INVENTOR GUIDANCE NOTES





TOPIC: EXCLUSION LISTS* FOR PATENTING	AUTHOR: SNEHA KANITKAR A207, PAML National Chemical Laboratory Pune – 411008 Phone: +91-20-2590-2757 Email: sv.kanitkar@ncl.res.in
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SCOPE: This Inventor Guidance Notes provides information for scientists regarding non-patentable inventions across various jurisdictions.	DATE: 15 th 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. 13.	Mere scheme or rule or method of performing mental act or method of playing game Presentation of information	Eg: A new game called anti-chess which inverses the normal rules of chess Eg: Delivering lectures
14.	Topography of integrated circuits 50 W1085 from CSIR India	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
1.	USA 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 2	Inventions the commercial exploitation of which would be contrary to public order or morality Plant or animal varieties or essentially biological processes for the production of plants or animals; (Excluding	
3	microbiological processes or the products thereof) Methods for treatment of the human or animal body by surgery or therapy and diagnos human or animal body.	tic methods practised on the
4	EPC offers patent protection for computer program with a technical contribution . How and programs for computer are not patentable as such.	ever, mathematical methods

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.
- 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.

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

Case Study 2:	God English and Control of the Contr	
The Case	The Verdict	The Impact
On April 1, 2013, the Supreme	India has refused protection for Glivec on the grounds that it is not a new medicine,	Public-health groups in developing
Court upheld the Intellectual	but an amended version of a known compound.	nations praised the judging on
Property Appellate Board's decision	The patent application had initially been rejected by the Controller of Patents in	account that it protects Indian
to deny patent protection to	2006, after hearing 5 pre-grant oppositions filed by various generic pharmaceutical	companies that produce low-cost
Novartis's application covering a	companies including Ranbaxy, Cipla, Hetero and one patients group – the Cancer	generic forms of drugs such as
beta crystalline form of imatinib	Patient Aid Association (CPAA). Novartis had initially filed an appeal with the Madras	Glivec, allowing them to continue
(1602/MAS/1998) —the medicine	High Court which subsequently transferred the appeal to the Intellectual Property	producing and, most importantly,
Novartis brands as Glivec, and	Appellate Board (IPAB). In a separate petition Novartis had also unsuccessfully	exporting their cheaper product to
which is very effective against the	challenged Section 3(d) of the Patents Act before the Madras High Court. In 2009,	developing nations in Asia and
form of cancer known as chronic	the IPAB upheld the rejection by the Controller.	Africa. Currently in India, Glivec
myeloid leukaemia (CML). The	Supreme Court had considered the entire case de novo despite it being an appeal	treatments cost \$1,900 per month,
judgment marked a crucial	from the IPAB, which had itself delivered a lengthy judgment.	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.	The invention was related to pharmaceutical composition exhibiting anti-phlogistic,	It was held by the Controller that the active
782/CAL/I981, dated	antipyretic and analgesic activity and high gastroenteric tolerance in unit doses form	compound such as imidazole salicylate was
13th July, 1981, an	which contained imidazol salicylate as the active ingredient in the amount of 100-600	known in the art and applicant could not
invention	mg and an inert carrier was claimed which was later amended to a process for the	develop any special property or even improve
related to	preparation of novel composition containing imidazole salicylate having formula 1, as	upon the property of the compound to be
pharmaceutical	the active principle. The invention was characterized in a product that was previously	mixed up with the usual carrier to form the
composition exhibiting	obtained by reacting, mole by mole, acetylsalicylic acid with imidazole in an inert	composition. Furthermore, the description
anti-phlogistic,	organic solvent and that, using the solid product obtained in the reaction after	contained no indication of using any special
antipyretic	purification by recrystalization, homogenous composition were produced with	type of solvent for its purification by re-
and analgesic activity	pharmaceutically acceptable vehicles suitable for oral, parental or topical	crystallization and, therefore, the invention
and high gastroenteric	administration.	was not patentable under section 3(d) of the
tolerance.		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	It is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different
Radhey Shyam v.	matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of
Hindustan Metal	invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a
Industries [1978]	better or cheaper article than before. The combination of old known integers may be so combined that by their working inter relation they
Insc 255 (13th	produce a new process or improved result. Mere collocation of more than one integers or things, not involving the exercise of any
December, 1978)	inventive faculty, does not qualify for the grant of a patent.
	Solutions from CSIR India

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.

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:

composition.

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

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

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. UNITED STATES:

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

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C. REFERENCES:

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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