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Patent Law and Biotechnology

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ABSTRACT

A Patent is an exclusive right granted to an inventor to protect their invention without secrecy and to exploit it to the exclusion of others for a period of 20 years. A patent can be considered one of the most important form of Intellectual Property Rights, having tremendous economic value. Patents have a vast history and the laws regarding them keep on evolving over the years depending on the need of the society and the pace and technicality of the innovations. In India, the Patent law is governed by the Patent Act, 1970 as amended by the Patents (Amendment) Act, 2005, and Patents Act RULES, 2006. Biotechnology has emerged to become an important tool for many researchers and the inventions arising out of it have spurred the creation of many inventors along with playing an important role in improving the nation's health. It becomes impertinent that the rights of these inventors are protected and therefore, many biotechnological inventions related to pharmaceuticals, microorganisms and transgenic animals have been granted Patent protection all over the world.

This paper aims to analyze the Patent law pertaining within India focusing mainly on the effect of the same on biotechnological inventions. It throws light on the patenting in the pharmaceutical industry, micro-organisms, and transgenic animals and how a check is maintained on the abuse of patent law by compulsory licensing.

Keywords: *Patent, Biotechnological Inventions, Pharmaceutical Industry, Micro-Organisms, Transgenic Animals, Compulsory Licensing.*

I. INTRODUCTION

A Patent is a legal document that is granted by the government to an inventor for their invention of a new product or a process that provides a new method for doing something or a new solution for a problem. It gives the inventor the sole right to exploit their invention for a limited time, which is usually for twenty years, in exchange for a detailed public disclosure of the particular invention. The goal is to award the inventor with the special rights to benefit from their inventions. It is a way of protecting an invention without the need for secrecy. Patents prevent the imitators and even independent divisors of the same idea from making use of the invention

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or selling it until the duration of the patent is over. A patent is a cartel right as it grants an exclusive monopoly to the patentee for twenty years after which it falls into the public domain and available to others for commercial exploitation. However, the patent owner has the authority to give permission or license to the other parties to use their inventions on terms that are agreed upon by each other. The owner can also sell their rights on the invention to any other person, who then becomes the owner of the patent. Patents have a very extensive history and the law regarding them has also evolved with time, depending on the advancement of technology and the needs of the society.

II. HISTORY

The history of patents in India goes back to the time when India was still a colony of the British empire, thus, the first act on the protection of inventions in India i.e. Act VI of 1856 was based on the British patent law of 1852. It was later modified in 1859 to grant certain exclusive privileges to the inventors. Later, The Patterns and Designs Protection Act, 1872 and the Protection of Inventions Act, 1883 were passed and subsequently merged into the Inventions and Designs Act, 1888.

The Indian Patents and Design Act, 1911 replaced all the previous acts related to patent law and brought patent administration under the management of the Controller of Patents. However, after the independence, it was found that this act failed to fulfill its objective and it was decided that the substantial changes in political and economic conditions of the country calls for a more comprehensive patent law. Thus, a committee was constituted under the Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 to review the patent law in India and to ensure that the patent system is conducive to the national interest. Based on the recommendation of this committee, the Act of 1911 was amended in 1950. In 1957, Justice N. Rajagopala Ayyangar committee was formed to examine the question of revision of Patent law and to advise the government accordingly.

The contributions and recommendations made by both these committees led to the formation of the Patents Act, 1970 which came into force on April 20th 1972 with publication of the patent rules, 1972. In order to make some modifications and to bring the Act in line with international instruments such as the TRIPS agreement, subsequent amendments were made in 1992, 2002, and 2005. The Indian Patent Act handles both products as well as the process.

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III. PATENT RULES

The Central Government, under the provisions of section 159 of the Patents Act, 1970 is empowered to make rules for implementing the Act and regulating patent administration according to which the Patent Rules, 1972 were notified and brought into force w.e.f. 20.4.1972. Thereafter, these rules were amended occasionally till 20th May 2003 when new Patent Rules, 2003 were brought into force. They were further amended by the Patents (Amendment) Rules, 2005, and the Patents (Amendment) Rules, 2006.

IV. WHAT CAN BE PATENTED?

The Patent Act, 1970 grants patent to the inventions that meet the three prerequisite tests. The first requirement of the test is that the invention should not exist previously i.e. it must be novel. Second, the invention must be a significant improvement to existing technology and thus, it must be non-obvious and not merely a simple change to previously known devices. Lastly, the invention must be useful which can be interpreted t the idea that no patent can be granted for inventions that can only be used for illegal and immoral purposes.

The Indian Patent Act does not expressly state which kind of inventions are eligible for patent but rather defines the eligibility for a patent in a negative sense which means that instead of stating what is patentable, they lay down a category of inventions that are not patent-eligible under clause (a) to (p) of section 3 of the act.

V. CAN AN IDEA BE PATENTED?

The patentability of an idea is one of the most controversial, arguable, and hardest questions a patent lawyer has to regularly respond to in almost every meeting with a passionate Entrepreneur. However, there is no clear solution to this query because the solution to this question may vary from one idea to another. The Patent Act, 1970 does not mention if an idea can or cannot be patented. In order to get a patent, the discovery desires to be novel, industrially beneficial, and non-apparent to someone who is a professional in that art and an idea is capable of meeting all three of these requirements.

Section 10 of The Patents Act 1970 provides certain must-haves for submitting a patent application and mentions in it that a patent application may be filed as a provisional or a complete specification. Under this section, ideas can be patented provided that they meet certain specific criteria. The idea must have practicability and the potential to be changed into a full-scale invention, without which, one cannot apply for a provisional application. After describing the idea and filing for a patent in the provisional application, one can work out a

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way out with a technique for its performance within 12 months of filing the provisional application and then subsequently file the complete application.

VI. PROCEDURE

1. **Disclosure of the invention**: The first step is to disclose your invention to a professional. This is done by signing a non-disclosure agreement. One must submit all known facts about their invention and not miss anything.
2. **Search for patentability:** Usually, a professional charges a fee for this step which is approximately INR 10,000 to INR 20,000. At this stage, the professional will conduct a thorough investigation to obtain prior evidence in all possible databases. They will also prepare a patentability report based on the invention
3. **Decision to apply for a patent:** After a detailed examination of the (possibly) existing history of the invention, one can decide whether they want to proceed with the patent application. It must be noted that the invention must be compared to existing prior artworks to qualify for a patent. Therefore, it must be 'technically advanced' or 'economically significant' or both on an existing work of art.
4. **Patent Drafting:** An application can be prepared by either the inventor or a professional. A fee between INR 20,000 and INR 30,000 is to be paid to a professional. This is one of the most important steps in the whole process and requires technical and legal knowledge.
5. **Filing the patent application:** One can submit the patent application in the prescribed manner using the appropriate forms, subject to a fee of INR 1,600 or INR 4,000 or 8,000 depending on the type of application. These are payable for filing the patent application with the Patent Office. If a request is not submitted for an early publication, the patent application will be published within 18 months.
6. **Request for examination:** This is the step where the applicant is required to request the Indian patent office to examine the patent application, within 48 hours and the request for examination fees ranges from INR 4,000 to INR 20,000.
7. **Responding to Objections:** This step thoroughly examines the draft and report that will be presented to the Patent Office officials. In this step, the inventor has the opportunity to apply their novelty or inventive step to any other work of art found during the appraisal.
8. **Granting of the patent:** If the application meets all the prescribed requirements; it will be released for grant and will be announced by a published magazine.

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9. **Renewal of the patent:** A patent is usually valid for 20 years. After a period of 20 years, the owner must renew the patent in exchange for a small fee.

VII. BIOTECHNOLOGICAL INVENTIONS

Biotechnological inventions mention the technique which includes living organisms, or any part of them/components, etc, to create or to refine the products or to make them better or transform certain or all features of plants, or animals to develop microorganisms, and organisms intended for specific uses. Biotechnological inventions are used in a wide range of fields including agriculture, agro-industry, fertilizers, the food industry, diagnostics, zoo techniques, semiconductors, pharmaceuticals, the refuse industry, fuel, chemistry, etc. However, for Biotechnological inventions, everything set aside, what's already been laid down, the norms relating to the patent of inventions are applied. Further, the life sciences and pharmaceutical sector have had a great influence on life expectancy and the quality of life. Now, most modern medicines are based on biotechnology.Inventions relating to process or methods of production of Tangible and Intangible substances (enzymes, antibiotics, insulin, interferon, alcohols, vaccines, etc) by using such microorganisms or by utilizing the above biologically referred chemical substances produced by using genetically engineered organisms and substances, were made more economically by the use of biotechnologically and/or micro biotechnology under the patent act 1970.

In inclusion to granting patents of products such as drugs, DNA, antibodies, the Patent Offices also grants patents to methods of doing things and processes for making things. The claims of these patents will reflect the steps which are to be taken in the invention's method or process.

Biotechnological inventions have given the ability to exploit genes, proteins, and organisms. It has the potential to change the way diseases are diagnosed & treated, our food is produced, our energy is generated, and how we deal with our waste. The authenticity of biotechnological inventions is judged in the same way as other inventions: the invention must be novel, non-obvious, and capable of industrial use.

The pharmaceutical sector is linked to economic activity focused on research and manufacturing and promoting drugs, and biotechnology means any technological inventions that use biological material to create or update products or processes.

Apart from all this, one of the major biotechnological items that cannot be patented is DNA, because Genes are identified as discrete units of a DNA segment that encode the whole individual body. The data encrypted in one's genetic code is probably the future diary of an individual because it describes a reclusive character of personal future. Taking of DNA samples

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intrudes into three forms of individual privacy: bodily privacy, wherein cases the sample is taken from a person's body; genetic privacy, where anticipatory health and other information about the person is obtained from that DNA sample; and behavioral privacy, where the data is used to decide where a person has been and what he has done. Gene patenting and gene sequence may interfere with rights of privacy as it allows to hinder a body part. Genes are the base of human life and part of each cell in the body. The aspect of privacy could be violated by allowing gene patent rights. Gene patenting critics point to the privacy infringement innate in giving ownership interests in which every individual is a part-owner merely for the dignity of a human being. Patenting of Gene may violate basic principles of individual and collective privacy.

VIII. PATENT IN PHARMACEUTICAL INDUSTRY

The Pharmaceutical industry in India is ranked as the fourth largest in terms of production and 13th largest in terms of domestic consumption value thus marking it one of the largest Pharmaceutical industry in the developing world. Over the past 30 years, it emerged from being almost non-existent to a world leader in the production of generic drugs. The Indian Patent Act of 1970 allowed the Indian drug manufacturers to increase the supply of less expensive copies of the world's best selling patent-protected drugs by becoming experts in the field of reverse engineering. All this was possible only because there was no products patent system for drugs and medicines although the act of 1970 did provide an exception in section 5(which has now been omitted by the act of 2005) by offering process patent for foods, medicines, or drug substances but specifically excluded product patents for the same. Thus India was able to copy patented drugs without paying a license fee which made it possible for the industries to make the drugs available to the masses at reasonable prices.

This scenario changed after the amendment of 2005, which was introduced in order to comply with Trade Related Aspects of Intellectual Property Subjects (TRIPS). This amendment thus introduced the patent of pharmaceutical products and extends full TRIPS coverage to food, drugs, and medicines. It also extended the term for patent protection to 20 years as compared to the 7-year term provided by the act of 1970. The introduction of product patent was done not to discourage the bulk generic drug production at cheap prices but to encourage innovation of new and more effective drugs in India and provide an alternative solution to counter the problem of access to medicines.

The product patent, however, brings to light the issue of higher prices for drugs for the public and abuse of rights by the patent holder who can do so by not commercializing their invention

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or manufacturing it in the richer countries to earn more revenue. In order to counter such abuses of patent rights, TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) gave the provision of compulsory license so as to keep a check on the use of the invention on grounds of public morality.[3]

IX. COMPULSORY LICENSING

When the government allows a third party to carry out the same rights as the patent holder without his consent then it is called compulsory licensing. It is an authorization given to a third party by the Controller General to make, use or sell a particular product or use a particular process that has been patented, without requiring the permission of the patent owner. Compulsory licensing keeps a check on the abuse of patent rights and helps in resolving the conflict of interest between two parties, thus, ensures development and fair returns. The system of compulsory licensing is recognized at both international and national levels and has an express mention in the TRIPS Agreement and Indian Patent Act, 1970. Section 84 of the act states that after the expiration of three years from the date of grant of patent any person may make an application for grant of compulsory license on fulfillment of three conditions:

1. that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
2. that the patented invention is not available to the public at a reasonably affordable price, or
3. that the patented invention is not worked in the territory of India.[4]

Under section 92 of the patent act, 1970, a compulsory license can be issued suo moto by the controller under after a notification issued by the Central Government if there is either a national emergency or extreme urgency or in cases of public non-commercial use.

The first compulsory license in India was granted by the Patent Office on March 9, 2012, in the case of Natco Pharma Ltd. v. Bayer Corporation[5]. In this case, Natco Pharma was granted the compulsory license for the generic production of Bayer Corporation's Nexavar, a life-saving medicine that was used for treating Liver and Kidney Cancer. Where Bayers was selling this drug at exorbitant rates, with one month's worth of dosage costing around Rs 2.8 Lakh, Natco Pharma offered to sell it around for Rs 9000 making it affordable for people of every stratum. Thus, all the 3 conditions of section 84 were fulfilled and the decision was taken for

[3] Love J, Recent examples of compulsory licensing of patents, KEI, Research Note 2007:2.
[4] Patents Act,1970, Section 84, cl. 1.
[5] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, 40 (Intellectual Property Appellate Board), Chennai

the benefit of the general public.

Compulsory licensing is an exception and provides flexibility to the general rule of Patent. It neither provides full patent protection nor does it deny the same. It directly affects innovation funding and has become the hope for financially challenged patients in underdeveloped countries.

X. PATENT OF MICROORGANISMS

A microorganism is a microscopic organism, recognized to be one of the earliest life forms on earth. Viruses, fungi, bacteria, archaea, protozoa, and algae are the six prime forms of micro-organisms, utilized swiftly by biotechnologists and micro-biologists for analysis purposes. From beer brewing, bread making to lump production of antibiotics, microorganisms are used in all such processes by the scientists to reach the required results.

In 1970, the Indian Patents Act added micro-organisms under the sight of patentability through the Patents (Amendment) Act, 2002, in conformity with the TRIPS. TRIPS makes it mandatory for all its signatories to extend patents for microorganisms, non-biological, and microbiological processes

The important judgment of the Calcutta High court in the case of **Dimminaco A.G. v. Controller of Patents & Designs**[6] on 15th January 2001, just before the 2002 amendment in Indian Patent Act, 1970 set the new level in the field of microbiological research. In this case, a plea was filed against the Assistant Controller of Patents & Designs, In this procedure for the devising of infectious Bursitis, the vaccine was declined because the procedure of devising of vaccine that holds a living virus cannot be considered, build, and that a vaccine involving of an active virus cannot be considered a substance or inactive object. The court, in this case, reversed the verdict of the Assistant controller and held that, the procedure of preparing a vendible commodity containing an active substance is not excluded from the sight of the word, 'manufacture' and that the controller misjudged in denying patent protection to the vaccine just because it contained a live virus. Either way, the finished product was novel, capable of industrial application, and was useful for protecting poultry against contagious Bursitis infection, thus making the procedure an invention. The court further sanctioned the appeal and managed the petitioner's patent application to be review within 2 months of the publication/delivery of the verdict.

In the latest Supreme Court's judgment in the case of, Monsanto Technology Pvt. Ltd. v.

[6](2002) I.P.L.R. 255 (Cal).

Nuziveedu Seeds[7], The plaintiff professes that their patent in the man-made, chemical product called NAS(Nucleotide Acid Sequence) containing the gene Bacillus thuringiensis (Bt gene), able to kill bollworms when put in cotton, and it was not an infringement under section 3(j) of the patents act, 1970, as held by the Division bench of the Delhi High Court. Nuziveedu claimed that NAS was just a chemical composition that is not able of reproduce and is not a man-made inventive micro-organism, competent of industrial application. The Supreme Court in this case put aside the order of the division bench and reinstated the order of the single bench and reverted the matter to the single bench of the Delhi High Court to be marked based on specialist advice and evidence, who had said that, the assertions on NAS were correctly entertained by the Indian Patent office and that the parties shall remain intact to their sub-lease agreement.

XI. PATENT OF TRANSGENIC ANIMALS

The first animal patent was released in April 1988 to Harvard University for a particular type of mammal, namely the Harvard oncomouse, genetically contrived to obtain cancer-causing gene. The oncomouse has been genetically contrived to carry a particular type of gene called the oncogene which makes it dangerous to cancer and hence makes it perfect for cancer research, lately the USPTO put out that it would think about non-natural occurring non-human, multi-cellular organisms, which includes animals to be a patentable subject matter under its laws.

Most of the patents related to animals have been given to transgenic animals build by recombinant DNA or genetic engineering. Transgenic animals have DNA that has been altered by including DNA from another source other than the parental germplasm, usually from different animals or humans.

Genetically build animals are used in the agricultural, pharmaceuticals, and biomedical research industries. These industries all incur high research and development costs because huge investments of time and money are required before there is a finished product. The only pragmatic way to retrieve funding is by the protection of Patents. The patent holders may retrieve their funding through royalties. While other forms of security are available, they are not as authentic. For example, trade secret protection only protects an invention that has not become public and does not safeguard it from others creating the same invention. Thus, an investor who depends on trade secrets risks the chance that someone else will form a similar invention and will be able to take some of the market shares away from the original inventor.

[7] Monsanto Technology LLC v. Nuziveedu & Ors, AIR 2019 S.C. 559(India)

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For animal patents, in particular, a subsidiary goal is to promote research and development in grasping and fighting disease[8]. Also, granting animal patents will promote industry-wide revelation of important biotechnological research developments. The main applications for transgenic animals are in the pharmaceutical, agricultural, and medical research industries. These industries are critical to the development of LDCs because two of the biggest problems faced by developing countries are starvation and disease. Protecting animal patents for the advancement of the pharmaceutical industry can promote the availability of medicines because many pharmaceutical products come from transgenic animals. Protecting animal patents for medical research will assist the health of citizens through an acknowledgment of disease and the means for treating disease.

XII. CONCLUSION

The Patent Act gives no proper definition of patentable subject matter, providing only a list of non-patentable items. Unfortunately, these exceptions can be indistinctive, leading sometimes to unpredictability and this is mainly true for biotechnology inventions, due to the confusing nature of the technology. Innovators, investors, and patent practitioners must see through their inventions in light of Indian patent law before making any plans regarding patenting in India. In the worldwide scenario, the TRIPS agreement makes it compulsory to give patent protection to microorganisms and non-biological and microbiological production of plants and animals. This makes it difficult for the developing countries to not involve the inventions within this category altogether. Therefore, the strategy should be how to control the scope of these provisions. As far as the patent protection of microorganisms is concerned, TRIPS do not furnish a definition of microorganism. Compulsory licensing plays a vital role for underdeveloped or developing countries. The resources which are not available in a particular country can be an essential requirement for that country. Medicine is a major need for society and if a patented drug is available in a country but is very costly, that a normal person cannot afford it, then the government of that country has to do something for the people who are not able to afford it. Here, the compulsory license plays a major role. Compulsory licenses will make similar products available to the people who cannot afford that drug.TRIPS agreement for public health was the primary step by WHO to safeguard the people from illness and diseases which is common in countries but the medicine is not available. Patenting in the case

[8] JUDITH CURRY, THE PATENTABILITY OF GENETICALLY ENGINEERED PLANTS AND ANIMALS IN THE U.S. AND EUROPE: A COMPARATIVE STUDY (1987); Michael B. Landau, Multicellular Vertebrate Mammals as Patentable Subject Matter Under 35 U.S.C. § 101: Promotion of Science or an Open Invitation for Abuse, 97 DICK. L. REV. 203, 216-17 (1993)

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of trans generic animals is also very important because the main applications for transgenic animals are in the pharmaceutical, agricultural, and medical research industries, therefore Protecting animal patents for the advancement of the pharmaceutical industry can promote the availability of medicines because many pharmaceutical products come from transgenic animals. Thus, Patent plays a vital role in protecting the rights of an inventor, entrepreneur, practitioner, or everyone who comes up with an idea that fulfills the basic essentials required to file for a patent and safeguards the ideas, innovations, productions from getting exploited.

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