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Management of Intellectual Property

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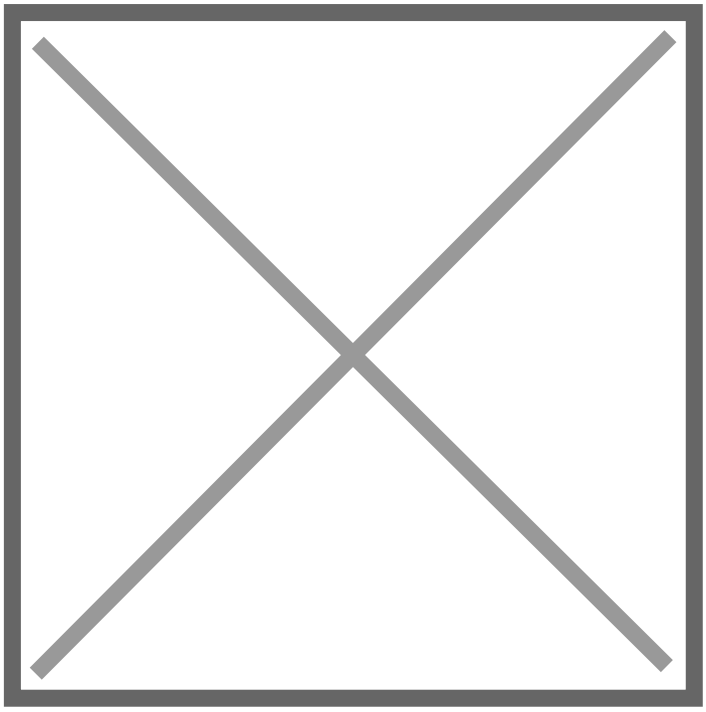

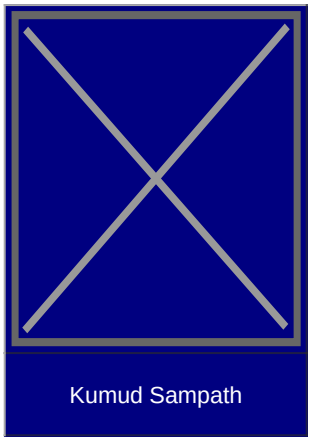

Kumud Sampath

The steady growth in Biotechnology education, entrepreneurial spirit among technocrats, investment in biotech industries and the impact of globalisation of Indian economy, has inevitably brought to fore the importance of Intellectual Property Rights for inventions. It is strongly believed that India will pass all the pending bills in the parliament pertinent to IPR laws and implement them on or before January 1, 2005 to comply with WTO agreements.

Creativity in the application of knowledge derived from advances in science is directly proportional to the creation of National Wealth. Einstein's famous equation can best fit the economic theory of the 21 century. E =mC2 where E is the economic wealth, m is a constant and C is creativity. (After all, Einstein was a Patent Officer before he became a Physicist). Innovative capability of Indian Scientists and Technologists has been well recognized in the burgeoning Information Technology industry and it is hoped that India's next frontier in knowledge-based innovations would be in Biotechnology. Intellectual Property Rights (IPR), which include Patents, Copyrights and Trademarks are important assets for any company, but in the case of knowledge-based industries such as Biotechnology, patents play a significant role in attracting investment. There is a mistaken notion that patents are impediments to academic freedom for the pursuit of science. A patent is only a protection afforded by the government to the inventor to commercially exploit the invention for a period of time in a privileged manner. Hence applications of scientific knowledge to produce new and novel products will only advance because of this incentive rather than hinder progress in the creation of new knowledge through research. Grant of a patent demands full disclosure of the invention so that others can learn from it and expand upon it.

What is patentable?

Inventive concepts in biological research arose when an Indian Scientist, Dr. Ananda Chakrabarty in 1980, then working at General Electric R&D Laboratories in Schenectady (NY, USA), was granted a patent by a landmark decision of the United

States Supreme Court, for his invention of a genetically engineered microorganism capable of degrading hydrocarbons. In fact the modern biotechnology industry owes its origin to this event in history. Today biotechnology patent literature is inundated with inventions pertaining to:

(i) living entities derived from processes of manipulation of chromosomal or extrachromosomal genetic elements which include methods of recombination, gene deletion or disruptions, gene insertions, mutations, transformation, transfection, chromosomal integrations, cell fusions and other techniques of molecular biology.

(ii) Products produced by living entities, natural or genetically altered

(iii) Processes involving living entities which include their cultivation and multiplication, optimal conditions for the production of desired substances, purification and isolation of such substances

(iv) Transgenic plants and animals, including methods of producing plants and animals capable of expressing heterologous genes

These areas and other related subject matter form the basis of numerous patent applications filed in the USA, Europe and Japan. For a relatively new industry, which is just about 20 years old, the number of patents applied for and granted is phenomenal. Biological diversity is so large that there is plenty of room for non- obvious inventions, which are novel and have industrial utility. Creative biotechnologists in India have unlimited opportunities for innovation. Another area where India may have an edge over competitors is bioinformatics. Bioinformatics is a major enabling technology platform, which encompasses molecular biology, genetics, computer science, mathematics and informatics. The tools of Bioinformatics have predictive potential, which can add value to biotech research and improve the international competitiveness of biotech industries. Indian scientists can develop novel and effective bioinformatics tools. It must be noted that algorithms are not patentable per se. However, EPO and USPTO have accepted that computer implemented inventions have a "technical character" in providing solutions to biological problems and thus not excluded from patentability. Patent attorneys have crafted claims, which include " a model of a ligand binding domain in a receptor" or "a computer generated model of a protein comprising of three dimensional display of atomic coordinates defining a specific shape and volume". Indian patent examiners and courts must recognize the predictive capabilities of bioinformatics tools and allow claims in patent applications of biotechnological inventions, which are solely derived from computer simulations.

One must bear in mind that "A patent by itself does not provide the right to commercialize the protected technology but only provides the right to exclude all others from commercializing it". The exclusivity provided by the grant of a patent is the powerful driving force behind the incentive to invest, to innovate, to license the innovation and to compete.

Culture of innovation

Innovation is primarily an intelligent management of information which includes both experimentally generated in-house information and that available in literature. Thus, information obtained for the development of a product or a process is an asset with potential value to the enterprise. The value can be realized if the information is used as an invention and protected as an intellectual property. There are three cardinal principles for the creation of an inventive environment in a biotech company; Identification of inventions in research projects, Confidentiality and accurate Documentation of data.

(i) Identification of inventions in research projects:

It is of utmost importance for the success of the organization that the employees understand the inventive potential of the information that is generated in a research project. Research project teams should frequently evaluate the information for novelty, unobviousness and utility. Thus, organizations should have procedures to identify and protect valuable information. Often an invention appears obvious to a highly-qualified scientist but it may not be obvious in a legal sense. Natural diversity in Biospace is so large that there are unlimited opportunities for innovation. Data mining of scientific literature and patent literature play important roles in sighting inventions in ongoing research or to conceive of a novel idea for a new invention. CSIR has set up a Unit for Research and Development of Information Products (URDIP) in Pune, which provides services to industries in data mining and creating novel databases.

ii. Confidentiality

One of the most important operational rules is the strict enforcement of Non Disclosure Agreement (NDA). Prior disclosure of information is detrimental to patent registration and reduce the chances of successful commercialization. The culture of accepting not to disclose information for a period of time specified in the agreement, which is deemed to be confidential (Non-Disclosure Agreement), is vital to inventive capability of a biotech company. It must be noted that if the idea has been disclosed at a conference, in an abstract or as a poster or referred to in an oral presentation at a conference (including a casual discussion with a person who has not signed a confidentiality agreement), in a thesis or published in a journal, then it can no longer be protected by a patent.

It is quite common amongst academic personnel that many research tools including genetically engineered DNA, plasmids, phages and microbes are collected from other investigators. When such people are recruited, it is very important to make a record of material brought into the company by the person concerned. The details of when and from whom the materials were obtained and under what understanding must be documented. It is now an accepted practice to transfer biological material through a materials transfer agreement (MTA), which stipulates the conditions of transfer. Similarly any material given to investigators outside the company/research institute must also have a signed MTA.

iii.Documentation

Recording of experimental details accurately in designated books, dated and signed by both the experimenter and his/her supervisor, is crucial for defending challenges to patent claims by competitors in courts of law. The use of erasable writing media should be forbidden.

Strict enforcement of discipline in observing the rules mentioned above will enhance the possibility of generating much valuable intellectual property for biotech companies, particularly for start-up biotech enterprises. Clear and detailed recording of data plays a significant role during technology transfer even when the original investigators are no longer available to the company.

... To be concluded in Jan 2005 issue.

Kumud Sampath is Head of Operations at AstraZeneca India. She is a member of the Vision Group for Biotechnology in Karnataka State and member of the Executive Council of ABLE. The views expressed in this article are her own and do not necessarily reflect the policies of the Vision Group, ABLE or her employer, AstraZeneca.