Management of Intellectual Property Rights: A Focus on Biotechnology

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Abstract

The present paper talks about the role of Intellectual Property Rights (IPR) in an R&D system like Biotechnology and how it operates at a larger social, political, economic and technical platform to safeguard the noble ideas, inventions and research methodologies of an inventor. The Industries and Govt. believe that the IPR acts as a catalyst in Biotechnology inventions. However academic research suggests the role of IPR in stimulating innovation is not always certain and there may be opposite effect in some cases also. A detail on Intellectual Property management as an essential requirement has also been stated.

1. Introduction: Intellectual Property Rights (IPRs) and Related Issues

IPRs are rights to thoughts, novel ideas, and information on new processes and inventions loosely defined, intellectual property is a “product of mind” and like other property, no other person can lawfully use his / her property without consent. The underlying objective in establishing IPRs was to protect the interest of inventor and to exclude imitators from the market for a specified period. Although, there are several categories of such rights, the most commonly known include copyrights, trademarks, designs, know-how and patents.
2. Types of Intellectual Properties and their Descriptions
Originally, only patent, trademarks, and industrial designs were protected as 'Industrial Property', but now the term 'Intellectual Property' has a much wider meaning. IPR enhances technology advancement in the following ways:
   a) It provides a mechanism of handling infringement, piracy, and unauthorized use
   b) It provides a pool of information to the general public since all forms of IP are published except in case of trade secrets.
Types of IP Protections are:
   i) Patents, (ii) Copyrights, (iii) Trade secrets
   ii) Geographical Indications and (v) Trademarks

3. Indian Patent Act
The Indian Patent Act of 1970 forbids the granting of patents on life forms and related technologies. Further, biosubstances used in the areas of agriculture, horticulture, and responsible for curing or enhancing human animal or plant life are not patentable. The Indian Patent Act for biological materials is based on the law of mortality and concern for the health of human kind. Only process patents are allowed in India (Dogra, 1993). The term ‘patent’ in a broad sense is applied to refer an official declaration granting exclusive right, privilege to produce, sell or to get profit from an invention process, etc. In technological patents – process and product patents are described (Weiner, 1987; WIPO, 1988). The IPRs issues are dealt in India by Patent Act of 1970 with amendment of 1994 and design Act of 1911. Trade and merchandise Act of 1958 and copyright Act of 1957 and are also parts of IPR protection. The international treaties are agreement on trade related aspects of intellectual treaty under WTO and Berne convention for the protection of literary and artistic work. There is nothing like ‘World Patent’.

3.1 Patenting in Biotechnology
Patenting biotechnology has emerged as an issue in the past two or three decades. Biotechnology involves use of organic changes in animals, plants, microorganisms and any biological material that can be assimilated by living matter. It includes any technique that uses living organisms (or their parts) to make or modify products to improve plants or animals or develop microorganisms for specific uses. The unforeseen potential of biotechnology has been contributing to difficulties regarding patenting. Living organisms have been used for many years in activities such as brewing and baking. Agriculturists have improved farm animals and plant varieties through breeding. Should these conventional and modern biotechnological innovations be accepted for patenting is a question to ponder.
4. Cellular and Molecular Technologies
The developments like recombinant DNA technology; cell fusion techniques, monoclonal antibody technology, stem cell technology and other biotechnological technologies could definitely improve attributes of existing organisms and radically alter the efficiency of any biological process. These developments have potential to uplift the socio-economic status of the human beings. Biotechnological developments in the last decade of 20th century are poised to revolutionize the agriculture and health sector. The latest technologies: stem cell technologies, transgenesis and cloning are few of these to mention. The moral, ethical and IPR issues over transgenic and cloned animals and cloning in particular of human embryos are being debated at several levels.

4.1 Transgenesis and Higher Life Forms
The transgenic animals are created through the introduction of foreign genes into an animal, while it is in embryonic state. The transgenic animal exhibits a permanent alteration in the genome of its host. The developments in transgenic animals will have economic impact equal to that made by historical advances in agriculture through traditional selection and breeding, and this will be achieved in a much shorter time period. The transgenic technology is a significant advancement and cannot be considered a mere hastening of traditional methods. The debates over whether or not a patent should be issued for higher life forms usually exceeds the simple question of appropriateness of patents, focusing on ethical and economic considerations. The debates include issues such as biodiversity, human and animal health considerations, environmental safety, economic benefits and risks associated with patenting animals. The issues of biotechnology and patenting life forms are interwoven and are complicated by the fact these developments in biotechnological research involve creation of inventions that are essentially products of nature, are living and reproduce themselves usually. In the case of patents on animals, a morality clause directs patent examiner to consider the benefits to human or veterinary medicine against any possible suffering of the animal that is a result of the genetic modification.

5. Nanobiotechnology
Nanobiotechnology, more descriptively known as molecular manufacturing, involves the design, modeling, fabrication and manipulation of materials and devices at the atomic scale. It necessitates thorough spatial control of matter at the level of molecules and atoms, with capabilities to process and rearrange them into custom designs. Biosensors, Medical application, Environmental application, and Cosmetics are some of the nanobiotechnology applications areas
6. Challenges to the nanotechnology patent processes
For small companies patents are the only protections from infringement by large corporations. As companies grow, their ability to keep trade secrets decreases and patents again become a chief method of IP protection. However, it is important to keep in mind that a patent application gets published 18 months after filing, unless the applicant opts out, in which case a foreign patent may not be pursued for the invention. Hence, unless the applicant opts out and foregoes foreign filing, the description of the invention will end up in the public domain and accessible to competitors, whether a patent issues or not.

6.1 Some Special Aspects of Drug Patent Specification
Writing patent specification is a highly professional skill, which is acquired over a period of time and needs a good combination of scientific, technological, and legal knowledge. Claims in any patent specification constitute the soul of the patent over which legal proprietary is sought. Discovery of a new property in a known material is not patentable. If one can put the property to a practical use one has made an invention which may be patentable. A discovery that a known substance is able to withstand mechanical shock would not be patentable but a railway sleeper made from the material could well be patented. A substance may not be new but has been found to have a new property. It may be possible to patent it in combination with some other known substances if in combination they exhibit some new result. The reason is that no one has earlier used that combination for producing an insecticide or fertilizer or drug. It is quite possible that an inventor has created a new molecule but its precise structure is not known. In such a case, description of the substance along with its properties and the method of producing the same will play an important role.

7. IP Management in R&D- The Global Scenario
Competition in the global pharmaceutical industry is driven by scientific knowledge rather than manufacturing know-how and a company's success will be largely dependent on its R&D efforts. Therefore, investments in R&D in the drug industry are very high as a percentage of total sales; reports suggest that it could be as much as 15% of the sale. One of the key issues in this industry is the management of innovative risks while one strives to gain a competitive advantage over rival organizations. There is high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the stringent safety standards, being terminated, sometimes after many years of investment. For those medicines that do clear development hurdles, it takes about 8-10 years from the date when the compound was first synthesized. As product patents emerge as the main tools for protecting IP, the drug companies will have to shift their focus of R&D from development of new processes for producing known drugs towards development of a new drug molecule and new chemical entity (NCE). During the 1980s, after a period of successfully
treated many diseases of short-term duration, the R&D focus shifted to long duration (chronic) diseases.

While looking for the global market, one has to ensure that requirements different regulatory authorities must be satisfied. Further, for inventions involving genes, gene expression, DNA, and RNA, the sequences also have to be described in the patent specification as has been seen in the past. The alliances could be for many different objectives such as for sharing R&D expertise and facilities, utilizing marketing networks and sharing production facilities. While entering into an R&D alliance, it is always advisable to enter into a formal agreement covering issues like ownership of IP in different countries, sharing of costs of obtaining and maintaining IP and revenue accruing from it, methods of keeping trade secrets, accounting for IP of each company before the alliance and IP created during the project but not addressed in the plan, dispute settlements. It must be remembered that an alliance would be favorable if the IP portfolio is stronger than that of concerned partner. There could be many other elements of this agreement. Many drug companies will soon use the services of academic institutions, private R&D agencies, R&D institutions under government in India and abroad by way of contract research. All the above aspects mentioned above will be useful. Special attention will have to be paid towards maintaining confidentiality of research.

8. Conclusion
The current state of the Bio-pharmaceutical industry indicates that IPR are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of risk and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. The grant of patents on minor elements of an old drug, reformulations of old drugs to secure new patents, and the use of advertising and brand name development to increase the barriers for generic market entrants are all areas in which antitrust law can help stabilize the balance between rewarding innovation and preserving competition. Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics.

Each Biotechnology R&D industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty. Bio-Pharmaceutical industry currently has an evolving IP strategy. IPR is a strong tool to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/creator an exclusive right for a certain period of time for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth.
References


