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# Patent primer

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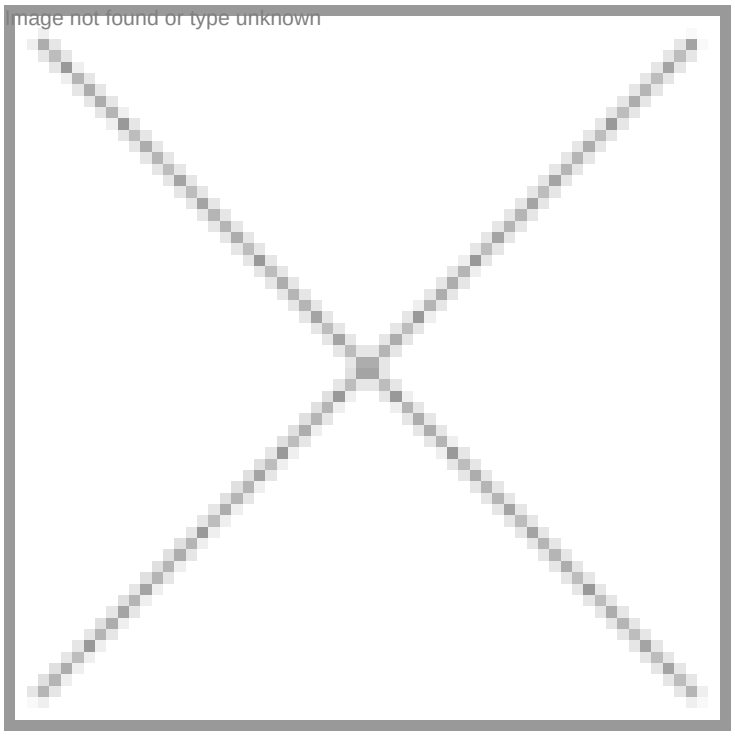
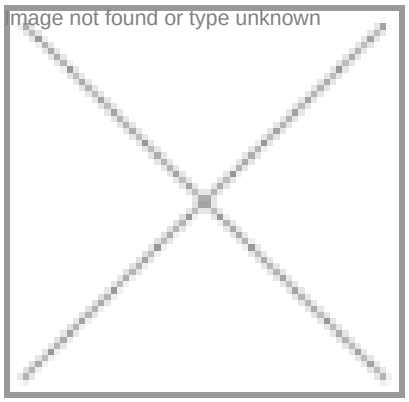



**LEGAL VIEW**




Patents were granted as early as the14th century. According to reports, Filippo Burnelleschi, the architect of Florence's remarkable cathedral won the world's first patent for conveying goods up to the Arno River. He divulged his invention only when the State of Italy gave him a monopoly for three years. Interestingly, Thomas Edison obtained more than 400 patents a year and about 1,093 patents in his lifetime! Therefore, patents as a vehicle of monopoly have been in existence for centuries, although the TRIPs has added momentum and brought it to the stage.

In simple terms, a patent is a contract between a government and an inventor (patent seeker). In exchange for complete disclosure of the invention, the inventor is granted a monopolistic right to exclude members of the public from making, using, selling or importing the invention in a territory for a limited period. But for the patent protection, inventions would have been kept as secrets and innovative technologies would have died with the inventor. The objective of the patent laws is to encourage disclosure of inventions and also to protect the inventor from copycats trying to make a fast buck.

## Pharmaceutical patents

The current law permits only process patents in case of pharmaceuticals and agro-chemicals in India. As for the products per se in these areas, it is possible to file applications and wait in the queue until 2005 for its examination and grant (also called "mailbox" provision).

This rule applies to any pharmaceutical/agricultural products including isolated genes, proteins or pharmaceutical compositions based on those genes or proteins, a novel or new chemical entity/molecule used for diagnosis, treatment, mitigation or prevention of diseases in human beings or animals, etc.

While the mailbox application for the product is being examined, it may be possible to apply and obtain Exclusive Marketing Rights (EMR), if the applicant meets one of the two following set of conditions:

- Filed a product patent application in India for the invention.
- Obtained patent rights to sell the product in a convention country.
- Obtained Drug Controller's permission to sell that product in India.
- Made an application for grant of exclusive marketing rights in India.

Or

- Filed and obtained a process-patent in India post-January 1, 1995,
- Simultaneously filed product-patent application under mailbox provision in India.
- Obtained Drug Controller's approval to sell the product in India.
- Made an application for exclusive marketing rights.

If the EMR applicant satisfies any one of the above set of conditions, he will be granted EMR for a period of five years from the date of grant till the product patent is granted/rejected, whichever is earlier.

So far, at least 10 applications for exclusive marketing rights have been filed in India, of which a few applications were rejected on procedural grounds, and the rest of the applications are reportedly being processed. The EMR grantees include Novartis for Glivec and United Phosphorous.

## Plants, animals and methods of treatment

In India, no patents are granted for plants and animals in whole or any part (including seeds, varieties and species), biological processes, methods of propagation of plants and animals. The list excludes microorganisms. Similarly, any medicinal, surgical, curative, prophylactic techniques for treatment of human beings or animals are not patentable. Hence, new surgical techniques, method of corneal transplant, cardiac surgery, method of treating cancer or any method that renders human beings free of diseases are not patentable in India. However, the above methods of treatment are patentable in a few other countries such as the US.

One reason is perhaps that millions of people suffer from various diseases and granting monopolistic rights in this field may confine the already expensive medical facilities to the rich alone. Another reason is that Article 27 of the TRIPs Agreement itself gives countries the option not to grant patents for methods of medical treatment. Hence, even after 2005, it is possible that these methods may not be eligible for patent protection.

However, methods that do not "treat humans" are patentable: e.g., methods for killing bacteria, treating a dead body, preserving dead bodies, mummification and producing artificial limbs. Also patentable are prosthetic devices, pacemakers,

implants, artificial limbs and contraceptive devices.

In countries around the globe, especially the US, the position is radically different. It may come as a surprise that as far back as 1873, Louis Pasteur received a US patent for yeast "free from organic germs or disease." Till the 1980s, the US was conservative in granting patents to living organisms. The floodgates were opened by the landmark case of Anand Chakrabarty, which involved a bacterium genetically engineered to degrade crude oil. In 1980, the US Supreme Court clearly stated that new microorganisms not found in nature, such as Chakrabarty's bacterium, were patentable.

In the case of Ex-parte Allen, the question that arose was: if microorganisms are okay, what about multi-cellular animals? The case involved a new kind of "polyploid" sterile oyster that had an extra set of chromosomes, which was edible all year round because it did not reproduce and waste body mass in that activity. The court ruled in the affirmative. No patent issued for this invention since the technique was in the public domain.

Following this invention in 1988, Philip Leder and Timothy Stewart were granted a patent for Harvard mouse, which was genetically engineered to serve as model for study of cancer.

## Stem cell

Stem cell research is an emerging field, wherein Indian Institutions such as National Centre for Biological Sciences, Reliance Life Sciences and Centre for Cellular and Molecular Biology, Hyderabad have reportedly developed stem cell lines which may be of potential use to the National Institute of Health, USA.

Neither Indian laws nor government policies prohibit research on stem cells or use of embryos or foetuses. No patents have been granted so far in India in this field since the field is nascent and growing. Although difficult, it may be possible to obtain patent protection for novel stem cell lines and artificial organs generated through stem cell research.

In fact, an Indian doctor developed an in vivo method of regenerating organs within the human and animal body using a person's own baby stem cells and won two US patents.

## Microorganisms

Under the current law, microorganisms per se in its natural state of existence would not be patentable, as it would qualify as a "discovery". No new and useful genetically modified and mutant microorganisms may claim patent protection. Such organisms should be adequately described and their source properly indicated in the patent application. The organism may be deposited at an international depository. The Microbial Type Culture Collection & Gene Bank (MTCC), Chandigarh, India having acquired the status of an international depository facilitates such deposit.

Thus, the scope of patentable subject matter is vast and incapable of being captured in a few words or sentences. Research, like the indefinite sky is beyond human imagination. Let's try to make the most of the grain of sand at hand. As Thomas Alva Edison said: "Verily a pioneer has to get his justice in the same way that a florist gets bouquets from century plants."

| What can be patented? | What cannot be patented? |
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| In India, the patent system is governed by the Patent Act 1970 (as amended in 1999 and 2002). According to the Act, an invention, which is novel, involves an inventive step and has industrial application, i.e., practical use, may be patented. "Novel" means the invention must be new, not, published or used by any one in the world. "Inventive step" is that feature of the invention that makes a skilled addressee sit up to say "Ah! I couldn't have thought of it!" In other words, any invention, which is new, inventive and useful may be patented and that includes improvements. | Now, everything that is new and useful cannot be patented, since the patent laws in every country invariably prescribe certain restrictions. The subject matter excluded from patent protection in India include discoveries; laws of nature, natural or physical phenomena, and abstract theories; computer programs per se, business methods; agricultural and horticultural methods; plants and animals, except microorganisms; traditional knowledge; presentation of information, scheme or rule or method of performing mental act, playing games; any invention relating to atomic energy; mere admixtures; discovery of a new property of a known substance. |

by

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J Sagar Associates is a leading national full service law firm and K& S Partners is an IP focused law firm. Both the firms provide legal services to several domestic and international biotech clients. Henceforth senior people from these companies will write on the patent issue.