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An overview on Intellectual Property Rights in Pharmaceutical and Biotechnology Industries

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ABSTRACT

The role of Intellectual Property Rights (IPR) is very effective in pharmaceutical and biotechnology industries. In pharmaceutical industry regarding health sector it clearly defines the market price of the drugs whereas during recession most company owners were spent their money to build the R&D and also they strengthened the IPR cells. It also clearly defines the patent, patent term restoration and the change of laws which are recently adopted by other countries. Moreover it covers ever greening of patents and drug cost factor. The relation between General Agreement on Tariffs and Trade (GATT) and IPR is established. In biotechnology, IPR states the profit of biotechnology industries through intellectual property protection whereas the new trends implies in the field of biotechnology is covered. The patenting process of biotechnology is a controversial aspect through IPR. A solution was appeared and also it helped to survive biotechnology industries in India and in world.

Key words: Patent, PTR, TRIPs, Evergreening, GATT,

INTRODUCTION

Intellectual property is all about human creativities^[1]. Intellectual property rights are considered as reward for creative and skillful work in execution of ideas^[2]. In other manner, industrial property and intellectual property are closely associated sometimes ago and IP was considered as industrial property^[3]. Traditionally a number of intellectual property rights such as, trademarks and industrial designs were collectively known as industrial property^[4]. Finally we can define that the intellectual property is a “product of mind”. It is similar to any property consisting of moveable or immovable things wherein the proprietor or owner may use his/her property as he/she wishes and nobody else can lawfully uses his property without his/her permission. The different kinds of intellectual property rights could be categorized as 1. Copyright, 2. Trademark,

3. Geographical indications, 4. Industrial designs, 5. Semiconductor chips and integrated circuits, 6. Patents and 7. Trade secrets ^[5].

IMPACT OF RIGHTS ON HEALTH SECTOR:

In India because of low level income of the people, most people prefer for the local medications like ayurveda etc., and also the prices of medicines were raised too high so the common people can't afford to buy the modern medicines and antibiotics.

Moreover, many of the new medical researchers are targeting developed countries with promising profits for medicines for lifestyle diseases whereas developing countries are still in need of basic health care except three sectors i.e., food processing, pharmaceutical and agrochemicals. The Indian patent act allows product patent only. Only in these three sectors process patent is allowed, as on today. India has only process patent regime with relation to pharmaceuticals product ^[6].

PHARMACEUTICAL COMPANIES DURING RECESSION:

According to Tyron Stading ^[7], when money becomes tight, companies look for alternatives to increase their cash flow and find two paths i) product innovation, and ii) litigation. Some companies neglecting innovation or protection of innovation for the sake of cutting costs or avoiding risk will be at a disadvantage both in current downturn markets and, to a greater extent, when the economic storm passes and trading activities increase again. Companies that continue to focus on their IP assets during the downturn will definitely gain a competitive edge after it ^[8]. At the time of recession most of the pharma companies were concentrated in the field of R&D areas. As far as wockhardt limited, a renowned Indian pharmaceutical and biotechnology company, Mumbai concerned, did maximum R & D works during recession period. Its IP policy states that being a research and technology driven organization, they strongly believe in creating, maintaining and respecting IP.

However, IP budgets for most of the industries such as wockhardt was a major concern during recession budgeting. This put a lot of focus on creating the intellectual wealth, increased by 7 to 10 % and hovered in the range of Rs 15-20 crores during recession we can conclude as i) Spending in R&D and IP has not stopped during recession, ii) Innovation is the way to emerge, iii) Cost cutting in the areas where it is necessary will be helpful during recession. Since cash flow is less, investments should be limited to selected areas, and iv) There is huge concentration on maintaining only that patent which promises to generate potential products or have high market value however rest are being abandoned ^[9].

PATENTS:

The term patent can be defined as “a monopoly right conferred to the inventor who has invented a new product or process through his/her intellectual efforts capable of industrial application ^[10]. These are granted on the basis of certain requirements they are novelty, inventive step, industrial application and written description. It gives full rights to use or exploit the invention to the owner. The assignee only enjoys the rights. if the owner can assign or license the invention to the assignee. The inventor needs to disclose the invention in written form with description in order to obtain exclusive monopoly over the invention for a specific duration ^[11]. If the patent expires the invention is considered to be as public domain and anyone can use it. All inventions are not patentable; certain inventions have been prohibited from the purview of patents though satisfy all the requirements of patenting. Inventions, which are against public order and morality ^[12], are generally not patentable ^[13]

Patent law - a branch of law, which regulates the issue and maintenance of exclusive monopoly over inventions it, intends to strike a balance between the promotion of technological innovation and dissemination of its fruits ^[14]. The Paris convention on IP states that the first international attempt to protect inventions postulates for the protection of novel inventions through patents in order to encourage scientific and technological development ^[15]. Then the TRIPs agreement mandates patent protection for all inventions in all fields of technology ^[16].

PATENT TERM RESTORATION ^[17]:

Several countries have adopted the practice of Patent Term Restoration to compensate for the time lost in testing the pharmaceutical product to assure its safety and efficacy. These tests, performed after or granting of the patent, are sometimes as long as half the patent term of 20 years, leaving a short period to the company to recover its investments after launching the product in the market. The Patent Term Restoration (PTR) gives back to the patent owner time lost due to regulatory delay. In the USA, the system adopted is governed by the Hatch-Waxman Act of 1984, which provides up to a maximum restoration of five years to give a maximum effective patent life of 14 years from marketing.

In Japan, since January 1, 1988, PTR provides up to a maximum restoration of 5 years. In Europe, PTR is implemented through the system of Supplementary Protection Certificate (SPC). In the European Union, SPC was brought into effect on January 2, 1993, by Regulation No.1778/92 dated June 18; 1992. It applies to pharmaceutical products only. The SPC has a maximum term of five years to give a maximum effective patent life of 15 years from the date on which a product is authorized for the marketing in a EU country. The SPC is applied for in each of the countries where the patent exists. Korea, Taiwan, Mexico, Slovenia and Australia have adopted or are implementing laws providing PTR for pharmaceuticals.

RECENT CHANGES IN IPR LAWS IMPACTING PHARMACEUTICAL INDUSTRY:

The pre-Trade Related Intellectual Property Rights (TRIPs) era saw the world divided into group of nations i) allowing patent in all fields of technologies (products and processes) and ii) Having restrictive patent laws providing for process patents in all fields except for product patents in selected fields such as pharmaceuticals and drugs, food etc. In addition, the term of patents, conditions for compulsory licensing, whether importation should be considered as working of patents, etc., varied based on existing national laws. TRIPs attempt to harmonize the IPR laws by bringing the disparities into focus.

Since the formation of the World Trade Organization (WTO) on January 1, 1995, several nations have made significant changes in their national laws governing IPR. Proper understanding and utilization of the IPR laws in various countries would help in the global positioning of pharmaceutical companies.

The European Parliament on July 8, 1998, approved the biotechnology directive, which set the guidelines for legal protection to biotechnology products and processes within the European Union. This would markedly influence the pharmaceutical industry in Europe. It was implemented in the European Union by July 2000. However, there had been some opposition from Holland. The outcome of the opposition proceedings decided the future of the biotechnology directive in Europe. Since June 1995, USA changed the term of patents from 17 to 20 years. The practice of "first of invent" as opposed to "first to file" has been extended to all members of WTO. All patents in force on 8th June, 1995, will have a term of 20 years from the date of issue, whichever is longer. As per this provision, several patents received an extension of their term. This has had a significant effect on the pharmaceutical industry. In November 1999,

the US introduced the system that a patent specification will be published 18 months after its filing.

The Japanese Patent Law was amended on December 14, 1994, with amendments falling into two groups, one effective from July 1, 1995 and the other from January 1, 1996. With effect from July 1, 1995 the term of patents was made 20 years from the date of filing. There were other features dealing with provisions for the restoration of lapsed patents, priority-based filing in WTO Member-countries, etc. The second category, effective from January 1, 1996, was the replacement of pregrant opposition proceedings to post-grant opposition and procedures for accelerated patent processing. A few landmark judgments related to “parallel imports” into Japan and “research exemption” in the area of development of generic drugs are of significance. Further amendments were introduced in 1999 that were made effective from January 2000.

On March 10, 1999, the Indian Parliament passed a Patent Amendment Bill, which regularized the transitory “mail-box provision” (with effect from January 1, 1995) to file product patents for inventions relating to drugs, pharmaceuticals, agrochemicals and to grant “exclusive marketing rights” in these selected fields only. Other changes in the Patent Act, 1970, have been introduced to meet the immediate obligations of TRIPS such as the withdrawal of Section 39 that required inventions in India to be first filed in India before being filed elsewhere, considering importation as the working of an invention in India, etc. A second patent amendment bill (1999) was introduced in the Parliament in December 1999 to meet all the other obligations of TRIPS. This is presently under review. India also joined the Paris Convention and the Patents Cooperation Treaty on December 7, 1998.

In Spain, the patent law was amended in January 1998 to remove the requirement that pharmaceutical companies must make the patented product in Spain before an injunction would be granted against an accused infringer. Now it is getting easier to obtain interim injunctions from Spanish courts.

In Argentina, the 1995 Patent Law brought provisions in line with TRIPS to make the term of patents 20 years from the date of filing, rather than 15 years from the granting date. The problems of where the old patent law ends and where the 1995 legislation starts have not been satisfactorily resolved.

The Australian Patent Act was changed on August 10, 1998, to give pharmaceutical patents an effective term of 20 years to bring them in line with the laws in USA, Japan and Europe. The most significant provision in Australia for pharmaceutical patent owners has been the extension of patents to give an effective term of 15 years, where product registration requirements have held up the introduction of the product to the market.

IPR AND INDIAN PHARMACEUTICAL INDUSTRIES:

After the GATT changed into WTO, most of the developed countries were awakened to protect their products. Initially most of the world leading pharmaceutical industries built a separate cell for IPR and regulated very well. So the profit of the companies were increased and IP played a major role in controlling the counterfeit and copycat drugs. But in India that time only pharma companies were plan to set their IP cell some of the companies in India established the IPR cell in the year 1995. Majority of the companies started IPR cell after 2000 in India. By the end of year 2004, majority of companies started a separate department to look after the issues related to patents. It can be safely presumed that the patents that are granted to Indian pharma companies or applied by these companies are for either new processes or new drug delivery systems^[18].

EVERGREENING STRATEGY IN PHARMACEUTICAL INDUSTRY:

So many number of strategies have been followed by the innovator companies to extend the term of patent, like methods of treatment, mechanism of action, packaging, derivatives, isomeric forms, delivery profiles, dosing regimen, dosing range, dosing route, combinations, screening methods, biological targets and field of use. These strategies involve skilled addition of patents to the product by the innovator companies that force the generic manufacturer to maintain forbearance for all the patents to expire and applying for marketing authorization bearing the risks of litigation and associated penalties and delays^[19]. The innovator companies in the name of life-cycle management maximize revenues from their so called evergreen products and also choke their generic competition at the outset of product life-cycles. Even though strict strategies are followed still most of these companies represent misuse of pharmaceutical patents and regulations governing authorization.

Ever greening strategies that have been usually followed by the pharmaceutical industries involve: a) redundant extensions and creation of next generation drugs which result in superfluous variation to a product and then patenting it as a new application, b) prescription to OTC switch, c) exclusive partnerships with cream of generic players in the market prior to patent expiry thus significantly enhancing the brand value and interim earning royalties on the product, d) defensive pricing strategies practice wherein the innovator companies decrease the price of the product in line with the generic players for healthy competition and e) establishment of subsidiary units by respective innovator companies in generic domain before the advent of rival generic players^[20].

PATENTING AND PHARMA RESEARCH COST:

Pharmaceutical organizations pour resources into R&D of various molecules for the benefit of mankind. The development of a pharmaceutical goes through a series of permutations and combinations resulting in uncertainties which could be many and substantial. Maximizing the certainty that a research-based manufacturer can obtain enforce, defend, and make full, legitimate use of IP rights is essential to maintain the cycle of innovation for the benefit of public health. In the absence of strong IP rights at each stage of the innovation cycle, promise of pharmaceutical innovation could be lost^[21].

Pharmaceutical products often rely on substantial amounts of upfront investment and technical knowledge and for the resources involved, companies eventually secure patents for every product they develop. The pharmaceutical companies screen large number of molecules and out of the thousand potential drugs screened, only 4-5 reach clinical trials stage form, of which finally one is approved for marketing. It costs on an average around 800 million dollars to develop and test a new drug before it is approved for use. In the case of pharmaceutical companies, monopolies over the fruits of their R&D efforts are vehicles through which they could recoup huge investments. The costs of research done on screening out the molecule and taking into clinical trial stage are recovered through appropriate pricing mechanisms from the patients who receive the patented drugs. Providing market exclusivity to an inventor through patent protection can encourage the initial outlay of resources needed to develop the products^[22]. Capital investment by the innovator companies in the development of new molecules which have reached the stage of marketing also encourage the challenge to invest more in further research, development and refinement of related innovations to expand and improve therapies and cures. Moreover due to innovation in providing products of medicinal importance, patent protection on the same creates a platform wherein generic companies compete with research oriented innovator companies following the expiration of IP rights. After the patent on a drug expires, any pharmaceutical company can manufacture and sell that drug. Since the drug has already been

tested and approved, the cost of simply manufacturing the drug will be a fraction of the original cost of testing and developing that particular drug. e.g. Lamictal is an anticonvulsant medication (active ingredient: lamotrigine) sold by GlaxoSmithKline (GSK) for use in the treatment of epilepsy in adults and children. Lamictal is indicated as adjunctive therapy for partial seizures, generalized seizures of Lennox-Gastaut syndrome, and primary generalized tonic-clonic seizures in adults and pediatric patients. Lamictal is indicated for conversion to monotherapy in adults with partial seizures who are receiving treatment with carbamazepine, phenytoin, Phenobarbital, primidone, or valproate as the single AED. GSK had applied the patent for the active ingredient in 1980 which expired in many countries in 2000. Lamictal is marketed as chewable/dispersible tablets which may be swallowed, chewed or dispersed in water or diluted fruit juice (swallowing the resulting liquid dispersion). GSK also applied for a patent in 1992 for the chewable/dispersible tablet formulation of lamotrigine which will expire in most of the countries in 2012. The chewable tablets have the advantage of providing ease of use and compliance to patients. An earlier patent claiming lamotrigine as the active ingredient had already expired in many European countries. This provided the scope of use of the particular patent in European territories. It could be comprehended that any generic manufacturer could make the formulation and compete with the innovator product. Several such generic products are being sold, and it depends on the market that has the option to choose between the original GSK product and a generic version.^[23]

GATT AND THE INDIAN PHARMA INDUSTRIES:

With the advent of the product patent era, as required by his/her obligations under the WTO's mandate, India can no longer produce and market patented products in any country where valid product patents exist. During the last four decades nearly, since the advent of IPA 1970 (operative since 1972), Indian companies launched patented drugs in India within 3 years of their first launch by innovator companies at prices one fifth to one tenth of their patented versions. In the new era, Indian companies have to rely on manufacturing and marketing generic (off patent) drugs unless they get licenses from the patent owners. If they are to launch new drugs, they need to develop strategies, skills and adequate resources to enter the drug discovery and development area. The top 15 Indian companies have already initiated major efforts in this area fully realizing that it is indeed a very expensive, long gestation and high risk activity with little guarantee of success. Total investments of the order of around a billion dollars are being expended annually which, however is still less than one sixth of what Pfizer spends annually on R&D^[24].

BIOTECHNOLOGY:

Biotechnology is a study relating to the practical application of living beings in different fields^[25]. Basically it is a study relating to living organisms in the industrial utilization^[26]. It is the technology, which uses living organisms or its parts for specific commercial use^[27]. Now-a-days it is being used in different fields for better results^[28]. The new emerging field pharmaceutical biotechnology is developing rapidly for those people working in the field of pharmacy and pharmaceutical sciences, completely new and novel techniques and product appear at a rapid place^[29]. This is the result of interplay between a number of different areas like molecular biology, molecular genetics, chemistry and pharmaceutical sciences^[30].

IPR AND BIOTECHNOLOGY:

IP protection in the sphere of biotechnological invention is emerging as a subject matter of fierce debate at national and international level. The inventions in biotechnology cut across Issues related to science, technology policies, ethics, economics, legal regulations and complexities of international trade^[31]. The total worldwide sales of biotechnology produced pharmaceuticals continue to increase fast. For instance in 1990 US sales amounted to approximately \$2 billion,

sales increased to \$ 5.1 billion in 1994 and \$7.7 billion in 1995 whereas it reaches \$16 billion in 2002^[32]. At last the IPR helpful for new business opportunities and for value adding knowledge based industry it is high time that India rapidly adapts to the challenges posed by a continuously evolving technological environment of the world^[33].

NEW TRENDS IN BIOTECHNOLOGY:

Biotechnology plays a major role in three areas viz., i) plant breeding, ii) animal breeding and iii) industrial microbiology. The new inventions like rDNA technology, protoplast fusion technology and hybridism technology play a vital role in plant, animals and human life. These technologies have been employed in the production of genetically engineered organisms and altered genes DNA falling in the area of genetic engineering, protein engineering, cell fusion, tissue culture, gene therapy, genetically modified organism (GMO) and fermentation technology. Other important mark in biotechnology like cloning of mammals i.e., recent claim of human cloning has taken whole world by surprise and disguise. Cloning of human beings is still a gray area of creative genius of bio-scientist surrounded by host of ethical and legal issues^[34].

BIOTECHNOLOGICAL PATENTING PROCESSES:

Non-natural or genetically modified living beings are the results of non-natural and genetically modified biological processes. In *hybertech Inc v. monoclonal antibodies Inc.*,^[35] a patent was claimed for process of utilizing proteins to fight against diseases. The inventors convinced the court that the method is a non-natural since it utilized proteins produced inside the body on human prescription and obtained patent. In *re wands*^[36] patent was granted on a process of detecting viruses causing hepatitis-B disease. In *re Farrell*^[37] invention was a process to produce foreign proteins in bacteria in a non natural way. Wherever, in Europe *Chiron corporation case*^[38] upholding the new trend of patent law a patent was granted on a process of producing proteins through *in vitro* propagation of Hepatitis C virus in a natural and biotechnological way. Recent patent law states that non natural life; living beings and non-natural living processes are patentable. Biotechnological and microbiological processes are non-natural processes, which involve addition of human intelligence to the natural processes in producing non-natural and genetically modified living beings.

BIOTECHNOLOGY INDUSTRIES IN INDIA:

Like software companies, biotechnology companies' role in Indian economy is a prestigious thing. In 2008-09, the Indian biotech industry had a total turnover of US \$2.51 billion comparing to US \$2.13 billion during 2007-08. In recent times, India is emerging hub for biotechnology industry and one of the important sector receiving outsourced jobs from abroad^[39]. This sector stands 4th position in volume and 13th in terms of value. This sector had a rapid growth rate of 40% with an annual turnover of US \$1.07 billion in 2005 and a recorded growth of 36.55 %^[40].

CONCLUSION

IPR in the pharmaceutical company scenario plays a vital role in the patent filling, legally punishing the counterfeit drug manufacturing industries and establishing the industry name in the market for their drug safety and quality. Whereas in India it increased awareness regarding patents which helped companies file patents in lucrative markets and international treaties that were done will be helpful to Indian companies with respect to filing multiple applications. While in the field of biotechnology, response of IPR had a huge role in protecting plant, animal and human welfare. For coming years GMO will be the great supplement of proteins to the human life. Hence these are legally protected whereas the hazardous activities like cloning are strictly banned in human with the help of IPR.

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