INVENTOR GUIDANCE NOTES

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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 CDRI, 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 CDRI, A25S in CDRI, F32Y in CDRI, M33L in CDRI, N34A in CDRI, 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

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*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