteran insect damage. Also provided are assays for detecting the presence of the MON15985 event based on the DNA sequence of the recombinant construct inserted into the cotton genome that resulted in the MON15985 event and/or the genomic sequences flanking the insertion site.

P2: 247258 A TRANSGENIC EXPRESSION CONSTRUCT
The invention relates to efficient, high-throughput methods, systems, and DNA constructs for identification and isolation of transcription termination sequences. The invention relates further to specific terminator sequences identified by said methods isolated from rice.

P3: 246792 A METHOD FOR OBTAINING A MARKER-FREE UNIFORM TRANSGENIC PLANT
The present invention relates to a method for obtaining a marker-free, uniform transgenic plant, comprising -transforming a plant cell with a recombinant nucleic acid comprising a T-DNA construct wherein said T-DNA is provided with a foreign nucleic acid that is free of a reporter gene -regeneration of said cell under no selective pressure -testing said cell or progeny thereof for the presence or absence of at least a functional part of said foreign nucleic acid and identify transformed plant cells or progeny thereof -growing a plant from said identified cell or progeny thereof -testing the obtained plant for uniformity and selecting a uniform plant.

P4: 240297 A RECOMBINANT POLYNUCLEOTIDE FOR AN INSECT RESISTANT TRANSGENIC COT102 COTTON PLANT AND ITS METHOD OF DETECTION
The invention relates to poly-nucleotides which are characteristic of the transgenic cotton event COT102, plants comprising said poly-nucleotides, and methods of detecting the COT102 event. The COT102 event exhibits a novel genotype comprising two expression cassettes. The first cassette comprises a suitable promoter for expression in plants operably linked to a gene that encodes a V1P3A insecticidal toxin, useful in controlling a wide spectrum of lepidopteran insect pests, and a suitable poly-adenylation signal. The second cassette comprises a gene which, when expressed, can be used as a selectable marker.

P5: 219270 A METHOD FOR OBTAINING CELL LINES IN PROTEIN-FREE MEDIA AND CELL LINE OBTAINED BY THE METHOD
The present invention relates to a method of recovering mammalian cell clones adapted to serum and protein-free media; the procedure includes a two-stage adaptation process to grow in that condition. The present invention discloses a critical protein concentration interval in which cells must grow in order to gain the capacity to survive in serum and protein-free condition. Once the cells have grown at the critical interval concentrations, subsequent decreases of the concentration will affect neither viability nor cellular doubling time. The critical protein concentration interval is cell line specific. Furthermore, in the present invention mammalian cells clones are disclosed, which are stable in serum- and protein-free media for at least 40 generations; additionally, clones disclosed in the present invention express a recombinant product. The cell clones disclosed in the present invention produce the humanized anti~ EGF-R antibody hR3, the humanized anti-CD6 antibody TlhT, the chimeric anti CD3 antibody T3Q, or fragments thereof.

P6: 212093 A DIAGNOSTIC KIT FOR THE DETECTION AND/OR QUANTIFICATION OF THE NUCLEIC ACIDS OF ANY COMBINATION OF THE MICROBIAL SPECIES AND/OR GENERA SELECTED FROM THE GROUP CONSISTING OF ENTEROCOCCUS FAECIUM, LISTERIA MONOCYTOGENES, NEISSERIA MENINGITIDIS, STAPHYLOCOCCUS SAPROPHYTICUS, STREPTOCOCCUS AGALACTIAE, CANDIDA ALBICANS, ENTEROCOCCUS SPECIES, NEISSERIA SPECIES, STAPHYLOCOCCUS SPECIES, STREPTOCOCCUS SPECIES AND CANDIDA SPECIES.

P7: 216295 SEQUENCE OF A PORTION OF THE GENOME OF WHITESPOT SYNDROME VIRUS (WSSV) AFFECTING SHRIMP
White spot syndrome virus (WSSV) is the major shrimp viral pathogen of Asia which causes serious losses to the shrimp culture industry in several Asian countries. The invention provides sequence information on the WSSV which enables development of diagnostics based on Polymerase Chain Reaction (PCR), which are highly specific for WSSV and much more sensitive compared to PCR based on the WSSV sequence information known in the art.

P8: 216568 A CHIMERIC GENE COMPRISING A NUCLEIC ACID FRAGMENT CONFERRING DISEASE RESISTANCE TO PLANTS
The preparation and use of an isolated nucleic acid fragment which confers a Pi-ta resistance gene-mediated defense response in plants against disease caused by fungal pathogens is described. Genes incorporating such nucleic acid fragments either alone or in combination with an AVR-Pita isolated nucleic acid fragment or functionally equivalent subfragments thereof and suitable regulatory sequences can be used to create transgenic plants which can produce a Pi-ta resistance gene-mediated defense response against a variety of fungal pathogens, in particular, the rice blast fungus.

P9: 225580 A METHOD OF PRODUCING A DROUGHT TOLERANT PLANT
The present invention relates to a method of producing a drought tolerant plant comprising: a) providing a nucleic acid construct comprising a promoter operably linked to a nucleic acid that inhibits farnesyl transferase beta activity; b) inserting said nucleic acid construct into a vector; c) transforming a plant, tissue culture, or a plant cell with the vector to obtain a plant, tissue culture or a plant cell with decreased farnesyl transferase beta activity; and d) growing said plant or regenerating a plant from said tissue culture or plant cell, wherein a drought tolerant plant is produced.

P10 : 223740 A RECOMBINANT DNA MOLECULE USEFUL AS A PROMOTER IN DICOT AS WELL AS MONOCOT PLANT CELLS
The invention relates to an artificial promoter which is characterised in that it comprises a chimeric molecule of recombinant DNA which, once introduced into plant cells of any class, promotes high expression levels of any DNA molecule that is fused to the 3' end thereof. The basic genetic elements of the inventive promoter molecule are as follows: a promoter nucleus with a consensus TATA box followed by an Exon/Intron/Exon region and a translational activity-potentiating element, all of which are produced artificially. Transcriptional expression-regulating elements can be inserted upstream of the promoter in order to provide the expression with the specific time-response capacity of organ or tissue. The artificial genetic elements designed can be functionally inserted between any active promoter in plant cells and any DNA sequence in order to increase the transcription/translation levels of the latter.

P11: 230713 POLYPEPTIDE OF THE HUMAN IMMUNOGLOBULIN SUPERFAMILY
A polypeptide in isolated form belonging to a subfamily of the human Immunoglobulin Superfamily selected from the group consisting of: a) a polypeptide comprising the amino acid sequence of murine Confluency Regulated Adhesion Molecule 1 (CRAM-1) as depicted in SEQ ID NO: 19; b) a polypeptide showing at least 70% sequence homology over the entire length to the polypeptide of (a); c) a polypeptide comprising the amino acid sequence of human Confluency Regulated Adhesion Molecule 1 (CRAM-1) as depicted in SEQ ID NO:23; d) a fragment of (a) comprising (i) the V domain of murine CRAM-1 as depicted in SEQ ID NO: 19 from amino acids 53 to 115; (ii) the V domain of murine CRAM-1 as depicted in SEQ ID NO: 19 from amino acids 53 to 115 and the C2 domain of murine CRAM-1 as depicted in SEQ ID NO: 19 from amino acids 160 to 219; (iii) amino acids 1 to 159 of murine CRAM-1 as depicted in SEQ ID NO: 19; or (iv) amino acids 1 to 238 of murine CRAM-1 as depicted in SEQ ID NO: 19; and e) a fragment of (c) comprising (i) the V domain of

human CRAM-1 as depicted in SEQ ID NO:23 from amino acids 53 to 115; or (ii) the V domain of human CRAM-1 as depicted in SEQ ID NO:23 from amino acids 53 to 115 and the C2 domain of human CRAM-1 as depicted in SEQ ID NO:23 from amino acids 160 to 219.

P12: 227983 ANTI-CD16A ANTIBODY
This invention relates to an anti-CD16A antibody comprising a VH domain comprising complementarily determining regions (CDRs) a CDRI having the amino acid sequence of SEQ ill NO:35, a CDR2 having the amino acid sequence of SEQ ill NO:39,' and a CDR3 having the amino acid sequence of SEQ ill NO:59 and a V L domain comprising a CDRI having the amino acid sequence of SEQ ill NO:67, a CDR2 having the amino acid sequence of SEQ ill NO:75, and a CDR3 having the amino acid sequence of SEQ ill NO:88, wherein at least one of said CDRs comprises at least one amino acid substitution selected from the group consisting of, in the V H domain, M34Y in CDRl, H50L in CDR2, W52F in CDR2, D54N in CDR2, N60S in CDR2, A62S in CDR2, W99Y in CDR3, AIOID in CDR3, and, in the VL domain, K24R in CDRl, A25S in CDRI, F32Y in CDRl, M33L in CDRl, N34A in CDRl, T50A, T50W, or T50S in CDR2, T51A in CDR2, N53S in CDR2, E55A or E55Q in CDR2, S56T in CDR2, N92Y in CDR3, N93S in CDR3, and D92T in CDR3, which positions are according to the Kabat numbering scheme.

USA:

Plant Patent Claim:
Eg: A new and distinct variety of peach tree, Prunus persica, designated 'Redhaven' substantially as herein shown and described.

Utility Patent Claim:
Eg:
1. A broccoli seed designated 393-2-19 and having ATCC Accession Number 203533.14
2. A broccoli plant having all the phenotypic characteristics of a plant produced from the seed of claim 1.
3. A seed from the plant of claim 2.

Patents Granted:

P1: The Terminator patent is an example of a utility patent. It claims patent protection for the method used to make Terminator plants as well as the seeds and plants that are made.

P2: 7652194 – Processes & Vectors for producing transgenic plants.

P3: 7956242 – Plant Quality traits.

P4: 4970151 - Plant Culture cell & use thereof.

P5: 5180676 – Method of Cultivating animal or plant cells.

P6: 6127606: Method of using trans-activation proteins to control expressions in transgenic plants.

P7: 5159135 - Genetic engineering of cotton plants and lines

P8: 6018109 – Hybrid maize plant & seeds

P9: PP12030 - Hybrid mint plant named 'Neerkalka' [**CSIR's plant patent**]

Applications Filed:

A1: US 2003/ 0121070 - Genes for modifying plant traits.

A2: US 2003/0101481 – Plant Gene Sequences I

A3: US 2004/0025204 – Plants & Plant Products

A4: US 2009/0320160 - Soybean transcription Terminators & use in expression of Transgenic genes in plants.

EUROPE:

P1: 1211926 – Method for breeding tomatoes having reduced water content and product of the method. [patent has been opposed and case hearing is going on]

P2: 1297113 – Cyanobacterial nucleic acid fragments encoding proteins useful for controlling plant traits via nuclear or plastome transformation

P3: 0724641 - Antimicrobial proteins

P4: 2173885 - Expression cassette, T-DNA molecule, plant expression vector, transgenic plant cell as well as their use in the manufacturing of a vaccine

P5: 301749 - Particle-mediated transformation of soybean plants and lines

P6: 388186 - External regulation of gene expression

P7: 263017- Gramineous hybrid plants and process for preparing them

E. REFERENCES

1. THE PATENT ACT, 1970
2. United States Code Title 35 – Patents
3. European Patent Convention
4. General information concerning patents, USPTO, Jan 2011
5. Regulations under the Patent Cooperation Treaty
6. THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001
7. BIOTECHNOLOGY: The Patenting of DNA, John J Doll, Science, 1 May 1998:Vol. 280. no. 5364, pp. 689 - 69DOI 110.1126/science.280.5364.689
8. DNA FINGERPRINTING & CULTIVAR IDENTIFICATION, K V Bhat http://www.iasri.res.in/ebook/EBADAT/6-Other%20Useful%20Techniques/9-DNA%20Fingerprinting-IASRI-KVB.pdf
9. PLANT VARIETIES PROTECTION, http://www.witts.org/IPR_biotech/biotech_10_aug01/wista_bio_answer.htm
10. GENES & PATENTING: http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml
11. Patentability of Biotechnology Inventions in India: http://www.sinapseblog.com/2011/01/patentability-of-biotechnology.html
12. Patentability of Genetically Engineered Plants in Europe www.jurisdiction.com/par0001.htm
13. Patentability of protein structures, mobile.vossiusandpartner.com/pdf/pdf_27.pdf
14. www.biotech-info.net/europe_lifts.html
15. Patenting in Biotechnology Sujit Bhattacharya *DESIDOC Bulletin of Information Technology,* Vol. 27, No. 6, November 2007, pp. 31-39 © 2007,DESIDOC
16. www.ipeg.eu/?p=1991
17. Patents and Agricultural Biotechnology agribiotech.info/details/Daviespatentssent%20to%20web%2002.pdf
18. www.patentlens.net/daisy/bios/1234
19. Plant Varieties Rights; A study in the light of TRIPS and UPOV
20. Intellectual Property Rights for Medicinal and Aromatic Plants in India openmed.nic.in/
21. India: Transgenic crops and IP rights www.internationallawoffice.com/newsletters/detail.aspx?g=34d02c61
22. Transgenic crops: an introduction & resource guide, cls.casa.colostate.edu/transgeniccrops/patent.html
23. Patentability of plants: technical & legal aspects. nopr.niscair.res.in/bitstream/123456789/.../JIPR%2014(3)%20203-213.pdf
24. www.indianpatents.org
25. http://www.managingip.com/Article/1321869/EuropeHow-to-patent-protein-structures.html
26. http://books.google.co.in/books?id=Hay9Hw1lbLAC&pg=PA276&lpg=PA276&dq=A+cell+line+is+patentable+in+India+only+if+artificially+produced&source=bl&ots=_dwV6Vdhtk&sig=eduFxS4UKwzOi5G9rz1yRfdmhhA&hl=en#v=onepage&q&f=false

*Note: This IGN was finalized in the current form on 16th Nov 2011. 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

INVENTOR GUIDANCE NOTES

(White papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

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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 Microorganisms, Institut Pasteur.

✓ Patentable

* Not naturally occurring; inventions with considerable human intervention.

B. RELEVENT LEGAL EXTRACTS:

COUNTRY & LAW	LEGAL EXCERPTS
[1]**INDIA [The Patents Act 1970]**	**S3. What are not inventions** (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 (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
[2]**USA [35 USC]**	**35 U.S.C. 101Inventions patentable.** 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. **35 U.S.C. 103Conditions for patentability; non-obvious subject matter.** (3)For purposes of paragraph (1), the term "biotechnological process" means- (A)a process of genetically altering or otherwise inducing a single- or multi-celled organism to- (i)express an exogenous nucleotide sequence, (ii)inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii)express a specific physiological characteristic not naturally associated with said organism; (B)cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (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)
[3]**EUROPE [EPC]**	**Article 53** **Exceptions to patentability** European patents shall not be granted in respect of: (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; (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.

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.

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

Indian Patent IN 223392 titled MODIFIED FREE-LIVING MICROBES, VACCINE COMPOSITIONS AND METHODS OF USE THEREOF	Independent Claims: -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...

Other areas involving microorganisms like microbial products and processes thereof are also patentable in India.

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

Indian Patent 209517 titled PROBIOTICS FOR PET FOOD APPLICATIONS	Independent Claims: - 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...

[12]The 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 233428 titled 'ATTENUATED STRAINS OF VIBRIO CHOLERAE 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....

USA :

The US Patent system is liberal in granting patents to new microbiological inventions with proved utility and considerable human intervention.
For eg. [16]A 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 :

[18]The 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 136/CAL/98 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 228892	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 226136	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 225709	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:
[18]Funk Brothers Seed Co v. Kalo Inoculant co. (33US 127(1948)).	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.	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.	**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.**
[11,17]Diamond v. Chakrabarty [44U.S. 303 1980]	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. 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. 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. 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.	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.	**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.**

Patent No	Title	Types of Claims	Independent claims
Chakrabarty's Patent: US 4259444:	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 5589168	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.

[18]In 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 2343319	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	cell, a pure culture, A polymer, A probiotic composition, A primer, An isolated transporter peptide, & An isolated nucleotide sequence. Related Process claims.	-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.

E. REFERENCES:

1. The Patent Act, 1970
2. United States Code Title 35 – Patents
3. European Patent Convention
4. Agreement On Trade-Related Aspects Of Intellectual Property Rights
5. General information concerning patents, USPTO, Jan 2011
6. Regulations under the Patent Cooperation Treaty
7. Draft Manual of Patent Practice & Procedures, India.
8. www.delphion.com
9. www.ipindia.nic.in
10. http://www.itagbs.com/articles/patent_micro.html
11. http://www.lexorbis.com/pdf/patenting-microorganisms.pdf
12. http://legalservicesindia.com/article/article/patenting-of-micro-organisms-in-india-an-overview-231-1.html
13. http://www.hg.org/article.asp?id=5510
14. http://www.scribd.com/doc/8672130/Patent-Ability-of-MicroOrganisms
15. http://www.biotecnika.org/blog/sampada/patenting-living-organisms-india-dimminaco-g-case
16. http://www.luthra.com/admin/article_images/Patenting-Micro-Organisms-Globally.pdf
17. http://lex-warrierlegalsolutions.blogspot.com/2010/11/patenting-of-microorganisms.html
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

INVENTOR GUIDANCE NOTES

(White papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC: **SOFTWARE/ALGORITHMS**	AUTHOR: **SNEHA KANITKAR** **A207, PAML** **National Chemical Laboratory** **Pune – 411008** **Phone: +91-20-2590-2757** **Email: sv.kanitkar@ncl.res.in**
IGN Number: **IGN-03**	VERSION: **02**
SCOPE: **This Inventor Guidance Notes provides information for scientists working in the area of Software/Algorithms and explains what can and what cannot be patented.**	DATE: **29th December 2011**
TABLE OF CONTENTS: **A. Summary** **B. Relevant legal extracts** **C. Interpretation of the law and explanations** **D. Examples and cases** **E. References**	REVIEWER: **Nitin S Tewari** **V. Premnath**

A. SUMMARY:

DETAILS	INDIA	USA	EUROPE
The Law	The Patent Act, 1970	United States Code Title 35 – Patents	European Patent Convention
Criterion For Patentability of software/algorithm based inventions	Novelty, Non-obviousness, Industrial Application, proven technical application/ software intrinsic to or embedded in hardware	Novelty, non-obviousness and industrial application, invention should have useful, concrete and tangible result.	Novelty, Non-obviousness, Industrial Application, application sufficiently technical in nature.
Computer program/ Software	Not Patentable per se. But Patentable if the software: 1.Has a proven technical application [IN 227390] 2.Is embedded in hardware [IN227663]	Patentable if 'useful'. Inventions need not be of a technical nature, but must fulfil the "usefulness" criterion. [US7110848]	Not Patentable as such. But patentable if the software makes a considerable technical contribution to the invention. [EP2084535]
Computer program encoded on a computer readable medium [CD/DVD/Floppy etc]	Not patentable as such. But may be granted as one of the claims in an invention with proven technical application. [IN223889]	Patentable. Commonly known as Beauregard claims. [US6728315]	Beauregard claims allowed. Patentable if encoded software has a "technical effect." [EP1579689]
Mathematical Methods/Algorithms	Not Patentable per se but its application is patentable if applied to solve a technical problem. [IN224863]	Not patentable as such. Application of the algorithm may be patentable if the usefulness criterion is fulfilled. [US4344142]	Not Patentable. May be incorporated in a patentable invention to achieve a technical application. [EP2394572]
Business Methods	Not Patentable.	Patentable. [US5960411]	Not Patentable.
Data Structures / Graphical User Interface	Patentable [IN220099, IN245514]	Patentable [US6961664, US6941317]	Patentable [EP1739656, EP1049089]
Software patents relevant to NCL's area of research:	IN 214400 An Apparatus For The Identification And/or Separation Of Complex Composite Signals Into Its Deterministic And Noise Components [NCL] IN 227390 Volume Measurement In 3d Datasets[For Tumour Measurements] IN227663 Device, Method And System For Monitoring Pressure In Body Cavities IN181392 Automatic Reading Lactometer Reading Indicator.	US 7660709 Bioinformatics research and analysis system and methods associated therewith US7920994 Method for the evolutionary design of biochemical reaction networks US6490573 Neural network for modelling ecological and biological systems US 6826513 Method And Apparatus For Online Identification Of Safe Operation And Advance Detection Of Unsafe Operation Of A System Or Process [NCL]	EP1552472 Methods and systems to identify operational reaction pathways GB2434225 Random Forest Modelling Of Cellular Phenotypes EP1600864 Modelling tool for chemical processes
Example: A software patent on motion estimation granted to APPLE Computers ,Inc in IN, US & EP claims:	IN 223889 Titled: A method of performing motion estimation in a digital video system claims: -A method of performing motion estimation in a digital video system.. -A computer readable medium storing a set of instructions... -A method for decoding a bitstream... -A bitstream comprising of... -A method for computing a motion vector, the method comprising... -A computer readable medium storing a set of instructions, which when executed by one or more processors, causes... -A method for decoding video picture.. -For a stream comprising first, second, and third video pictures, comprising...	US6728315 Titled: Method and apparatus for variable accuracy inter-picture timing specification for digital video encoding with reduced requirements for division operations claims: - -A method of performing motion estimation in a digital video system, said method comprising.... - A computer readable medium, said computer readable medium comprising a set of computer instructions for performing motion estimation, said set of computer instructions implementing a set of steps comprising...	EP1579689 titled Method and apparatus for variable accuracy inter-picture timing specification for digital video encoding with reduced requirements for division operations claims : - -A method of performing motion estimation in a digital video system, said method comprising... -A computer readable medium, said computer readable medium comprising.....

[Note: The Copyright Law of each country protects Computer program/ software per se as literary works]

[Note: Refer Section D of this document for the corresponding claims of above mentioned patents of each country]

B. RELEVENT LEGAL EXTRACTS:

COUNTRY & LAW:	LEGAL EXCERPTS:
India: The Patent Act, 1970	**S 3 Non Patentable Inventions:** (c) the mere discovery of a scientific principle or the formulation of an abstract theory (k) a mathematical or business method or a computer program per se or algorithms (m) a mere scheme or rule or method of performing mental act or method of playing game; (n) a presentation of information;
USA: 35 U.S.C.	**101 Inventions patentable.** 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 therefor, subject to the conditions and requirements of this title.
Europe: EPC	**Article 52** **Patentable inventions** (1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information

C. INTERPRETATION OF THE LAW & EXPLANATION:

INDIA:

The Patents Act 1970 prohibits patenting of mathematical or business methods, algorithms and computer programme/software per se.(Sec 3 k)

However if the computer program is 'sufficiently technical in nature' i.e. if the computer program possesses a technical application to the industry, it may be patentable provided it satisfies the basic criteria of Novelty, Non-Obviousness & Utility. Software based patent, with proven technical application have been granted in India.

For Eg: IN 227390 titled VOLUME MEASUREMENT IN 3D DATASETS presents, an automated method , corresponding device and computer software, which analyze a volume of interest around a singled out tumour, and which, by virtue of a 3D distance transform and a region drawing scheme, automatically segment a tumour out of a given volume.
This invention clearly solves a technical problem and provides a technical solution for the measurement of the tumour volume and was hence granted a patent by the Indian Patent Office.

Software which is intrinsic to or "embedded" in the hardware is patentable as per the Patents Amendment Ordinance, 2004. An invention consisting of hardware along with software or computer program in order to perform the function of the hardware may be considered patentable.

For Eg: IN227663 titled DEVICE, METHOD AND SYSTEM FOR MONITORING PRESSURE IN BODY CAVITIES relates to a portable apparatus for monitoring, sampling and storing pressure and software for analysis of pressures. The invention includes an algorithm for analysis and presentations of pressures and software for performing the analysis. The computer software may be integrated in the portable apparatus and in a variety of systems.

Embedding software in hardware easily overcomes the hurdle of non-patentability of 'computer programs per se' [Sec 3k]. Even then, it is important that the software sought to be protected is not merely a new version or an improvement over an existing code.

Algorithms/ Mathematical formulae as such are not-patentable in India; however their technical application to solve a given problem may well be patentable.

For Eg: IN 224863 titled A METHOD OF OPTIMISING ALLOCATION OF RESOURCES FOR A RESOURCE ALLOCATION PROBLEM talks of a heuristic search method which can be carried out to optimize a solution for a modelled problem. The Patent claims a method comprising of constructing a heuristic searching algorithm from a plurality of heuristic searching parts and applying the constructed heuristic search algorithm to the constructed model in order to optimise a solution for the modelled problem.

[4]In another example, in *Vicom/Computer-related invention* [1987] 1 OJEPO 14 (T208/84) the invention concerned a mathematical method for manipulating data representing an image, leading to an enhanced digital image. Claims to a method of digitally filtering data performed on a conventional general purpose computer were rejected, since those claims were held to define an abstract concept not distinguished from a mathematical method. However, claims to a method of image processing which used the mathematical method to operate on numbers representing an image can be allowed.
The reasoning was that the image processing performed was a technical (i.e. non- excluded) process which related to technical quality of the image and that a claim directed to a technical process in which the method used does not seek protection for the mathematical method as such. Therefore the allowable claims as such went beyond a mathematical method.

[4]The claims relating to software programme product are nothing but computer programme *per se* simply expressed on a computer readable storage medium and are not patentable as such. However it may be granted as a part of the claims wherein the invention is software based with a proven technical application.
For Eg.: A claim for a computer readable medium storing the set of instructions has been granted to Apple Computers Inc. in patent no IN223889 titled A METHOD OF PERFORMING MOTION ESTIMATION IN A DIGITAL VIDEO SYSTEM. Claim no 53 is 'A computer readable medium storing a set of instructions, which when executed by one or more processors, causes the one or more processors to perform the steps of...'

Data Structures and GUIs have been granted patents in India.
For Eg: IN 220099 titled A MICROPROCESSOR CONTROLLED INTUITIVE GESTURE-BASED GRAPHICAL USER INTERFACED ELECTRONIC COMMUNICATION DEVICE &

IN245514 titled DATA STRUCTURE FOR DATA STREAMING SYSTEM

USA:

Software-related inventions and applications of mathematical algorithms are patentable in the US provided they produce useful, concrete and tangible results. [in addition to the basic criteria of novelty, non-obviousness and industrial application]

US Patent law doesn't require the invention to be of a 'technical' nature as such but the invention must fulfil a 'Usefulness' criterion. Thus methods of performing computer-aided human activities can also be granted patents. Such patents are called 'Business Method patents' and are widely accepted in US Patent regime. For Eg: US5960411 : Amazon.com- Patent for 1 click online shopping

In USA, patenting of inventive software/computer program encoded on a computer readable medium such as a CD-ROM or a floppy Disc is patentable. In such type of claims,(commonly known as Beauregard type Patent claims) certain pure software is protectable, provided it is encoded on a computer-readable medium.
A typical Beauregard claim would read like:
A computer-readable medium having computer-executable instructions for performing a method comprising:
•maintaining a DB identifying real property buyers and the corresponding real property interests;
•scanning ... an electronic listing service...
•controlling a printer to print a report.

Invention related to Data structures & Graphical User Interface (GUI) is also patentable in the US. [US6728315]
A typical data structure claim would be as follows:
A computer-readable medium having stored there on a data structure comprising:
•a first field containing data representing a desired real property characteristic of interest to a buyer;
•a second field containing data representing a second real property characteristic; and
•a third field containing data representing an interest correlation derived from the first field and the second field.

Eg. US6961664 titled METHODS OF POPULATING DATA STRUCTURES FOR USE IN EVOLUTIONARY SIMULATIONS PROVIDES NOVEL METHODS OF POPULATING DATA STRUCTURES FOR USE IN EVOLUTIONARY MODELLING.

A typical GUI claim would be : [US7856603]
An apparatus comprising:
- a display screen;
- a symbol generator that generates for display on the display screen a set of first graphical symbols in a 3 by 3 matrix arrangement; wherein ....
- a selector for selection of graphical symbols on the display screen,....; and
- a controller, connected to the symbol generator and the selector,....

Eg. US6941317 titled 'GRAPHICAL USER INTERFACE FOR DISPLAY AND ANALYSIS OF BIOLOGICAL SEQUENCE DATA' provides a computer research tool for searching and displaying biological data. Specifically, the invention provides a computer research tool for performing computerized research of biological data from various databases and for providing a novel graphical user interface that significantly enhances biological data representation, progressive querying and cross-navigation of windows and databases.

Mathematical methods/ Algorithms are not patentable as such because they are abstract concepts. But the applications of such methods/algorithms may be patentable.
For Eg: US4344142 titled Direct digital control of rubber moulding presses provides a process for curing rubber which is digitally controlled by means of a mathematical equation.

EUROPE:

In Europe software/ computer programs are as such not patentable. However if the invention is "*sufficiently technical in nature*"; patent can be granted for the same.

Beauregard claims i.e claims for inventive software/computer program encoded on a computer readable medium such as a CD-ROM or a floppy Disc are patentable provided that the encoded software has a

"technical effect."

Graphical user Interface and Data structures with technical applications are patentable in EP.
Eg. EP1739656B1 Speech recognition method and speech recognition apparatus provides an interactive process using speech recognition together with a graphical user interface comprising a plurality of settable graphical user interface items; the recognition rate is improved by reducing recognition target vocabulary.
EP1049089B1 Data structure for control information on rewriteable data storage media.

Business methods are excluded from patentability.

According to the guidelines issued by the EPC, a computer program that improves the working of a general purpose computer, e.g. by organizing its memory in a manner so as to increase its speed, would be patentable as it has a technical effect.

Mathematical methods are clearly not patentable. But the technical applications of mathematical methods/algorithms may be granted patents in EP.
Eg. EP2394572 titled 'Apparatus for detecting and discriminating breathing patterns from respiratory signals' employs an algorithm for diagnosis of sleep disorders employing a classifier algorithm to manipulate the epoch.

D. EXAMPLES AND CASES:

INDIA:

A Compilation Table of Granted Patents and their Claims:

Patent No:	Title:	Types of Claims granted:	Independent Claims:
IN214400	An Apparatus For The Identification And/or Separation Of Complex Composite Signals Into Its Deterministic And Noise Components [NCL's Patent]	1.Product Claim-Apparatus	1. An apparatus for identification and/or separation of composite signals obtained from an instrument/equipment recording the variations in a system property as sequential or time-series data from the said instruments/equipments selected from medical diagnostic and scanning equipment, seismographic instruments, tomography, image analyzers, molecular spectroscopy, chemical reactors/reactions, into its deterministic (true signal) and noisy parts which comprises, (a) source means for obtaining the signal to be identified and/or separated from suitable sensors appropriately located in an apparatus/equipment; (b) means for digitizing the said composite signal, obtained as sequential or time-series data relating to a variation in a system property, (c) computing means for subjecting the said digitized data obtained from step (b) above to wavelet transform to obtain a scalogram in terms of wavelet coefficients; (d) computing means for organizing the said resulting wavelet coefficients in each of the scales to form new sets of data; (e) computing means for taking each of the above said data sets and carry out their wavelet transform to obtain another scalogram in terms of wavelet coefficients; (f) computing means for implementing steps ctf e. recursively with testing for the constancy in the power distribution, the said power distribution being the ratio of the power in a particular scale with respect to the total power in all the scales of that scalogram for two consecutive recursive scalograms and thereby identifying the recursive wavelet scales contributing to noise in the signal; (g) computing means for eliminating the above said wavelet coefficients in the recursive wavelet scales contributing to noise by setting them to zero; (h) computing means for inverting above said the wavelet coefficients by inverse recursive wavelet transformation and thereby determining the deterministic signal component, the said signal component being the true signal in digitized form separated from the noise component. (i) means for converting the above said digitized deterministic signal component to an analog signal using D to A converter
IN227390	Volume Measurement In 3d Datasets[For Tumour Measurements]	1. Process Claim for A method of determining 6.Product Claim for a device 10. Product Claim for a computer program to achieve a technical output.	1. A method for determining a volume of an object from three-dimensional volume data including graphic information units, comprising: determining a volume of interest including the object; determining thresholds of the graphic information units in the volume of interest; performing a distance transform on the basis of the thresholds for determining a distance map consisting of voxels; providing a seed point in the distance map, which seed point is on the object; determining a number of core-voxels and a number of front-voxels by using the seed point; and determining the volume of the object on the basis of the number of core-voxels and the number of front-voxels. 6. Image processing device, comprising: a memory for storing three-dimensional volume data; and an image processor for determining a volume of an object from the three-dimensional volume data which includes graphic information units, which image processor is adapted to perform the following operation: determining a volume of interest including the object; determining thresholds of the graphic information units in the volume of interest; performing a distance transform on the basis of the thresholds for determining a distance map consisting of voxels; providing a seed point in the distance map, which seed point is on the object; determining a number of core-voxels and a number of front-voxels by using the seed point; and determining the volume of the object on the basis of the number of core-voxels and the number of front-voxels. 10. Computer program comprising computer code means for performing the following operation for determining a volume of an object form three-dimensional volume data including graphic information units when the computer code means is executed on a computerized image processing device: determining a volume of interest including the object; determining thresholds of the graphic information units in the volume of interest; performing a distance transform on the basis of the thresholds for determining a distance map consisting of voxels; providing a seed point in the distance map, which seed point is on the object; determining a number of core-voxels and a number of front-voxels by using the

			seed point; and determining the volume of the object on the basis of the number of core-voxels and the number of front-voxels.
IN227663	Device, Method And System For Monitoring Pressure In Body Cavities	Process Claim for a method of analysis.	A method for analysing pressure signals comprising pressure related digital data with a time reference, derived from pressure measurements on or in a body of a human being or animal, said method comprising the steps of: identifying from said digital data features related to single pressure waves in said pressure signals, said identifying step including determination of a minimum pressure value related to diastolic minimum value and a maximum pressure value related to systolic maximum value, and determining at least one parameter of the single wave parameters elected from the group of: pressure amplitude = ?P = [(maximum pressure value) - (minimum pressure value)], latency (?T), rise time or rise time coefficient = ?P/?T, and wavelength of the single wave, and comprising the further step of: determining numbers of said single pressure waves occurring during a given time sequence, wherein said determining of numbers includes: determining numbers of single pressure waves with pre-selected values of one or more of said single pressure wave parameters during said given time sequence, and further includes determining numbers of single pressure waves with pre-selected combinations of two or more of said single pressure wave parameters during said given time sequence.
IN181392	Automatic Reading Lactometer Reading Indicator.	Product Claim for an automatic device with a supporting software for its functioning.	An Automatic corrected lactometer reading indicator to determine the correct specific gravity of liquids more specifically milk, without any additional diluents, chemicals ; the said indicator comprising:(a)..... (e) The said measuring head connected to a microprocessor based electronic control unit along with appropriate firmware and software to control the various controls of the unit.
IN224863	A Method Of Optimising Allocation Of Resources For A Resource Allocation Problem	1.Process Claim 2. Process Claim 3. Process Claim for a method of constructing a heuristic searching algorithm.	1.A method of optimising allocation of resources for a resource allocation problem, the problem being defined by problem variables, problem expressions, problem constraints and an objective function to be optimised in accordance with a predetermined optimisation criterion, wherein the problem variables are representative of at least some of resources to be allocated, temporal parameters associated with allocation of the resources, tasks to be performed, costs associated with allocation of resources, capabilities of the resources and capacity of the resources, wherein the problem expressions are representative of relationships between the problem variables, wherein the problem constraints are representative of constraints placed upon the problem variables, and wherein said problem variables, problem expressions, problem constraints and objective function are stored on a memory, the method being carried out by a data processor and comprising the steps of: (i) building a model of said resource allocation problem in accordance with said problem variables, problem expressions, problem constraints, and objective function and storing said model in said memory, (ii) generating a solution to the modelled problem and storing said solution in said memory, the solution comprising a set of values representative of at least some of the problem variables, (iii) applying a change to the generated solution by modifying one or more values in the set, (iv) identifying problem expressions directly and/or indirectly dependent on the modified values, (v) of the dependent problem expressions identified at step (iv), (a) selecting an identified problem expression from the dependent problem expressions identified at step (iv), (b) evaluating whether one or more inputs to the selected problem expression has changed, (c) if the or each input has not changed, marking the selected problem expression, and all problem expressions dependent on the said selected problem expression as unchanged, (d) selecting the next problem expression identified at step (iv), and (e) («) repeating steps (b) - (d) until there are no further problem expressions to be selected; (vi) generating a further solution to the modelled problem in accordance with the modified one or more values in the set applied in step (iii) and the problem expressions identified in step (iv); (viii) determining whether the generated further solution better satisfies the objective function and if so, setting the generated further solution as the solution to be modified in step (iii);

			(vii) repeating steps (iii) to (vi) until a predetermined number of solutions have been generated; (ix) outputting the solution which best satisfies the objective function as a solution to the modelled problem. 6. A method of constructing a model of a problem that involves a plurality of variables, the problem being definable by predetermined conditions, constraints and objectives, the method being carried out by a data processor and comprising the step of: defining a plurality of expressions as corresponding one or more declarative statements, wherein at least some of the expressions are dependent on at least one of said variables and describe at least in part the conditions, constraints and objectives of said problem. 8. A method of optimising a model of a problem constructed according to claim 6 or claim 7, comprising the step of constructing a heuristic searching algorithm from a plurality of heuristic searching parts and applying the constructed heuristic search algorithm to the constructed model in order to optimise a solution for the modelled problem.
IN220099	A MICROPROCESSOR CONTROLLED INTUITIVE GESTURE-BASED GRAPHICAL USER INTERFACED ELECTRONIC COMMUNICATION DEVICE	1. Product claim for a graphical user interfaced electronic communication device	1. A microprocessor-controlled intuitive gesture-based graphical user interfaced electronic communication device comprising: (A) gesture-based graphical user interface enabled touch-sensitive screen for displaying at least one gesture-supported screen object; and (B) receiving the user input corresponding to a selection of the said screen object and evaluating the said user input corresponding to gesture selection; and (C) providing at least one user feedback acknowledging the said gesture selection; and determining if the said user input is said function call; and if the user input is the said function call performing a function; and if the user input is not the said function call, returning to the step of automatically presenting on the screen a said directional palette (step C) 1)).
IN245514	DATA STRUCTURE FOR DATA STREAMING SYSTEM	1. Product Claim for a data structure. 8. Product claim for a computer readable medium on which the data structure has been encoded.	1. A data structure for storing a data source for a streaming system, the data source including a plurality of encoded data streams, each of the plurality of data streams being an independent representation of data from the data source encoded at a different resolution to the other of the plurality of data streams, the data structure comprising a header (600-680), a stream data structure (700) for each of the encoded data streams and one or more packets (800) of the encoded data streams, the header (600-680) being linked to one of the stream data structures (700), wherein each stream data structure (700) includes a header (705,740, 750), a link (710) to a next stream data structure and a link (720) to a first packet of the encoded data stream. 8. A data structure according to any of claims 1 to 7 encoded on a computer readable medium.

USA:

A Compilation Table of Granted Patents and their Claims:

Patent No:	Title:	Types of Claims:	Independent Claims:
US5960411	Method and system for placing a purchase	6. Business Method claim 9. Process claim for a server	6. A client system for ordering an item comprising: an identifier that identifies a customer; a display component for displaying information identifying the item; a single-action ordering component that in response to performance of only a single action, sends a request to a server system to order the identified

	order via a communications network	system	item, the request including the identifier so that the server system can locate additional information needed to complete the order and so that the server system can fulfill the generated order to complete purchase of the item; and a shopping cart ordering component that in response to performance of an add-to-shopping-cart action, sends a request to the server system to add the item to a shopping cart. 9. A server system for generating an order comprising: a shopping cart ordering component; and a single-action ordering component including: a data storage medium storing information for a plurality of users; a receiving component for receiving requests to order an item, a request including an indication of one of the plurality of users, the request being sent in response to only a single action being performed; and an order placement component that retrieves from the data storage medium information for the indicated user and that uses the retrieved information to place an order for the indicated user for the item; and an order fulfilment component that completes a purchase of the item in accordance with the order placed by the single-action ordering component.
US7660709	Bioinformatics research and analysis system and methods associated therewith	1.Process claim for genotype analysis 3. Product claim for a system for performing biomedical research.	1. A method for detennining genotype analysis for an application of specific drug treatments for identified genes using at least one database comprising the steps of: identifying at least one condition-specific genomic, proteomic or metabolic profile; identifying a statistically significant discriminator; accessing a global network defining known biological molecular processes; identifying a set of condition-specific nodes in the global network; calculating at least one shortest network path from a first node (j) to every other condition- specific node wherever a path exists in the global network; counting the number of condition specific nodes connected to the first node (j) by the shortest path containing a second node (i); determining a pre-calculated table of the shortest network paths from every node in the global network of interactions to all other nodes wherever such directed paths exist; counting the total number of nodes that are connected to the first node (j) by a shortest paths containing the second node (i) in the global network; calculating a probability score using a hypergeometric distribution with parameters determined by the number of nodes in the global network and number of condition specific nodes and number of nodes connected to the first node (j) by the shortest network paths containing the second node (i); utilizing the probability score for providing connectivity among genes or proteins of interest to assess role of nodes in the application of specific drug treatments; and wherein the hypergeometric distribution is p ij # (K ij) = (N ij K ij) (N - N ij - 1 K - K ij - 1) (N - 1 K - 1) = N ij ! (K - 1) ! (N - N ij - 1) ! (N - K) ! K ij ! (N - 1) ! (N ij - K ij) ! (K - K ij - 1) ! (N - N ij - K + K ij) ! such that PjKij is the probability of determining the shortest path network of nodes i and j; K is a set of experimentally-derived nodes of interest; and N is the total number of network nodes; and outputting a result to a user of the applicable drugs with the genomic or proteomic profiles, wherein all steps are performed on a processor. 3. A system for performing biomedical research comprising: a first database for classifying molecular-based samples from various subjects; a second database utilizing a plurality of predetermined tables of shortest network paths for a network of identified biological processes; and a processor for determining at least one statistically-significant discriminator using a computational distribution for scoring nodes in a network built from a set of experimentally-derived condition-specific genomic or proteomic profiles to identify applicable drugs with the genomic or proteomic profiles using the computational distribution p ij # (K ij) = (N ij K ij) (N - N ij - 1 K - K ij - 1) (N - 1 K - 1) = N ij ! (K - 1) ! (N - N ij - 1) ! (N - K) ! K ij ! (N - 1) ! (N ij - K ij) ! (K - K ij - 1) ! (N - N ij - K + K ij) ! such that PjKij is the probability of determining the shortest path network of nodes i and j; K is a set of experimentally-derived nodes of interest; and N is the total number of network nodes; andsuch that P]-Ky is the probability of determining the shortest path network of nodes i and j; K is a set of

			experimentally derived nodes of interest; and N is the total number of network nodes; and wherein a result is displayed to a user of the applicable drugs with the genomic or proteomic profiles.
US7734420	Methods and systems to identify operational reaction pathways	1. Process claim for software-aided reaction pathway identification.	1. A method of identifying an operational reaction pathway of a biosystem, wherein the steps of said method are performed on a suitably programmed computer programmed to execute the steps comprising: (a) providing a set of systemic reaction pathways through a reaction network representing said biosystem; (b) providing a set of phenomenological reaction pathways of said biosystem; (c) comparing said set of systemic reaction pathways with said set of phenomenological reaction pathways; and (d) Providing an output to a user of the selection of a pathway common to said set of systemic reaction pathways and said phenomenological reaction pathways of said biosystem, wherein said pathway common to said sets is an operational reaction pathway of said biosystem.
US7920994	Method for the evolutionary design of biochemical reaction networks	1. Software aided Process claim for biochemical reaction network.	1. A method for achieving an optimal function of a biochemical reaction network in an eukaryotic cell comprising: (a) calculating optimal properties of a biochemical reaction network by applying a computational optimization method to a list of reactions representing said biochemical reaction network; (b) altering said list of reactions in the biochemical reaction network and re-computing the optimal properties; (c) repeating (b) until a desired optimal function is reached; (d) constructing an eukaryotic cell having the genetic makeup containing the biochemical reactions which result from (c); (e) placing the eukaryotic cell constructed under (d) in culture under a specified environment to obtain a population of eukaryotic cells; and (f) Cultivating the eukaryotic cells as in step (e) for a sufficient period of time and under conditions to allow the cells to evolve to the desired optimal function determined under (c), wherein the biochemical reaction network comprises a comprehensive biochemical reaction network.
US7769576	Method and apparatus for integrated modelling, simulation and analysis of	1. Process claim for an electronic device implemented simulation system for chemical reactions. 18. Product claim for computer readable storage medium.	1. An electronic device-implemented method for simulating a system that comprises a plurality of chemical reactions, the method comprising: stochastically simulating the system, using the electronic device, by: determining, using the electronic device, a reaction occurrence time for a first chemical reaction using a first probability distribution associated with the first chemical reaction, wherein the first chemical reaction is a non-mass action chemical reaction in which a reaction rate is not proportional to a product of reactant quantities of reactants involved in the non-mass action chemical reaction, and determining, using the electronic device, a reaction time for a second chemical reaction using a second probability distribution associated with the second chemical reaction; and storing the reaction occurrence time for the first chemical reaction and the reaction time for the second chemical reaction in a memory associated with the electronic device. 18. A tangible computer-readable storage medium storing instructions for simulating a system that comprises a plurality of chemical reactions that, when executed by a processor, cause the processor to: stochastically simulate the system by: determining a reaction time for a first chemical reaction using a first probability distribution associated with the first chemical reaction, wherein the first chemical reaction is a non-mass action chemical reaction in which a reaction rate is not proportional to a product of reactant quantities of reactants involved in the non-mass action chemical reaction, and determining a reaction time for a second chemical reaction using a second probability distribution associated with the second chemical reaction; and store the reaction time for the first chemical reaction and the reaction time for the second chemical reaction in a memory.
US6490573	Neural network for modelling ecological and biological systems	1. Process claim for computational modelling of ecological/biological systems. 17. Process claim for operating the neural network	1. A method of operating a neural network for modelling ecological and biological systems having a plurality of hidden layer neurons, said method comprising the following steps: (a) distributing network inputs to said hidden layer neurons as driving independent variables; (b) said hidden layer neurons performing a user-specified regression model using the neuron weights as the dependent variable; (c) said regression model at each step evaluates whether the fit of the model to the data has improved from the previous step, and calculating the loss function; (d) said loss function is estimated using least squares estimation procedure aimed at minimizing the sum of squared deviations of the observed values for the independent variable from those predicted by the model stated as:

		19. Process claim for operating the neural network	Loss(PredObs)**2 wherein Pred and Obs indicate predicted and observed values respectively; (e) said loss function can also be estimated using weighted least squares stated as: Loss(ObsPred)2*(1/x2); (f) said loss function using a user-specified minimization algorithm; (g) said minimization algorithm using a Simplex procedure such that when a minimum appears to have been found, the Simplex will again be expanded to a larger size to see whether the respective minimum is a local minimum; (h) said loss function minimization algorithm using a quasi-Newton method; (i) said quasi-Newton method at each step of the iteration will evaluate the function at different points to estimate the first-order derivatives and second-order derivatives; (j) said minimization algorithm using the Hooke-Jeeves pattern moves; (k) said Hooke-Jeeves pattern moves at each iteration first defines a pattern of points by moving each parameter one by one, so as to optimize the current loss function; (l) said Hooke-Jeeves pattern to be tried if both the quasi-Newton and Simplex methods fail to produce reasonable estimates; (m) said minimization algorithm using Rosenbrock pattern search or method of rotating coordinates; (n) said Rosenbrock pattern search involving rotating the parameter space and aligning one axis with ridge and all other axes remaining orthogonal to this axis; (o) said detectable ridges pointing towards a minimum of function; (p) said Rosenbrock pattern search method to be tried if other methods fail to provide a reasonable estimate; otherwise (q) said Rosenbrock pattern search method terminates early when there are several constraint boundaries that intersect, leading to a discontinuity in the ridges; (r) said algorithms performed by each neuron of the hidden and output layers; (s) said output neuron(s) performs a test of the appropriateness of the overall model using the plot of the observed versus predicted (target) values. 17. A method of operating a neural network for ecological and biological system modeling having a plurality of hidden layer neurons said method comprising the following steps: (a) distributing network inputs as driving independent variables; (b) said independent variables comprising ecosystem parameters selected on the basis of biological or physical relationships; (c) said independent variables providing input to first layer of hidden neurons; (d) said neurons comprising processes within the elements of the ecological and biological systems; (e) said ecological and biological systems comprising bacteria, zooplankton, phytoplankton and hydrogeological features; (f) said processes within the ecological and biological systems comprising neuron weights; (g) said neuron weights having established biological relationship with neuron output; (h) said output of the first layer neurons being fed as input to the second layer of hidden neurons; (i) said second layer neurons generating input either to plurality of other hidden neuron layers or to the output neuron layer; (j) said output neuron layer generating the total output of the network. 19. A method of operating a neural network for ecological and biological system modeling having a plurality of hidden layer neurons said method comprising: a plurality of network inputs and at least one network output, said plurality of neurons, each receiving a plurality of inputs applied to the network, reproduces the network using a current model, and compares the output values with given target values, said current regression model "hierarchially relates" such that the current model is identical to the previous model with the exception of an addition or deletion of one or more driving or independent variables to the previous model and using the comparison between the goodness of fit for the two models or difference to set the learning rules without need for repetitive training and yielding a global minimum for each given set of input variables.
US7110848	Computer program	1.Product claim for a computer	1. A computer program product embodied on a computer readable medium containing instructions to perform a method that generates an NC program from a CAD drawing for a sheet metal processing CAD/CAM system, the computer program product comprising:

	product	program product embodied on a computer readable medium	division and tool assignment means for searching for the shape of an arc, the shape of an inner processing arc, and the shape of an oblique line from sheet metal processing graphics of a CAD drawing, and converting them to divided processing shapes enclosed by orthogonal lines, which are then defined as material slug shapes; rectangular division and tool assignment means for dividing a remnant rectangular shape obtained based on the generated material slug shapes into rectangles and subjecting them to a tool assignment process; NC program generation means for generating an NC program from tool assignment data; and output means for outputting control commands based on the generated NC program.
US4344142	Direct digital control of rubber moulding presses	1. Process claim for an algorithm–aided rubber-moulding procedure.	1. A method of operating a rubber-moulding press for precision moulded compounds with the aid of a digital computer, comprising: providing said computer with a data base for said press including at least, natural logarithm conversion data (1n), the activation energy constant (C) unique to each batch of said compound being moulded, and a constant (x) dependent upon the geometry of the particular mould of the press, initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure, constantly determining the temperature (Z) of the mould at a location closely adjacent to the mould cavity in the press during moulding, constantly providing the computer with the temperature (Z), repetitively performing in the computer, at frequent intervals during each cure, integrations to calculate from the series of temperature determinations the Arrhenius equation for reaction time during the cure, which is 1n v=CZ+x where v is the total required cure time, repetitively comparing in the computer at frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and opening the press automatically when a said comparison indicates completion of curing.
US6961664	Methods of populating data structures for use in evolutionary simulations	Process claim	1. A method of identifying molecules for production, wherein the molecules are represented by concatenated strings, said method comprising: i) encoding two or more biological molecules into a data structure of initial character strings to provide a collection of two or more different initial character strings wherein each of said biological molecules comprises at least about 10 subunits; ii) selecting at least two substrings from said initial character strings; iii) concatenating said substrings to form one or more product strings about the same length as one or more of the initial character strings; iv) adding the product strings to a data structure to populate a data structure of product strings; v) determining sequence identities of at least one of the product strings relative to at least one initial character string; and vi) selecting one or more product biological molecules for production, wherein the one or more product biological molecules correspond to one or more of the product strings having greater than 30% sequence identity with the at least one initial character string. 30. A computer program product on a computer readable media comprising computer code that: i) encodes two or more biological molecules into initial character strings to provide a collection of two or more different initial character strings wherein each of said biological molecules comprises at least about ten subunits; ii) selects at least two substrings from said initial character strings; iii) concatenates said substrings to form one or more product strings about the same length as one or more of the initial character strings; iv) adds the product strings to a data structure to populate a data structure of product strings; v) determines sequence identities of at least one of the product strings relative to at least one initial character string; and vi) selects one or more product biological molecules for production, wherein the one or more product biological molecules correspond to one or more of the product strings having greater than 30% sequence identity with the at least one initial character string.
US6941317	Graphical user interface for display and analysis of biological	Process claim embodying a GUI	1. A method of navigating a biological database in computer storage, the biological database including at least one catalog containing an organized body of related biological data, the method comprising the acts of: selecting at least one catalog; searching the catalog by entering search criteria into a computer and thereby display on the computer a list of search results including at least one module representing a region of a protein sequence; selecting a first module of interest from the list of search results; displaying on the computer a family of all protein sequences in the database having the first module of interest, each protein sequence also being

	sequence data		associated with a graphical representation of all modules of the protein sequence; and displaying a multiple sequence alignment for the family of protein sequences in a separate display area, the multiple sequence alignment presenting an amino-acid-by-amino-acid relationship between protein sequences in the same family. 34. A method of performing a computerized protein sequence analysis to detect similarities in the composition of different proteins, the method comprising: accessing a biological database in computer storage, the biological database incorporating data of at least one pre-existing database and having pre-computed families described by a probabilistic sequence; navigating the biological database with a graphical user interface to query the database for a list of search results; displaying the list of search results including at least one module representing a region of a protein sequence; and navigating the biological database with the graphical user interface to select one or more of the modules for representation on a computer as a family; wherein multiple families are presented in separate display areas.

EUROPE:

A Compilation Table of Granted Patents and their Claims:

Patent No:	Title:	Types of claims:	Independent Claims:
EP1552472	Methods and systems to identify operational reaction pathways	Process claims	1.A method of identifying an operational reaction pathway of a biosystem, comprising: (a) providing a set of systemic reaction pathways through a reaction network representing said biosystem, (b) providing a set of phenomenological reaction pathways of said biosystem, (c) comparing said set of systemic reaction pathways with said set of phenomenological reaction pathways, wherein a pathway common to said sets is an perational reaction pathway of said biosystem. 29. A method of reconciling biosystem data sets, comprising: (a) providing a first reaction network reconstructed from legacy data comprising a plurality of hierarchical reaction categories; (b) providing a second reaction network obtained from empirical data, and (c) determining a consistency measure between said hierarchical reaction categories in said first reaction network and elements in said second reaction network, wherein a high degree of said consistency measure for said hierarchical reaction categories indicates the validity of said first reaction network or a subcomponent thereof. 39. A method of determining the effect of a genetic polymorphism on whole cell function, comprising: (a) generating a reaction network representing a biosystem with a genetic polymorphism-mediated pathology; (b) applying a biochemical or physiological condition stressing a physiological state of said reaction network, and (c) determining a sensitivity to said applied biochemical or physiological condition in said stressed physiological state compared to a reaction network representing a normal biosystem, wherein said sensitivity is indicative of a phenotypic consequence of said genetic polymorphism-mediated pathology. 42. A method of diagnosing a genetic polymorphism-mediated pathology, comprising: (a) applying a biochemical or physiological condition stressing a physiological state of a reaction network representing a biosystem with a genetic polymorphism-mediated pathology, said applied biochemical or physiological condition correlating with said genetic polymorphism-mediated pathology, and (b) measuring one or more biochemical or physiological indicators of said pathology within said reaction network, wherein a change in said one or more biochemical or physiological indicators in said stressed state compared to an unstressed physiological state indicates the presence of a genetic polymorphism corresponding to said pathology.
EP1600864	Modelling tool for chemical processes	Process claims	1.Method of amending an interaction complex (12) in a computer displayed graphical model (7) of a biochemical process, said graphical model corresponding to a mathematical representation (6) in which said interaction complex (12) is associated with a flow rate (r) between at least two entity variables (s1, p2) in the process, characterized by receiving input from a user indicating an amendment of the interaction complex by addition of an interaction object (18) to the interaction complex, said interaction object being associated with an additional entity variable (s2) and having at least one terminal point (20), graphically connecting said terminal point (20) to the interaction complex (12), and displaying an updated interaction complex, and in the mathematical representation (6), associating the updated interaction complex (12) with one single flow rate (r), dependent on said at least two entity variables (s1, p1) and said additional entity variable (s2) . 11. System for amending an interaction complex (12) in a computer displayed graphical model (7) of a biochemical process, said graphical model

			corresponding to a mathematical representation (6) in which said interaction complex (12) is associated with a flow rate (r) between at least two entity variables (s1, p2) in the process, characterized by means for receiving input from a user indicating an amendment of the interaction complex by addition of an interaction object (18) to the interaction complex, said interaction object being associated with an additional entity variable (s2) and having at least one terminal point (20), means for graphically connecting said terminal point (20) to the interaction complex (12), and displaying an updated interaction complex, and means for, in the mathematical representation (6), associating the updated interaction complex (12) with one single flow rate (r), dependent on said at least two entity variables (s1, p1) and said additional entity variable (s2) .
EP1739656	Speech recognition method and speech recognition apparatus	1. Process claim 13.Product claim for a control program 15.Product claim for An information processing apparatus	1.An information processing method which sets data to each of a plurality of settable graphical user interface items, comprising: detecting a settable graphical user interface item not displayed on a display screen (S201, S202); selecting a speech recognition grammar corresponding to the item detected in the detecting step (S204); recognizing received speech information using the speech recognition grammar selected in the selecting step (S208); and, setting data to the detected item using the recognition result of the recognizing step. 13. A control program which, when loaded into a computer and executed, implements an information processing method as claimed in any one of claims 1 to 7. 15. An information processing apparatus which sets data to each of a plurality of settable graphical user interface items (802), comprising: a detecting unit (102) configured to detect a settable graphical user interface item not displayed on a display screen (101); a selecting unit (103) configured to select speech recognition grammar corresponding to the item detected by the detecting unit; a recognizing unit (107) configured to recognize received speech information using the speech recognition grammar (601) selected by the selecting unit; and, a setting unit configured to set data to the detected item using the recognition result of the recognizing unit.
EP1049089	Data structure for control information on rewriteable data storage media.	1.Process claim 5. Product claim for a data storage medium/data structure.	1. A method of providing control information to a drive by a data storage medium (100), the method comprising the following steps: reading, by the drive, a control data structure (108, 110, 200, 300) on the data storage medium; extracting (400), by the drive, from the control data structure, an identification (202,302 of the control data structure; and when the identification of the control data structure is recognized by the drive, then extracting (404), from the control data structure, control information (208, 308-320) that is specific to the identification. 5. A data storage medium (100), the data storage medium having control data stored in the form of a data structure (108, 110, 200) the data structure comprising: a data area (208) that includes information for control of access to regions of the data storage medium, wherein a region is less than the entire data storage medium; and a header (202-206), the header further comprising a set of bits (204), each bit corresponding to a form of control for access to the entire data storage medium.
EP2084535	BIOINFORMATIC APPROACH TO DISEASE DIAGNOSIS	Process claim for an algorithm-aided invention	1.A method for constructing a multivariate predictive model for diagnosing a disease for which a plurality of test methods are individually inadequate, said method comprising: (a) performing a panel of laboratory tests for diagnosing said disease on a test population comprising a statistically significant sample of individuals with at least one objective sign of disease and a statistically significant control sample of healthy individuals or persons with cross-reacting medical conditions; (b) generating a score function from a linear combination of said test panel results, said linear combination expressed as [beta] Y, wherein D is the disease; F1, ..., Yk is a set of K diagnostic tests for D; Y is a vector of diagnostic test results (Y1, ..., Yk }; D' = not D; [beta] is a vector of coefficients {[beta][iota], ..., [beta]u\ for Y; and/?<r> is the transpose of [beta]; (c) performing a receiver operating characteristic (ROC) regression or alternative regression technique of the score function, wherein the test panel is selected and [beta] coefficients are calculated simultaneously to maximize the area under the curve (AUC) of the empiric ROC as approximated by: i EUR DJ EUR H wherein / is a sigmoid function, N = the number of study subjects, n<D> in the number of patients with disease D, n<H> is the number of healthy controls, n<D> + n<H> =N; i = 1, ..., n<D>, i EUR D are patients with disease; j = 1, ..., n<H>, j EUR H are healthy controls; (d) calculating for each individual the pre-test odds of disease; generating a diagnostic likelihood ratio of disease by determining the frequency of each individual's test score in said diseased population relative to said control population; and multiplying said pretest odds by said likelihood ratio to determine the post-test odds of disease for each individual;

			(e) converting a set of posttest odds into posttest probabilities for each methodology and creating an ROC curve for each methodology by altering its respective post-test probability cutoff value; (f) comparing the ROC areas generated by one or more regression techniques to determine an optimal methodology, comprising the tests to be included in an optimum test panel and the weight to be assigned each test score alone or in combination; (g) dichotomizing the optimal methodology by finding that point on the final ROC graph tangent to a line with a slope of (l-p)- C/p B, where p is the population prevalence of disease, B is the regret associated with failing to treat patients with disease and C is the regret associated with treating a patient without disease; thereby generating a posttest probability cutoff value; and (h) displaying the optimum test panel for disease diagnosis, the weight each individual test score is to be assigned alone or in combination, and the cutoff value against which positive or negative diagnoses are to be made. 19. A computer based method for diagnosing a disease for which a plurality of test methods are individually inadequate, said method comprising combining weighted scores from a panel of laboratory test results, comparing the combined weighted results to a cutoff value and displaying a diagnosis based on said comparison to said cutoff value, wherein said laboratory tests, the weighting assigned thereto and cutoff value above which individuals tested have said disease are determined by the method of Claim 1.
GB2434225	Random forest modelling of cellular phenotypes	1. Process claim for a computer program-aided invention. 13. Product claim for a computer program product	I. A method for classifying a test population of cells based on one or more dependent variables, comprising: receiving a training set comprising values for independent and dependent variables associated with populations of cells; clustering the training set such that clusters of the populations of cells are produced, each cluster having values for independent and dependent variables for its cell populations; randomly selecting clusters of cell populations from the training set to construct multiple bootstrap samples; generating a random forest model for each bootstrap sample; and classifying the test population using an ensemble of the random forest models 13. A computer program product comprising a machine readable medium on which is provided program instructions for classifying a test population of cells based on one or more dependent variables, the program instructions comprising: (a) code for receiving a training set comprising values for independent and dependent variables associated with populations of cells; (b) code for clustering the training set such that clusters of the populations of cells are produced, each cluster having values for independent and dependent variables for its cell populations; (c) code for randomly selecting clusters of cell populations from the training set to construct multiple bootstrap samples of the size of the training set; (d) code for generating a random forest model for each bootstrap sample; and (e) code for classifying the test population using an ensemble of the random forest models.
EP2394572	Apparatus for detecting and discriminating breathing patterns from respiratory signals	1. Process Claim for diagnosis of sleep disorders employing a classifier algorithm to manipulate the epoch. 8,34,40,46. Process claims.	1. A method for diagnosing the presence of sleep disorders comprising pre-processing a signal representative of a patient's respiration to filter out noise and zero the baseline, splitting the signal into equal length epochs, . extracting from each epoch one or more primary features from the signal that act as a compressed representation of signal events, apply statistics to the primary feature(s) to produce one or more secondary - features which represent the entire epoch, grouping each secondary feature with one or more other features that is extracted from the entire epoch to form an epoch pattern, manipulate the epoch pattern with a classifier algorithm to produce a probability for each possible class that the signal may be representative of, assign the epoch to the class with the highest probability, report the class and the strength of the probability as an indication of the underlying disease state. 8. A method for diagnosing the presence of sleep disorders comprising recording a signal representative of respiration from a patient using a logging device which includes a data-acquisition system and a memory, processing the respiratory signal either on-board by the recording device or offline using a computer, dividing the signal into n epochs of equal length, recording events consisting of an hypopnoea followed by an hyperpnoea, detecting for each event the beginning and end points, calculating event lengths, and processing each hyperpnoea to derive shape features. 34. A method for detecting the presence or absence of Cheyne-Stokes breathing in a patient comprising the steps of: (i) Determining a signal indicative of at least one respiratory parameter of the patient; (ii) Analyzing the signal to detect at least one region of hyperpnoea; (iii) Upon detection, determining the duration of said at least one hyperpnoea; and (iv) Determining that Cheyne-Stokes breathing is present when said duration exceeds a threshold. 40. A method of detecting the presence or absence of Cheyne-Stokes breathing in a patient comprising the steps of: (i) Determining a signal indicative of at least one respiratory parameter of the patient; (ii) Analyzing the signal to detect at least one region of an hyperpnoea following an hypopnea; (iii) Upon detection, analyzing the rate of increase of signal in the region from the hypopnea to the hyperpnoea; (iv) Where the rate of increase is a slow increase, concluding that Cheyne-Stokes breathing is present and where the rate of increase is a sudden increase, concluding that Cheyne-Stokes breathing is absent.

			46. A method of detecting the presence or absence of Cheyne-Stokes breathing in a patient comprising the steps of: (i) Determining a signal indicative of at least one respiratory parameter of the patient; (ii) Determining a spectrogram of said signal; (iii) Determining that Cheyne-Stokes breathing is present if the spectrogram indicates the signal has a peak. 49. A method of detecting the presence or absence of Cheyne-Stokes breathing in a patient comprising the steps of: (i) Determining a signal indicative of at least one respiratory parameter of the patient; (ii) Detecting at least, one region of hyperpnoea; (iii) Determining the morphology of said at least one region of hyperpnoea; (iv) Determining that Cheyne-Stokes breathing is present where said at least one region has a "Sydney Harbor bridge" shape.

Compilation of NCL's Software/Mathematical Algorithm related Patents/Applications:

1. AUTOMATIC HARVESTING OF MOLECULAR INFORMATION RASTER GRAPHICS
   KARTHIKEYAN M
   2420DEL2011
   Provisional application filed

2. NADI TARANGINI: AYURVEDIC PULSE-BASED DIAGNOSTIC SYSTEM INCORPORATING MACHINE LEARNING
   BHAT ASHOK
   IN 1675DEL2007 / US 12/733153
   Complete specification filed

3. METHOD AND APPARATUS FOR ONLINE IDENTIFICATION OF SAFE OPERATION AND ADVANCE DETECTION OF UNSAFE OPERATION OF A SYSTEM OR PROCESS
   US 6826513
   Granted

4. A METHOD FOR IMPROVED PERFORMANCE OF ARTIFICIAL NEURAL NETWORK MODELS IN THE PRESENCE OF INSTRUMENTAL NOISE AND MEASUREMENT ERRORS
   2614DELNP2004
   Complete specification filed

5. IDENTIFICATION AND/OR SEPARATION OF COMPLEX COMPOSITE SIGNALS INTO ITS DETERMINISTIC AND NOISY COMPONENTS
   US 6208951
   Granted

6. AN APPARATUS FOR THE IDENTIFICATION AND/OR SEPARATION OF COMPLEX COMPOSITE SIGNALS INTO ITS DETERMINISTIC AND NOISY COMPONENTS
   IN 214400
   Granted

[Data Source: IPMS, http://172.16.14.200/ipms/]

Compilation of Patent Applications' Filed in the area of Software based Biological/ chemical modelling in last few years in US:

Application No:	Title:	Abstract:	Principle Claims:
12/664,444 Filing date: 20 Jun 2008	METHOD, SYSTEM AND COMPUTER SIMULATION ENVIRONMENT FOR TESTING OF MONITORING AND CONTROL STRATEGIES IN DIABETES	A simulation environment for in silico testing of monitoring methods, open-loop and closed-loop treatment strategies in type 1 diabetes. Some exemplary principal components of the simulation environment comprise, but not limited thereto, the following: 1) a "population" of in silico "subjects" with type 1 diabetes in three age groups; 2) a simulator of CGM sensor errors; 3) a simulator of insulin pumps and discrete insulin delivery; 4) an interface allowing the input of user-specified treatment scenarios; and 5) a set of standardized outcome measures and graphs evaluating the quality of the tested treatment strategies. These components can be used separately or in combination for the preclinical evaluation of open-loop or closed-loop control treatments of diabetes.	1. A computer method for testing of monitoring and/or treatment strategies for diabetes using a computer simulation environment. 2. The method of claim 1, wherein said testing method comprises: representation of the human metabolic system, wherein said representation of the human metabolic system comprises: applying a mathematical model of the human metabolic system; and providing a plurality of instances of a simulated subject, creating a simulated population. 12. A computer simulation system environment for testing of monitoring and/or treatment strategies for diabetes. 13. The system of claim 12, wherein said computer simulation system environment comprises: a representation module of the human metabolic system, wherein said representation module comprises a processor configured to: apply a mathematical model means of the human metabolic system, and provide a plurality of instances of simulated subjects comprising a simulated population. 23. A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system for testing of monitoring and/or treatment strategies for diabetes using a computer simulation environment, said testing method of said computer program logic comprising: representation of the human metabolic system, wherein said representation of the human metabolic system comprises: applying a mathematical model of the human metabolic system; and providing a plurality of instances of a simulated subject, creating a simulated population.
12/222813 Filing date: 18 Aug 2008	BIO-EXPRESSION SYSTEM WITH MODULE FOR CREATING THE STANDARD DROSOPHILA BRAIN MODEL AND ITS COORDINATE SYSTEM	A method of generating standard brain model from a bioexpression system includes performing steps of registration to input standard surface and individual surface into affine registration; recording a transformation parameters from the affine registration; performing steps of inputting a individual neuropil and transform parameters into an affine transformation; applying the data of the affine transformation to transform individual neuropil to achieve transformed individual neuropil; and performing a step of affine registration to register a standard neuropil to the transformed individual neuropil to achieve a resulting transformation, wherein the resulting transformation can be output as a position and orientation of standard neuropil within the standard surface.	1. A method for generating standard brain model from a bio-expression system comprising: determining a global coordinate to present entire said standard brain model; determining a local coordinate to present a sub-structure of said standard brain model; and determining characteristics of said local coordinate with respect to said global coordinate. 16. A bio-expression system comprising: a process system used to process data; an average model generating module embedded in said computing system, wherein while an input of two-dimensional individual model sections is fed into said process system, said average model generating module is responsive to said input of two-dimensional individual model sections and is capable of processing an individual model construction and model-averaging procedure, thereby generating an average model from all the input datasets; a database including a bio-expression sub-database, cellular network sub-database and bio-fine structure sub-database, wherein said database is coupled to said process system to store at least said average model; and a module for creating standard brain model and coordinate system.
12/462,783	INTELLIGENT	The intelligent medical device (iMD) system	1. A system for operation of a medical device for therapeutics, comprising:

Filing date: 7 Aug 2009	MEDICAL DEVICE SYSTEM DYNAMICS FOR BIOLOGICAL NETWORK REGULATION	coordinates the dynamics of hardware and software components in a self-organizing autonomous system. The iMD system uses advanced modeling and metaheuristics to solve complex optimization problems involving the customization of medical therapies. The system uses evolvable hardware and reprogrammable features to coordinate the diagnostic and therapeutic functions of the iMDs.	a therapeutic module consisting of at least two layers; an analytical module consisting of a system-on-a-chip (SoC); a set of compartments for storage of chemicals and biologicals; a set of electrical interconnects; a set of microfluidic components, including tubes, valves and gates; at least one integrated circuit; wherein the layers of components are connected by the electrical interconnects; wherein the process is controlled by the integrated circuit; wherein the analytical module uses the SoC to model solutions to pathology optimization problems and transfers the data to the therapeutic module; wherein the medical device components include a set of compartments for combining chemicals and biologicals on at least one of a set of layers; wherein the medical device compartments are capable of transforming their configurations; wherein the medical device components are activated after obtaining data from a medical device model for therapeutic recommendations; wherein the medical device components on one layer transform their configuration by folding gates down to remove partitions and folding gates up to add partitions to create newly configured compartments; wherein the medical device flushes fluids from its compartments before the transformation process is initiated; wherein the medical device places chemicals and biologicals into the newly configured compartments on one layer of the device; wherein the medical device components are coordinated to release specific chemicals and biologicals from newly configured compartments on at least one of a set of layers through the microfluidic components in specific measured doses according to the model recommendations; wherein the chemicals and biologicals are combined in a chamber of the medical device module in one of a set of layers; wherein the resulting therapeutic combination is transmitted to a cell site in a patient; wherein the feedback is obtained about the remedy and the analytical module updates the model and sends solution options to the pathology to the therapeutic module; wherein the therapeutic module reconfigures to solve the pathology and combines a new set of chemicals and biologicals according to the revised model in a chamber on one of its layers; and wherein the resulting revised therapeutic combination is transmitted to a cell site in a patient until the pathology is solved.
13/019,036 Filing date: 1 Feb 2011	METHOD OF RATIONAL-BASED DRUG DESIGN USING OSTEOCALCIN	The invention relates to a method of identifying a compound that affects osteocalcin activity, comprising obtaining a 3D structure of osteocalcin or a fragment thereof, designing a compound to interact with, or mimic, the 3D structure of osteocalcin or fragment thereof, obtaining the compound, and determining whether the compound affects osteocalcin activity.	1. A computer-implemented method of identifying a compound that reduces osteocalcin activity, comprising providing a computer program for execution on a computer, wherein the computer program, when executing on the computer, generates a 3D structure comprising i) amino acids 13-34 of SEQ ID NO: 5 of osteocalcin and ii) the structural coordinates in Table 3 corresponding to amino acids 13-34 of SEQ ID NO: 5; designing a compound to mimic the 3D structure; obtaining or synthesizing the compound and determining the ability of the compound to compete with osteocalcin for binding to hydroxyapatite in an assay, wherein reduced binding of osteocalcin to hydroxyapatite in the presence of the compound in the assay indicates that the compound reduces osteocalcin activity.
13/168,654 Filing date:	METHODS, SYSTEMS, AND SOFTWARE FOR	The present invention generally relates to methods of rapidly and efficiently searching biologically-related data space. More	1. A method for identifying nucleotides for variation in nucleic acids encoding a protein variant library, said method comprising: (a) receiving data characterizing a training set of a protein variant library, wherein the data comprises activity and a

24 Jun 2011	IDENTIFYING FUNCTIONAL BIOMOLECULES	specifically, the invention includes methods of identifying bio-molecules with desired properties, or which are most suitable for acquiring such properties, from complex bio-molecule libraries or sets of such libraries. The invention also provides methods of modeling sequence-activity relationships. As many of the methods are computer-implemented, the invention additionally provides digital systems and software for performing these methods.	nucleotide sequence for each protein variant in the training set; (b) from the data, developing a sequence activity model for predicting activity from multiple independent variables, each specifying the presence or absence of a specific nucleotide in a sequence; (c) using the sequence activity model to identify one or more nucleotides that are to be varied or fixed in order to impact the desired activity; and (d) Generating a new protein variant library containing one or more new protein variants having amino acid sequences encoded by nucleic acids in which the identified nucleotides are varied or fixed in order as identified in (c). 21. A computer program product comprising a non-transitory machine readable medium storing program code for identifying nucleotides for variation in nucleic acids encoding a protein variant library, said program code comprising: (a) code for receiving data characterizing a training set of a protein variant library, wherein the data comprises activity and a nucleotide sequence for each protein variant in the training set; (b) code for using the data to develop a sequence activity model for predicting activity from multiple independent variables, each specifying the presence or absence of a specific nucleotide in a sequence; (c) code for using the sequence activity model to identify one or more nucleotides that are to be varied or fixed in order to impact the desired activity; and (d) code for defining a new protein variant library containing one or more new protein variants having amino acid sequences encoded by nucleic acids in which the identified nucleotides are varied or fixed in order by executing the code in (c).

E. REFERENCES:

1. The Patents Act, 1970
2. United States Code Title 35 – Patents
3. European Patent Convention
4. Draft manual of Patent Practice & Procedures
5. Indian Copyright Act, 1957
6. The Copyright (Computer Software) Amendment Act 1985
7. United States Code Title 17-Copyright
8. Information Technology Related Intellectual Property Rights , Dr T. Ramakrishna, Centre for Intellectual Property Rights Research and Advocacy, National Law School of India University, Bangalore.
9. http://www.isaonline.org/documents/patentingofsoftware_nainakrishnamurthy.pdf
10. http://en.wikipedia.org/wiki/1-Click
11. http://ipindia.nic.in/ipirs1/patentsearch.htm
12. http://worldwide.espacenet.com/advancedSearch?locale=en_EP
13. http://www.ladas.com/Patents/Computer/Copyright.USA.html
14. http://172.16.14.200/ipms/
15. http://www.google.co.in/patents/
16. http://worldwide.espacenet.com/advancedSearch?locale=en_EP

Note: This IGN was finalized in the current form on 29th Dec 2011. This is intended as a working document. Readers are requested to provide comments/suggestions & point to errors (if any) so as to help improve this document. Comments may be sent to sv.kanitkar@ncl.res.in

INVENTOR GUIDANCE NOTES

(White papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC: **PHARMA RELATED INVENTIONS**	AUTHOR: **SNEHA KANITKAR** **A207, PAML** **National Chemical Laboratory** **Pune – 411008** **Phone: +91-20-2590-2757** **Email: sv.kanitkar@ncl.res.in**
IGN Number: **IGN-04**	VERSION: **02**
SCOPE: **This Inventor Guidance Notes provides information for scientists working in the area of Pharmaceutical science and explains what can and what cannot be patented.**	DATE: **02nd Feb 2013**
TABLE OF CONTENTS: **A. Summary** **B. Relevant legal extracts** **C. Interpretation of the law and explanations** **D. Examples and cases** **E. References**	REVIEWER: **Nitin S Tewari** **V. Premnath**

A. SUMMARY

Category of invention	IN	USA	EP	Possible Eg Claim/Explanation
Chemical entity [drugs, chemicals]	✓ IN 228922	✓ US 5077297	✓ EP 675899	A compound having the formula R-CH= N-S-X, wherein R is an alkyl group selected from the group consisting of methyl, ethyl and isopropyl; and X is a halogen selected from the group consisting of chlorine and bromine….
New form of known substance [salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers etc]	X	X	X	With same efficiency as the known Form
	✓ IN239402	✓ US6043262	✓ EP2436377	With improved efficacy or surprisingly superior properties as compared to the known Form.
Diagnostic Kits	✓ IN219359	✓ US6478749	✓ 1813943	A kit for the detection of HCV...
Medical devices	✓ IN213643	✓ US5967973	✓ 1762255	Pressurized metered dose inhalers.
First medical use of novel (inventive) compounds	X	✓	✓	A chemical compound of chemical formula R-CH= N-S-X used as a medicine to treat skin burns…
Second medical use of known compounds	X	X	X	A chemical compound of chemical formula X used as a medicine to treat acne...
	X	✓	X	A process of using a known compound X for a novel medical use [heart medication]…
Method of preparation	✓ IN226803	✓ US6495651	✓ 1103546	A method for preparation of compound having the formula R-CH= N-S-X comprising steps of Taking substance (a) and heating at 60^{O} C…… adding substance (b)
Formulation/ Pharmaceutical product	✓ IN228654	✓ US6984395	✓ 778778	A pharmaceutical formulation adapted for intra-muscular injection comprising fulvestrant, 30% or less weight...
Method of treatment/ surgery/ prophylaxis/ diagnosis	X	✓ US5967973 US4845115 US3660559	X	A method for treatment of dementia and other cognitive disorders which comprises administering to a human or animal subject suffering from dementia or other cognitive disorders an effective amount for the treatment of said dementia or other cognitive disorders of 1,2,3,9,-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one or a physiologically acceptable salt or solvate thereof.

B. RELEVENT LEGAL EXTRACTS

COUNTRY	LEGAL EXCERPTS
INDIA **[The Patents Act,1970]**	S2 (1)(j) "invention" means a new product or process involving an inventive step and capable of industrial application S2 (1)(ia) "pharmaceutical substance" means any new entity involving one or more inventive steps. Drug includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals S3 (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; S3 (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; S3 (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; S3 (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.
USA **[Title 35 USC]**	**35 U.S.C. 101 Inventions patentable.** 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 thereof, subject to the conditions and requirements of this title.
EUROPE **[EPC]**	**Article 53** **Exceptions to patentability** European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (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; (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.

C. INTERPRETATION OF THE LAW AND EXPLANATION

INDIA:

Indian Patent Act -2005 [as amended] has provisions for granting product as well as process patent in all fields of Technology including chemicals, food, drugs & agrochemicals.

1. **Section 3 b:** Prohibits patenting of subject matter which could be contrary to public order or morality. Thus a Chemical/drug exclusively meant for Euthanasia or suicide is not Patentable in India.

2. **Section 3 d :**

Section 3d is a major obstacle for new forms (salts, polymorphs, solvates... *etc*) of pharmaceutical drugs substances, unless the patentee shows improved effectiveness over existing product.

According to the proviso to this sub-section, a known substance in its new form such as amorphous or crystalline, Hygroscopic or dried, one isomer to other isomer, metabolite, complex, combination of plurality of forms, salts, hydrates, polymorphs, esters, ethers, or in new particle size, shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy.

Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable.

The Patents Act, as it exists today, accommodates incremental innovations, since the patents granted are not only for new molecules but also for new processes as well as new uses, combinations and dosage forms.

It is also worth noting that a limited study by the Indian Pharmaceutical Alliance has come out with a list of 86 patents granted for pharmaceutical products by India after 2005 which inventions are not breakthrough drugs but only minor variations of existing pharmaceutical products.

Table 1 illustrates a list of Patents for New Form of a Known Substance.

Table 2 illustrates a List of Patents for Combinations.

CASE STUDY:

The ruling:	Message:
Patent application No. 1577/Del/1996 was refused, *inter alia,* under the provisions of section 3(d) of the Patents Act, 1970. The Controller in his decision dated 12th June, 2007 held that "the present invention provides a new form of known substance either in anhydrous or hydrated form III of Atorvastatine having same therapeutic activity and in the same field. It only claims some improvement in physical property, which does not make any change in therapeutic efficacy of the compound as compared to the prior art compound. Therefore this new form does not qualify the requirement under section 3(d)	Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable.

3. **Mere discovery of new property of a known substance**

A mere discovery of a new property of known substance is not considered patentable. For instance, Paracetamol has proven antipyretic property. But further discovery of new property of paracetamol as analgesic cannot be patented.

Similarly, ethyl alcohol is used as solvent but further discovery of its new property as anti knocking, thereby making it usable as fuel, cannot be considered patentable.

CASE STUDY:

Invention:	Verdict:	Message:
In a patent application No. 782/Cal/l981, dated 13th July, 1981, an invention related to pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastroenteric tolerance in unit doses form which contained imidazol salicylate as the active ingredient in the amount of 100-600 mg and an inert carrier was claimed which was later amended to a process for the preparation of novel composition containing imidazole salicylate having	It was held by the Controller that the active compound such as imidazole salicylate was known in the art and applicant could not develop any special property or even improve upon the property of the compound to be mixed up with	A mere discovery of a new property of known

formula 1, as the active principle . The invention was characterized in a product that was previously obtained by reacting, mole by mole, acetylsalicylic acid with imidazole in an inert organic solvent and that, using the solid product obtained in the reaction after purification by recrystalization , homogenous composition were produced with pharmaceutically acceptable vehicles suitable for oral, parental or topic administration.	the usual carrier to form the composition. Furthermore, the description contained no indication of using any special type of solvent for its purification by re-crystallization and, therefore, the invention was not patentable under section 3(d) of the Act.	substance is not considered patentable.

4. **Mere discovery of any new use of known process**

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:- Mere use of a known process is not patentable unless such known process results in a new product or employs at least one new reactant. Similarly mere use of known apparatus or machine for another purpose is also not considered patentable.

5. **Section 3 e**

Section 3 e of the Patent act states that a mere admixture resulting only in the aggregation of properties is not patentable unless the admixture shows synergistic effect.

In the patent application No. 782/CAL/l981, dated 13th July, 1981, it was held by the Controller that the pharmaceutical vehicle having the primary intended function of acting as vehicle or carrier or diluents performed the very function when incorporated in the composition. There was no explicit disclosure or experimental data to indicate that the presence of the carrier in any way influenced the antiphlogistic, antipyretic and analgesic activity of the active ingredients. Therefore, the invention was held not allowable under Section 3(e) of the Act as well as and merely an admixture.

Thus, a mixture of different types of medicament or medicine to cure multiple diseases is also a mere admixture of substances and is not a patentable invention.

However, an admixture resulting into synergistic properties of a mixture is not considered as mere admixture, e.g., soap, detergent, lubricants and polymer composition etc.

CASE STUDY:

The ruling:	Message:
In the patent No. 143270 for the invention entitled "A fertiliser composition", it was held that alleged invention falls within sub-section(e) of Section 3 of the Act and the opponent had established the fourth ground of opposition, i.e. "not an invention or not patentable as the crop nutrient properties of the constituents like zinc sulphate, manganese sulphate, copper sulphate and magnesium sulphate were known as seen from know-how report and the steps of grinding, mixing and homogenizing were conventionally used in manufacture of the fertiliser.	A mere admixture resulting only in the aggregation of properties is not patentable unless the admixture shows synergistic effect.

6. **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.*

Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements therefor on the human body are patentable.

Methods of diagnosis practised on the human or animal body are excluded. Methods of diagnosis performed on tissues or fluids, which have been permanently removed from the body, are, therefore, not excluded from patentability.

Contraceptives processes are not patentable. However as Chemical contraceptives are notified as a Drug by the central government under the Drug & Cosmetics Act 1940, Chemical contraceptives are patentable.

USA:

1. Section 101 defines the subject matter that may be patented. According to the statute, one who invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore.

2. An invention that falls within one of the four statutory categories – processes, machines, manufactures, and compositions of matter – may be subject to a so-called “utility patent.”

3. The pharmaceutical industry principally claims inventions that are chemical compounds, compositions of matter or processes.

4. Process claims are commonly: “method of using” and “method of making” claims.
   Suppose that an inventor manufactures a new pharmaceutical compound and also discovers that the compound may be used to treat a particular ailment. The manner in which the pharmaceutical may be employed to achieve a result may be drafted in the form of a claim towards a method of using. As well, the inventor may obtain claims for a method of making the compound, stating the techniques he employed to synthesize the compound.

5. Section 100(b) of the Patent Act notes that a process “includes a new use of known process, machine, manufacture, composition of matter, or method.” The statute thus allows inventors to obtain a proprietary interest in a newly discovered property of a known product.
   Suppose, for example, that an inventor discovers that a well-known chemical compound, understood to act as an explosive, also serves as a heart medication. The inventor could not obtain patent protection on a compound that already lies within the public domain. But he could seek a patent claiming a process of using the compound as a heart medication.

6. The United States Patents Act does not exclude methods of medical treatment of humans from patentability. [See US 4845115]

EUROPE:

1. The European Patent Convention (EPC) excludes "methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body" from patentability. The reason for this exclusion is the belief that public health would be at risk if patent rights could be used to impede physicians in the normal course of practicing medicine. However, this exclusion does not extend to known compounds or compositions for use in the treatment methods.

2. The inventor of the first use of a known compound for a therapeutic treatment can obtain claims covering all therapeutic uses, in other words protection for a generic medical use. This type of claim is referred to as the "first medical use claim" and takes the form:
   [Known compound or composition] for use as a medicament or as a therapeutic substance

3. The situation is more complex when the invention lies in the finding that a known compound which has already been used for a therapeutic purpose (first medical use) can be used to treat a different disease or disorder. An example of this is Aspirin. First, Aspirin was used to treat pain, then it was discovered that it could also be used in the treatment of cardiovascular disease. Until recently, European patent law enabled protection of such a "second medical use" invention by way of a "Swiss-type" claim which takes the form:
   [Known compound or composition] for use in the manufacture of a medicament for the treatment of [new disease]

4. A recent European decision (G 2/08) provides that where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of the Swiss-type claim. This is due to the absence of any functional relationship of the features conferring novelty and inventiveness (i.e., the new therapeutic use) and the claimed manufacturing process. Instead, the "first medical use" form of claim must now be used, allowing claiming of second or further medical uses in a less convoluted manner. Such a claim would take the form:
   [Known compound or composition] for use in [new therapeutic use]

5. Importantly, this decision confirmed that second and further medical uses are not restricted to the treatment of a different disease or disorder but are directed to "any specific use" including a new dosage regime of a known therapeutic compound, a novel group of subjects to be treated, or a new route or mode of administration.

D. EXAMPLES:

List of Granted Patents:

India:

Patent No. & Title	Types of allowed claims	Granted Claims
213643 DEVICE FOR SEPARATING BETWEEN THE UPPER AND LOWER JAWS	1. Product claim for the device	1. A device, for separating between the upper and lower jaws, said device comprising two substantially U-shaped" ribs, connected at at least one end to one another, and a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof such that said member gradually changes its shape when a pressure is applied on said ribs by the jaws, wherein the yield strength of said ribs is significantly greater than that of said deformable member.
219359 A KIT FOR THE DETECTION OF HCV	1. Product claim for a diagnostic kit	1.A kit for the detection of HCV comprising a)a solid phase coated with modified hcv core protein, hcv non-core protein, and at least one anti-hcv core monoclonal antibody, and b) a labeled anti-hcv core monoclonal antibody, wherein the modified core protein of part a) has been modified by removing the binding sites of the anti-core monoclonal antibodies of part a) and part b).
228654 AN UNIQUE COMBINATION OF AYURVEDIC COMPOUNDS FOR CORRECTING A RARE FORM OF MULLERIAN DYSGENESIS	1. Product claim for an Ayurvedic combination preparation	1.An unique combination for correcting a natural defect of a rare form of Mullerian Digenesis - rudimentary uterus - comprising l.Asoka Ghritham (AG), 2.Kalyanaka Ghritham (KG), S.Aswagandhadi Lehyam (AGL), 4. Rajapravavarthana Vati (RPV) , S.Kulatthadi Kashayam (KK), 6.Bala Thailam (BT), 7.Varanadi Kashayam (VK), S.Chandraprabha Vati (CPV),9. Pushing Choomam Tablet (PCT), 10. Asoka Arishtam (AA) and 1 l.Phalasarpis(PS).
227427 A PHARMACEUTICAL FORMULATION	1. Product claim for a pharmaceutical formulation	1. A pharmaceutical formulation comprising: - an immune response modifier (IRM) compound selected from the group consisting of imidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimi dazopyridine amines, 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo- quinolinamines and pyridinamines, imidazonaphthyridine and tetrahydroimidazonaphthyridine amines; a fatty acid; a preservative system; and a carbomer.
228922 CYSTEINE PROTEASE INHIBITORS	1.Product claim for compounds of a general formula (I)	1.Compounds of general formula (I) wherein: Z = CR3R4, where R3.....
226803 NOVEL α-HYDRAZINO-α,β-UNSATURATED NITRO COMPOUNDS AND METHODS OF PREPARATION THEREOF	1.Product claim 2.Process claim for the novel compound	1. Novel vinylic nitro compounds of formula 5 with a hydrazino group at the a position and substituent R, p to the nitro group wherein R is alkyl, aryl, aralkyl, alkaryl, alkenyl; E is a group such as COOR', COR', CONR2\ CN, CF3, R'S02. 2. A process for the preparation of novel vinylic nitro compounds of formula 5, comprising reaction steps of: - reacting a nitroalkene and azo compound in the presence of an amine catalyst optionally in a solvent until the reaction goes to completion, - diluting the said reaction mixture with aqueous acid, - separating the aqueous layer, - extracting the said aqueous layer with organic solvent, - concentrating the combined organic layers to yield the vinylic nitro compound.

USA:

Patent No. & Title	Types of allowed claims	Claims
5967973 SURGICAL RETRACTOR AND METHOD OF SURGERY	1.Product claim for a medical device 18. Process claim for a method of surgery.	1. A surgical retractor comprising..... 18. A method of surgery comprising the steps of.....
6478749 DIAGNOSTIC KIT FOR SKIN TESTS, AND METHOD	1.Product claim for a diagnostic kit 11.Process claim for the method of use of the diagnostic kit.	1.A skin test diagnosis kit for detecting an cellular immune reaction against the oncoprotein E6 and/or E7 of a human papilloma virus type, said diagnosis kit containing an effective amount of the oncoprotein E6 and/or E7 and/or at least an immunologically effective portion of E6 and/or E7 of a human papilloma virus type. 11. A process for carrying out a skin test for detecting an immunological response with respect to the oncoproteins E6 and/or E7 of an HPV type, comprising the following steps; a) providing a diagnosis kit of claim 1; b) intracutaneous application of an effective amount of at least one oncoprotein E6 and E7 or effective portions thereof into a test person; c) after a sufficient incubation time, visual inspection of the skin regions of the application to detect an immunological response.
6984395 DRUG DELIVERY SYSTEM FOR HYDROPHOBIC DRUGS	1. Product claim for a pharmaceutical composition	1. A composition comprising micelles, said micelles comprising saturated and unsaturated phospholipids and one or more hydro-monobenzo-porphyrin photosensitizer Wherein the micelles in the composition have an average diameter below about 100 nm.
5077297 NOVEL COMPOUNDS	1.Product claim for a compound 8.Process claim for method of use 9.Product claim for a composition containing the claimed compound.	1. A compound of formula (I): ##STR14## wherein R.sup.1 and R.sup.2 are independently selected from halogen or nitro; R.sup.3 and R.sup.4 are independently selected from hydrogen or halogen; R.sup.5 is hydrogen, halogen or cyano; and R.sup.6 is halogen or haloalkyl; provided that R.sup.1, R.sup.2, R.sup.3 and R.sup.4 are not all fluorine 8. A method of killing or controlling insect or acarine pests which method comprises applying to the pest or to a locus thereof a insecticidally or acaricidally effective amount of a compound of formula (I) as defined in claim 1. 9. An insecticidal or acaricidal composition comprising a compound of formula (I) according to claim 1 in combination with a diluent or carrier.

7799353 PHARMACEUTICAL MIXTURE FOR HEPATITIS TREATMENT AND ITS PREPARATION METHOD	1.Product by process claim for a mixture 11. A product claim for its pharmaceutical formulation.	1. A hepatoprotective mixture prepared by a method comprising the following steps: (a) pulverizing a plant, macerating and extracting the plant with water to form an aqueous extract, wherein said plant is Boehmeria frutescens Thunberg or Boehmeria nivea; (b) concentrating the aqueous extract to form a first concentrate; (c) adding ethanol to said first concentrate to produce a precipitate and a liquid phase; (d) collecting and concentrating said liquid phase to form a second concentrate; (e) purifying said second concentrate with a macroporous, styrene serial adsorption/desorption resin by loading said second concentrate onto the resin and eluting the resin with water, water-ethanol mixture, and then ethanol; (f) collecting and combining the water-ethanol and ethanol elution fraction; and (g) Concentrating said combined elution fraction to form a third concentrate. 11. A pharmaceutical composition having a hepatoprotective effect containing a hepatoprotective effective amount of the mixture of claim 1.
4845115 METHOD OF MEDICAL TREATMENT	1. Process claim for a method of treatment by the claimed drug	1. A method for treatment of dementia and other cognitive disorders which comprises administering to a human or animal subject suffering from dementia or other cognitive disorders an effective amount for the treatment of said dementia or other cognitive disorders of 1,2,3,9,-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one or a physiologically acceptable salt or solvate thereof.
5290775 EUTHANASIA COMPOSITIONS	1.Process claim for a method of providing euthanasia 21.Product claim for the composition	1. A method for providing euthanasia in a mammal in need thereof which comprises: (a) premedicating by intravenous administration to tranquilize the mammal with a tranquilizer immediately prior to euthanasia; and (b) Introducing by injection into the mammal an aqueous euthanasia solution comprising an effective amount for producing euthanasia of a cardiotoxic compound selected from the group consisting of a quinacrine compound and a chloroquine compound and a water solubilized gamma-hydroxybutramide in an anesthetic amount, wherein euthanasia occurs in the mammal. 21. A composition for providing euthanasia in a mammal which comprises in admixture in an injectable aqueous solution: (a) a cardiotoxic compound selected from the group consisting of a quinacrine compound and a chloroquine compound; (b) a lidocaine selected from the group consisting of a water solubilized lidocaine as a base and water soluble salts thereof; (c) gamma-hydroxybutramide, wherein the solution contains a ratio of gamma-hydroxybutramide to chloroquine or quinacrine of between about 3 to 1 and 6 to 1 and a ratio of lidocaine to gamma-hydroxybutramide of between about 0.01 and 0.15 to 1 in an amount sufficient to produce euthanasia; and (d) an injectable carrier

EP patents:

Patent No. & Title	Types of allowed claims	Claims
1762255 COATED MEDICAL DEVICES	Product claims for medical device	1.A medical device for implantation into a treatment site of a living organism, comprising: a biocompatible vehicle affixed to at least a portion of the medical device; and at least one agent in therapeutic dosages incorporated into the biocompatible vehicle for the treatment of reactions by the living organism caused by the medical device or the implantation thereof. 81.A local drug delivery device comprising: a stent having a substantially tubular member having open ends, and a first diameter for insertion into a lumen of a vessel and a second diameter for anchoring in the lumen of a vessel; a biocompatible polymeric vehicle affixed to at least a portion of the stent; and rapamycin, in therapeutic dosages, incorporated into the polymeric vehicle.
1103546 PROCESS FOR PREPARATION OF PYRIDINE DERIVATIVES	Process claim for a method of manufacture of a drug	1. A process for the manufacture of a compound of formula EMI25.1 wherein R<1> is.....
675899 NOVEL INHIBITORS OF FACTOR Xa	Product claim for a new compound	1. A compound which selectively inhibits the catalytic activity of factor Xa but which does not appreciably inhibit the activity of factor XIa, thrombin or tissue plasminogen activator wherein said compound is a peptide aldehyde having a molecular weight less than about 1000 and wherein said compound is characterized by having Percent Selectivities for factor XIa, thrombin and tissue plasminogen activator which are less than or equal to 10.
1813943 NOVEL DIAGNOSTIC KIT FOR MALIGNANT MELANOMA	1.Product claim for a diagnostic kit 2. Process claim for a diagnostic method	1. A diagnostic kit for malignant melanoma, which comprises an antibody against SPARC and an antibody against GPC3. 2. A diagnostic method for malignant melanoma, wherein SPARC and GPC3 in a sample are measured.
778778 PROBIOTIC COMPOSITIONS	1. & 2. Product claim for a composition 16. Process claim for a method of forming the composition.	1.A probiotic composition comprising one or more probiotic microorganisms and a carrier which will function to transport the one or more probiotic microorganisms to the large bowel or other regions of the gastrointestinal tract, the carrier comprising a modified or unmodified resistant starch or mixtures thereof, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract. 2. A two part probiotic composition comprising a first part which includes one or more probiotic microorganisms and a second part which includes a carrier, the carrier comprising a modified or unmodified resistant starch or mixtures thereof, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract. 16. A method of forming a probiotic composition comprising drying, blending, co-extruding, spray cooling, entrapment, adhesion or micro-encapsulating one or more probiotic microorganisms with a modified or unmodified resistant starch or mixtures thereof.

E. REFERENCES:

1. The Patent Act, 1970 [India]
2. United States Code Title 35 – Patents
3. European Patent Convention
4. Draft Manual of Patent Practice & Procedure, the Patent Office India.
5. US MPEP
6. General information concerning patents, USPTO, Jan 2011
7. Regulations under the Patent Cooperation Treaty
8. P Narayan , Patent Law, 4th Edition, Chapter 21, Patenting of Certain Special Categories of subject matter.
9. Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")-Wendy H. Schacht, John R. Thomas
10. Interpretation Of Section 3(D) In The Indian Patents Act 2005: A Case Study Of Novartis-K D Raju
11. P Narayan , Patent Law, 4th Edition, Chapter 2, 2.01 -2.44
12. www.nipoonline.org/Section-report.doc
13. http://ipindia.nic.in/ipirs1/patentsearch.htm
14. http://india.bigpatents.org/search/
15. http://www.fbrice.com.au/publication/Education_Series_-_Number_three__Patents_for_Methods_of_Medical_Treatment_of_Humans.aspx
16. http://www.google.com/patents/
17. https://www.delphion.com/fcgi-bin/patsearch
18. The patentability of Diagnostic & surgical methods in the European Patent Office, Carpmael & Ransford, 2010
19. http://www.epo.org/law-practice/case-law-appeals/recent/g040001ep1.html

Note: This IGN was finalized in the current form on 02nd Feb 2013. 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

INVENTOR GUIDANCE NOTES

(White papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

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IGN Number: **IGN-05**	VERSION: **03**
SCOPE: **This Inventor Guidance Notes provides information for scientists regarding inventorship of patents.**	DATE: **11 November 2011**
TABLE OF CONTENTS: **A. Summary** **B. Relevant legal extracts** **C. Interpretation of the law and explanations** **D. Examples and cases** **E. References**	REVIEWER: **Nitin S Tewari** **V. Premnath** **Srividya Ravi**

A. SUMMARY:

[The rules and guidelines for determining inventors are established by laws and judicial decisions and can differ from country to country]

WHO IS AN INVENTOR?

CONCEPTION: An inventor is a person who made an inventive contribution to the invention as defined by the claims of the patent application. One who has made initial conception of the invention, i.e. the formation of a definitive & permanent idea of the complete & operative invention in his mind

REDUCTION TO PRACTICE: Note that the mere reduction of the invention into practice without contributing to the conception of the Idea **doesn't** qualify one to be named as an inventor.

That means: Colleagues, students, research assistants, technicians, mechanists, or their Supervisors [including those who gather essential data or construct a practical embodiment of the invention] aren't inventors unless they have made an inventive contribution.

Thus, someone participating in the reduction to practice AND contributing to the final, complete conception is an inventor, but participation only in the "reduction to practice" does not warrant inventorship.

CO-INVENTORS: In case of joint inventors, each inventor should have made conceptual contribution to at least one claim of the invention.

Inventorship is determined on a claim-by-claim basis. Thus, if a claim is abandoned during examination of the patent, inventorship is re-assessed. If an inventor was named for the purposes of that claim alone, then that inventor is removed by request of the applicant.

All inventors of a patent are awarded equal rights.

WHO IS NOT AN INVENTOR?

An individual is not an inventor if he:

- Merely suggested an idea without a way to implement the idea,
- Contributed an obvious element to the invention,
- Only followed instructions in working on the invention,
- Participated in consultations about the invention before or after
- Is the first importer of an invention into India, or a person to whom an invention is first communicated from outside India
- Is the HOD or head of a Research group, but his inventive contribution was zero.
- Only makes changes to the production method while reducing the invention to practice.

As sometimes occurs, the original conception provides a prototype or basis for the invention but does not represent the final invention which is eventually claimed. An inventor can seek the help of others when perfecting the invention without the helper necessarily becoming an inventor.

B. RELEVENT LEGAL EXTRACTS:

COUNTRY & LAW:	LEGAL EXCERPTS:
1. INDIA: [INDIAN PATENT ACT, 1970]	**S 2(y) "true and first inventor"** does not include either the first importer of an invention into India, or a person to whom an invention is first communicated from outside India.
	S 6. Persons entitled to apply for patents (1) Subject to the provisions contained in section 134, an application for a patent for an invention may be made by any of the following persons, that is to say,— (a) by any person claiming to be the true and first inventor of the invention; (b) by any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application; (c) By the legal representative of any deceased person who immediately before his death was entitled to make such an application. (2) An application under sub-section (1) may be made by any of the persons referred to therein either alone or jointly with any other person.
	S 50. Rights of co-owners of patents (1) Where a patent is granted to two or more persons, each of those persons shall, unless an agreement to the contrary is in force, be entitled to an equal undivided share in the patent. (2) Subject to the provisions contained in this section and in section 51, where two or more persons are registered as grantee or proprietor of a patent, then, unless an agreement to the contrary is in force, each of those persons shall be entitled, by himself or his agents, to [the rights conferred by section 48] for his own benefit without accounting to the other person or persons. (3) Subject to the provisions contained in this section and in section 51 and to any agreement for the time being in force, where two or more persons are registered as grantee or proprietor of a patent, then, a licence under the patent shall not be granted and a share in the patent shall not be assigned by one of such persons except with the consent of the other person or persons.
2. UNITED STATES: [35 U.S.C]	**35 U.S.C. 116 Inventors.** When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent. If a joint inventor refuses to join in an application for patent or cannot be found or reached after diligent effort, the application may be made by the other inventor on behalf of himself and the omitted inventor. The Director, on proof of the pertinent facts and after such notice to the omitted inventor as he prescribes, may grant a patent to the inventor making the application, subject to the same rights which the omitted inventor would have had if he had been joined. The omitted inventor may subsequently join in the application. Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be

	amended accordingly, under such terms as he prescribes.
	35 U.S.C. 117 Death or incapacity of inventor. Legal representatives of deceased inventors and of those under legal incapacity may make application for patent upon compliance with the requirements and on the same terms and conditions applicable to the inventor.
	35 U.S.C. 118 Filing by other than inventor. Whenever an inventor refuses to execute an application for patent, or cannot be found or reached after diligent effort, a person to whom the inventor has assigned or agreed in writing to assign the invention or who otherwise shows sufficient proprietary interest in the matter justifying such action, may make application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage; and the Director may grant a patent to such inventor upon such notice to him as the Director deems sufficient, and on compliance with such regulations as he prescribes.
	35 U.S.C. 262 Joint owners. In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.
3. EUROPE: **[EPC]**	**Article 59** **Multiple applicants** A European patent application may also be filed either by joint applicants or by two or more applicants designating different Contracting States.
	Article 60 **Right to a European patent** (1) The right to a European patent shall belong to the inventor or his successor in title. If the inventor is an employee, the right to a European patent shall be determined in accordance with the law of the State in which the employee is mainly employed; if the State in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the State in which the employer has the place of business to which the employee is attached. (2) If two or more persons have made an invention independently of each other, the right to a European patent therefore shall belong to the person whose European patent application has the earliest date of filing, provided that this first application has been published. (3) In proceedings before the European Patent Office, the applicant shall be deemed to be entitled to exercise the right to a European patent.

C. INTERPRETATION OF THE LAWS AND EXPLANATION:

	India	United States	Australia	Europe
Inventor	"True and first inventor" does not include – 1.the first importer of an invention into India, or 2. A person to whom an invention is first communicated from outside India. [S2(y)]	Must make an inventive contribution to the invention as defined by the claims	As in United States	Defined by national legislation in Individual EU member countries. It is generally recognized that the actual deviser is the person(s) who contribute(s) to the novelty or inventive step of the invention.
Test to determine inventorship	Not defined under the Indian Patent Act 1970	Contribution to overall conception of invention	'But for' and 'material effect' test. In the 'but for' test: if the invention would not have occurred but for the involvement of a particular person, then that person is an inventor. In the 'material effect' test: a person is defined as an inventor if her contribution had a 'material effect' on the final concept of the invention	Although a patent may issue from the European Patent Office (EPO) and have identical claims in each designated country, the determination of inventorship is made on a country-by-country basis.
Joint inventors	An application may be made by any of the persons referred to therein either alone or jointly with any other person. [S6(2)]	No need for inventors: - to physically work together; -make same amount or type of contributions; -make contribution to	Allowed under s63 Patents Act 1990; If a person solves a problem not recognized by initial inventors; solves a recognized problem that initial inventors had been unable to solve; or produced an	Recognized in Article 59 of the EPC, may also be filed either by joint applicants or by two or more applicants designating different Contracting States.

		every claim (35 U.S.C. 116)	advantage not contemplated by the named inventors they are usually named as joint inventors	
Rights of Co-owners/Joint Inventors	Equal undivided share in the patent. - each of those persons shall be entitled to the rights for his own benefit without accounting to the other co-inventors - No licence under the patent can be granted and no share in the patent can be assigned except with the consent of the all inventors. (S 50)	Equal and undivided rights; - can be assigned; - no need to obtain each inventor's consent for licensing agreements or practicing the invention (35 U.S.C. 262).	As in United States EXCEPT Consent needed from all inventors before any licensing agreement can occur (s16 Patents Act 1990).	Most European countries require permission of other inventors before licensing agreements can be entered into.
Penalty for incorrectly naming inventors	The true inventor can file an opposition and a plea for revocation of the patent on the grounds that the invention has been wrongfully obtained from him. And the patent may stand amended in the name of the opponent alone or added to existing inventors. If some portion of the specification has been contributed by the inventor but not named; the specification may be edited to remove those portions	Possibly patent declared invalid if deception exists. However, most often the court will order a change in inventorship.	Same as United States.	Penalties under national legislation (EPC Article 64(3)). Patent may be declared invalid.

D. EXAMPLES AND CASES:

USA:

Ex 1: Simone, a PhD student, constructs a new plasmid according to the scheme devised by her supervisor. She does not become an inventor because she was merely following the directions of her supervisor. Her supervisor is the true inventor.

Ex 2: Tony is a manufacturer who makes a new product according to the specifications given to him by his boss. Tony is not the inventor because he has merely contributed to the reduction to practice. However, if he contributed to the conception of the new product, both he AND his boss would be inventors.

Ex 3: A post-doctoral physicist adds a feature to a prototype which her laboratory is working on. The additional feature will give the prototype another useful purpose. If the new purpose is claimed in the patent application, the post-doc has contributed to the conception of the invention and, as a result, is an inventor.

Ex 4: Lisa and Margaret are co-inventors and thus, co-owners of the rights to an invention. Bart seeks the permission of Lisa to use it. Lisa does not have to consult Margaret in regards to Bart being able to use the invention. She can allow Bart to use the invention without seeking Margaret's permission. (Note: If Lisa and Margaret have assigned their rights in the invention to their employer, as is often the case in an employment agreement, Bart would have to seek the employer's permission).

Ex 5: Dr Buick is a scientist employed by General M. University. Dr Buick invents a new system of growing hydroponic plants and wishes to patent the invention. Dr Buick is the inventor of the system and is named as such on the patent application. However given that the system was developed at General M. University in the course of Dr Buick's employment, General M. University will be the owner of the system. Therefore General M. University will be designated as the assignee on the patent, and has the right to confer licenses to use the patented technology or not.

Case Study 1: In a real-life example, a university graduate student who contributed to an invention was not named as an inventor on the associated patent application. The patent sought to cover transgenic cotton and methods for transforming it. Monsanto was later assigned the patent by her fellow inventors who were named on the application. Monsanto's competitor, Aventis, discovered the unnamed inventor and sought to have her correct the inventorship on the patent and then transfer her rights to the technology to Aventis. She did so and Aventis received the same ownership rights as Monsanto (see section 3.1 on joint inventorship). If the graduate student had been named initially as an inventor, Aventis would have needed a license from Monsanto to use the technology.

EUROPE:

Ex 1: Pierre is a French national working in Germany, in the German laboratory of a large multinational agricultural biotechnology company, which is incorporated in England. While employed in Germany, Pierre is involved in developing a new method of plant transformation. According to the EPC, whether Pierre is an inventor is determined by the national laws of the country where the employer holds his business. At first glance it would appear that Pierre's status would be governed by German law, but the fact that the employer is a company which is incorporated in England suggests that the laws of England governing inventorship should apply.

E. REFERENCES:

1. The Patents Act, 1970.
2. United States Code Title 35 – Patents
3. European Patent Convention
4. http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2138_04.htm
5. http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2137_01.htm
6. http://www.fenwick.com/docstore/publications/ip/ip_articles/correct_inventorship.pdf
7. http://www.cags.ca/media/docs/cags-publication/Guide_Intellectual_Property.pdf
8. http://www.mcgill.ca/files/research/Guidelines_to_inventorship_Jan_10_2011_final.pdf
9. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=976397
10. http://www.bios.net/daisy/patentlens/g4/tutorials/205.html
11. http://www.foley.com/files/tbl_s31Publications/FileUpload137/723/maebius_invent.pdf
12. www.k-state.edu/tech.transfer/forms/Inventorship%20Guidelines.doc
13. www.stoel.com/showarticle.aspx?Show=1786
14. http://en.wikipedia.org/wiki/Inventor_(patent)
15. Case Nos. 94-1527 and 94-1531 In the Supreme Court of The United States October term, 1995 barr laboratories, petitioner v.burroughs wellcome co. novopharm, inc., and novopharm, ltd., petitioners v.burroughs wellcome co.
16. http://www.labmanager.com/?articles.view/articleNo/3375/article/Navigating-Patent-Inventorship-Issues
17. http://www.yale.edu/ocr/pfg/guidelines/patent/inventorship.html
18. http://fishiplaw.com/strategic-patenting/chapter-2---considerations-before-the-drafting-begins_5.html
19. http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2136_04.htm
20. http://www.bios.net/daisy/patentlens/g4/tutorials/205.html
21. http://www.adec.edu/user/ip-policies.html

Note: This IGN was finalized in the current form on 11Th Nov 2011. 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

INVENTOR GUIDANCE NOTES

(White papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC: **PUBLIC DISCLOSURE OF INVENTION**	AUTHOR: **SNEHA KANITKAR** **A207, PAML** **National Chemical Laboratory** **Pune – 411008** **Phone: +91-20-2590-2757** **Email: sv.kanitkar@ncl.res.in**
IGN Number: **IGN-06**	VERSION: **02**
SCOPE: **This Inventor Guidance Notes provides information for scientists regarding Public Disclosure of Inventions.**	DATE: **10th 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: **Nitin S Tewari** **V. Premnath**

A. SUMMARY:

Points to Remember:	Details:	Take home message:
Novelty of the invention.	Novelty is -The most important parameter for determining patentability, -Assessed in a global context, -Determined through extensive literature and patent searches An invention is novel if it does not form a part of the global state of the art. Novelty, Non-obviousness & Utility will lead to Patentability.	**Safeguard your invention's novelty till a patent is filed.**
Destruction of Novelty = Loss of Patentability.	What amounts to destruction of Novelty: Public Disclosure / Prior Publication/ Prior Commercial Use	**Do not publish or disclose publicly your invention before priority filing of the patent application.**
Public disclosure: Theoretically: Any written or oral disclosure, even to a single person, counts as a "public disclosure". In Practice: Any document dated before the filing date of the patent application which can be searched in public domain amounts to public disclosure.	Public disclosure/prior art includes: Articles in newspapers, newsletters, bulletins, textbooks, journals, theses, reports, letters to the editor , oral presentations , distribution of a paper at a public meeting, disclosure through electronic communications such as e-mail, placing of a thesis or dissertation on the library shelves or on the Internet , the cataloguing of a thesis or dissertation for microfilm distribution ,the submission of an abstract as a proposal for a book or journal, a poster presentation, participation in a television or radio interview, the submission of a proposal to a federal agency, making a report to a public or private research sponsor etc Prior Public use doesn't include the use of the invention done for further research/experimental studies. Public disclosure doesn't include the disclosure to work place colleagues/fellow scientists/research students/technical staff etc. Verbal disclosures although difficult to trace, shouldn't be done to a large group of people without prior precautions like non-disclosure agreements.	
Priority Filing: File a provisional specification- publish the paper- file a complete specification within 12 months.	We do not have to file in all the countries before disclosing the invention publicly. We only have to file a patent application in one country before you make the public disclosure. We then have another 12 months after that "priority filing" to file a complete specification in all the other countries in which you want patent protection.	**IP Group will secure a priority date for your invention in one country and you are free to publish.**
Disclosure to a third party outside NCL before patent filing:	If you want to discuss the invention with others, outside NCL, before you have filed a patent application, discuss only the non-confidential part of the subject matter. We can then decide whether it is worth entering a confidentiality agreement with the third person (or company), for non-disclosure of your invention.	**Consult IP Group for a confidentiality agreement [only if necessary].**
If you accidentally make a public disclosure:	In the US you have a one year grace period after the public display/ public disclosure within which to file a complete specification. But In Europe, a public disclosure is an absolute bar to patentability. In India, section 31 of the Act has ambiguous interpretations and it is advised not to publish before securing a priority date. The key test is that the publication should be 'enabling' i.e. it must describe the invention in sufficient detail that it could be duplicated or put into use. Don't assume that all patent rights are lost simply because a public disclosure has already occurred. Your "public disclosure" may not have been enabling, or there may be some residual valuable, patentable information that you did not disclose; or it may be within the grace period allowed in some countries.	**Check with the IP Group before despairing or deciding not to try for a patent.**
[16]The "Donald Duck as prior art" case: There is a famous story about a Donald Duck story being used as prior art against a patent on a method of raising a sunken ship. A 1949 Donald Duck story used the same technique.	Danish inventor Karl Krøyer came up with a method of quickly raising this sunken ship by filling it with buoyant bodies fed through a tube. Krøyer received patents for this method in the United Kingdom (GB 1070600) and Germany (DE1247893). According to the patent claim, buoyant bodies are inserted into a sunken vessel through a tube from a salvage ship. This story is usually told as relating to the Dutch patent (NL 6514306) Krøyer had applied for. This application was not approved. According to the story, the Dutch Patent Office found an old issue of the Donald Duck magazine which showed the same invention. Since an invention has to be new to be patentable, the application was refused. *	**It doesn't matter whether the relevant prior art was a part of a scholarly scientific paper, a sci-fi movie or a high school text book. Any disclosure which gives enabling/workable details of the invention constitutes prior art.**

[*Whole story with illustrations in section D of this document]

B. RELEVANT LEGAL EXTRACTS:

COUNTRY & LAW:	LEGAL EXCERPTS:
INDIA [THE PATENTS ACT,1970]	**2.(l)** "**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; **13. Search for anticipation by previous publication and by prior claim** (1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification— (a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912; (b) Is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date. (2) The examiner shall, in addition, make an investigation for the purpose of ascertaining, whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub-section (1) before the date of filing of the applicant's complete specification. **29. Anticipation by previous publication** (1) An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention was published in a specification filed in pursuance of an application for a patent made in India and dated before the 1st day of January, 1912. (2) Subject as hereinafter provided, an invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention was published before the priority date of the relevant claim of the specification, if the patentee or the applicant for the patent proves— (a) that the matter published was obtained from him, or (where he is not himself the true and first inventor) from any person from whom he derives title and was published without his consent or the consent of any such person; and (b) where the patentee or the applicant for the patent or any person from whom he derives title learned of the publication before the date of the application for the patent, or in the case of a convention application, before the date of the application for protection in a convention country, that the application or the application in the convention country, as the case may be, was made as soon, as reasonably practicable thereafter: PROVIDED that this sub-section shall not apply if the invention was before the priority date of the claim commercially worked in India, otherwise than for the purpose of reasonable trial, either by the patentee or the applicant for the patent or any person from whom he derives title or by any other person with the consent of the patentee or the applicant for the patent or any person from whom he derives title. (3) Where a complete specification is filed in pursuance of an application for a patent made by a person being the true and first inventor or deriving title from him, an invention claimed in that specification shall not be deemed to have been anticipated by reason only of any other application for a patent in respect of the same invention made in contravention of the rights of that person, or by reason only that after the date of filing of that other application the invention was used or published, without the consent of that person, by the applicant in respect of that other application, or by any other person in consequence of any disclosure of any invention by that applicant. **30. Anticipation by previous communication to government** An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of the communication of the invention to the government or to any person authorised by the government to investigate the invention or its merits, or of anything done, in consequence of such a communication, for the purpose of the investigation. **31. Anticipation by public display, etc.** An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of— (a) the display of the invention with the consent of the true and first inventor or a person deriving title from him at an industrial or other exhibition to which the provisions of this section have been extended by the Central Government by notification, in the Official Gazette, or the use thereof with his consent for the purpose of such an exhibition in the place where it is held; or (b) the publication of any description of the invention in consequence of the display or use of the invention at any such exhibition as aforesaid; or (c) the use of the invention, after it has been displayed or used at any such exhibition as aforesaid and during the period of the exhibition, by any person without the consent of the true and first inventor or a person deriving title from him; or (d) the description of the invention in a paper read by the true and first inventor before a learned society or published with his consent in the transactions of such a society, if the application for

	the patent is made by the true and first inventor or a person deriving title from him [not later than twelve months] after the opening of the exhibition or the reading or publication of the paper, as the case may be. **32. Anticipation by public working** An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that at any time within one year before the priority date of the relevant claim of the specification, the invention was publicly worked in India— (a) by the patentee or applicant for the patent or any person from whom he derives title; or (b) by any other person with the consent of the patentee or applicant for the patent or any person from whom he derives title, if the working was effected for the purpose of reasonable trial only and if it was reasonably necessary, having regard to the nature of the invention, that the working for that purpose should be effected in public. **33. Anticipation by use and publication after provisional specification** (1) Where a complete specification is filed or proceeded with in pursuance of an application which was accompanied by a provisional specification or where a complete specification filed along with an application is treated by virtue of a direction under sub-section (3) of section 9 as a provisional specification, then, notwithstanding anything contained in this Act, the Controller shall not refuse to grant the patent, and the patent shall not be revoked or invalidated, by reason only that any matter described in the provisional specification or in the specification treated as aforesaid as a provisional specification was used in India or published in India or elsewhere at any time after the date of the filing of that specification. (2) Where a complete specification is filed in pursuance of a convention application, then, notwithstanding anything contained in this Act, the Controller shall not refuse to grant the patent, and the patent shall not be revoked or invalidated, by reason only that any matter disclosed in any application for protection in *a* convention country upon which the convention application is founded was used in India or published in India or elsewhere at any time after the date of that application for protection. **34. No anticipation if circumstances are only as described in sections 29,30,31 and 32** Notwithstanding anything contained in this Act, the Controller shall not refuse to grant a patent, and a patent shall not be revoked or invalidated by reason only of any circumstances which, by virtue of section 29 or section 30 or section 31 or section 32 do not constitute an anticipation of the invention claimed in the specification.
USA **[35 USC]**	**§ 102. Conditions for patentability; novelty** (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless— (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention. (b) EXCEPTIONS.— (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if— (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor. (2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.— A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if— (A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor; (B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or (C) The subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

EUROPE [EPC]	**Article 54** **Novelty** (1) An invention shall be considered to be new if it does not form part of the state of the art. (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. (3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art. (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art. (5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art. **Article 55** **Non-prejudicial disclosures** (1) For the application of Article 54, a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: (a) an evident abuse in relation to the applicant or his legal predecessor, or (b) The fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972. (2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application that the invention has been so displayed and files a supporting certificate within the time limit and under the conditions laid down in the Implementing Regulations.

C. INTERPRETATION OF THE LAW & EXPLANATION:

INDIA:

[7]The Indian Patent Office's suggestion to the inventors is,

"The most common mistake is to publish their inventions in newspapers or scientific and technical journals, before applying for patents. Publication of an invention, even by the inventor himself, would (except under certain rare circumstances) constitute a bar for the subsequent patenting of it. Similarly, the use of the invention in Public, or the commercial use of the invention in public or even in secrecy, prior to the date of filing patent application would be a fatal objection to the grant of a patent for such invention, thereafter. There is, however, no objection to the secret working of the invention by way of reasonable trial or experiment, or to the disclosure of the invention to other confidentially."

[8]Publication of an invention in any form by the inventor before filing of a patent application would disqualify the invention to be patentable. Hence, inventors should not disclose their inventions before filing the patent application. The invention should be considered for publication after a patent application has been filed.

[5]The invention is not anticipated i.e. novelty of an invention is not destroyed in certain exceptional conditions, specially provided in the Act in Sections 29-34.

Not Anticipations:

a) Prior Publication (S. 29)

The invention claimed in the complete specification will not be considered as anticipated by a specification accompanying an application in India, which was published before the 1st day of January, 1912.

A prior publication of an invention before its priority date will not be deemed as anticipation, if the patentee or the applicant proves that the matter was obtained from him or the inventor or assignor, and that the publication was done without their knowledge, and the application for patent was therefore made immediately after learning that the publication had happened.

This provision will not apply if the invention was commercially worked in India, otherwise for the purpose of reasonable trial before the priority date of the claim by the inventor, patentee or applicant, their assignor or assignee or someone else having their consent.

An invention claimed in an application made by the inventor or his assignee should not be deemed as anticipated by another application for patent in respect of the same invention made in contravention of the rights of that person, or its publication or use by the other applicant or any other person in consequence of its disclosure by him without the consent of the first mentioned applicant.

b) Previous communication to Government (S. 30)

The invention will not be deemed as anticipated by its communication to the government or to any person authorized by the government to investigate the invention or its merits, or of anything done in consequence of such communication for the purpose of the investigation.

c) Prior Public Display etc. (S. 31)

If the application for the patent is made by the inventor or his assignee not later than twelve months after the opening of the exhibition (notified by the Central Government) where the invention is first displayed and published by the applicant or used with his consent, it will not be deemed as anticipated. The use of the invention (so displayed) by an unauthorized person during the period of exhibition also will be deemed as non-anticipation.

(d) The description of the invention in a paper read by the true and first inventor or its publication with his consent in the transactions before a learned society also does not constitute anticipation, if the application is made within the period of twelve months.

e) Prior Public Working (S. 32)

This deals with public working of an invention claimed in a complete specification for a reasonable trial because the nature of the invention is such that it was necessary to do so. This type of public working will not be deemed as anticipation if performed within one year before the priority date by the patentee, applicant (or assignor) or by any person with their consent.

f) Use and Publication after provisional specifications (S. 33)

An invention in an application should not be considered as anticipated by public use and/or publication of the invention in India or elsewhere after the corresponding filing date of the provisional specification or the prior application in a convention country for which a priority is claimed.

US:

[9]The U.S. patent law system is among the most lenient in the world with regards to prior disclosure of your invention. It allows you to publish your invention or offer it for sale prior to filing a patent application, provided that you file your patent application within one year of the publication or offer for sale. If you wait longer than one year, your patent rights are forfeited. The one-year period is a "grace period."
In the U.S., the "public disclosure" must be a "publication"--that is, in writing. However, do note that slides at meetings and poster sessions are "publications"--as is private correspondence, advertisements, etc.

[9]An "offer for sale" counts as a bar to patenting (after the one year "grace period") in the U.S. Same is true for showcasing your product at a trade show.

Simply announcing that you have made an invention is not a "public disclosure" of the invention. In order to act as a patent bar, the disclosure must be "enabling"--that is, it must teach someone "of ordinary skill in the art" how to actually duplicate the invention.
An offer for sale, even if it does not teach someone how to make the invention, is a bar to patentability (after the grace period) in the U.S.

[11]Under United States law, a public disclosure occurs when an invention is:
A. Described in a printed publication anywhere in the world;
B. Placed in public use in the United States; or
C. Offered for sale in the United States.

For U.S. patent purposes, a “printed publication” is any communication that:
A. Appears in a fixed-media form (i.e., not necessarily “printed”);
B. Is considered to be available to the public (either because it was intended to be made public, as an article in a scientific journal, or because it was made without an obligation of confidentiality, as a casual letter to a friend); and
C. Describes an invention in such detail that one familiar with the field (“skilled in the art”) could duplicate it or put it into use.
Virtually anything is deemed to be a printed publication for patent purposes. The most obvious examples include books and treatises, articles in scientific or trade journals, and articles in newsletters and bulletins. However, printed matter that is less obviously available to the public is generally more likely to cause the inadvertent loss of patent rights.

[11]Under the right circumstances, virtually *anything* can constitute a printed publication for patent purposes.
For example, a printed publication may occur in each of the following circumstances: • the placing of a thesis or dissertation on the library shelves or on the Internet • the cataloguing of a thesis or dissertation for microfilm distribution • the submission of an abstract as a proposal for a book or journal • the e-mailing of an abstract to prospective attendees of a professional conference • the appearance of a newspaper or web article written by a reporter who attended an oral presentation • a poster presentation • participation in a television or radio interview • the submission of a proposal to a federal agency • making a report to a public or private research sponsor.

[11]To impact patentability, the disclosure must contain a description of the invention that is detailed enough to enable a person skilled in the art to duplicate or use it (see Rule 3.C. above). This requirement is sufficient to exclude some abstracts, articles, etc., from the realm of public disclosure. But as a practical matter, when deciding whether or not to discuss an invention in any way outside of your own research environment, you should assume that it will constitute a public disclosure for patent purposes.

For patent purposes, a “public use” may be:
A. Any use of the completed invention by someone who is not under a duty to keep the invention a secret;
B. Any authorized commercial use of the completed invention (even if the invention is kept secret).

It is clear that a "public" use need not be public at all -- in fact, it may be very private. However, there *are* exceptions and each case will be decided on its own facts. As a result, what may be a public use in one situation in one court may not be a public use in another situation in another court. When attempting to decide whether a proposed use will constitute a "public use" for patent purposes, the safest route is to assume that it is to be interpreted broadly. By doing so, patent rights won't be inadvertently lost by engaging in an activity that you think is acceptable but later turns out to be a "public use" of the invention.
However, there is one significant caveat to the "public use" rule that is important for academic inventors:
A so-called exception to the "public use" rule as stated above is a *bona fide* experimental use, if its motive is truly the testing and/or perfection of the invention.
In determining whether a use is truly experimental, the courts have developed a laundry list of factors to consider, but the focus of the inquiry is the inventor's *motive*, as evidenced by his or her behaviour. If the inventor's motive in allowing the public use was primarily commercial, patentability will be barred unless a U.S. patent application is filed within the one-year grace period.

[11]A single offer to sell an article, device, or composition embodying the invention is enough to bar patentability, even if that offer is not accepted.
This applies only to a physical *embodiment* of the invention. Thus: The licensing or assignment of rights in an invention or a patent does not constitute placing the invention "on sale." Only the sale or offer for sale of a "thing" embodying the invention or capable of performing the invention will result in an "on sale" bar to patentability.

EUROPE:

The basic requirements for patentability under the European Patent Convention (EPC) are:
1) New Invention;
2) Invention susceptible of industrial application; &
3) The invention inclusive of an inventive step. (Article 52).

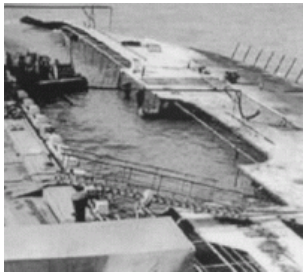
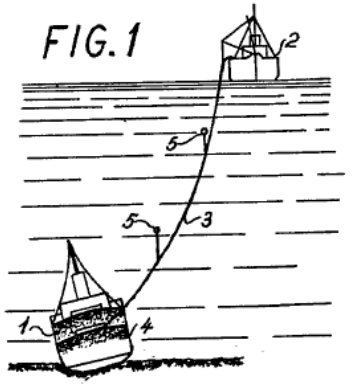
[10]Many people run into problems when applying for European patents because they disclose their invention before filing either a U.S. or European patent application. While this may be acceptable (with certain limitations) in the U.S., it can create insurmountable problems in many other countries like EP.

According to Article 54(1) of the EPC, an invention is considered to be new if it does not form part of the state of the art. Article 54(2) goes on to define "state of the art" as everything made available to the public, whether written, oral, in use, or any other way before the date of filing of the European patent application.
So, any public disclosure before the filing date of your invention, including writing about your invention on your blog, or using your invention as part of your newly launched website, can result in loss of international patent rights.
The only situations where public disclosure is not taken into consideration is if the public disclosure was made within six months of the filing of the European patent application, and was the result of some sort of abuse, such as a breach of confidence, or if it was made at a recognized international exhibition (Article 55).

Since the EPO only searches printed publications during examination, an oral disclosure is unlikely to affect the grant of a patent. However, the oral disclosure could be used by others after grant, for example, during an EPO opposition proceeding or national revocation proceeding.

Therefore, those considering filing international patent applications should be extremely careful about any public disclosure and, preferably, seek the advice of qualified patent counsel at IP Group.

D. EXAMPLES & CASES: The Donald Duck story as prior art case

The Case:	The invention:	The patents:	The Donald Duck story:
There is a famous case about a Donald Duck story being used as prior art against a patent on a method of raising a sunken ship. A 1949 Donald Duck story used the same technique. 	The invention has been used in practice on several occasions. The most famous one, shown in the photograph below, was in 1964 in Kuwait. On September 14, 1964, the freighter Al Kuwait capsized at the docks in Kuwait's harbour. The ship was carrying 5,000 sheep that started decomposing in the harbour's water. Since this threatened to contaminate the city of Kuwait's drinking water supply, the ship had to be raised as quickly as possible. Bringing in cranes would have taken too long, and with such methods there is a significant risk that the ship will break. The Danish inventor Karl Krøyer came up with a method of raising this sunken ship by filling it with buoyant bodies fed through a tube. On December 31, 1964, he filled the ship with 27 million plastic balls made of expandable polystyrene foam and weighing 65 tons. The balls had been airlifted from Berlin to Kuwait. 	Inventor Karl Krøyer received patents for this method in the United Kingdom (GB 1070600) and Germany (DE1247893). According to the patent claim, buoyant bodies 1 are inserted into a sunken vessel 4 through a tube 3 from a salvage ship 2. The story is usually told as relating to the Dutch patent (NL 6514306) Krøyer applied for. This application was not approved. According to the story, the Dutch Patent Office found an old issue of the Donald Duck magazine which showed the same invention. Since an invention has to be new to be patentable, the application was refused. This story was recently repeated by the Dutch patent office (in Dutch), although surprisingly this confirmation did not give any detail on which patent office or how the Duck story came to its attention.  Figure 1 of Krøyer's patent	In 1949 the Donald Duck story The Sunken Yacht (by Carl Barks) shows Donald and the nephews raising a ship by filling it with ping pong balls shoved through a tube, as can be seen below in the images cited from that story. Since ping pong balls are buoyant bodies, and they were fed to the yacht through a tube, the Donald Duck episode discloses the same technique as that which is claimed in the patents. Consequently, the Duck story has to be considered novelty-destroying prior art: given the story, any Patent Office would have rejected Krøyer's patent application. It remains an open question whether the Dutch patent office in fact used this document as prior art to refuse the patent application. Regrettably the files of the cases have been destroyed by now, and the Dutch patent attorney who represented the inventor has passed away several years ago. 

[Source: http://www.iusmentis.com/patents/priorart/donaldduck/]

E. REFERENCES:

1. The Patents Act, 1970.
2. United States Code Title 35 – Patents
3. Leahy-Smith America Invents Act, 2011
4. European Patent Convention
5. Manual of Patent Practice & Procedure, Indian Patent Office.
6. www.ipindia.nic.in
7. www.ipindia.nic.in/ipr/patent/patents_filing.pdf
8. www.indianpatents.org.in/faqpat.htm
9. http://web.mit.edu/tlo/www/community/preserving_patent_rights.html
10. http://patentauthority.com/2007/03/public-disclosure-european-patent/
11. http://utrf.tennessee.edu/PDF/Impact_of_PD%202-16-09.pdf
12. http://www.grad.wisc.edu/research/ip/publicdisclosure.html
13. http://www.mateoaboy.com/f6/blog_files/874912ee2802a38923c533ba23ecf6c5-32.html
14. http://olv.duke.edu/Inventors/LearningCenter/PublicDisclosure
15. http://www.iusmentis.com/patents/priorart/#earlier-application
16. http://www.iusmentis.com/patents/priorart/donaldduck/

Note: This IGN was finalized in the current form on 10th 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

INVENTOR GUIDANCE NOTES

(While papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC:	AUTHOR:
EXCLUSION LISTS* FOR PATENTING	**SNEHA KANITKAR** **A207, PAML** **National Chemical Laboratory** **Pune – 411008** **Phone: +91-20-2590-2757** **Email: sv.kanitkar@ncl.res.in**
IGN Number: **IGN-08**	**VERSION:** **01**
SCOPE: **This Inventor Guidance Notes provides information for scientists regarding non-patentable inventions across various jurisdictions.**	**DATE:** **15th April 2013**
TABLE OF CONTENTS: **A. Summary Table** **B. Exclusion lists table highlighting:** • **Relevant legal extracts** • **Interpretation of the law and explanations** • **Examples and cases** **C. References**	**REVIEWERS:** **Nitin S Tewari** **V. Premnath**

[***Disclaimer:** This IGN is intended for creating awareness about the legal interpretation of the patent law regarding non-patentable subject matter. Although this IGN lists all non-patentable inventions under the IN, EP & US patent laws; it is not intended as a legal advice by the IPG. Kindly consult IPG, NCL before deciding not to file a patent for your invention as the claims can be drafted around the law in many cases & patents can be filed.]

A. SUMMARY TABLE: COUNTRY SPECIFIC EXCLUSION LISTS FOR PATENTING

INDIA		
1.	Inventions which are **frivolous or contrary to well established natural laws.**	Eg: A method of showing time on the basis of metric system
2.	**Contrary to public order or morality** or which causes serious prejudice to human, animal or plant life or health or to the environment	Eg: Novel Guillotine apparatus
3.	**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	Eg: New species of Fish, laws of gravity
4.	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.	Eg: Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, etc
5.	Substance obtained by a **mere admixture** resulting only in the aggregation of the properties	Eg: Fertilizer combination without any synergistic effect
6.	**Mere arrangement or re-arrangement or duplication of known devices** each functioning independently of one another in a known way	Eg: An umbrella fitted with a torch.
7.	**Method of agriculture or horticulture**	Eg: Farming technique
8.	**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.	Eg: Surgical methods
9.	**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	Eg: Living organs
10.	**A mathematical or business method or a computer program per se or algorithms**	Eg: Mathematical formulas
11.	**A literary, dramatic, musical or artistic work or any other aesthetic creation** whatsoever including cinematographic works and television productions	Eg: Cinematic films
12.	Mere scheme or rule or **method of performing mental act** or **method of playing game**	Eg: A new game called anti-chess which inverses the normal rules of chess
13.	**Presentation of information**	Eg: Delivering lectures
14.	**Topography of integrated circuits**	Eg: Novel IC layouts
15.	An invention which, in effect, is **traditional knowledge** or which is an **aggregation or duplication of known properties of traditionally known component or components**	Eg: Wound healing property of turmeric
16.	Inventions relating to atomic energy are not patentable	Eg: Alpha-emitting radio nuclides
USA		
1.	US laws on patenting are most liberal and hence there is no exclusion list as such. The rule of the land there is 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 therefore. US patent law also offers patent protection to software, plants & designs. However, un- ethical & inventions contradictory to moral values will not be allowed a patent.	
EUROPE		
1	Inventions the commercial exploitation of which would be **contrary to public order or morality**	
2	**Plant or animal varieties or essentially biological processes for the production of plants or animals**; (Excluding microbiological processes or the products thereof)	
3	**Methods for treatment** of the human or animal body **by surgery or therapy and diagnostic methods** practised on the human or animal body.	
4	EPC offers patent protection for **computer program with a technical contribution**. However, mathematical methods and programs for computer are not patentable as such.	

B. EXCLUSION LISTS TABLE: Interpretation of the law & explanation based on examples & case studies

INDIA: THE PATENTS ACT, 1970

Section 3:What are not inventions

The following are not inventions within the meaning of this Act,—

1 **Anything frivolous or contrary to well established natural laws:**

Merely making in one piece, articles, previously made in two or more pieces is frivolous. Mere usefulness is not sufficient.

Examples:
a. "A method of showing time on the basis of metric system" wherein dial of time piece having three hands for indicating, hour, minutes and seconds was divided into 10 parts for hours, each hour into 100 minutes and each minute into 100 seconds. The invention was held frivolous and not considered a patentable invention. (Indian patent application No. 101/BOM/72).
b. Merely making in one piece, articles previously made in two or more pieces is frivolous. Mere usefulness is not sufficient [*Indian Vacuum Brake' Company Ltd v. Laurd* (AIR 1962, Cal 152)].

2 **Contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment:**

This clause bars the patentability of inventions, the commercial exploitation of which could be potentially harmful to the well being of Human beings & other life forms as well as the ecosystem.

Examples:
a.The **terminator gene technology** is the name given to proposed methods for restricting the reproduction of genetically modified plants by causing second generation seeds to be sterile. Initially developed as a concept by the United States Department of Agriculture and multinational seed companies, Terminator seeds have not been commercialized anywhere in the world due to opposition from farmers, indigenous peoples, NGOs, and some governments. In 2000, the United Nations Convention on Biological Diversity recommended a *de facto* moratorium on field-testing and commercial sale of terminator seeds; the moratorium was re-affirmed in 2006. India and Brazil have passed national laws to prohibit the technology. [8]
b. An automated guillotine used for the decapitation of human beings cannot be the subject matter of a patentable invention. c. A patent for a method of adulteration of food will also be excluded from patentability.

3 **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**

Explanation: Scientific principles as such are not patentable irrespective of the fact how revolutionary these might be. But if someone comes up with a practical application of such a theory, then it shall be a patentable invention.

Further, discovery of any living or non-living substance occurring in nature is not patentable.

Example:
a.X-ray diffraction pattern of diamond in itself is not patentable. But a method of identifying diamonds by means of photographic records of their X-ray diffraction patterns is patentable.

B.Genes present in living organisms are non-patentable. However, if someone invents the method of isolating a gene, it shall be considered as patentable subject matter of a process patent as substantial human intervention is involved.

4 **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.**

1.**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**.

Example:

1. A patent was granted to Roche on an anti-HIV pro-drug Valganciclovir per se & its crystalline form which is a new from of a known drug Ganciclovir. This patent was granted since Roche was able to prove that the prodrug Valganciclovir is more efficacious by showing that the known drug Ganciclovir has poor bioavailability when administered orally & Valganciclovir offers a solution to this problem by being more bioavailable when administered orally.

Case Study 1:

The case	The Verdict	Basis of judgement
Pre-grant opposition by Torrent Pharmaceuticals against Warner-Lambert's application for the crystalline form III of atorvastatin and hydrates. Patent application No. 1577/DEL/1996. Atorvastatin (marketed as Lipitor) is a compound used to lower blood cholesterol.	Application was refused, inter alia, under the provisions of section 3(d) of the Patents Act, 1970.	The Controller in his decision dated 12th June, 2007 held that "the present invention provides a new form of known substance either in anhydrous or hydrated form III of Atorvastatine having same therapeutic activity and in the same field. It only claims some improvement in physical property, which does not make any change in therapeutic efficacy of the compound as compared to the prior art compound. Therefore this new form does not qualify the requirement under section 3(d)."

Case Study 2:

The Case	The Verdict	The Impact
On April 1, 2013, the Supreme Court upheld the Intellectual Property Appellate Board's decision to deny patent protection to Novartis's application covering a beta crystalline form of imatinib (1602/MAS/1998) —the medicine Novartis brands as Glivec, and which is very effective against the form of cancer known as chronic myeloid leukaemia (CML). The judgment marked a crucial	India has refused protection for Glivec on the grounds that it is not a new medicine, but an amended version of a known compound. The patent application had initially been rejected by the Controller of Patents in 2006, after hearing 5 pre-grant oppositions filed by various generic pharmaceutical companies including Ranbaxy, Cipla, Hetero and one patients group – the Cancer Patient Aid Association (CPAA). Novartis had initially filed an appeal with the Madras High Court which subsequently transferred the appeal to the Intellectual Property Appellate Board (IPAB). In a separate petition Novartis had also unsuccessfully challenged Section 3(d) of the Patents Act before the Madras High Court. In 2009, the IPAB upheld the rejection by the Controller. Supreme Court had considered the entire case *de novo* despite it being an appeal from the IPAB, which had itself delivered a lengthy judgment.	Public-health groups in developing nations praised the judging on account that it protects Indian companies that produce low-cost generic forms of drugs such as Glivec, allowing them to continue producing and, most importantly, exporting their cheaper product to developing nations in Asia and Africa. Currently in India, Glivec treatments cost $1,900 per month, whereas generic forms of the drug

conclusion to a saga that has been several decades in the making.	On the merits, not only did Novartis lose its main ground of appeal regarding Section 3(d) but it also lost the points raised by the generics in their cross-appeals against certain aspects of the IPAB's judgment.	go for about $175 per month.

2.**A mere discovery of a new property of known substance is not considered patentable**. For instance, the paracetamol has antipyretic property. Further discovery of new property of paracetamol as analgesic cannot be patented.

Example:
Ethyl alcohol is used as solvent but further discovery of its new property as anti knocking, thereby making it usable as fuel, cannot be considered patentable.

3.**A mere discovery of new use of known substance is not considered patentable**. For instance, new use of Aspirin for treatment of the cardiovascular disease, which was earlier used for analgesic purpose, is not patentable. However, a new and alternative process for preparing Aspirin is patentable. Similarly, the new use of methyl alcohol as antifreeze in automobiles. The use of methanol as a solvent is known in the prior art.

Example: A new use of Chloroquine for Sarcoidosis (a fungal disease) and for Infectious mononucleosis (a viral disease) and for Diabetic Neuritis (inflammation of nerves) is not patentable.

Case study:

The case	The details	The verdict
Patent application No. 782/CAL/l981, dated 13th July, 1981, an invention related to pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastroenteric tolerance.	The invention was related to pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastroenteric tolerance in unit doses form which contained imidazol salicylate as the active ingredient in the amount of 100-600 mg and an inert carrier was claimed which was later amended to a process for the preparation of novel composition containing imidazole salicylate having formula 1, as the active principle. The invention was characterized in a product that was previously obtained by reacting, mole by mole, acetylsalicylic acid with imidazole in an inert organic solvent and that, using the solid product obtained in the reaction after purification by recrystalization, homogenous composition were produced with pharmaceutically acceptable vehicles suitable for oral, parental or topical administration.	It was held by the Controller that the active compound such as imidazole salicylate was known in the art and applicant could not develop any special property or even improve upon the property of the compound to be mixed up with the usual carrier to form the composition. Furthermore, the description contained no indication of using any special type of solvent for its purification by re-crystallization and, therefore, the invention was not patentable under section 3(d) of the Act.

5 **Substance obtained by a mere admixture resulting only in the aggregation of the properties**

Thus substances in a novel composition having synergistic effects will be patentable. However those which lead to mere aggregation of properties will not be deemed patentable.

For eg: A mixture of sugar and some colorants in water to produce a soft drink is a mere admixture resulting into aggregation of the properties.

Similarly, a mixture of different types of medicament or medicine to cure multiple diseases is also a mere admixture of substances and is not a patentable invention. A process for producing a substance by admixing, which is resulting into the aggregation of the properties of the components thereof, is also not patentable invention.

Case Study:

The Case	The verdict
Patent application No. 63/BOM/75 for an invention relating to an antiperspirant composition filed by Hindustan Lever Limited	It was held by the Controller that an admixture having only the aggregation of the individual properties of the components thereof is not an invention within the meaning of the Act and is thus not patentable, A process for producing such an admixture is also not patentable. In case the presence of one or more components of the composition influence the properties of the other components of the composition with the result that the ultimate properties of the composition would be different from the aggregation of the individual properties of the components thereof, such an admixture would be patentable under the Patents Act, 1970.
Patent No. 143270 for the invention entitled "A fertiliser composition"	It was held that alleged invention falls within sub-section (e) of Section 3 of the Act, i.e. "not an invention or not patentable" as the crop nutrient properties of the constituents like zinc sulphate, manganese sulphate, copper sulphate and magnesium sulphate were known as seen from know-how report and the steps of grinding, mixing and homogenizing were conventionally used in manufacture of the fertiliser.

6 **Mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way**

Case Study:

The Case	The Verdict
Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries [1978] Insc 255 (13th December, 1978)	It is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working inter relation they produce a new process or improved result. Mere collocation of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent.

For eg: An umbrella fitted with a torch doesn't qualify as a patentable invention as both the umbrella & the torch function independently of each other & their combination although useful is a mere workshop improvement, & hence doesn't qualify as a patentable invention.

7 **Method of agriculture or horticulture**

On humanitarian grounds, methods of Agriculture & horticulture are not patentable, so as to avoid granting monopoly rights on the production of food via these methods.

For eg: A method of producing mushroom plant (64/CAL/79) and a method for cultivation of an algae (445/DEL/93] were held not patentable.

8 **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.**

-An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application and hence not Patentable. The art of curing illness cannot be said to be patentable.

Example:

1. A method of treatment of malignant tumour cells and method of removal of dental plaque and caries are not patentable, since they are held as treatment of human beings. Also, treatment of sheep for increasing wool yield (1958 RPC 85) was held as not patentable.
2. In *Unilever Limited (Davis1) Application*, [1983] RPC 219, it was observed that any method of surgical treatment, whether curative, prophylactic or cosmetic, is not patentable. This view was upheld in an another case also, while refusing to allow claims to a method of implanting an embryo transplant from a donor mammal into the uterus of a recipient mammal, since the method would necessarily have to be carried out by a surgeon or veterinary surgeon.

-Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements therefore on the human body are patentable.

-Similarly, methods of diagnosis practised on the human or animal body are excluded. However, methods of diagnosis performed on tissues or fluids, which have been permanently removed from the body, are, therefore, not excluded from patentability.

-Methods of therapy carried out on materials temporarily removed from the body, for example, when blood is circulated through an apparatus while remaining in living communication with the body, are not patentable [15]

Case Study :

The Invention	The Case	The Verdict
In Ciba-Geigy AG's Application, (BL 0/30/85) the objection was raised to certain claims for a method of controlling parasitic helminthes (worms which may develop in the animal body, for example, in the intestinal tract of animals such as sheep) by the use of a particular (novel and inventive) antihelmintic composition.	The applicants contended that the composition when administered to an animal would prevent the reproduction of the helminthes and kill them should they infest the animal, but without affecting the animal's body, and that its use was therefore not "therapy". However, the applicants' specification made it clear that an infestation of helminthes worms can result in restricted growth, damage to the animals and even death, if not properly treated. Moreover, the application made no mention of controlling helminthes by the use of the composition in any environment other than the animal body.	The hearing officer considered that such an infestation was therefore a disease requiring medical treatment of the animal and that such treatment, whether curative or Preventative, constituted therapy practiced on the animal body and consequently held that the claims in question were not allowable.

9 **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**

While plants and animals or any part of the plant or animal is not patentable, an exception is made in the case of micro-organisms. However, any discovered micro-organism from the nature is not patentable.

Case Details:	Case History:	The Verdict:	The Consequences:
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 136/CAL/98 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.**

Plant varieties are provided protection in India under the provisions of the Protection of Plant Varieties and Farmers' Rights Act, 2002.

10 **A mathematical or business method or a computer program per se or algorithms**

-Computer programs are not patentable per se under the Patent Act. However, those inventions which are in combination with hardware or provide a technical output may be deemed patentable.

-Mathematical & business method are not patentable in India.

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

-Writings, music, works of fine arts, paintings, sculptures, computer programmes, electronic databases, books, pamphlets, lectures, addresses, sermons, dramatic-musical works, choreographic works, cinematographic works, drawing, architecture, engraving, lithography, photographic works, applied art, illustrations, maps, plans, sketches, three-dimensional works relating to geography, topography, translations, adaptations, arrangements of music, multimedia productions, etc. are not patentable. Such works fall within the domain of the Copyright Act, 1957.

12 **Mere scheme or rule or method of performing mental act or method of playing game;**

-Method of performing mental act or method of playing game or a mere scheme or rule are as such excluded from patentability, because they are considered as outcome of mere mental process.

Example:

a. Method of learning a language.

b. Method of playing chess.

c. Method of teaching.

	d. Method of learning e. Method of operating a machine or equipment as per the set of instructions
13	**Presentation of information;** -Any manner, means or method of expressing information whether visual, audible or tangible by words, codes, signals, symbols, diagrams or any other mode of representation is not patentable. For example, a speech instruction means in the form of printed text where horizontal underlining indicated stress and vertical separating lines divided the works into rhythmic groups is held not patentable. For example: In the matter of application No. 94/CAL/2002, the Controller held, that patent system was meant for protecting only one kind of creativity , i.e., technological creativity and since the claimed invention related to business method and method of presenting information, it was not allowed.
14	**Topography of integrated circuits:** Since protection of Layout Designs of Integrated Circuits is governed separately under the Semiconductor Integrated Circuit Lay-out Designs Act, 2000, three-dimensional configuration of the electronic circuits used in microchips and semiconductor chips is not patentable.
15	**An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.** Traditional Knowledge, being knowledge already existing, is not novel & hence not patentable. An example is the anti septic property of turmeric for wound healing. Another example is the pesticidal and insecticidal properties of Neem.
16	**Section 4 of the patent Act, 1970:** **Inventions relating to atomic energy not patentable** No patent shall be granted in respect of an invention relating to atomic energy if it relates to elements like uranium, plutonium, thorium, beryllium, deuterium or any of their respective derivatives or compounds or any other materials containing any of the aforesaid substances. [Section 2(1) (g) of the AE Act] as notified by Govt of India. More specifically, no patent shall be granted for the invention which in the opinion of Central Government is useful for or related to the production, control, use or disposal of atomic energy or prospecting mining extraction, production, physical and chemical treatment fabrication, enrichment, canning or use of any prescribed substance or radioactive substance or the ensuring of safety in atomic energy operation. For eg: Neutron generators including neutron chain reacting assemblies and fusion assemblies of all kinds for producing fissile materials

II. <u>UNITED STATES:</u>

35 U.S.C. 101: Inventions patentable.
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 therefor, subject to the conditions and requirements of this title.

US laws on patenting are most liberal and hence there is no exclusion list as such. The rule of the land there is 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 therefore. US patent law also offers patent protection to software, plants & designs.

However, un- ethical & inventions contradictory to moral values will not be allowed a patent.

III. EUROPE:

EPC, Article 53

Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(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;

(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.

(d) EPC offers patent protection for Computer program with a technical contribution as well as Programs that improve the internal working of a computer. Mathematical methods and programs for computer are not patentable as such

C. REFERENCES:

1. THE PATENT ACT, 1970
2. 35 U.S.C
3. EPC
4. Draft Manual of Patent practice & procedures, The Patent Office India
5. Indian Vacuum Brake Co. V Luard AIR 1926 CAL 152
6. Newman v perpetual motion [1988] EPOR 301, T5/86
7. De beers Consolidated Mines ltd's application[1979]FSR 72 (CA)
8. http://en.wikipedia.org/wiki/Genetic_use_restriction_technology
9. http://www.i-mak.org/pharma-patent-decisions/
10. Decisions on Patent and Designs vol. (4) published by Patent Office Technical Society
11. Patent agent examination, Sheetal Chopra & Dr Akash Taneja, 2nd Edition, 2010
12. http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf
13. http://www.indiankanoon.org/doc/1905157/
14. Sub-section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962)
15. cf Calmic Engineering Co Ltd's Application, [1973] RPC 684
16. Inventor Guidance Notes- Microorganisms
17. Inventor Guidance notes- Software & Algorithms
18. Protection of Plant Varieties and Farmers' Rights Act, 2002
19. The Copyright Act, 1957
20. Semiconductor Integrated Circuit Lay-out Designs Act, 2000
21. http://www.thehindubusinessline.com/companies/novartis-glivec-case-stage-set-for-a-verdict/article4167349.ece
22. http://www.thehindu.com/opinion/lead/why-novartis-case-will-help-innovation/article4617473.ece
23. http://spicyipindia.blogspot.in/2013/04/supreme-court-rejects-bid-by-novartis.html

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Note: This IGN was finalized in the current form on 15th April 2013. 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

INVENTOR GUIDANCE NOTES

(While papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC: **TRADITIONAL KNOWLEDGE , BIODIVERSITY GUIDELINES on PATENT FILINGS IN INDIA**	**AUTHOR:** **SNEHA KANITKAR** **A207, PAML** **National Chemical Laboratory** **Pune – 411008** **Phone: +91-20-2590-2757** **Email: sv.kanitkar@ncl.res.in**
IGN Number: **IGN-09**	**VERSION:** **01**
SCOPE: **This Inventor Guidance Notes provides information for scientists regarding the impact of traditional knowledge & biodiversity guidelines on patenting life-sciences related inventions in India.**	**DATE:** **15th May 2013**
TABLE OF CONTENTS: **A. Summary** **B. Relevant legal extracts** **C. Interpretation of the law and explanations** **D. Examples and cases** **E. References**	**REVIEWERS:** **Nitin S Tewari** **V. Premnath**

A. SUMMARY:

Traditional knowledge, by its very definition, is in the public domain and hence, any application for patent relating to TK does not qualify as an invention. An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components, is not an invention and hence, not patentable, within the meaning of the Patents Act 1970.

Sr no	Certain Guiding Principles for TK related inventions	Examples	TK Reference/ prior art
1.	If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge.	1319/CHE/2013 Evaluation of anticancer properties of acalypha alnifolia klein ex willd - in vitro and in vivo	ME02/97 Rasaganthi Mezhugu Text Book Name: Pulippani vaithiyam 500 Origin Time: 10-15th Century A.D [relevant prior art in opinion of IGN authors]
2.	Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.	31/DEL/2008 A herbal extract obtained from the roots of burcea mollis	E O Ajaiyeoba et al., 'In vivo antimalarial activities of Quassia amara and Quassia undulate plant extracts in mice', Journal of Ethnopharmacology, Vol 67, Issue 3, 1999, 321-325 (Nigerian folk medical practices)
3.	In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.	218/DEL/2006 A novel herbal composition effective against coryza and a process for preparing thereof	Divya Swasari Kvath 100gm, Producted by: (Divya Yog Mandir (Trust), Swami Ramdev).
4.	Discovering the optimum or workable ranges of traditionally known ingredients by routine experimentation is not inventive.	1576/DEL/ 2006 Novel herbal composition effective against skin disorders and to a process for the preparation thereof	BA3/465 Hab Deedan ; BA3/478 Hab Barg-e- Neeb ; BA4/1745 Nuskha Dawa; BA4/1745A Habb Musaffi-e-khoon ; BA4/1754 Nuskha Naqoo ; Nature Heals, A glossary of selected indigenous medicinal plants of India.
5.	In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive.	1319/CHE/2013 Evaluation of anticancer properties of acalypha alnifolia klein ex willd - in vitro and in vivo	ME02/97 Rasaganthi Mezhugu Text Book Name: Pulippani vaithiyam 500 Origin Time: 10-15th Century A.D [relevant prior art in opinion of IGN authors]
6.	In case individual ingredients are already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).	1076/CHE/2007 A synergistic ayurvedic/functional food bioactive composition (cincata) and a process of preparation thereof	WO0172316

The Biological Diversity Act, 2002 provides mechanism for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty.

B. RELEVENT LEGAL EXTRACTS:

INDIA : THE PATENT ACT, 1970	
Section 2 (1) (j)	Defines invention as: “invention means a new product or process involving an inventive step and capable of industrial application".
Section 3(e)	A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable.
Section 3 (p)	An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components is not an invention and hence, not patentable, within the meaning of the Patents Act.
INDIA: BIODIVERSITY ACT, 2002	
Section 6	(1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application: Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned: Provided further that the National Biodiversity shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof. (2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights. (3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament. (4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

C. INTERPRETATION OF THE LAWS AND EXPLANATION:

Interpretation of the laws:

Traditional knowledge:

TK, by its very definition, is in the public domain and hence, any application for patent relating to TK does not qualify as an invention under section 2 (1) (j) of the Patents Act, 1970, which defines that "invention means a **new** product or process involving an inventive step and capable of industrial application".

Further, under section 3(e) of the Patents Act "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable. The Indian Patents Act also has a unique provision under Section 3 (p), wherein "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components" is not an invention and hence, not patentable, within the meaning of the Patents Act. Additionally, sections 3 (b), (c), (d), (f), (h), (i) and (j) are of relevance with respect to the patent applications related to TK and/or biological material.

Illustrative example:

Claim: Serum of pigeon possessing the 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 or is an aggregation or duplication of known properties of traditionally known component. 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), which discloses the use of pigeon blood for treating paralysis.

While considering the traditional knowledge based inventions, the following guiding principles must be followed in assessing the novelty and inventive step [5]:

Sr no	Guiding Principle	Illustration	Prior art	Analysis
1	If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge.	Patent application claims relate to an extract of Withania plant for the management of stress.	Discloses use of *Withania somnifera* roots and not Withania plant extract for the treatment of stress related disorders in Ayurveda and Unani systems of medicine.	The claims of alleged invention relate to an extract of Withania plant. Based on the prior art, it can be objected that the extract of *Withania somnifera* would be useful in treatment of chronic stress disorders such as insomnia, gastric ulcers, hyperacidity, restlessness and depression. Therefore, the subject-matter of claims is not considered as novel over the teaching of prior art obtained from TKDL.

2	Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.	Patent application claims relate to a composition comprising of Calendula officinallis, Aloe vera and Centellae asiatica as healing agent and for treatment of wound.	Discloses independent use of Calendula officinallis, Aloe vera and Centellae asiatica for the treatment of wound and as a Cicatrizant/healing agent in Ayurveda and Unani systems of medicine.	The claims of alleged invention were on a composition. Based on the prior art, it can be objected that the combination of these plants would be obvious for the treatment of skin diseases and healing of wounds. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disease is considered to be an obvious combination. It would normally be expected that such combinations of medicinal plants would be more effective than each of the medicinal plants when applied separately (additive effect).
3	In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.	Patent application claims relate to a combination of five constituents, one of these being a 1:2 watery extract of Cucumis melo containing catalase and superoxide dismutase; along with Pimiemta racemosa, Citrus aurantifolia, Coenzyme Q-10 and Pyridoxine Chlorhydrate for the treatment of vitiligo.	Discloses usefulness of only one of the constituents, watery extract of Cucumis melo for its anti-vitiligo property in the Unani system of medicine.	The claim of alleged invention relates to a composition comprising five constituents and not on a single constituent, the watery extract Cucumis melo for its anti-vitiligo property. Based on said cited documents, it can be objected that if one ingredient here, Cucumis melo, was already known for the treatment of vitiligo, then it is necessarily expected that a combination comprising this known active ingredient must be effective for treating vitiligo as long as no surprising (superior) effect of the claimed combination vis-a-vis the already known product comprising Cucumis Melo, inventive merits cannot be acknowledged.
4	Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive. In case of inventions relating to selection of optimum or workable range of ingredients, this is to be borne in mind that the selection of a particular range of known ingredients is not inventive since the	Patent application claims relate to a formulation comprising at least two of the following: an extract of Pongamia pinnata (in the range of 2 to 20%), an extract of Lawsonia alba (in the range of 5 to 15%), an extract of	Discloses use of said plants for the treatment of ulcer/wound in Ayurveda, Unani and Siddha systems of medicine.	The claims of alleged invention relate to a composition comprising plant parts in a specified ratio. The claims can be objected as unpatentable in so far as the alleged invention is obvious over Agasthiyar (TKDL) which taught a composition of extracts of two of the claimed plants, Karanj and Heena formulated as oil for topical treatment of ulcers and wounds. Although cited art does not specifically teach adding the ingredients in the percentages claimed by the applicant, however the amount of specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill

	selection of optimum or workable range is well within the expectation of a person skilled in the art.	Dhatura alba (in the range of 2 to 20%) and an extract of of Cocos nucifera (in the range of 20 to 60%) for the management of chronic ulcer, diabetes ulcer, and the management of bleeding in cuts and wounds.		in the art would routinely optimize.
5	In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive.	Patent application claims relate to an extract of Zingiber zerumbet (bitter ginger) for inflammation and also for allergic disorder like Asthma.	Discloses use of Zingiber zerumbet (bitter ginger) along with few other ingredients for the treatment of inflammation and Asthma in Unani system of medicine.	The claims of alleged invention relate to an extract of Zingiber zerumbet. As per the prior art disclosure, the multi-component formulation comprising Zingiber zerumbet have the same therapeutic activity (i.e. anti-bronchial asthmatic), therefore it is not surprising that one single component namely Zingiber zerumbet taken out of them again would have the same therapeutic activity. Hence, a person skilled in the art would have been motivated to arrive at the invention without exercise of inventive skills and thus, the claims of alleged invention can be objected for lacking in inventive step.
6	In case individual ingredients are already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).	Patent application claims relate to a composition comprising of theanine (Tea) and a herb selected from Sankhapuspi, Satavari or a mixture thereof for the treatment of a disease (cold and/or influenza) related to reduced immunity.	Discloses independent use of said plants for the treatment of cold and influenza and as immuno-potentiator in Ayurveda and Unani systems of medicine.	The claims of alleged invention relate to a composition. In view of the prior art, the use of theanine comprised in tea and extracts thereof, for prevention and/or treatment of cold and/or influenza was known from popular medicine since ages. The immunoadjuvant/ immunomodulatory potential of Asparagus racemosus (Satavari), aqueous exctracts/Evolulus alsinoides (Sankhapuspi) was also disclosed in prior art documents. Therefore, nothing inventive could be seen in the additional use of immunopotentiating herbs to treat these diseases. A combination of these plants would be obvious as an immunopotentiator and for the treatment of common cold and a variety of other diseases.

BIODIVERSITY RELATED ISSUES

Biodiversity related matters play a vital role in the patentability of the biological substances. The Biological Diversity Act, 2002 provides mechanism for conservation of

biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto.

In order to prevent misappropriation of biological resources and traditional knowledge of India, the Biological Diversity Act requires that access to the biological resources of India is subject to the equitable benefit sharing through the approval of National Biodiversity Authority (NBA). No Intellectual Property Rights (IPRs), including patents based on research or information on biological resources obtained from India shall be granted without the approval of the NBA.

The Patents Act provides interfaces with the process of obtaining patents and access to and benefits sharing from utilization of Indian biological resources. Thus, disclosure of the source and geographical origin of a biological material used in an application for a patent has been made mandatory as per Section 10 (4) of the Act. Also, as already discussed Section 3 (p) of the Act prohibits patenting of any invention which, in effect, is traditional knowledge.

DEPOSIT OF BIOLOGICAL MATERIAL

If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit.

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

D. EXAMPLES & CASES:

1. Patents applications classified as under traditional knowledge

Sr No.	Patent No & Title	Status	Claims	Basis for classification	TK reference/ Prior art
1	1319/CHE/2013 Evaluation of anticancer properties of acalypha alnifolia klein ex willd - in vitro and in vivo	Application awaiting examination	The plant *Acalypha alnifoUa* plant belongs to the Euphorbiaceae. • The plant is low cost and easily available. • *Acalypha alnifolia* plant extract have antioxidant property, where it can cure more than 200 diseases. • *Acalypha alnifolia* plant extract also have the cytotoxicity activity against different cell line. • It is active in prostate cancer cell line, liver cancer cell line, vero cancer cell line, DLA cell line and normal cell line. • The plant extract also shows the anticancer property.	- Plant patents are not allowed in India -Guiding principle 1- As the subject-matter claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge. - Guiding principle 5- Multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive.	ME02/97 Rasaganthi Mezhugu Text Book Name: Pulippani vaithiyam 500 Origin Time: 10-15th Century A.D
2	1576/DEL/2006 A novel herbal composition effective against skin disorders and to a process for the preparation thereof	Application refused grant of a patent	1.A herbal composition effective against skin disorder comprising of: i) seeds of Maghz-e-Nimkoli (Azadirachta indica A. Juss) 150-175mg ii) roots of Rasaut (Barberis aisatica Raxb) 150-175mg iii) whole plant of Chaksu (Cassia absus Linn) 150-175mg 2. A process for the preparations of a herbal composition effective against skin disorder comprising in the steps of separately preparing an extract of Neem, Rasaut bark, and Chaksu and mixing the three extracts, kneading for half hour, kneaded mass is dried at 85°C for 3 hours, evaporated in hard gelatin capsule.	Guiding Principle 4: Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive. In case of inventions relating to selection of optimum or workable range of ingredients, this is to be borne in mind that the selection of a particular range of known ingredients is not inventive since the selection of optimum or workable range is well within the expectation of a person skilled in the art. Although the cited references do not specifically teach adding the ingredients in the amounts claimed by the applicant, however the references does teach the ingredients Maghz-e-Nimkoli, Rasaut and Chaksu as a composition to treat skin disorders. This reasonable expectation of success would motivate an artisan of ordinary skill to use the said plant parts for reaching at the claimed composition. The amount of a specific ingredient in a composition that is used for a particular purpose is a result effective parameter that a person having ordinary skill in the art would routinely optimize. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. It would have been customary for an artisan of ordinary skill to determine the optimum amount of each ingredient to add in order to best achieve the desired results.	BA3/465 Hab Deedan ; BA3/478 Hab Barg-e-Neeb ; BA4/1745 Nuskha Dawa; BA4/1745A Habb Musaffi-e-khoon ; BA4/1754 Nuskha Naqoo ; MA3/122 Habb-e-Surkhbada; MA3/160 Habb-e- Musaffi-e-khoon Ba Nuskha Khaas ; MH1/2352 Hab Bara-e-Ishaal-e- Atfaal ; MH1/2352A Hab Barae Ishaal-e- Atfaal – A ; NA4/1027 Khesanda Surkhbada ; NA4/4068 Hab Barae Deedaan Deegar Qawitar ; NA4/4083 Habb-e-Bawaaseer Khooni ; Nature Heals, A glossary of selected indigenous medicinal palants of India, SRISTI Innovations Second Edition - February 2002 First Published by SRISTI Innovations October

					1997
3	31/DEL/2008 A herbal extract obtained from the roots of burcea mollis	Application refused grant of a patent	1.A herbal extract obtained from the roots of *Brucea mollis,* wherein the extract has antiplasmodial activity. 2. An extract as claimed in claim 1, wherein the extract is methanolic-chloroform, methanolic-aqueous, petroleum ether or water extract.	The cited references teach Brucea plant having antiplasmodial activity although not exactly Brucea mollis. If one species of the plant possesses antiplasmodial activity, there shall be reasonable expectation of success and motivation for a skilled artisan to use another species of the said plant part for testing the antiplasmodial activity. The cited prior arts teach methanolic chloroform and methanolic aqueous extracts of Brucea mollis roots. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover merely another species having same activity by routine experimentation. D4 discloses that plant family Simaroubaceae is well known for its antimalarial properties in Nigerian folkmedical practices and elsewhere. Guiding principle 2- Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.	E O Ajaiyeoba et al., 'In vivo antimalarial activities of Quassia amara and Quassia undulate plant extracts in mice', Journal of Ethnopharmacology, Vol 67, Issue 3, 1999, 321-325 (Nigerian folk medical practices)
4	1076/CHE/2007 A synergistic ayurvedic/functional food bioactive composition (cincata) and a process of preparation thereof	Patent Revoked	1.A synergistic ayurvedic / functional food bioactive composition for managing diabetes and related disorders, said composition comprising extracts of atleast two plants selected from a group comprising *Eugenia, Cinnamomum* and *Salacia* optionally along with pharmaceutically acceptable excipients.	Guiding Principle 6: In case individual ingredients are already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).	WO0172316
5	218/DEL/2006 A novel herbal composition effective against coryza and a process for preparing thereof	Granted Application, Patent Number : 249186	1.A novel herbal composition effective against coryza (Common Cold) comprising of Barg-e-Tulsi (Ocimum Sanctum Linn.) in an amount of 90-125 mg, Darchini (Cinnamomum Zeylanicum Blume) in an amount of 90-125 mg, Satte Ajwani (Ptychotic ajowan DC) in an amount of 95-105 mg, Zanjabeel (zingiber officinale Rose) in an amount of 90-125 mg and Satte Gilo (Tynospora cordifolia willd) in an amount of 95-130 mg.	Guiding principle 3- In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.	P Prakash, N Gupta - Indian journal of physiology and pharmacology, 2005, 49(2) : 125 -131 Divya Swasari Kvath 100gm, Producted by: (Divya Yog Mandir (Trust), Swami Ramdev).

2. Case studies related to Traditional knowledge & Biodiversity related inventions:

Case Study No: TK/01/Jeevani

The Drug	Traditional Knowledge	Intellectual Property	Benefit Sharing Model
"Jeevani" is a restorative,	. "Jeevani" drug, was developed by	The knowledge was divulged by three Kani tribal	A Trust Fund was established to share

immunoenhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant *arogyapaacha,* used by the Kani tribals in their traditional medicine	scientists at the Tropical Botanic Garden and Research Institute (TBGRI), based on the tribal medicinal knowledge of the Kani tribe in Kerala, South India. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by tribal healers, known as *Plathis*.	members to the Indian scientists who isolated 12 active compounds from *arogyapaacha*, developed the drug "Jeevani", and filed two patent applications on the drug (and another patent based on the same plant but for different use). The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations.	the benefits arising from the commercialization of the TK-based drug "Jevaani". Half of the royalties and license fees from the sale of 'Jeevani' are paid to the Kani in recognition of their intellectual property rights. It is one of the few cases in India where traditional knowledge has been rightly respected and paid for.

Case Study No: TK/02/ Jamun

The Patent	Claims	The case	The verdict
A patent was granted for "synergistic ayurvedic/ functional food bioactive composition". Patent application no 1076/ CHE/ 2007 was for the composition consisting of jamun, lavangpatti and chundun and this composition was to be used for treatment of diabetes	A synergistic ayurvedic / functional food bioactive composition for managing diabetes and related disorders, said composition comprising extracts of atleast two plants selected from a group comprising *Eugenia, Cinnamomum* and *Salacia* optionally along with pharmaceutically acceptable excipients.	Avesthagen filed for a patent in European Patent Office (EPO) for the above said composition but when the examiners checked the patent with TKDL database, they provided a report due to which the patent was not granted. The report said that patent did infringe upon TKDL. CSIR had made individual intervention for the same. In April 2012, a patent was granted to Avesthagen and this was the same patent which was rejected by EPO. IPO said that they did not have access to TKDL database that is why their examiners approved the patent.	In a first victory in India, Traditional Knowledge Digital Library (TKDL) database has been used to revoke a patent. Government of India revoked the patent granted to Avesthagen by Indian Patent Office (IPO) in April, 2012 on the grounds of being mischievous and prejudicial to the public. Government on getting knowledge about the same revoked patent using Section-66 of Patents Act, 1970 which is: ***Revocation of patent in public interest- Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.*** Government of India stated in revocation that the use of Jamun for the treatment of diabetes have been long known to India and thus the extract of Jamun will also give effective therapeutic activity for diabetes. Thus, this patent infringes on TK knowledge of India

Case Study No: TK/03/ Turmeric

Traditional Knowledge	Intellectual property Claimed	The case	The Verdict
The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and dyes. As a medicine, it has been traditionally used for centuries to heal wounds and rashes.	1. A method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient. 2. The method according to claim 1, wherein said turmeric is orally administered to said patient. 3. The method according to claim 1, wherein said turmeric is topically administered to said patient. 4. The method according to claim 1, wherein said turmeric is both orally and topically administered to said patient. 5. The method according to claim 1, wherein said wound is a surgical wound. 6. The method according to claim 1, wherein said wound is a body ulcer.	In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5, 401,504) on use of turmeric in wound healing. The Council of Scientific & Industrial Research (CSIR), India, New Delhi filed a re-examination case with the US PTO challenging the patent on the grounds of existing of prior art. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal by the patent holders, the US PTO upheld the CSIR objections and cancelled the patent.	The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

Case Study No: TK/04/ Neem

Traditional Knowledge	Intellectual property Claimed	The case	The Verdict
Neem extracts can be used against hundreds of pests and fungal diseases	Since the 1980s, many neem related process and products have been patented in Japan, USA and European countries. The first US patent was obtained by Terumo Corporation in 1983 for its therapeutic preparation from neem bark. In 1985 Robert Larson from (USDA) obtained a patent	In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company	In 1999, the EPO determined that according to the evidence all features of the present claim were disclosed to the public prior to the

that attack food crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis	for his preparation of neem seed extract and the Environmental Protection Agency approved this product for use in US market. In 1988 Robert Larson sold the patent on an extraction process to the US Company W.R. Grace (presently Certis). Having gathered their patents and clearance from the EPA, four years later, Grace commercialized its product by setting up manufacturing plant in collaboration with P.J. Margo Pvt. Ltd in India and continued to file patents from their own research in USA and other parts of world. Aside from Grace, neem based pesticides were also marketed by another company, AgriDyne Technologies Inc., USA, the market competition between the two companies was intense. In 1994, Grace accused AgriDyne a non-exclusive royalty-bearing license. During this period in India large number of companies also developed stabilized neem products and made them available commercially. The number of patents filed in this period were limited and geographically confined to few countries.	and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil. In 1995, a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops, and therefore, was unpatentable.	patent application and the patent was not considered to involve an inventive step. The patent granted on was Neem was revoked by the EPO in May 2000. EPO, in March 2006, rejected the challenge made in 2001 by the USDA and the chemicals multinational, W. R. Grace to the EPO's previous decision to cancel their patent on the fungicidal properties of the seeds extracted from the neem tree.

Case Study No: TK/05/Ginger

Application details	The Invention	Claims	The case	Traditional knowledge cited as prior art
A patent specification titled "Pharmaceutical composition for the treatment of excess mucous production" was filed at British Patent Office having a patent priority	The british patent application discloses a composition comprising ginkgo biloba or extract or component thereof; apocynin; and a gingerol. The composition may be used to treat diseases such as Cystic fibrosis (CF) and Chronic obstructive pulmonary disease (COPD). The patent applicant found that compositions according to the invention may have a remarkable effect in reducing excessive mucous production, especially excessive pulmonary mucous production. Moreover, the use of a gingerol (or	The important patent claims of the patent application are as follows: 1. A composition comprising ginkgo biloba or extract or component thereof; apocynin; and a gingerol. 2. A composition according to claim 1 wherein the gingerol is in the form of a natural gingerol. 3. A composition according to claim 1 or claim 2 wherein the gingerol is in the form of Zingiber Officinale.	Zingiber Officinale is the scientific name for ginger and commonly known as adrak in India. Ginger has been used as medicinal remedy for cough and cold since ages in India. Moreover, the medicinal properties of ginger has been the traditional knowledge of India. Consequently, the department of AYUSH and Council of Scientific and Industrial Research (CSIR) intervened and provided evidence from age-old ayurveda and unani books, dating back to the 18th century that talked about ginger to treat cough and	The books that were referred to as evidence by CSIR included Ilaaj-al-Amraaz (18th century), Bhaisajya Ratnavali and Bharata Bhaisajya Ratnakara (1000 BC),

date of March 16, 2006 by the inventor Nicholas John Larkins.	gingerols) in combination with ginkgo biloba (or extract or component thereof) and apocynin provided a substantial clinical improvement; and especially a substantial reduction in excessive mucous production. It is apparent that there is a synergistic clinical outcome when a gingerol (or gingerols) is added to a preparation comprising ginkgo biloba (or standardised extract or component thereof), and apocynin.	5. A composition according to any preceding claim comprising gingerol in the form of isolated gingerol. 23. A method of treatment or amelioration of disease by reduction of excessive mucous production comprising the step(s) of administering to the subject a composition comprising ginkgo biloba, or extract or component thereof; apocynin; and a gingerol.	other diseases. Patent prior art knowledge was retrieved from the Traditional Knowledge Digital Library (TKDL) database of India and submitted at the UK patent office. Subsequently, the patent examiner took into consideration of the prior art traditional knowledge of India and rejected the patent application for the ginger based pharmaceutical composition for the treatment of excess mucous production.	Bayaaz-e-Kabir (1938 AD), Muheet-e-Azam (19th century) and Khazaain-al-Advia from the 18th century.

Case Study No: TK/06/Basmati

The case	Intellectual property claimed	The Opposition	The verdict
Rice Tec. Inc. had applied for registration of a mark "Texmati" before the UK Trade Mark Registry. Agricultural and Processed Food Exports Development Authority (APEDA) successfully opposed it. One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest.	This US utility patent was unique in a way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The US PTO granted the patent to Rice Tec on September 2, 1997. The said patent covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15-17 would have come in the way of Indian exports to US, if legally enforced.	Evidence from the IARI (Indian Agricultural Research Institute) Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. CFTRI (Central Food Technological Research Institute) scientists evaluated the various grain characteristics and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics.	Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims 15-17 along with claim 4.

E. REFERENCES:

1. The Patent Act, 1970
2. Draft Manual of Patent practice & procedures, The Patent Office India
3. Protection of Plant Varieties and Farmers' Rights Act, 2002
4. Biodiversity Act 2002
5. http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf
6. http://www.ipindia.nic.in/whats_new/biotech_Guidelines_25March2013.pdf
7. http://ipindiaservices.gov.in/tk/
8. www.tkdl.res.in
9. http://www.indiankanoon.org/doc/1905157/
10. http://www.ipfrontline.com/downloads/Nitin_Shukla_TKDL.pdf
11. http://biotechpatentattorney.wordpress.com/2012/01/04/traditional-knowledge-of-india-on-ginger-rejected-by-the-british-patent-office/
12. http://ipindiaservices.gov.in/patentdecisionsearch/patentsearch.aspx
13. http://articles.timesofindia.indiatimes.com/2012-01-04/delhi/30588073_1_bhaisajya-ratnavali-tkdl-traditional-knowledge-digital-library
14. http://www.iimahd.ernet.in/publications/data/2002-08-02AnilKGupta.pdf
15. http://www.tkdl.res.in/tkdl/langdefault/common/Biopiracy.asp
16. http://www.iipta.com/ipr/blog/avesthagen-patent-revoked-1005

Note: This IGN was finalized in the current form on 21st Aug 2013. 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

INVENTOR GUIDANCE NOTES

(While papers published by the IP Group provide simple and accurate guidelines for inventors/ scientists)

TOPIC:	AUTHOR:
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IGN Number: IGN-10	**VERSION:** 01
SCOPE: This Inventor Guidance Notes compiles some important legal terminologies, definitions & timelines of Intellectual Property Rights.	**DATE:** 28th June 2013
TABLE OF CONTENTS: A. Important definitions related to IPR B. Important Timelines in Patent prosecution C. Glossary D. List of Abbreviations E. References	**REVIEWERS:** Nitin S Tewari V. Premnath

Note: All definitions as per Indian context & regulations.

A. Important Definitions related to IPR:

Patent

- **Legal Definition** Patent is a grant or right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it. (Ref. 1)
- **Explanation** A patent is an exclusive right granted for a certain period by a country to the owner of an invention to stop others from making, selling, importing or offering to sale his patented invention. The third party cannot make, use, import, manufacture, or market the invention without the consent of the patent holder. A patent in the law is a property right & hence can be gifted, inherited, assigned, sold or licensed. There is nothing like a global patent or a world patent. The patent right is territorial in nature & the inventors/their assignees have to prosecute the patent application in countries of their interest for obtaining patents in those countries. (Ref. 2)

Copyright

- **Legal Definition** Copyright means the exclusive right, to do or authorise the doing of any of the following acts in respect of a work or any substantial part thereof, namely:-
  (a) in the case of a literary, dramatic or musical work, not being a computer programme, -
  (i) to reproduce the work in any material form including the storing of it in any medium by electronic means;
  (ii) to issue copies of the work to the public not being copies already in circulation;
  (iii) to perform the work in public, or communicate it to the public;
  (iv) to make any cinematograph film or sound recording in respect of the work;
  (v) to make any translation of the work;
  (vi) to make any adaptation of the work;
  (vii) to do, in relation to a translation or an adaptation of the work, any of the acts specified in relation to the work in sub-clauses (i) to (vi);
  (b) in the case of a computer programme,-
  (i) to do any of the acts specified in clause (a);
  (ii) to sell or give on commercial rental or offer for sale or for commercial rental any copy of the computer programme: Provided that such commercial rental does not apply in respect of computer programmes where the programme itself is not the essential object of the rental."
  (c) in the case of an artistic work,-
  (i) to reproduce the work in any material form including depiction in three dimensions of a two dimensional work or in two dimensions of a three dimensional work;
  (ii) to communicate the work to the public;
  (iii) to issue copies of the work to the public not being copies already in circulation;
  (iv) to include the work in any cinematograph film;
  (v) to make any adaptation of the work;
  (vi) to do in relation to an adaptation of the work any of the acts specified in relation to the work in sub-clauses (i) to (iv);
  (d) In the case of cinematograph film, -

(i) to make a copy of the film, including a photograph of any image forming part thereof;
(ii) to sell or give on hire, or offer for sale or hire, any copy of the film, regardless of whether such copy has been sold or given on hire on earlier occasions;
(iii) to communicate the film to the public;
(e) In the case of sound recording, -
(i) to make any other sound recording embodying it;
(ii) to sell or give on hire, or offer for sale or hire, any copy of the sound recording regardless of whether such copy has been sold or given on hire on earlier occasions;
(iii) to communicate the sound recording to the public. (Ref. 3)

Designs:

- **Legal Definition** Design refers to the features of shape, configuration, pattern, ornamentation or composition of lines or colours applied to any article, whether in two or three dimensional (or both) forms. This may be applied by any industrial **process** or means (manual, mechanical or chemical) separately or by a combined process, which in the finished article appeals to and judged solely by the eye. Design does not include any mode or principle of construction or anything which is mere mechanical device. It also does not include any trade mark or any artistic work. (Ref. 4)

Trademark:

- **Explanation** A trademark is a distinctive sign capable of distinguishing the “goods” or “services” produced or provided by one enterprise from those of other enterprises.
- Any distinctive words, letters, numerals, drawings, pictures, shapes, colours, sounds, smells, logos, labels or combinations used to distinguish goods or services may be considered a trademark. (Ref. 5)

Invention:

- **Legal Definition** Invention means a new product or process involving an inventive step and capable of industrial application (section 2j of Patent Act, 1970) (Ref. 1)
- **Explanation** Invention may include any new art, process, method of manufacture, machine, apparatus, system, composition or a substance manufactured by a new process. (Ref.2)

Criteria for Patentable inventions:

- **Novelty:**
  Explanation An invention will be considered new if it does not form a part of the state-of-the-art also referred to as ‘prior art’. The Patent Act requires that the invention should not have been anticipated or disclosed through any publication or used anywhere in the world before the filing of a patent application in respect of the invention. In other words, the subject matter of the invention should not fall within the public domain or form a part of the state of the art. (Ref.2)

- **Non-Obviousness/ Inventive step:**
  Legal Definition "Inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art. (Ref. 1)

- **Utility:**
  Explanation An invention must be capable of industrial application; capable of being made or used in an industry (Ref.2)

Non- Patentable Inventions:

- An invention which is frivolous or which claims anything obviously contrary to well established natural laws;
- An invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
- 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;
- 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;

- 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;
- The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;
- A method of agriculture or horticulture;
- 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.
- 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;
- A mathematical or business method or a computer programme *per se* or algorithms;
- A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
- A mere scheme or rule or method of performing mental act or method of playing game;
- A presentation of information;
- Topography of integrated circuits;
- An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.
- Inventions relating to atomic energy not patentable. (Ref. 1 & 16)

Filing of Patent: An application for a patent may be filed at any of the branches of Indian patent office in the prescribed format accompanied by relevant forms, specification & prescribed government fees. (Ref.2)

Types of Patent Documents

- **Provisional specification:** A specification which does not contain claims is regarded as a provisional specification. A provisional specification is filed cases where the invention is not complete or is at a preliminary stage at the time of filing the application & requires further development. A complete specification must be filed within 12 months from the date of filing a provisional specification. [s 9 (1)]
  Thus provisional filing is a priority document which secures a priority date for the invention. As India follows a first to file system, securing an earlier priority for the invention is highly beneficial for the inventor & is facilitated by the provisional filing.
  An inventor is free to publish or go public with his invention once a provisional specification is filed at the patent office. (Ref.2)

- **Complete specification:** The complete specification is a techno-legal document which fully & completely describes the invention & the best mode of carrying out the invention. The invention should be described in a clear & succinct manner in the complete specification so that a person who is ordinarily skilled in the art should be able to work the invention without making any extra efforts. Claims are an important part of the complete specification, which describe the boundaries of the protection sought. A complete specification must be filed within 12 months from the date of filing a provisional specification. [s 9 (1)] (Ref.1, 2)

Types of Patent Applications (Ref.2)

- **Ordinary application:** It refers to an application, which is filed in the Indian patent office without claiming priority of any other application. It may be accompanied by a provisional or complete specification.

- **Conventional Application:** It is an application filed in the Indian patent Office claiming the priority of the same application filed in the convention country. The convention application must be accompanied with a complete specification & must be filed within 12 months from the date of filing the application in the convention country.

- **PCT/International Application:** The international patent application which is filed through patent cooperation treaty is also referred to as PCT application. If an application has been filed in the convention country, then the PCT application must be filed within 12 months from the date of filing the similar application in the convention country.

- **Divisional Application:** In accordance with s 10(5), the claims of a complete specification must relate to a single invention or to a group of inventions which are linked to each other by a single inventive concept. Subject to the provisions of s 16, if an application for patent contains more than one invention which are not linked to each other by a single inventive step, then a n applicant may upon the controllers order file a further application in respect of a non-related invention disclosed in provisional or complete specification. The application so divided claiming non-related inventions is called as divisional patent application.

- **Patent of Addition:** A patent of addition may be filed in respect of any improvement in or modification of an invention described or disclosed in the complete specification of parent patent application. It has to be filed by the same inventors as named on the parent application. (based on ref.1)

Publication of patent application

Every application for patent is published after 18 months from the date of its filing or priority date whichever is earlier. However, following applications are not published.

A) Application in which secrecy direction is imposed

B) Application which has been abandoned u/s 9(1) and

C) Application which has been withdrawn 3 months prior to 18 months (based on ref.1)

Early Publication: The patent act provides for an early publication of the filed specification when applied for it in the prescribed form & upon payment of the prescribed fees. Request for early publication can be filed any time after filing the complete specification. (Based on ref.1)

Patent Examination: The patent office examines the novelty, inventive step & industrial applicability of the invention when a request for examination is made in the prescribed form within 48 months from the date of priority or date of first filing. The examiner compiles his comments on the patentability of the application in a report known as the First Examination Report (FER). He shares this report with the applicant. The applicant must provide his reply to the examiners comments within 12 months from the date of receipt of the report. On going through the comments, if satisfied the examiner may grant a patent to the applicant. If not satisfied with the applicants reply to the queries raised by the examiner, the patent application is refused a grant of patent. (Based on ref.1)

Grant of a Patent: The examiner on receipt of the applicants reply to his queries, if satisfied that the concerned patent application is novel, has inventive step & industrial applicability, may grant a patent to the applicant. (Based on ref.1)

Term of a patent: The term of a patent is 20 years from the date of first filing. (Based on ref.1)

Rights of a Patentee: A patent granted under this Act shall confer upon the patentee—

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of **making, using, offering for sale, selling or importing for those purposes that product in India**;

(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that **process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India** (Ref. 1)

B. Important Timelines in Patent Prosecution

No.	Proceedings	Timelines
1.	Provisional specification/ Direct Complete specification	Priority filing – 0 month. All the time lines are usually counted from this date.
2.	Complete specification filed in pursuance of provisional specification	Within 12 months from the date of filing provisional specification
3.	Proof of right to make an application by virtue of assignment of right	At the time of filing an application or within 6 months from the date of such filing
4.	Conversion of complete specification into provisional specification	Within 12 month from the date of filing an application
5.	Publication of an application (automatic publication)	18 months from the date of priority filing
6.	Request for early publication	Any time after filing an application
7.	Withdrawal of an application before publication	3 months prior to the expiry of 18 months from the date of application
8.	Request for Examination	Within 48 months from the date of priority or date of first filing.
9.	Information & undertaking regarding foreign filing	At the time of filing an application or within 6 months from the date of such filing
10.	Pre-grant opposition	Any time after publication of an application & before the grant of the patent
11.	Post-grant opposition	Within 1 year from the date of publication for the grant of patent
12.	Application for the grant of compulsory license	Anytime after 3 years from the date of grant of patent
13.	Application for restoration of lapsed patent due to non-payment of renewal fees	Within 18 months from the date on which the patent lapsed
14.	Surrender of patent	Anytime after grant of the patent
15.	Post dating of an application	Anytime after filing & before the grant of a patent
16.	Information regarding the extent to which the invention has been worked on commercial scale in India	Shall be furnished in respect of each calendar year before the expiry of 3 months of the end of each year & within 2 months from the date of communication of controller.
17.	Declaration as to inventorship	Along with the application or before the expiry of 1 month from the date of priority filing

C. Glossary:

A

Abandonment: An inventor may decide to abandon a patent application that is pending in the patent office by not responding to communications from the patent office or by notifying the patent office that he or she officially wishes to abandon the application. Once an application is abandoned, patent office will no longer consider the application for patentability. (Adapted from Ref.7)

Abstract: The abstract is a required part of a patent application. The abstract should be designed to allow a reader to determine quickly the subject matter of the patent application. (Ref. 7)

Allowance: Allowance is the term used by some patent offices to indicate that a patent application is in a condition to become a granted patent. (Ref. 7)

Amendment: Any change to a patent application that is pending in the patent office may be changed by an amendment. Amendments are usually made in response to a communication from the patent office, but an inventor can submit a preliminary amendment before he or she receives any communication from the patent office. Amendments cannot add information that was not part of the original patent application, but portions of the application may be deleted or rewritten. Obvious errors in the application may also be corrected. Amendments may also be made to a granted patent, following which it will be published along with the amendment to facilitate opposition to the amendments if any. (Ref. 7)

Anticipation: A reference that contains all of the elements of a claim is considered to anticipate the claim. (Ref. 7)

Application: A written document seeking patent protection and filed with the Indian Patent Office or a patent office outside of the India. The application must include a disclosure of the invention that would, without undue experimentation, enable a person of ordinary skill in the art to make and use the invention; at least one claim (in case of complete specifications); drawings (if drawings are necessary to understand the invention); and disclosure of what the inventor views as the best mode for practicing the invention. The claims of the application define the invention and the scope of the coverage sought. The written description and enabling disclosure are typically found in the specification portion of the application. The specification is the narrative portion of the application, along with the drawings, if present. The specification includes the description of the preferred embodiments or best mode of practicing the invention. It may include a summary of the invention; a description of the background of the invention, including prior art or the problem dealt with by the invention; and a description of the drawings. The specification may also include an abstract of the disclosure. (Adapted from Ref. 8)

Appellate Board: Intellectual Property Appellate Board (IPAB) has been constituted by a Gazette notification of the Central Government in the Ministry of Commerce and Industry on 15th September 2003 to hear appeals against the decisions of the Registrar under the Trade Marks Act, 1999 and the Geographical Indications of Goods (Registration and Protection) Act, 1999. IPAB has its headquarters at Chennai and shall have sittings at Chennai, Mumbai, Delhi, Kolkata and Ahmadabad. In terms of the Notifications No.12/15/2006-IPR-III) dated 2/4/2007 issued by the Ministry of Commerce & Industry, the provisions of the Patent Amendment Act, 2002 and the Patents Amendment Act, 2005, relating to the Intellectual Property Appellate Board

have been brought into force. Thus, all the Appeals pending before the various High Courts will stand transferred to the IPAB. Likewise, fresh Rectification Applications under the Patents Act, 1970, will have to be filed before the IPAB. (Ref. 14)

Assignee: An assignee is the owner of a patent application or granted patent to whom the rights of a patent have been assigned. (Ref. 7)

Assignment: The transfer of ownership of patents or patent application is typically referred to as an assignment. (Ref. 7)

Assignor: Someone who is transferring their ownership of a patent application or granted patent is considered to be an assignor. (Ref. 7)

B

Best Mode: Patent Law requires that a patent application include the best mode in the description of the invention. The best mode is the best way that the inventor considers at the time of filing the patent application for making and using the claimed invention. (Ref. 7)

Budapest Treaty: Budapest treaty on International Recognition of deposit of Micro-organisms for the purposes of patent procedure. The authorized depository institution in India located at Chandigarh is the Microbial type Culture Collection & Gene bank (MTCC). When a patent application relates to a micro-organism, it is mandatory for the applicant to deposit a culture of the concerned microbe at the depository. (Based on Ref. 1 & 2)

C

Capable of Industrial Application: Means that an invention must be capable of being made or used in an Industry. This is an essential criterion for patentability. (Based on Ref. 1)

Citation: All the relevant prior arts found during the examination of a patent application, by an examiner, which may hamper the prospects of grant of a patent are called citations. These may include patent as well as non-patent literature. (Adapted from Ref. 15)

Claim: A claim in a patent application is the legally binding portion of the patent application. It describes the boundaries of the invention for which the protection is sought. Claims are the legal parts of a patent document. Typically an apparatus/ product claim consists of a series of elements related to one another that describe the invention. A method/process claim consists of a series of steps that describe the novel method. (Ref. 7)

Compulsory License: At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India. (Ref. 1)

Controller: Controller means Controller General of Patents, Designs & Trademarks. He is the signing authority for the grant of a patent. (Ref. 2)

Convention Country: Any country, which is a signatory or party or a group of countries, union of countries or intergovernmental organisations which are signatories or parties to an international, regional or bi-lateral treaty, convention or arrangement to which India is also a signatory or party and which affords to the applicants for patents in India or to citizens of India similar privileges as are granted to their own citizens or citizens to their member countries in respect of the grant of patents and protection of patent rights shall be a convention country or convention countries for the purposes of this Act. (Ref. 2)

D

Declaration as to Inventor-ship: An inventor or group of inventors are required to sign and submit a declaration as part of the patent application. The declaration or oath should state that the inventor believes that he is an inventor, that he is familiar with the contents of the patent application. (Ref. 2)

Design Patent: A design patent is a patent that protects the appearance of something not the combinations of elements or how they are interrelated which is considered a utility patent. (Ref. 7)

Description: A full & detailed explanation of the invention & how it works, filed at the office to initiate a patent application. The description must give away the best mode of performance of the invention & may be accompanied by one or more drawings. (Ref. 2)

Divisional Application: Patent law allows a patent owner to have only one invention per patent. In some cases that the patent examiner will determine that there are at least two different inventions claimed in a single patent application. In such a scenario, the examiner will require the patent owner to divide the application, one division will be elected to continue with the examination with the patent office and the other division may be withdraw to be filed as a new patent application, which is usually referred to as a divisional application. (Based on Ref. 1 & 7)

E

Enablement: Patent law requires that a patent application describe the claimed invention in such a way that anyone of ordinary skill in the technology that the invention is concern with will be able to make and use the claimed invention. (Ref. 7)

Examiner: The examiner is the employee of the patent office who reviews the patent application and judges the novelty of the claimed invention. (Ref. 7)

Exclusive License: A license from a patentee which confers on the licensee, or on the licensee & persons authorised by him, a right to exclude all persons (including the patentee) from using, selling, offering for sale, etc the patented invention. (Ref. 1)

Extension of Time: When the patent office communicates to the patent owner or his representative, the patent office usually mandates a time in which the owner or representative may respond without paying a late fee. If the owner or representative does not respond within the time period he or she must pay the late fee and request an extension of time. (Ref. 7)

F

File Wrapper: The file wrapper is the record of documentation kept by the United States patent office on a patent application or granted patent. (Ref. 7)

Filing Date: The filing date is the date on which the patent application was first filed at the patent office. (Ref. 7)

Filing Fee: The patent office requires a fee to process the patent application which is required at the time of filing. (Ref. 7)

First Examination Report: FER is the report provided by a patent examiner authorised by the Controller General of the Patent Office of India after examining a patent application. It mentions all objections to the grant of patent (if any) along with the citations hampering the grant of patent to an application. (Based on Ref 1 & 2)

First to File: In a first-to-file system, the right to the grant of a patent for a given invention lies with the first person to file a patent application for protection of that invention, regardless of the date of actual invention. (Based on Ref. 18)

First to Invent: Under this system, the date of filing a patent was not given preference if it could be proved by lab records etc that the invention was “first invented” by the claimant. Canada, the Philippines, and the United States were the only countries to use *first-to-invent* systems, but each switched to first-to-file in 1989, 1998, and 2013 respectively. (Based on Ref. 18)

G

Geographical Indication: Geographical Indications of Goods are defined as that aspect of industrial property which refers to the geographical indication referring to a country or to a place situated therein as being the country or place of origin of that product. Typically, such a name conveys an assurance of quality and distinctiveness which is essentially attributable to the fact of its origin in that defined geographical locality, region or country. (Ref. 6)

H

Hearing: The applicant can request for a hearing with the controller after receiving the First Examination report in order to convince the examiner by replying objectively to all the objections raised in the FER. (Ref. 2)

I

Infringement: Infringement is the term used for act of violating a patent owner's rights. (Ref. 7)

Intellectual Property: Patents, trademarks, copyrights, trade secrets and other intangible assets are considered to be intellectual property. (Ref. 7)

International Application: means an application for patent made in accordance with the Patent Cooperation Treaty. (Ref. 2)

Invention Disclosure: A patent agent or patent attorney will often ask the inventor to provide then with some kind of written description of their invention. This helps the attorney to better understand the invention and prepare a better patent application accordingly. (Ref. 7)

Inventive Step (Non-Obviousness): Means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both & that makes the invention not obvious to a person skilled in the art. (Ref. 1 & 2)

Inventor: In the patent world an inventor is someone who contributed to at least one of the claims in the patent application. (Ref. 7 & 17)

Issue: When a patent application becomes a patent, it is said to issue as a patent in many countries. In India a patent is said to be granted. (Adapted from Ref. 7)

J

K

L

Lapse: A granted patent is said to have lapsed due to non payment of renewal fees. A lapsed patent may be revived within a specific period from the date of lapse by payment of prescribed fees & making an application along with the reasons that led to the lapse. (Based on Ref. 1)

Legal Representative: Legal representative means a person who in law represents the estate of a deceased person. (Based on Ref. 1)

License: A patent owner can license a company to make their patented invention in exchange for sum of money and/or royalties. (Ref. 7)

M

Manual of Patent Examining Procedure (MPEP): The MPEP is the manual that the examiner at the patent office uses for reviewing patent applications. (Ref. 6)

N

National Biodiversity Authority: The National Biodiversity Authority (NBA) was established in 2003 to implement India's Biological Diversity Act (2002). The NBA is a Statutory, Autonomous Body and it performs facilitative, regulatory and advisory function for the Government of India on issues of conservation, sustainable use of biological resources and fair and equitable sharing of benefits arising out of the use of biological resources. The Biological Diversity Act (2002) mandates implementation of the Act through decentralized system with the NBA focusing on advising the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources; and advising the State Governments in the selection of areas of biodiversity importance to be notified under Sub-Section (1) of Section 37 as heritage sites and measures for the management of such heritage sites. (Ref. 19)

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 doesn't form a part of the state of the art. (Ref. 10)

Non-Obviousness: A patentable invention is required to be non-obviousness. This means that there are no references in combination or individually that teach all of the elements of the claimed invention. Non-obviousness also means that one of ordinary skill in the art would not feel that the claimed invention is obviousness. (Based on ref. 1)

O

Office Action: An office action is a communication from the US patent office requesting that an action be taken concerning the patent application. Typically the office action will request that the inventor overcome an objection (deals with a formatting error) or a rejection (deals with a statutory bar). The objection could request a change to the figures of the application or a spelling mistake; while on the other hand, the rejection may deal with claims that don't definitively define the invention or it may deal with a reference which discloses the claimed invention. (Ref. 7)

One of Ordinary Skill: One of ordinary skill in the art is someone who has ordinary skill in the technology that deals with the claimed invention. The MPEP discloses several characteristics which are used to determine who would be someone of ordinary skill in the art since it would change from field to field. During examination, an inventor has to determine if someone of ordinary skill in the art would consider the invention obvious. (Ref. 7)

Opposition of Patent: An opposition proceeding is an administrative process available under the patent and trademark law of many jurisdictions which allows third parties to formally dispute the validity of a pending patent application ("pre-grant opposition"), of a granted patent ("post-grant opposition") or of a trademark. (Ref. 11)

P

Paris Convention: The Paris Convention for the Protection of Industrial Property, signed in Paris, France, on 20 March 1883, was one of the first intellectual property treaties. It established a Union for the protection of industrial property. The Convention is still in force as of 2013. According to Articles 2 and 3 of this treaty, juristic and natural persons who are either national of or domiciled in a state party to the Convention shall, as regards the protection of industrial property, enjoy in all the other countries of the Union, the advantages that their respective laws grant to nationals. In other words, when an applicant files an application for a patent or a trademark in a foreign country member of the Union, the application receives the same treatment as if it came from a national of this foreign country. Furthermore, if the intellectual property right is granted (e.g. if the applicant becomes owners of a patent or of a registered trademark), the owner benefits from the same protection and the same legal remedy against any infringement as if the owner was a national owner of this right. (Ref. 13)

Patent: A patent is an exclusive right granted by a country to the owner of an invention to stop others from making, using, selling, importing or offering to sale his patented invention. The third party cannot make, use, import, manufacture or market the invention without the consent of the patent holder. This trade-off is designed to encourage innovation, while making society better off in the long run by exposing the public to new ideas. (Ref. 1)

Patentable: An invention that meets the requirements of patentability under relevant laws for being granted a patent is called as a patentable invention. Typically an invention needs to meet the following criteria: Novelty, Inventive step, Utility. Also it should not be of subject matter mentioned under non-patentable inventions under the act.

Patent Agent: A patent agent is a professional who is entitled to draft & file patent applications on behalf of an applicant whose name has been registered in the register of patent agents maintained by the patent office. (Based on Ref. 1)

Patent Cooperation Treaty (PCT): The PCT is a treaty that simplifies foreign patent filings in countries that are members of the World Trade Organization. A PCT filing allows an inventor to initially file a single patent application with a receiving office (usually the national patent office of that country) after which the patent application will receive an initial international examination before the inventor needs to decide which foreign countries he desires to file in. Once the application enters into a foreign country, the patent application will be reviewed again since all countries have different patent laws, but usually those national examinations rely heavily on the international examination. (Ref. 7)

Patent Examiner: A patent examiner is an employee at the patent office who is authorized to examine patent applications and legally determine the application's fate. (Ref. 7)

Patent Owner: Initially an inventor or group of inventors are the owners of the patent or patent application. All inventors have equal rights to the claimed invention regardless of the contribution of the claims, just as long as they made some contribution. Typically an inventor who works for a company is required under an employment contract to assign (or transfer ownership) of the patent or patent application to their employer. (Ref. 7)

Patent Search: A patent search is a search typically performed before the filing of a patent application to determine patentability of the invention. Patent law does not require that a patent search be performed although the law does require that anyone involved in the preparation of the patent application submit to the patent office any information that they feel would affect the patentability of the claimed invention. (Ref. 7)

Pending: While a patent application that is waiting to be either examined by a patent examiner or to be issued in the patent office, it is considered to be pending. (Ref. 7)

Person Interested: includes a person engages in, or in promoting research in the same field as that to which the invention relates. (Ref. 2)

Prior Art: Prior art is the term to describe all of the knowledge and references pertaining to the technology of the claimed invention in the patent application. (Ref. 7)

Priority Date: A priority date is the earliest filing date that a patent application can claim. Some patent applications that are related to earlier filed patent applications by the same inventor can claim priority to the earlier applications. (Ref. 7)

Process Patent: A patent granted for a new process i.e for a process claim or a method claim is known as a process patent.

Product Patent: A patent granted for a product i.e claims for a composition, system, new substance, new machine/gadget etc is said to be product patent under the patent laws.

Prosecution: Prosecution refers to the interactions, abiding of formalities etc between an inventor and the patent office dealing with making a patent application ready for grant. (Ref. 7)

Provisional Application: A provisional patent application is an application that is filed with the patent office that is intended to expire automatically in one year from its filing date without an examination. The intent of a provisional patent application is to allow an inventor time to carry on more work on his invention before filing a complete specification 12 months down the line. (Adapted from Ref. 7)

Published Patent Application: Eighteen months after the filing date of a patent application, the patent office publishes the application. This does not give the inventor any more rights, but simply informs the public of what the inventor has filed. Typically at this point the patent application will still be pending in the patent office. An inventor can pay to have a patent application publish earlier, later or not at all depending on the needs of the inventor. (Ref. 7)

Q

R

Reduction to Practice: An invention is required to be reduced to practice before a patent can be applied for in United States. Actual reduction means that there is at least a prototype of the invention made. Constructive reduction means that all of the details to enable someone to make and use the invention have been thought through. The Indian patent office doesn't have any such requirement. (Based on Ref. 7)

Register of Patents: It is the register of patents kept at the Patent Office containing the names & addresses of grantees of patents, notifications of assignments & of transmission of patents, of licenses under the patents & of amendments, extensions, & revocation of patents; and particulars of such other matters affecting the validity or proprietorship of patents. (Based on Ref. 6)

Renewal Fees: Maintenance fees or renewal fees are fees that are paid to maintain a granted patent in force. Some patent laws require the payment of maintenance fees for pending patent applications. Not all patent laws require the payment of maintenance fees and different laws provide different regulations concerning not only the amount payable but also the regularity of the payments. In countries where maintenance fees are to be paid annually, they are sometimes called patent annuities (Based on Ref. 1)

Rejection/Refusal: When after the examination, & taking into consideration the applicant's comments on the first examination report, the examiner is satisfied that the patent cannot be granted, it is deemed to be a refusal or rejection to the grant of the patent to the applicant. (Based on Ref. 1)

Revocation: Revocation of patents can be made under Section 64 of the Indian Patents Act 1970. A patent may be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter claim in a suit for infringement of the patent by the High Court. (Ref. 12)

S

Specification: The specification, which is also called the disclosure, is a written description of an invention. The patent specification is drafted both to satisfy the written requirements for patentability, as well as to define the scope of the claims. A specification in other words is a general explanation of the invention and how to practice it along with Specific examples of how to practice the invention. (Ref. 9)

T

Trade Secret: A trade secret is a formula, practice, process, design, instrument, pattern, or compilation of information which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors or customers. (Ref. 6)

Trademark: A trademark is a distinctive sign capable of distinguishing the “goods” or “services” produced or provided by one enterprise from those of other enterprises. (Ref. 6)

True & First Inventor: Does not include either the first importer of an invention into India or a person to whom the invention is first communicated from outside India. (Ref. 1)

U

Unity of Invention: It is mandatory that each patent application must relate to only one invention i.e. must have a single inventive step. This is known as unity of invention.

Usefulness/Utility: The invention must be capable of industrial application i.e it can be made or used in an industry. (Ref. 1)

V

W

WIPO: The World Intellectual Property Organization (WIPO) is the United Nations agency dedicated to the use of intellectual property (patents, copyright, trademarks, designs, etc.) as a means of stimulating innovation and creativity. (Ref. 13)

Withdrawal of Application: When at any time after filing an application, the application feels that he does not wish to pursue the application further; he can abandon the application by formally writing to the controller expressing his wish to do the same or by simply not following the prosecution timelines.

Working of Patent: As per the Patent Act 1970, it is mandatory that an invention is practiced in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. The Act requires every patentee and every licensee (whether exclusive or otherwise) to provide information on

the extent to which the ‘patented invention’ has been worked on a commercial scale in India (S. 146(2)). Failure to supply such information creates a presumption of non-working, and may assist the process of grant of compulsory licenses. (Based on Ref. 1)

X

Y

Z

D. List of Abbreviations:

No.	Abbreviation	Full form
1.	CGPDTM	Controller General of Patents, Design & Trademarks
2.	DO	Designated Office
3.	DOF	Date Of Filing
4.	EO	Elected Office
5.	EPO	European Patent Office
6.	FER	First Examination Report
7.	GATT	General Agreement on Tariff & Trade
8.	ISA	International Searching Authority
9.	IPEA	International Preliminary Examining Authority
10.	IB	International Bureau
11.	ISR	International Search Report
12.	IPRP	International Preliminary Report On Patentability
13.	IP	Intellectual Property
14.	IPR	Intellectual Property Right
15.	IPO	Indian Patent Office
16.	IPAB	Intellectual Property Appellate Board
17.	NBA	National Biodiversity Authority
18.	MOU	Memorandum Of Understanding
19.	MPPP	Manual of Patent Practice & Procedures
20.	NPE	National Phase Entry
21.	PCT	Patent Cooperation Treaty
22.	PA	Patent Agent & Patent Application
23.	POA	Patent Of Addition
24.	TRIPS	Trade Related Aspects of Intellectual Property Rights
25.	WIPO	World Intellectual Property Organization
26.	WTO	World Trade Organization
27.	WOSA	Written Opinion of Searching Authority
28.	USPTO	United States Patent & Trademark Office

E. References:

1. The Patent Act, 1970
2. Patent agent examination, Sheetal Chopra & Dr Akash Taneja, 2nd Edition, 2010
3. Indian Copyright Act, 1957
4. The Design Act, 2000
5. The Trademarks Act, 1999
6. http://www.ipindia.nic.in/
7. http://www.inventorbasics.com/Patent%20Glossary.htm
8. http://www.tms.org/pubs/journals/jom/matters/matters-9609.html
9. http://www.patentlens.net/daisy/patentlens/2341.html
10. http://www.ipindia.nic.in/ipr/patent/manual/HTML%20AND%20PDF/Manual%20of%20Patent%20Office%20Practice%20and%20Procedure%20-%20html/Chapter%208.htm
11. http://en.wikipedia.org/wiki/Opposition_proceeding
12. http://www.itagbs.com/articles/revocation.html
13. http://www.wipo.int/about-wipo/en/
14. http://www.ipab.tn.nic.in/
15. http://www.intellogist.com/wiki/Citations
16. http://www.nclinnovations.org/pdfs/ign/IGN-08-exclusion-list.pdf
17. http://www.nclinnovations.org/pdfs/ign/IGN-05-Inventorship-v03-20111111.pdf
18. http://en.wikipedia.org/wiki/First_to_file_and_first_to_invent
19. http://www.nbaindia.org/

Note: This IGN was finalized in the current form on 21st Aug 2013. 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