

Patenting: Product of Nature

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I. ABSTRACT

The history of mankind is replete by various revolutions and past century has witnessed a drastic development in the field of technology ranging from industrial revolution to the development of the information technology and yet one of the most advanced technologies of this century being the BIOTECHNOLOGY, this technology is a culmination of human inventions and natural processes. Biotechnology is not believed to be a new concept since as per Sans the technology had been a part of mankind ever since the ancient times earlier in the form of fermentation process in order to produce and protect food for a longer duration and in present the same fermentation coupled with genetic engineering is called biotechnology thus leading to a conclusion that the only difference is of the nomenclature and not of another technological development. With this conclusion we come to another important aspect of this century of development that is the identification of any object where in ancient Greek the cooks were given a special right when developed a new recipe that they were to grant permission to others in return of some sort of profit for other to enjoy the recipe and today the similar is given the concept of Intellectual Property Rights inclusive of copyright or patent whichever applies.

However whatever heights the humankind achieves or whatever milestones technological world achieve law is watching and governing everyone at every lapse of the journey to the zenith. Law is the clutch to the machine like society and is a watchdog to the humankind i.e. whatever distances the development crosses it shall always fall under the purview of Law.

Here in this paper author has dealt with the importance of Intellectual property Rights in the field of Biotechnology and how these laws have developed facing an enormous amount of criticism with the help of certain case laws, later in the paper authors have dealt with the ethical point of view with regards to the patenting of Biotechnological innovations also TRIPS agreement and it's take in the Biotechnological arena has been explained.

Methodology: *The author by qualitative and quantitative forms of research has tried to analyse the role of Intellectual Property Rights in the field of Biotechnology and how the ethical arguments has taken form with regards to the same with a special reference to the TRIPS agreements.*

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II. INTRODUCTION

In today's world of development nothing is out of the purview of law i.e. law has been the watchdog to the mankind keeping everybody in check and protecting one from the other. Now when the world is leading to development and a number of inventions are introduced to the mankind there is also a great chance of having chaos on the identification of the object and to which the importance of intellectual property rights is deemed necessary and with reference to this paper narrowing down the focus to the importance of Intellectual Property Rights in the field of Biotechnology.

Intellectual property, comprehensively, implies the lawful rights which result from intellectual activity in the industrial, scientific, literary and artistic fields. Nations have laws to ensure licensed innovation for two primary reasons. One is to provide rights to the originator or creators for their creativity and also do provide right to public to get access of it. The second is to advance, as a ponder demonstration of Government approach, imagination and the scattering and use of its outcomes and to empower reasonable exchanging which would add to financial and social improvement. As a rule, licensed innovation law goes for protecting makers by giving them certain time-constrained rights to control the utilization made of those creations.

The Convention Establishing the World Intellectual Property Organization (WIPO), concluded in Stockholm on July 14, 1967 (Article 2(viii)) provides that "intellectual property shall include rights relating to: - literary, artistic and scientific works, - performances of performing artists, phonograms and broadcasts, - inventions in all fields of human endeavor, - scientific discoveries, - industrial designs, - trademarks, service marks and commercial names and designations, - protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields."

Since scientific developments fall under the subject matter of patent laws here in this paper a particular field of science i.e. biotechnology is taken into consideration. "Biotechnology" is merely a new term from an ancient idea, the idea of technology based on the use of other living things³ i.e., technology based on biology, especially when used in agriculture, food science, and medicine. The UN Convention on Biological Diversity has come up with one of many definitions of biotechnology: "Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." Traditional pharmaceutical drugs are small chemicals molecules that treat the symptoms of a disease or illness - one molecule directed at a single target. Biopharmaceuticals are large biological molecules known as proteins and these target the underlying mechanisms and pathways of a malady;

³ Iver P. Cooper, *Biotechnology And The Law* 1-1, (1sted.,2014)

it is a relatively young industry. They can deal with targets in humans that are not accessible with traditional medicines. A patient typically is dosed with a small molecule via a tablet while a large molecule is typically injected. Small molecules are manufactured by chemistry but large molecules are created by living cells: for example, - bacteria cells, yeast cell, animal cells. Modern biotechnology is often associated with the use of genetically altered microorganisms such as E. coli or yeast for the production of substances like insulin or antibiotics. It can also refer to transgenic animals or transgenic plants, such as Bt corn. Genetically altered mammalian cells, such as Chinese Hamster Ovary (CHO) cells, are also widely used to manufacture pharmaceuticals. Another promising new biotechnology application is the development of plant-made pharmaceuticals.

Biotechnology in some frame has prospered since ancient occasions. At the point when the primary people understood that they could plant their own products and breed their own creatures, they figured out how to utilize biotechnology. The revelation that organic product juices matured into wine, or that drain could be changed over into cheddar or yogurt, or that lager could be made by aging arrangements of malt and jumps started the investigation of biotechnology. At the point when the main cooks found that they could make a delicate, light bread as opposed to a firm, thin wafer, they were going about as juvenile biotechnologists. The principal creature reproducers, understanding that distinctive physical qualities could be either amplified or lost by mating proper sets of creatures, occupied with the controls of biotechnology.

III. EVOLUTION OF PATENT LAWS IN BIOTECHNOLOGICAL ARENA

In early days patents on living organisms were rejected on the ground of the being natural product as per doctrine of Nature the philosophy behind the entire process of rejection was that living beings were products produced by nature ,which belonged to all beyond the monopoly of anybody.⁴

In Funk Brothers Seed Co. V Kalo Inoculants co.⁵ the claim was a mixed culture of different strains , each of which was useful in the inoculation of roots of various specious of leguminous plants which were helpful in the nitrogen fixation (various types of root- nodules were present in nature), the applicants tried to combine the various species in order to develop a mixed culture suitable for inoculation of a wide variety of crops thought the attempts failed since the species inhibited each other's effectiveness in combination.

The USSC invalidated the patent claim on the grounds of product of nature. It was held by the court that the subject matter of the patent claim was a product of nature and there were no efforts made in order to change its status from natural product to a man-made product and the only body that has a right over natural products is

⁴Dr. Sreenivasulu.N.S. & Dr. Raju.C.B., Biotechnology And Patent Law, Pp.22-23 (1st Ed., 2008), Manupatra Publications

⁵ 33 Us 127(1948)

GOD. The Supreme Court held that the products of nature did not fall under the purview of patentable subject matter.

In *Diamond V. Chakraburty*⁶ the patent claim was made for both process and the final product of genetically modified micro-organism which was capable of eating the crude oil spills. In this case for the first time in the history of patent law a question as to a natural object can be patented or not was raised. The claimant i.e. Chakraburty was granted patent on the trade secret or the process but no patent was granted on the actual bacteria developed on the ground of being a natural product which did not fall under the ambit of patentable subject matters which excludes all the living objects from being patented and bacteria being a micro-organism fall under the arena of living objects.

Further in *Shell Development Co. V Watson*⁷ in this case the expression “composition of matter” under patentable subject matter was interpreted and was given a wide ambit stating that all the compositions of two or more substances and all composite articles whether being a result of chemical or mechanical union or being a gas or a solid or a liquid. Now as per this interpretation the natural substances for that matter the biotechnological inventions do fall under the meaning of composition of matters i.e. it can be said that the biotechnological inventions are genetic compositions from different species or different parts of a living being’s body.

Later in the same case the supreme court by 5:4 majority overruled the previous judgment stating that the congress has all the rights in order to promote the scientific development and innovations and if the development of a bacteria is excluded than it shall deny the entire purpose of encouraging scientific developments since science does not only include physics or chemistry but also biology, zoology, botany science and a lot more which includes study of living objects.

Later in *HiBred International V JEM AG supply Inc. Supp*⁸ it was held that plant cells and tissues are patent eligible i.e. shall fall under the ambit of subject matter of patent laws where the US court of appeal for federal circuit upheld patents on plants stating that biotechnology is one of the fastest growing field of science breaking new frontiers-pace so fast that law is running behind it in order to regulate.

The viajar of patent law continues from plants and animals to the patenting of human genetic material⁹ i.e. it can be said that with the discovery of DNA¹⁰ the era of modern biotechnology began adding another feather in its cap by patenting human genetic material.

⁶ 1989 Us Sc 447 At 303

⁷ 149 F. Supp. 279 (D.D.C. 1957)

⁸ 2d 794 (Dalloway 1999) No.99-1035

⁹ Supra Note 1

In *Amgen V. Chugai*¹¹, the claim for isolated and purified DNA sequence. It was for the first time in history of patent law that a HUMAN genetic material i.e. DNA was claimed for patent. The claimed DNA codes for a protein called erythropoietin that boosts RBCs production which is helpful for the people suffering anemia i.e. having deficiency of RBCs. The inventors were interested in making the product commercialized by patenting it.

It is bizarre that patenting of human genetic material i.e. DNA did not attract opposition on the grounds of being a product of nature unlike that had happened in the case of plants and animals rather the prime concern of the opposition to check whether the inventor has conceived the invention for real. It was found that the inventors actually had the knowledge of DNA and had reduced successfully and in furtherance of the same patent was granted. It was held that the conception of DNA meant actual knowledge of DNA sequence with its physical and chemical characteristics and experimenting the DNA and had reduced successfully to practice, and eventually patent was granted. After reading this case in particular it can be deduced that biotechnology inventions, if interpreted in the said manner will be eligible for patents.

In *Harvard College V. Canada (commissioner of patents)*¹², the question arose whether the higher life forms fall under the subject matter of patent law or not. It was held that it is the duty of patent office to decide as to application of patent meet the requirement of novelty, non-obviousness and utility under patent act. “As per S.2 of the Patent Act of Canada, patentability of genetic material is a complex issue and requires carefully drafted legislative responses. It was further laid down that considering the necessity of information and technology sharing for innovation and development within biomedicine and biotechnology, a compulsory licensing system including private and public research firms must be established. Further a patent pool for genetic patent must be contemplated, considering the benefits possible from regulated technology patent pools.”¹³

In *American Fruit Growers Inc. V Brogdex Co.*¹⁴ in this case term manufacture was given a wide interpretation, here in this case the claim was for “coated oranges”. The court in this case interpreted term Manufacture to mean the product of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties and combinations whether by manual labor or by machinery. Here the definition was more

¹⁰ Living Beings Are Made Up Of Cells. Cell Is The Basic Part Of Every Living Being. There Are Unicellular Organisms Such As Bacteria And Multicellular Organisms Such As Plants, Animals And Humans. Cells Have A Capacity Of Self- Replication Through Which It Can Grow Into A Number As Necessary As Estimated There Are Around Three Trillion Cells In An Average Human Body. Cells Consist Of Genome Inside Which Chromosomes Are Found Made Of Dna. Gene Is A Specific Chemical Pattern Of Dna Which Controls Development Of Any Specific Characteristic Feature In Any Plant, Animal And Human Being. Genes Are Found In Sequence And They Have Specific Sequences. Inside Genome, Nucleic Acid Molecules Are Also Found (A Combination Of Dna And Ribonucleic Acid) Which Plays A Very Important Role In Replication Of Cells And Transfer Of Genetic Information.

¹¹ 927 F.2d 1200,18 Uspq 2d 1016 (Fed. Cir. 1991)

¹² [2002] S.Cj. No. 77, (2002), 21 C.P.R.(4th)417

¹³ Veena, Biotech Patent Law, 128, The Icfai University Press

¹⁴ 283 Us 1.11.51 S.Ct, 328,330,75 L.Ed.801 (1931).

of the economical definition i.e. manufacture implies the production of new articles using raw materials and giving such raw materials a new form, quality or properties or a combination of these. In this case the court rejected patent claim on the grounds that coated oranges were not sufficiently modified and were not attributed any new form or quality or property or combination of these in order to be considered as a manufacture. Reading the judgment it can be inferred that unlike earlier days where the living objects did not fall under the subject matter of patent law however existing living objects are being used as raw materials in order to develop new biotechnology inventions. The final product or the resulting living object was the manipulation and manifestation of a resulting living being giving it a new look or feature or property which it was not earlier. It can thus be deduced from the judgment that biotechnological inventions do come within the meaning of term “manufacture” forming part of patentable subject matter.¹⁵

Further, In case of *Ex Parte Hibberd*, question arose about the patentability of maize plant technologies including seeds, it is pertinent to note that the USPTO Board of Patent Appeals and Interferences ruled that seeds, plant tissue cultures, and plants constituted patentable subject matter for utility patents. In case of *J.E.M v. Pioneer* in 2001 also, the Supreme court emphasized on the patentability of plants regarding patented hybrid corn seed products, holding that newly developed plant breeds are within the ambit of coverage of patent eligible subject matter under § 101 and that § 101 is not limited by the Plant Patent Act or Plant Variety Protection Act.

IV. ETHICS IN PATENTING BIOTECHNOLOGICAL INVENTIONS

Morality is the essence of morality i.e. the basic principles stating what is right and what is wrong. Now since biotechnology is one of the fastest growing areas of scientific and industrial innovation in contemporary times thus has secured a place for discussion in public arena especially for the ethical values associated with it¹⁶. The prime difference between patenting of Biotechnological innovations and patenting of other fields is that, patenting in Biotechnology has introduced ethics in the Patent Laws since a lot of ethical questions have been raised while deciding as to patents are to be granted or not in a series of cases prominently on the grounds of the biotechnological innovations being Product of Nature, as per the Doctrine of Product of Nature¹⁷.

Ethics lays down a very interesting argument i.e. all the living beings are created by god and are beyond the control of human brains and God is the only owner of any and every living object present on this planet thus are vested with inherent dignity and integrity and trying to modify these inherent characteristics and to try to get it patented takes away this dignity and integrity which is basically going against the wisdom of God ethical

¹⁵Supra Note 1,P.22

¹⁶Bauer.M.W & Baskwell. G., *Biotechnology- The Making Of Global Controversy* , 1 (2002)Cambridge University Press,Cambridge (Uk).

¹⁷ Supra Note 12.

basically hits the moral side of the coin.¹⁸

As per the Natural School of Law, there are such intrinsic values such as self-preservation, dignity, sustenance, survival etc, that are attached to life of a person and each individual has right to protect these intrinsic values and not be tampered.¹⁹ Now Biotechnology tends to remove certain intrinsic values and add other novel properties to life of a living being including Humans and it is assumed that patenting Biotechnological innovations is nothing more than an incentive to the manipulation of human life and alteration of any intrinsic value from plants or animals or even the invisible micro-organisms does not only takes away dignity and integrity but also creates a disturbance in the balance of nature²⁰ and thus any sort of scientific development shall not tend to disturb these intrinsic values of nature.

Counter to the Natural law Theory is the theory given by John Locke, who stated that if a person puts his labor into something the person shall be provided with exclusive rights over the result of his inputs since he is providing a gift to the society²¹. Adding to the theory of Locke, the Utilitarian Theory by Jeremy Bentham, which states that maximum benefit to the maximum members of society, should be given primacy, basically if interpreted then biotechnological innovations including manipulation of living beings provides a great benefit to a number of people thus, patenting of Biotechnological innovations should be considered as it brings a enormous benefits to the modern world and potential harm to ethics over the utility can be sidelined.

Proceeding further to the TRIPS agreement, being part of it ethics, morality and public order have become new grounds in order to exclude patentability of any innovation²² not only this but the agreement also lays down the idea that the inventions that deteriorate the health of animals or plants or any living being for that matter or even deteriorate the environmental conditions is subject to be excluded from the patentability rights. In furtherance of the argument of TRIPS people who argue against patenting of living organisms claim that patenting any sort of living organisms is violating the main purpose of TRIPS agreement on the ethical grounds whereas those who argue in favor of patenting living organisms as well say that though TRIPS agreement prohibits patenting of natural plants, animals of human genetic material it does not prohibits the non- natural, genetically engineered plants or animal cells or human genetic material in a non- natural manner therefore such inventions can be provided patents.²³

¹⁸Supra Note 1, P.195-196

¹⁹ Chrost,A.H., Introduction To Aquinas,1974,19 Amj Of Jurisprudence 1

²⁰ Radhakrishna And P.T. Raju (Eds.), The Concept Of Man: A Study In Comparative Philosophy Harper Collins,17(1995).

²¹ Donald S. Chisum, Craig Allen Nard, Herbert F. Schwartz,Paulin Newman,F.Scott Kieff, Cases And Materials: Principles Of Patent Law, New York Foundation Press, New York,35-36(1998)

²² The Trips Agreement, Art. 27(2) And (3)

²³Supra Note 7

In late 90s biotechnology faced a drastic up rise specially with the greatest hue and cry on the cloning²⁴ of a six year of sheep i.e. Dolly (the clone sheep) where certain allegations such as biotechnology is devastating the natural life and is destroying the natural processes and thus an immediate injunction should be awarded to the ones involved in practice later cloning of certain other animals such as rabbits, monkeys and cow was followed. It was first contested that patenting of method of cloning is going against the natural rights or the inherent rights of a living being whereas it was later on held that cloning process took and extensive amount of research work also does not take away the inherent rights such as dignity or integrity of any living being the process can be patented²⁵ unlike that had happened in the case of Stuart Newman, where he claimed patent for a invention where he incorporated a human gene into an animal body resulting into development of an organism which was neither an animal nor a human being, this probably was the first time when ethical grounds were given primacy in the patent law.

Hence it can be said that patents should be granted to all those who engage into an extensive research work and develop something new provided that the ethical and moral grounds and the inherent natural rights of any living being remain intact not are not violated.

V. TRIPS AGREEMENT AND IPR REGIME CHANGE

The advent of biotechnology can be traced back to the very stages of its development wherein first of all the fermentation process was carried out for preparing food and eventually was used in making alcohol and other medicinal purposes. The modern-day biotechnology started with the DNA techniques and cloning of living organisms which has since then evolved into nanotechnology giving new areas to the human race to explore and exploit as well.

The patents cannot be made common for everyone i.e. in developed and developing countries laws relating to IPR in Biotechnology need to be bifurcated according to the needs of the industries and keeping in mind the profit and loss they would earn from these deals.

The developing countries are still not in the league of "countries with enough resources" to carry out their research and development process which puts them on a backfoot and the developed countries tend to have a monopoly over the Biotechnology market. Countries like India which are developing and have recently entered into the TRIPS agreement have been given relaxation in the IPR rules so that they can compete with the developed countries while making profits.

²⁴ Cloning Is The Process Of Developing Identical Organisms Through The Division Of Single Embryo Or Through Nuclear Transfer Or Replacement Of Nucleus In An Egg By A Foreign Nucleus. It Is A Method Of Reproduction Involving The Copying Of Cell Or An Individual From Its Dna.

²⁵ Pioneer Hibred International V. Holden Foundation Seeds Inc. , 35 F.3d 1226 (8th Cir. 1994)

The main motive behind this relaxation was to make the developing markets open to more patent registration and this was also seen after the TRIPS agreement was signed by India – about 1400 patent applications came for approval to the government. This was the second largest number of applications after USA. The patent laws in developing countries should be made according to the needs of inventors so that they have a scope to innovate their ideas and access to resources national as well as international should be provided in order to increase the capital market for Biotechnology patents.

The sudden increase and need to patent biotechnological innovations and inventions is the increasing scope of this field – on one hand, this field has its impact on all the living organisms through their modification and on the other hand, it has its roots buried deep in practical areas like robotics and genetic engineering.

The poor or underdeveloped and developing countries are suppressed due to lack of resources and countries having sound resources like USA, Russia, China, Japan are way ahead then the other countries in exploitation of such resources.

VI. TRIPS AND BIOTECHNOLOGY

At the time of TRIPS negotiations in Uruguay Round, the US and EU faced a difference of opinion on the subject-matter of patenting biotechnological inventions. Where on one hand US believed that everything under the sun developed by man, except for human beings, was patentable; the EU had a strong disagreement and had a strong internal resistance to bring living organisms under patentability.²⁶ As the debate had not been settled between the two international actors, in Europe the WTO members agreed to minimal agreement (*under Article 27.3(b)*) while committing to revisit on the same within a time period of four years from entering into effect of TRIPS Agreement.

Article 27 of TRIPS Agreement defines as to which inventions the nation states are obliged to patent and what inventions may be excluded from patenting, this article further requires that patent maybe available for both the product and the process, whereas Article 27.3(b) allow governments to exclude plants, animals and essentially biological processes from the ambit of patentability.²⁷

It is of prime importance that the three universally accepted criteria for patentability of any product that is novelty, non-obviousness and industrial applicability, that have been incorporated under Article 27.1 of TRIPS Agreement apply to all the inventions including the ones in the field of biotechnology.²⁸ This patentability of biotechnological inventions has however introduced a new controversy as to differentiation discovery of

²⁶Jayshree Watal, Intellectual Property Rights In Wto And Developing Countries, Oxford India Paperbacks, Ed.2014, P 128

²⁷[Http://Apps.Who.Int/Medicinedocs/En/D/Jh1459e/7.2.Html](http://Apps.Who.Int/Medicinedocs/En/D/Jh1459e/7.2.Html) Last Accessed: 23rd February 2018 At 4:27 Pm

²⁸C. Niranjan Rao, Patents For Biotechnology Inventions In Trips, Economic & Political Weekly, Vol 37, No.22 (June 1-7,2002), Pp. 2126-2129

something that already exists in nature and invention if something new involving a pre-determined degree of human effort or invention; as TRIPs do not provide for any guidelines as to the difference, it provides a flexibility to the developing countries in order to develop laws to avoid patenting product of nature.

There isn't a clear bifurcation under TRIPs with regards to microbiological process and essentially biological process and thus are subject to varied interpretation by experts in same and different jurisdictions, which calls for another controversy.

VII. PATENTING LIFE

When developments in the biotechnology came, it was the DNA techniques and cloning techniques which were legally as well as ethically contested by people because, higher life forms are natural in their being and no invention can be done in nature's cycle. The main issues arising in patenting life are infringement of "Right to life" because owning a human being's, animals' and plant's life is not acceptable by the society or the law and also, it hampers the integrity and identity of a natural being. The first idea of getting a medicine patented was considered to be absurd as the medicine was for "people" and they owned it. The creativity and intellect behind the different researches carried after that in the medicinal and human genes has brought about huge profits to companies and humans owning their own genes. As the time will progress, all the earlier objections would become trivial in front of the advantages of patenting genes like cure for diseases and even the idea of synthesizing life from scratch in future.

The conflicts which arise in patenting genes is that, many countries had an approach of giving the patents earlier even when laws governing the use of same was not present or made. this gives enormous power to the patent holder and in today's era when the most resourceful countries are the developed ones they tend to create monopolistic market for their own patent holding companies while pushing the developing companies on the verge of exiting the market.

The laws need to be implemented prior to giving patents so that no claims of applying retrospective laws can be made and no issues arise in conflict of the interests of both the developed and developing countries. Contemporary patent laws which have a wide scope cannot be implemented to govern such patents which reach out to a wider public and have a huge number of interested parties.

VIII. INDIAN PATENT LAW

When it comes to Indian Patent Law, Section 3(b) of the Indian Patent Act provides that "an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment is not patentable." As per the section an invention would not be patentable if it is immoral or against public order, harmful to

human, animal or plant life or harmful to environment which includes processes for cloning human beings or animals, processes for modifying the germ line, genetic identity of human beings or animals, uses of human or animal embryos etc. Further, The law also provides for deposit of such biological materials at a recognized depository. The systematic procedure requires the invention to be described completely in the specification to enable a person skilled in the art to be able to carry out the invention by reading the specification. However, there are no cases in India that talk about differing written description or enablement standards for biotechnology inventions. With respect to novelty of biotechnology inventions as well, Act does not have any explicit provisions. However, the Draft Manual of patent practice and procedure, 2008 provides that biological material such as recombinant DNA, Plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention.

POST TRIPS AGREEMENT REGIME IN INDIA

India is one of the countries to sign the TRIPS agreement and though, all its laws are in accordance with that of other countries. The Patent Act needed amendments to make it fully compliant with TRIPS and other countries' laws. The regulatory framework regarding patents has been really strict until now and narrower in its reach in areas such as biotechnology. The TRIPS agreement gave the developing countries a new way out by publicizing the knowledge and increasing the access people have over various technologies and research work. Developing countries were encouraged to sign the TRIPS agreement, follow WTO's rules and within that area make room for one's own country's laws.²⁹

The Indian Patent Act has a narrow scope but, World Trade Organization (WTO) provides for a broader framework in order to cover product patents and all related fields. The WTO provides for patents in life forms wherein any inventive step is taken along with legible subject –matter of invention but, Indian Patents Act doesn't allow patenting of higher life forms. The life duration of patent that WTO provides is of 20 years but, the Indian Patents Act did not bring it at par until the third amendment was done, earlier the patent life was 7 years only. The main areas where the problem is faced is in the biological space are

1. No clear bifurcation between discoveries and inventions has been done;
2. Scope of patentability in higher life forms like plants, animals;
3. Scope of patentability in lower life forms – microbial organisms; and
4. Condition of depositions covering living organisms connected with patentable inventions.³⁰

These problems still persist as even WTO hasn't clearly bifurcated many things and given recommendations for

²⁹Supra Note 10, Pg 192-195

³⁰Supra Note 10, Pg 196-197

the same. A similar impact of patents has been seen on the Pharmaceutical Industry which is the new facet of efficient drug development and increased life expectancy rate. This market is an ongoing innovation factory where the cure to all diseases is found and patents in this industry are a hard ball to catch and further add to the distance between rich and poor countries. If any drug is made by a national pharmaceutical company it can be sold at prices favorable for people but, the same coming from an international pharmaceutical company would charge their own prices adding their own costs to it and it would create a burden on the pockets of the citizens of poor countries. Thus, access to biotechnology and other researches remains a far-fetched goal for many countries. Here, the social and ethical part comes in play which points that, society's benefits and welfare state must be kept in mind while restricting the developing nations from moving forward by taking over their markets. Corporate Social Responsibility should be used as a tool to ensure that, the companies are to serve people and not just fill their pockets by putting undue prices on medicines. The social and ethical elements of the TRIPs agreement are also taken into account for which it is stated that, all the policies and agreements so made must be in accordance with the social culture and moral values of the country they are to be implemented in. the culture of the society would determine the base line of morality and ethics that would further govern the situation if any arises.

The Indian government has formulated the Patent Act keeping in mind its contradictions and implications with the TRIPs agreement. The government policies keep a tab on piracy activities and help the national companies to access and indulge in various technological developments and invest their money into something which would gain them profits along with patentability over products so made under the TRIPs agreement. Maximum enforcement of IPR related international laws and policies in accordance with international authorities are the main aim to achieve so that, no claim over the already patented products arises in future.³¹

IX. CONCLUSION

The product of nature theory is becoming not only outdated but also the applicability of this theory, especially in the developing and developed countries, is getting limited due to various factors such the development in technology and changing dimensions of law and judiciary. Going by the guidelines of TRIPs, TRIPs do not mandate patenting product of nature however a more isolated or a modified version of any microorganism may fall under the patentability requirements of TRIPs. While on one hand the WTO members may have a different notion and may come up with a different interpretation of these compliances, a country cannot prevent another country to have a distinct opinion on the same subject matter.

Traditionally, India is famous for making knowledge or any sort of discovery or innovation a public property. This philosophy i.e. the jurisprudence behind having Intellectual Property Rights has done well for this country

³¹Supra Note 10, Pg 207-208

and the society in general enabling access to a wide range of research work and technical development of society as a whole. Yet there remain some or the other drawback or loophole to each and every philosophy. In order to overcome the demerits in the field of IPR the authors hereby present a set of suggestions:

- As it has been seen in the paper that patenting of various Biotechnological inventions has been accepted over the period of time except for the transgeneric human being, therefore it is better if the local statutes are modified in a manner that also takes into consideration the ethical and moral standards of the society in order to exclude transgeneric human beings.
- After reading the TRIPS agreement it can be deduced that a universal declaration or convention on the prohibition on cloning process for the reproduction process not only of human beings but for animals and other micro-organisms may be adopted.
- The time period for patent grants in India should be reduced and the entire bureaucratic process should be amended and it should be granted within three years provided the dynamic nature of Biotechnology where some or the other changes take place on a regular basis.
- There should be an inclusion of an expert committee based on the field the patent is to be granted considering the technicalities and the complex nature of Biotechnology.
- The TRIPS agreement can be amended to mandate compulsory licensing in the field of Biotechnological patenting based on certain conditions to be satisfied.
- There shall be a universally applicable biosafety mechanism addressing the danger posed by the inventions of biotechnology in order to ensure safe production, in view of patent protection to biotechnology.
- Biotechnology can go to an extent of producing biological weapons thus provisions prohibiting the misuse of biotechnological patenting can be introduced.

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