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Key issues for senior life sciences executives

IP issues for life sciences companies in India

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The life sciences have expanded in all fields of technology, leading to the creation of one of the most complex systems of our time. The discipline of life sciences is no longer a standalone subject; it is an ever-evolving dynamic domain rapidly expanding and merging with other subjects, which has given rise to an increasing list of interdisciplinary branches such as biotechnology, bioinformatics, nanotechnology and biopharmaceuticals. Simultaneously, intellectual property has also evolved as one of the key business assets in today's global market. Intellectual property now serves as an important tool for diverse business activities such as fundraising, attracting investors, mergers and acquisitions, strategic alliances, company valuation and licensing relationships. Ownership and exploitation of intellectual property are key factors in determining the intellectual and commercial success of any organisation.

Inventions in life sciences companies in general require a comparatively greater investment of time and economic resources. Investment of such nature necessitates effective generation and protection of high-value intellectual property. This is essential for attracting investors and strategic partners, which is crucial for the sustenance and growth of life sciences companies, especially small and medium-sized companies.

Complex statutory and regulatory requirements

IP generation and management for life sciences companies in India require not only compliance to national laws pertaining to IP rights, but also compliance to other national laws, guidelines and orders. All of these statutory and regulatory requirements assimilate to form a stringent and complex web of requirements. These statutory and regulatory requirements have been devised as per national and international policies and agreements (eg, the National Environment Policy, the National Drug Policy, the EXIM Policy, the National Seed Policy, the Convention on Biodiversity, the Cartagena Protocol on Biosafety, the Codex Standard and Hazard Analysis and the Critical Control Point). Compliance with the array of diverse statutory and regulatory mechanisms starts from the initial stage of product development and is a serious IP-management concern among life sciences companies. In addition, lack of clarity with respect to appropriate application of certain ambiguous regulatory provisions further perplexes the situation, particularly for emerging technologies (eg, biotechnology). Although, different regulatory bodies are continuously reforming and streamlining to remove the stumbling blocks, complex statutory and regulatory requirements still remain a major impediment for life sciences companies in India and require due and timely consideration.

Securing patents in life sciences

IP protection in life sciences has always been a point of debate in India, whether it is regarding pharmaceuticals, *Bacillus thuringiensis* technology, use of biological resources or traditional knowledge. This is because inventions in life sciences impinge on issues relating to policies, ethics, public interest and socio-economic factors. Life sciences companies deal with a wide and diverse range of products and processes, which may be broadly grouped on the basis of the sector

in which they are used (eg, health, agriculture, industry and environment).

Apart from dealing with the inherent uncertainties and risks associated with product development and reaping commercial benefits, inventions in life sciences are often faced with the challenge of imperative requirement for the professionals who can identify, understand and effectively navigate the complex web of regulatory, statutory, social, ethical and commercial requirements for IP protection and promotion.

In order to come up with technologically and economically viable innovations, life sciences companies must analyse complex patent landscapes and freedom-to-operate reports. Catering to this requirement remains a challenge for life sciences companies targeting innovations and inventions. There are also difficulties associated with predicting market value and life span of inventions in life sciences companies. This problem is intrinsic to many such inventions because they involve greater social, moral and ethical considerations.

Another important concern for life sciences companies is that the patent protection regarding the related technology and innovation is particularly vulnerable to damage by minor tweaking. The technology or innovation related to the life sciences domain generally requires more time for technology transfer because of complex and stringent legal compliances regarding the safety of innovation or technology. These issues would eventually affect the effective lifespan of the technology or associated product developed at the cost of huge investment and would reduce the potential of recouping commercial benefits. Thus, life sciences companies are well advised to consider these issues while planning, developing and protecting their innovations and technologies.

Non-patentable inventions

Patents are among the most important IP assets for technology and innovation-based life sciences companies. A patent right enables the developer company to have a chance of recovering its investment and to have capital gains sufficient for the continuous support and maintenance of stakeholders' interests. Apart from the general patentability requirements of novelty and inventive step, life sciences inventions in India must qualify the barriers created by Section 3 of the Patents Act. Referred as 'non-patentable inventions', Section 3 defines exceptions that have been primarily drafted to safeguard the social and economic interests of the country. A sizeable percentage of technology and innovations in the life sciences domain relates to the health sector and must therefore overcome the barriers of Subsections (b), (c), (d), (i) and (p) of Section 3 of the act. Similarly, technology and innovations related to the agriculture sector must overcome the barriers of Subsections (b), (c), (d), (h), (j) and (p) of Section 3. Multifaceted implication of most of the provisions of Section 3 and a lack of eloquent judicial precedents further contribute to the ambiguity in application of said provisions and may hinder the development of technology and innovation. Life sciences companies must therefore proactively consider and understand the possibilities of such restrictive provisions and engage in strategies to address the concerns caused by their application.

Another perplexing situation exists due to India's rich geographical, cultural and biological diversity and comprehensive traditional knowledge base. Section 3(p) of the Patents Act is devised to protect the invaluable asset of 'traditional knowledge', which often comes in the way of protecting innovations or developments, particularly in the health sector, which have some contributions from traditional knowledge with respect to the use of a particular material for arriving at a particular purpose. The issue is aggravated by sporadic practice, whereby this barrier cannot be overcome by the technical advancement contributed by the innovations. Life sciences companies should therefore give due consideration to developing strategies to address the concerns generated by Section 3(p), while selecting and developing a product or innovation that might be considered to be traditional knowledge.

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India's patent law does not provide patent protection to inventions developed with a novel use aspect, something which is patentable subject matter in many other countries. This restriction is due to a mandatory requirement of the Patents Act, which requires an invention to be a new product or process. Excluding this group of inventions eliminates a significant percentage of innovations which otherwise have commercial and industrial applicability. Many such innovations of life sciences companies fall under this group and accordingly the related intellectual property should be managed using alternative methods (eg, trade secrets).

Working, compulsory licence and technology access

Another issue which appears at the post-grant level with respect to local working and compulsory licences is of particular concern for life sciences companies. According to statutory provisions, at any point after three years following the grant of a patent, any person may apply to the controller of patents for a compulsory licence of a patent on the grounds that, among other things, the patented invention is not worked in India. This includes deciding on whether the patentee has taken adequate steps to at least begin working the invention on a commercial scale in India. Working of a patent is a core requirement in the post-grant stage and is directly associated with threats of compulsory licensing. Keeping in mind issues of complex legal and regulatory requirements, technology access and technology transfer time, a three-year period may be insufficient for operational local working of patents.

Technology access is another issue which small and medium-sized life sciences companies must face. Technology access is one of the key foundations of any IP regime and is reflected in various provisions related to complete disclosure, publication and enablement. This is further emphasised by the Patents Act, which has carved out an exemption with respect to permitted use of patents and patented technology for R&D purposes. This permitted use of patents and patented technology for development of new technologies and innovations is of immense significance for small and medium-sized life sciences companies with limited resources. However, to protect and commercialise the developed intellectual property, the company must have authorised access to all patents and technologies used to develop the technology or innovation, which in many cases involves complex

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and expensive cross-border IP transactions. Therefore, life sciences companies must give due consideration to technology-access requirements, which may eventually lead to increased financial implications for the company and in certain cases render the developed technology or innovation economically impractical.

Securing registrations of plant varieties

A fraction of innovations in life sciences companies will be considered non-patentable because certain inventions are related to the patenting of plants or any part thereof (including seeds, varieties and species). India has devised provisions to protect farmers' interests and for various socio-economic reasons. However, to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights, India came up with the *sui generis* option of the Protection of Plant Varieties and Farmers' Rights Act 2001, which is intended to protect innovations related to the development of plant varieties. Life sciences companies involved in the development of plant varieties that are commercially exploited by the production and sale of seeds or plant material can protect their IP interests by registering the varieties under the act. Registration of plant varieties is a new system in India, which is under-developed and liable to a number of hurdles and glitches. Even after more than decade of an operationalisation, the Protection of Plant Varieties and Farmers' Rights Authority is still developing the process to examine claims for the registration of plant varieties. The lack of clarity in statutory provisions not only slows down the entire process of protection but also weakens the protection system required to effectively protect the generated intellectual property.

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. Other issues include the process adopted for distinctness, uniformity and stability (DUS) testing. The time taken to complete the testing of claimed varieties is sometimes detrimental to the applicant's interests. There is no mechanism to expedite the process and it remains at the mercy of the operational efficiency of government machinery.

The developer company should carefully select the reference variety during research and development, as there is no clear option available for the developer to select reference varieties during DUS testing. Issues relating to the selection of reference variety become more important due to non-availability of an option to repeat testing in case of inadequate expression of the claimed trait.

Grey areas

Life sciences companies have recently encountered another emerging issue due to provisions related to the benefit of sharing patents using biological resources from India under the Biodiversity Act 2002. The National Biodiversity Authority is yet to provide a proper and efficient mechanism for the practical implementation of the Biodiversity Act. However, the National Biodiversity Authority has recently made significant improvements to its functioning, which is undoubtedly a positive move for life sciences companies.

There is little doubt that considerable effort at different levels is required to strike a balance regarding legislative requirements and the interest of IP creators in effectively securing the gains of huge investment of resources in developing innovations. The past decade has witnessed considerable improvements in Indian IP practices by adopting different procedural and policy measures, which have undoubtedly benefited IP protection.

However, there remain several grey areas due to a lack of judicial precedents adequately addressing contentious IP issues. At present, Indian IP jurisprudence struggles for clear and lucid judicial precedents regarding inventive step, which is among the fundamental technical requirements of IP protection. This evolutionary phase of Indian IP jurisprudence is an opportunity to borrow precedents from the well-developed and evolved IP systems of Europe and the United States.

This will enable India to develop a more refined and harmonised Indian IP jurisprudence in a comparatively short time.

India is advancing rapidly towards an IP regime that is striving to strike a balance between company interests in protecting IP and public policy. *iam*

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