

India's Unique Provisions for Life Science Patents

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Patents in India are allowed in all fields of technology, even though the factors determining patentability of an invention varies for different technologies. Among different technologies, inventions in life sciences are unique with respect to the huge amount of investment and comparatively longer gestation period to arrive at a viable invention. Thus, as the stakes are so high, both in terms of finance and time, it requires dedicated planning for developing and protecting the innovations in such technologies.



Adding to the requirement of high investment is the ever increasing complexity in inventions arising due to requirements of interdisciplinary research activities, to provide solutions to modern day problems and necessities. Such complex research activities in biotechnology, bioinformatics, nanotechnology and biopharmaceuticals results into high value Intellectual Property (IP) and by protecting the same, it becomes an important tool for diverse business developmental activities apart from funding and sustaining the research.

The protection of generated IP in the form of patents is one of the preferred rights, but it also needs unique strategies to make it compliant to different national laws, guidelines and directives. Care must be taken to adhere to various statutory and regulatory laws from the initial stage of product development for generation of an efficient IP portfolio.

Patent protection in India brings unique considerations for life sciences industry because of the typical statutory exclusions on certain aspects of innovations, for which no patent protection is available. Apart from the regular three leg test of novelty, inventive step and industrial applicability, Indian patent laws have specifically listed certain subject matters, which despite passing the three leg test, may not be protected. Some of the relevant subject matters related to life sciences industry that are excluded from patent protection in India are, inventions that could be contrary public order or morality or which cause serious prejudice to human, animal or plant life or health or to the environment - clause 3(b); inventions that are mere discovery of living or non-living substance occurring in nature- clause 3(c); inventions that are mere discovery of a new form of a known substance and does not have enhanced efficacy or the mere discovery of any new property or new use of a known substance or 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 - clause 3(d); inventions that are directed to a substance obtained by a mere admixture or a process for producing such substance - clause 3(e); inventions directed to methods of agriculture or horticulture - clause 3(h); inventions that are a process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or animals- clause 3(i); inventions that are directed to plants and animals in whole or any part thereof other than micro-organisms or essentially biological processes - clause 3(j); and inventions that are related to aggregation or duplication of the traditional knowledge - clause 3(p).

Since most of the technologies and innovations in life sciences domain relate to the health sector and are directly or indirectly associated with life forms. Such inventions invariably attract application of one or the other such exclusionary clauses. While the provisions defined in clauses 3(b), 3(c), 3(d), 3(i) and 3(p) are more relevant to inventions in the health care sector, the inventions relating to the agriculture sector attract the provisions of clauses 3(b), 3(c), 3(d), 3(h), 3(j) and 3(p). As India is gaining in the ranks of 'ease of doing business' and provides a large consumer base for various technologies and inventions, it is important for the life sciences industry to manoeuvre their IP generation and protection by giving a due considerations to the unique provisions of Indian patent laws. *Prima facie* it may appear that these are burdensome compliances, but in practical terms strategizing the invention and innovation development from the initial stage of research, would undoubtedly result in the generation of a high value IP.

Innovators in life sciences sector also need to address another aspect of regulation in India, if they are utilizing Indian biological or genetic resources. India is a party to the Convention on Biological Diversity and is bound to contribute for conservation of biological diversity, its sustainable use and sharing of benefits arising out of such use of biological resources and associated knowledge. The players in this sector need to consider the different requirements and compliances with respect to access of biological resources and associated knowledge, transfer of research information based on such resources, and obtaining IP protection on such research information. In India, the National Biodiversity Authority regulates such requirements along with State Biodiversity Boards and has recently taken extensive initiatives to improve awareness and compliance to the provisions related to access and utilization of biological resources and associated knowledge.

India also provides a *sui generis* law to protect inventions/ innovations related with the development of plant varieties, which are commercially exploited by production and sale of seeds or plant material. However, protection under the Protection of Plant Varieties and Farmers' Rights Act is available only for notified varieties and any plant variety that is not in the notified list cannot be protected.

In India considerable efforts at different levels have been made to strike a balance regarding legislative requirements and the interest of industry, particularly in IP for effectively securing the gains of huge investment of resources in developing the inventions/innovations. The past decade has witnessed considerable improvements in Indian industrial policies and IP practices by adopting different procedural and policy measures, which have created conducive environment for the growth of industry and IP protection. India is undoubtedly advancing rapidly towards a strongly supported Industrial regime with strong IP environment.



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