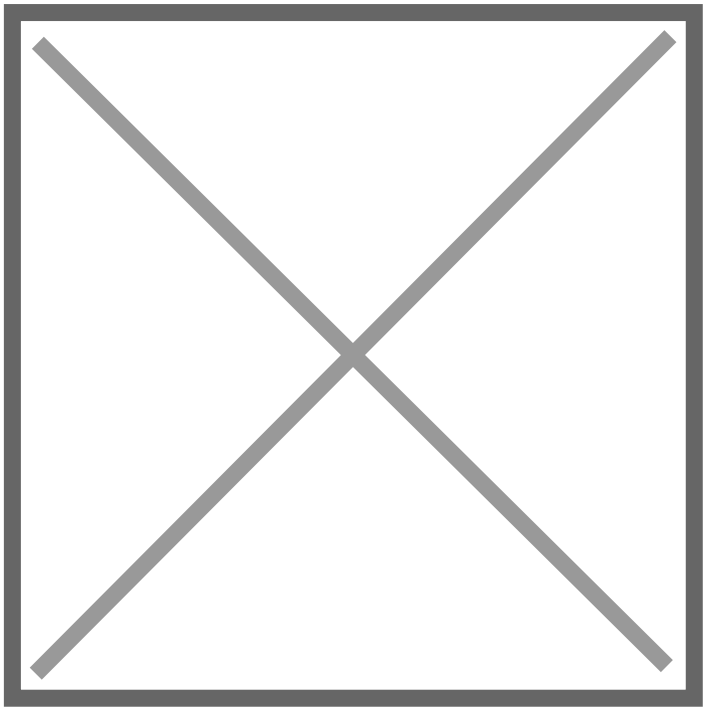
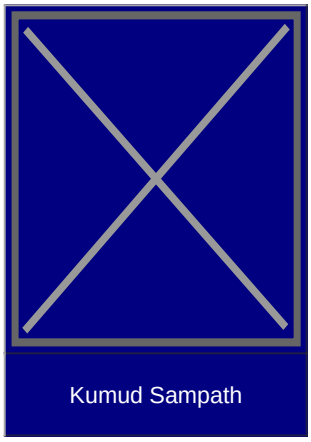
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Management of Intellectual PropertyÃ?Â - The Driver of Biotechnology Industry

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(Continued from December 2004 issue)



Inventor designation on a patent application

Inventor identification is very challenging and a sensitive issue to a project manager in a biotechnology company. Unlike authorship on research papers, not all members of a research team can be considered as inventors. Inventors by definition are those members of a research team who conceived the complete and operative aspects of the invention. Of course the invention has to be worked through appropriate experimental examples, otherwise called "reduction to practice" which can be performed by anyone trained in the scientific disciplines. Therefore, those experimenters cannot be designated as inventors. Sometimes, although rare, reduction to practice may require extraordinary skills and in such cases contributions made by the experimenter may qualify for inventorship.

Ownership of a patent

Inventorship provides the basis for determining the ownership. Most often a signed employment agreement obligates the inventor to assign the rights of the invention to the employer. Thus, for biotechnology enterprises it is very important that legally well drafted employment agreements are executed by all employees, which require that the employer be assigned of all rights to the invention conceived and reduced to practice in connection with the employment.

Intellectual property portfolio strategy

The development of a IPR portfolio strategy varies from the needs of a start-up biotech company which is centred around a scientific concept or a technology platform to a biopharmaceutical company which produces or markets biopharmaceutical products or an agricultural biotech company which produces or markets products such as pest resistant plant seeds or strains or biopesticides and others. Nevertheless, a well thought out IPR strategy is essential in all cases.

The term of a patent is 20 years, which starts from the date of filing. Thus, the timing assumes importance in terms of the duration for marketing a product. If the patent is filed too early during R&D, the window of opportunity to market the product as well as the size of the market will be smaller.

Granting patent rights to inventors is a legal provision created by each nation according to its constitution. Therefore, patent applications have to be filed in countries where the applicant seeks the protection. However, several nations including India have entered into a treaty called Patent Cooperation Treaty (PCT), which is administered by the World Intellectual Property Organization (WIPO). Thus, a single PCT filing establishes a common priority date for the invention in all the countries, which are signatories to the treaty. A PCT application can be filed at any of the Regional Patent Offices in India. It must be remembered that the PCT prosecution does not result in the issuance of any national patents, but it provides a cost effective means of establishing the priority date and also buys in 18 months of time from the date of filing to determine the commercial value of the invention. The decision on choosing, in which countries the patent application designated in the PCT application should be prosecuted, rests with the biotech company and its commercial strategy or business plan. The PCT route offers several advantages. One can obtain a patentability search and initial examination on a single application, which limits the costs for examination in each country, but the disadvantage is that a single examiner rules on the patentability. Alternatively, by filing a PCT application and choosing an option to file for Intellectual Property Protection in selected countries, one can defer for up to eighteen months for examination thus delaying the expenses involved in prosecuting the patent application.

Evaluation of inventions in biotechnology

The monetary worth of inventions is the prime consideration for bioentrepreneurs to seek investments from banks and venture firms. Although at the moment, investing organizations and banking community in India are not accepting patents as collateral, it is bound to come into vogue soon. There are many approaches to put a price tag on biotechnological inventions such as the cost of invention, the market and income from licensing. A novel method of risk adjusted net present value has been described recently which helps in arriving at a fair value for an invention (J.J.Stewart, P.N.Allison & R.S.Johnson, Nature Biotechnology 19 (2001) 5-9). However, it is important to realize that intellectual property (IP) has a value cycle, which has three distinct stages. The first stage is the growth phase during which technology and market development takes place. As the technology matures and the market uncertainty is lowered, the value of IP increases. The second stage is when the value of IP reaches a peak and the revenue generation reaches a maximum and the third stage is the period when the "net present value" drops due to competing products entering the market. Therefore, the evaluation of IP has to be made carefully by allocating weightings to a number of factors such as duration of IP protection, market forces and the size of the stage II window of opportunity.

Licensing of biotechnological inventions

A successful licensing strategy depends on the company's (institution's) business objectives. Different inventions require different licensing strategies. Small biotech start-up companies or university departments or public research institutions usually have technology platform type of inventions such as scientific tools or very early stage "proof of principle" type of inventions with potential wide applications. These are licensed on a nonexclusive basis whereas inventions, which require significant investments and/or resources, are generally licensed on an exclusive basis.

The concept of "freedom to operate" agreement among pharmaceutical companies is becoming a common practice, which includes a non-exclusive cross- licensing provision. By this agreement, the companies agree to use each other's intellectual property for research and development of some defined number of products for a specified time and financial consideration. Such agreements minimize the risk of infringement of each other's intellectual property and save considerable resources.

There are large numbers of patents on enabling technologies, which are owned both by private and public institutions world over. These include mainly tools of biotechnological research, such as expression vectors, selectable markers on plasmids, synthetic or constitutive promoters, transformation methodologies, assay methods, genes and gene products, etc. Prof. David Zilberman and colleagues at the University of California Berkeley (Calif. USA) have proposed a novel concept of a form of collective rights organization (Clearinghouse), whose functions include, identification and extent of availability of technologies for licensing, facilitating an interaction between patent owners and potential users and assisting in contractual licensing agreements. Clearinghouse concept of Prof. Zilberman is a viable strategy for Indian biotechnology research based industry

The governance of IPRs

Intellectual Properties are essentially intangible resources and assets not only for business enterprises but also to the country,

which influence economic growth. The governance of Intellectual Property Rights therefore, assumes a crucial role in policy making. The adoption of IPR regime inevitably brings into fore claims, conflicts and disputes particularly in the fiercely competitive knowledge-based industries. Thus the implementation of IPR laws through an efficient legal system assumes greater importance in the governance of the IPR regime since benefits of the IPR system can be realized only if there is an effective enforcement process in place. Although the Indian Legal system is known for fair dispensation of the law, it has the reputation of being extremely slow and riddled with complex procedures. There is an urgent need to streamline the process and establish new institutions to handle IPR litigations. However litigations in India and elsewhere are expensive in addition to being time-consuming. Hence, many business firms are opting for alternative dispute resolution (ADR) processes.The World Intellectual Property Organization (WIPO) Arbitration and Mediation Centre located in Geneva (Switzerland) offers dispute resolution services particularly for cross-border IPR disputes, which include both contractual disputes (patent licenses) and non-contractual disputes (patent infringement).

IPR licensing practices sometimes introduce conflicts related to monopoly and national interests, such as unilateral refusal to license a patent or sell items covered by such a patent. Although there are many potential benefits to cross licensing, concerns may arise with agreements, which are intentionally designed to facilitate product-market collusion. Adequate safeguards are to be built into laws related to monopoly and restrictive trade practices (MRTP).

Opportunities knocking on our doors

There is little doubt that India is embarking on a knowledge-based economy. There is also an unprecedented hope that biotechnology will provide an opportunity to garner a significant part of the world market for Indian biotech products and services. Although the hope is well founded because India has trained human resources and scientific expertise but at the moment India is ill prepared to meet the challenges to realize the dream. Educational systems have to be revised to include innovation culture by removing rigid barriers to widen opportunities. There has to be a war front effort to mobilize resources and streamline operations to drive the industry to compete in the world market. Indian government must perceive that Intellectual Property Rights are essential for the rapid growth of the biotech industry. Subsequent to the introduction of the patent regime, Indian Patent offices will receive a large number of patent applications from within the country and outside, which will provide a significant revenue source. However, Indian patent offices lack both human resources and expertise in examining biotechnological inventions and the claims made. Human resource mobilization to process biomedical, agro-biotech and other biological inventions is of immediate need. Thus, there exists an enormous opportunity for students engaged in biological, chemical and medical sciences in a variety of functions both in public and private sectors, such as in technology development, technical writing for IP protection, mining data for innovation, legal drafting of patent applications, patent search and examination of claims, as well as in litigation, arbitration and mediation.

Another area where Indian biotech entrepreneur could greatly benefit from is, private funding of research. Although there is considerable venture-funding activity in India, there is very little investment into biotechnology research leading to novel products. Bankers and investment managers allude to ignorance of domain knowledge. There is an urgent need to provide basic courses in biotechnology and business opportunities to bankers, investment managers, SEBI and other investing agencies.

It is hoped that with the introduction of laws to protect Intellectual property rights, India will usher-in the culture of innovation and propel the Indian economy to achieve the goal of transforming India to a developed country by 2020.

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