



What Cannot be Patented in the Jurisdiction of India?

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The exceptions to patentable inventions are reviewed and analyzed. These are Sections 3, 4 and 5 of The Patents Act, 1970. They are accompanied with examples that demonstrate that it is not sufficient for the inventions to satisfy just the three criteria of patentability. The working of an invention should also promote and address public order, social harmony, rights of farmers and public health concerns. Patentable inventions that concern us most are related to agriculture and human health. The Patent Laws while supporting inventors must also provide for equitable distribution of the benefits of the invention across all sections of the society. In the broader scheme of things, the laws governing what inventions can be patented and what cannot be patented should be in harmony with the provisions of the TRIPS Agreement administered by WTO.

Keywords: TRIPS, Invention, Patent, Therapeutic Efficacy, Traditional Knowledge, Human Intervention, Patent Ever-Greening, Non-Obviousness, Inventive Step, Industrial Applicability, Validity of the Patent

Inventions that cannot be patented form a very important component of every jurisdiction of a country.¹ In India Section 3, 4, and 5 (omitted since 1.1.2005) of the Patents Act, 1970² (hereinafter the Act) enumerate on non-patentable inventions.³ Section 3 is formally titled — What are not inventions, Section 4 is formally titled — Inventions relating to atomic energy not patentable. Section 5 is omitted as per the Patents (Amendment) Act 2005 to make way for product patents. There are two types of patents granted: patents for products and patents for process. Prior to the Patents (Amendment) Act 2005, India like most developing countries granted only process patents. It offered less protection to the inventor because the same product could be manufactured by different ways and there would be more than one manufacturer. The pharmaceutical industry benefitted hugely from this arrangement. The companies would manufacture the generic versions of the newly discovered drugs. On the other hand the generic versions were made available and affordable by the large masses in our society. Product patents offer higher level of protection to the inventor because it implies that no one can manufacture the product irrespective of the process used except with the consent of the inventor. Products will include medicines, drugs, agrochemicals, metal alloys, and products that are used in semiconductor devices or solid state devices in general and microorganisms.

TRIPS (Trade Related Aspects for Intellectual Property Rights) Agreement administered by WTO follow the product patent regime. The 2005 Amendment to the Indian Patents Act 1970 omitted the Section 5 which prohibited product patent thus setting the stage for fully aligning the Indian patent system with the provisions of TRIPS – an effective step in establishing India as global player in the world ecosystem of Intellectual Property. TRIPS provides for minimum standards in order for an invention to qualify for a grant of patent. The three criteria of patentability namely: novelty, inventive step which is non-obviousness to a person skilled in the art and industrial applicability are universally accepted.⁴ Novelty is searched by examination of prior art which includes patent and non-patent literature. Non-obviousness is a difficult criterion and is best decided by the technical experts in the field and lastly, the industrial applicability test is passed if the invention is used and can be made by the industry.⁵ The phrase — technological advance⁶ is often encountered in defining these criteria and describing an invention. In the field of intellectual property an invention is mostly synonymous with technology. Simply put it means that the invention is a technological model or a process and is technologically superior to the existing apparatus/machine/article or process.

Section 3 of the Patents Act, 1970

Section 3(a) forbids inventions which are frivolous. Frivolous inventions for the purpose of this Act are

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classified as those which go against the laws of nature. Many inventions based on perpetual motion giving rise to perpetual machines are filed. The laws of thermodynamics are violated here. A machine with 100% efficiency can never be accomplished. In practice, we know that 55% efficiency is attainable with ingenuity and clever design of the machine. Another example could be a clock with ten hours calibration.

Section 3(b) says that inventions whose commercial exploitation is harmful to public order and morality cannot be patented. Let's say someone comes with an invention where a recombinant gene is introduced in the flower whereby butterflies are not attracted to it. Human genomes are modified and such modification is harmful under the law. Human cloning is also unlawful under this section. Inventions relating to bio-war, bio-terrorism, gambling machines, counterfeiting of currency cannot be patented. Objections to stem cell research also fall under this category since this research makes use of human embryos. Research has led to obtaining stem cells from non-embryonic sources such as cord blood and amniotic cell lining. Embryos obtained from wasted in-vitro fertilization cycles, aborted fetuses and asexually grown embryos are deemed to be within ethical considerations. European countries, Canada and the United States provide stringent conditions for research due to the ethical issues involved. Belgium, Israel, South Korea, China, UK and India actively support research in this field. Policy makers use Section 3(b) as a primary reason behind discouraging research in Stem cell therapy. The first human embryonic stem cell patents were U.S. Patent Nos. 5,843,780, 6,200,806, and 7,029,913 issued to James Thomson, University of Wisconsin. Inventions based on stem cell research satisfy all the three criteria of patentability and is very much a patentable subject matter in the Indian jurisdiction.

Section 3(c) concerns with living or non-living things that occur in nature and forbids their patenting. Discovering a living or non-living thing is a discovery and not an invention. An example could be discovery of a galaxy or an asteroid or a species of plant or animal. It also concerns with formalism of an abstract theory or discovery of a scientific phenomenon/fact/principle. These are not inventions and hence not subject to patentability. The discovery of the phenomenon of electromagnetic induction by Michael Faraday was unpatentable. Based on the same

principle, Graham Bell came up with the invention of telephone and even acquired a patent for it (US Patent: 174,465, granted in 1876)

Section 3(d) famously called as the *Grandfather's Clause* is the most controversial clause, having given rise to the popular case of *Novartis v Union of India*.⁶ The litigation went on for seven years. This is also the clause that juxtaposes health issues against Intellectual property of the crucial life-saving drugs protected by patents. Section 3(d) really is made up of three parts. The first part of this clause deals with therapeutic efficacy. It says that a mere discovery of a new form of a known substance (for which a patent may already be in existence) which does not result in the enhancement of the known efficacy of that substance then that substance is not eligible to get a patent. For the sake of the clause the new form of a known substance is described as its salt, ester, polymorph, isomer, derivative or a metabolite. In 2003, the patent application of Novartis claimed the final form of Gleevac which is the beta crystalline form of the known substance Imatinib mesylate, an anti-cancer drug. Novartis claimed that Gleevac showed better stability, better storage properties and 30% increase in bioavailability. The Supreme Court of India ruled that this is not enough, that this does not prove that the beta crystalline form has better therapeutic efficacy over imatinib mesylate. Novartis lost the case.⁷ The purpose of 3(d) is also to prevent what we call as patent evergreening.⁸ But then again Pharmaceutical companies spent millions of dollars and about a decade of research to invent a drug. It is justifiable that they will look towards regaining the spent amount through market share. Also can we quantify efficacy? There are numerous research papers claiming to do so. But close examination reveals that the efficacy is always indirectly expressed. There we are at the cross roads. What matters most? Public health or IP of the pharmaceutical companies who have spent millions of dollars and plenty of years to come up with a new drug.⁹ The second part of this clause is that a secondary use of a known substance cannot be patented. The third part is that if one is using a known process than that known process should lead to a new product or if one is using a known process involving reactants then the known process should use at least one new substance or reactant.

Section 3(e) states a substance obtained by a mere admixture resulting only in the aggregation of the

properties of components thereof or the process producing such a substance cannot be patented. Prominent examples in this category are the food recipes and herbal mixtures. The food recipes are patentable only if there is human intervention in form of baking, roasting, steaming and so on. The patentability of food recipes should be really decided on case-to-case basis. Herbal mixtures attract a lot of patents. Here again the applicant must demonstrate that the components in the mixture are not just acting independently of each other but are acting synergistically to give the desired effect. Demonstration of synergy supported by biological data will help to overcome the objections raised by the patent office based on this clause. Another factor that concerns herbal mixtures is traditional knowledge. If the herbal mixtures uses herbs then the objections to patentability could be raised based on Section 3(p). Nevertheless, the synergistic effect must be suitably demonstrated to overcome the objection that the components in any mixture are not just acting independently but synergistically.

Section 3(f) states that mere rearrangement of devices functioning independently of each other in a known way is not an invention. The clause says that one cannot put two different things which work independently of each other and call it an invention. An example of putting a clock and a fan in a single cabinet or coupling a torch with a bucket are not patentable. Another example could be a smart phone.

Section 3(g) is omitted by the Patents Amendment Act, 2002. Prior to the amendment it said that any method of testing used to improve the existing machine, article, apparatus or any other equipment cannot be patented.

Section 3(h) states a method of agriculture or horticulture is not patentable. Straightforward examples could be methods of cultivating algae, mushrooms. Methods of improving soil quality and method involving green house effects are also not patentable under this clause. A rule of thumb to follow is any modifications of conditions related to growing plants where natural phenomena would pursue their inevitable course is non-patentable. Identification of inventive step becomes difficult in inventions involving natural phenomena such as growth of plants and germination of seeds. The difficulty here is to identify the inventive step - where the human intervention stops and natural processes take over.

Section 3(i) states any method of treatment to render plants and animals free of diseases in order to increase their economic value or that of their products is not patentable. The method of treatment can be classified as medicinal (process of orally or through injections), surgical (stitch-free incision for removal of cataract or laser-based surgery), curative (plaque removal from teeth, cleaning of Uterus), prophylactic (a method of vaccination), and Diagnostic methods. Diagnostic methods employ laws of nature in the sense that general physical parameters are considered and this fact makes diagnostic methods non-patentable inventions. However if someone invents a surgical knife, that would be a patentable subject matter. A general term for these methods is therapy. "therapy" includes prevention, cure and treatment of diseases. Under this clause, an applicant has to prove that the subject of his invention is not a therapy- is not a method of treatment. Stem cell therapy is an exception.

Section 3(j) states what one cannot consider an invention under this act is any process for production and propagation of plants and animals, in whole or in part and seeds. Microorganisms are patentable subject matter if human intervention is responsible for their invention. As such microorganisms discovered directly from nature cannot be patented. Seeds which are the very symbol of life's renewal are primarily the subject of Section 3(j). The question is whether genetically modified seeds are patentable or not. The answer is yes: genetically modified seeds are patentable subject matter.¹⁰ Monsanto; a US biotech company developed bollworm resistant *Bt* cotton seeds by introducing a nucleic acid sequence. Monsanto's genetically modified seeds have transformed the company and are radically altering global agriculture.¹¹ So far, the company has produced GM seeds for soybeans, corn, canola, and cotton. Many more products have been developed or are in the pipeline, including seeds for sugar beets and alfalfa. They applied for a patent for the cotton *Bt* seeds in India. The Indian Patent Office granted Patent No. 214436 (Date of Grant: 12 February 2008) to Monsanto Technology LLC for genetically modified cotton seeds. Monsanto filed a case against The Nuziveedu Seeds Ltd, a Hyderabad based company for infringement of their patent in 2016. Nuziveedu Ltd responded with a counterclaim for invalidity of the patent by virtue of Section 3(j). Indeed the Division Bench of Delhi High Court in

2018 ruled in favour of Nuziveedu Ltd in the appeal against the Single Bench's order. But the Supreme Court of India restored the Single Judge's March 2017 order and remanded the suit to the learned Single Judge for disposal in accordance with law in view of the importance of the question involved. In the strictest sense, it was not a method of propagation of production of plant because the genetic modification introduced by the scientists at Monsanto, consisted of introducing a nucleic sequence which cannot propagate on its own. Can we call this a loophole or not? India enacted 'The Protection of Plant Varieties and Farmers' Rights' (PPVFR) Act, 2001 to protect the farmers from unfair competition. However, the argument continues whether a single company should be encouraged by IPR laws to decide what we should put on our table. On the other hand the Monsanto cotton seeds propelled India into one of the top producers of the fibre. The Monsanto verdict included India among nations that respect biotechnological inventions. Another subject matter of Section 3(j) is whether genetically modified plants and animals are patentable subject matter or not. Here are the exact words of Section 3(j):—*Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.* The essentially biological processes can be interpreted as including naturally occurring plants and animals and not including microbiologically processes which encompass genetic modifications. These inventions fall in the field of biotechnology. A casual search on *in PASS* (Indian Patents Database, http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf) will lead to some examples of biotechnology inventions. Prior to the 2002 Amendment of the Patents Act, 1970, inventions relating to living organisms were non-patentable subject matter. Patents were granted only for inventions based on non-living subject matter such as vaccines, antibodies and proteins. After the 2002 Amendment, inventions relating to living organisms, both natural and artificial, became patentable subject matter. The living substances also include nucleic acid and any other material that have replicating properties. Any process leading to manufacture of a living organism or living matter is an invention and eligible for patent protection. In the landmark *Dimminaco Case*, the process for which protection

was claimed resulted in a living organism which was a live vaccine for treating the poultry infection of *Bursitis*. The case opened the doors for biotechnology patents where process and products were related to living matter.

Section 3(k) states that mathematical models, business methods, computer program *per se* and algorithms are non-patentable subject matter. Mathematical models are considered to be acts of mental skill. A method of calculation, formation of equations, finding square roots, and cube roots are examples of mathematical model. The term business method involves a whole gamut of activities in a commercial enterprise relating to transaction of goods or service. With development of technology, business activities have grown tremendously through e-commerce and related to B2B (Business-to-Business) and B2C (Business-to-Consumer) transactions. An algorithm is defined as "procedure for solving a given type of mathematical problem". A mathematical problem is based on law of nature and therefore is excluded from patentability. Computer programs are protected by Copyright and not by patents.^{12,13} A rule of thumb is to consider a computer program as patentable subject matter only if it is written for a specific hardware. A computer program written to control temperature for instance, cannot be patented because it can be used on practically any hardware which needs temperature control. Computer programs, whatever their form or mode of expression is protected by the WIPO Copyright Treaty (WCT, 1996).

Section 3(l) basically involves creations that lend themselves to copyright protection. These are literary creations, drama, paintings, creation of art, song lyrics, music, translations, adaptations, cinematographic works, multimedia production and the broadcasters' right. They fall under the copyright act of India, 1957.

Section 3(m) states —a mere scheme or rule or method of performing mental act or method of playing game is not an invention because these are considered to be an outcome of mere mental process. A method of playing chess, a method of teaching, method of learning are not patentable because they do not result in any product or an invention.

Section 3(n) states "Presentation of Information" is not an invention. Information that is presented by visual, audible or tangible modes employing words, codes, signal, symbol, diagrams is not patentable. The basis of this clause is that presentation of information does not involve any technological expertise or

advance. Since Patent System is meant primarily for technological inventions, any mode of presenting information such as a railway timetable comes outside of patentable matter.

Section(o) states topography of integrated circuits cannot be patented. The 3-D configuration of Layout designs of Integrated circuits is protected by the Semiconductor Integrated Circuits Layout Designs Act, 2000. This law was passed to confirm with the TRIPS agreement to which India is a signatory and which is administered by WTO. This Act empowers a registered proprietor and protects his IP from infringement.

Section (p) states that any invention that makes use of components that are traditional knowledge and claims the aggregation/duplication of properties arising out of these is not patentable under this clause. Traditional knowledge comprises of knowledge that has been in existence for many years, sometimes centuries old, belonging to a certain country or community. To put it simply, traditional knowledge is prior art. Herbal mixtures employing ayurvedic substances are common examples. The well known examples are 1) the revocation of the Neem Patent by European Patent Office in 2004 granted to US Department of Agriculture and a multinational WR Grace and 2) revocation of the Haldi Patent in 1995 by USPTO granted to two researchers, Soman K. Das and Harihar Kohli of the University of Mississippi Medical Center. Their patent claims covered the oral and topical use of turmeric powder to heal surgical wounds and ulcers. There have been many patents granted to inventions involving traditional knowledge. A patent was granted for a process for producing herbal water containing tulsi extracts. As far as patentability issues are concerned, the applicant must take permission from National Biodiversity Authorities if he is using a genetic resource.¹⁴

Section 4 and Section 5 of the Patents Act, 1970

Section 4 of the Patents Act, 1970 excludes patents based on use of Atomic energy falling within subsection (1) of Section 20 of Atomic Energy Act 1962. The inventions may be significant to defense purposes of India. Not all inventions based on atomic energy are non-patentable or significant to the defense purpose of India but the decision lies with the Central Government and the Patent Office acts accordingly. Section 5 was omitted by the Patents Amendment Act, 2005. Prior to the amendment the section prohibited patents on products pertaining to food industry, medicine and agrochemicals, alloys and inter-metallic compounds used in semi-conductor industry. The omission of this section effectively lead the way to obtaining product patents in India. The industry most affected by this omission was the pharmaceutical companies which were involved in manufacture of generic drugs. Before the amendment these companies made the generic versions of these product-medicines by finding alternate process to the patented process. The World Trade Organization administers the treaty of TRIPS. India is a signatory to this treaty (1 January 1995).¹⁵ In order to make the IP laws of India TRIPS-compliant, India brought in the Amendments from time to time.

Analysis

The inventions can generally be classified as absolute exceptions, conditional exceptions and non-inventions (Table 1). Kindly note these are just the views of the author as being another aspect of these non-patentable inventions. The classification generally helps to remember the exceptions in their order. In the table below the overlapping exceptions are given in Italics.

Absolute exceptions are the ones where there is absolutely no scope for patentability. These arise from two reasons: 1) frivolity 2) policy and legal reasons.

Table 1 — Classification of inventions

Absolute exceptions	Conditional exceptions	Non-inventions
3(a): Frivolity	3(d): Known process	3(c): Natural things, theory
3(b):Public order	3(d): Grandfather's clause	3(d): New use
3(h): Agriculture	3(e): Admixture & synergy	3(f): Known devices
3(i): Treatment	3(k): Computer programs	3(l): Copyright
3(j): Biological process	3(p): Traditional Knowledge	3(m): Scheme/rule/method
3(o): Integrated circuits		3(n): Presentation
		3(j): Biological process
		3(k): Computer programsetc.
		3(p):Traditional knowledge

Inventions based on 3(a) are frivolous inventions as they flout the laws of nature. In these cases, the Patent Office will usually ask for a model to be submitted. 3(b) inventions are harmful to public order and morality. Inventions under this clause may satisfy all the conditions of novelty, non-obviousness and industrial application. Despite this, they cannot be patented as they are harmful to society. It's a matter of policy as their use will lead to lawlessness in society. Inventions of Sections 3(h), 3(i), 3(j) may satisfy the aforementioned conditions but yet are not conducive to growth and progress of society. 3(h) and 3(j) protects the farmer's rights.¹⁶ 3(i) protects the right of every citizen to access for medical treatment. As mentioned earlier the intellectual property associated with integrated circuits is protected by the SICLD Act. Government will make these policies and accordingly enact laws to support them. Any invention that goes against the existing legal and policy issues will be ineligible for patentability.

Conditional exceptions are the ones which are non-patentable but with suitable modifications can become patentable. 3(d) covers the grandfather's clause which says that if the inventor can demonstrate greater therapeutic efficacy than the existing one, the invention can be patented. Also under the same clause, it is clearly mentioned that if the known process employs at least one new reactant, that known process can be patented. 3(e) is about synergy without which the invention is non-patentable. An admixture is patentable subject to the condition that the applicant proves the synergy associated with the components. A computer program falls in the domain of copyright but if specific hardware is designed to go with specific software, then that computer program becomes eligible for patentability. The reason why computer programs are not patentable is because most of them are incremental in nature and identification of

inventive step becomes nearly impossible. Traditional knowledge is actually prior art which a given community may have been practicing for centuries. But if the invention involves considerable human intervention, then that invention although based on Traditional knowledge becomes patentable. However, the applicant for patent must disclose the source of the traditional knowledge and materials and also if required take the permission from the relevant authority.¹⁷ It is also desirable that should the working of patented invention lead to profits, the community to whom the traditional knowledge belongs, have a right to a share in the profits.¹⁸

The easiest category to understand is the category which covers the non-inventions. 3(c) clause leads to non-inventions. To formulate a scientific theory or discover a law of nature requires extreme human intellect and intervention. Yet it is not an invention. Also anything existing in nature encompassing all living and non-living things are a discovery and not an invention. The part of the 3(d) clause where a mere secondary use of a known substance is discovered does not qualify as an invention and 3(f) pertains to a mere rearrangement of known devices which function in a known way. 3(l) pertains to copyrighted material which concerns with creative forms of art and not inventions. 3(m) is a mental process not leading to any invention. Activity under clause 3(n) is not an invention. It does and can attract copyright protection under copyright laws though it cannot lead to an invention. Biological process in 3(j) is an event that occurs in nature. If a strand of DNA is introduced in the genetic code of living thing and if this strand replicates itself, it is not an invention because the DNA strand anyway is doing its job: that of replicating itself. By that virtue alone inventions claiming these become non-patentable. Computer programs as such are considered literary creations and

Table 2 — Relevant sections under different categories

Subject	Patentable/Non-patentable	Relevant Section
Microorganisms	Patentable after the patent of Ananda Mohan Chakrabarty	Omission of Section 5
Drugs/medicines/agrochemicals/metallic compounds/microorganisms	Patentable after the amendment of 2005	Omission of Section 5
Stem cell therapy	Patentable	Section 3(b)
Genetically modified plants and animals	May be Patentable.	Section 3(j) gives no clear provision
Biotechnology inventions	Patentable	Section 3(j)
Genetically modified seeds	Patentable after the <i>Monsanto</i> case	Section 3(j)
Human cloning	Non-patentable	Section 3(b)
Computer software	Non-patentable (most of the times)	Section 3(l)
Algorithms	Non-patentable (most of the times)	Section 3(k)

fall in the domain of copyright. Algorithms arise from scientific principle or from some law of nature. An algorithm is another expression of a scientific law and therefore not an invention. However consider the US Patent No. 4,405,829 granted to Adelman *et al* in 1983 for the famous RSA algorithm for public-key cryptography. Business methods here in this context mean ideas governing commercial activities. Examples could be online marketing, advertising and online trading of shares. A business method is non-patentable in India. But then again consider the US Patent No. 6,041,345 granted to Steven Levi *et al* of Microsoft Corporation for Advanced Systems Format – a format for storing and streaming media. Ideas cannot be patented just as they cannot be the subject matter of copyright even. But the expression of idea leading to a literary creation can be copyrighted and an expression of the idea leading to an invention can be patented. Traditional knowledge without any human intervention is basically prior art and just another non-invention.

Conclusion

India is a party to the TRIPS Agreement. The 2005 Amendment of The Patents Act, 1970, by omission of Section 5 as well as through various amendments made the intellectual property laws of India fully TRIPS-complaint. Several questions are always raised: Are microorganisms patentable?^{19,20} Yes, a microorganism whose discovery involves human intervention is patentable and qualifies for a product patent. Is human cloning patentable? No, because human cloning is not subject to patentability on the grounds of Section 3(b). Is stem cell research patentable?^{21,22} Are genetically modified seeds patentable? Yes, they are. Are genetically modified plants and animals patentable? This article provides some insight into these answers. Any invention must satisfy the three universal criteria of patentability namely, novelty, inventive step (non-obviousness) and industrial applicability. Inventions that concern biological processes and software are challenging because in these cases the identification of inventive step becomes difficult. In the former it is important to identify the step where human intervention stops and biological process takes over. In the latter the incremental changes make the identification of inventive step a very difficult process. These conclusions can be summarized in a form of table to have answers at a single glance (Table 2).

The provisions of the law give us broad answers but more often than not it becomes necessary to investigate the inventions on case-by-case basis.

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