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CONCEPTUAL ISSUES IN PATENTING OF LIFE FORMS

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ABSTRACT

A patent as described in numerous legal texts is an intellectual property wherein a person is granted monopoly rights for inventing a useful, new or an improvement over an existing article or making of an article including its process. Initially in 1873, improvements in manufacturing and processing of yeast and beer was given as a patent in USA, Italy and France. It is to be noted that the importance of patenting of life forms only emerged after 1970's during the booming period of biotechnology related to Hybridoma technology, DNA technology etc. It is only due to such technologies that the industries and researchers were able to exploit and use the biological resources for production of pharmaceuticals and agricultural products in a commercial and large-scale form.

Patenting of life forms as a critical and crucial issue is due to its commercial potential from usage of biotechnology. The subject matter in biotechnology patenting is different than that of patenting in machinery which are comparatively more traditional when compared to likes of plants, human cells, animals, genes etc. This paper will be tackling the issues of following standards in context of TRIPS agreement regarding the patenting of life forms.

Introduction:

A patent as described in numerous legal texts is an intellectual property wherein a person is granted monopoly rights for inventing a useful, new or an improvement over an existing article or making of an article including its process. Initially in 1873, improvements in manufacturing and processing of yeast and beer was given as a patent in USA, Italy and France. It is to be noted that the importance of patenting of life forms only emerged after 1970's during the booming period of biotechnology related to Hybridoma technology, DNA technology etc. It is only due to such technologies that the industries and researchers were able to exploit and use the biological resources for production of pharmaceuticals and agricultural products in a commercial and large-scale form.

Patenting of life forms as a critical and crucial issue is due to its commercial potential from usage of biotechnology. The subject matter in biotechnology patenting is different than that of patenting in machinery which are comparatively more traditional when compared to likes of plants, human cells, animals, genes etc. This paper will be tackling the issues of following standards in context of TRIPS agreement regarding the patenting of life forms.

The idea behind Intellectual property is for the recognition and protection of the innovator, as it provides for reward for fostering the technical and industrial progress in the current economic and social structure. Any unnecessary encroachment on such innovations or inventions need to be protected for maximizing growth and development. The context is this is of much more relevance when talking about the huge

strides being set in information and biotechnology technology. There has been a leap in the advancements being made in biotechnological research including the pharmaceutical industry which calls out for mounting pressure on the parliament to encourage patenting of life forms to encourage development and research initiatives. Such a positive enforcement by the policy makers would contributes towards exploring unrecognized and undiscovered commercial usage of life forms. Creation of life forms like genetically modified animal species or plants, genes, etc. can be patented as bio-patents.[1] Though it is evident that laws protecting and regulating such research and experiments are at an inchoate path. One such reason of this debacle is the difference in ethical and economical standing of the countries and supposed trade secrets under the provisions of World Trade Organization. The debate of the hour with respect to this is the limit for granting for protection. Therefore, a critical analysis of the current position and situation of law on patentability of microorganisms is vital for future prospectus of the biotechnological industry.

Trips agreement on microorganisms:

The TRIPS agreement, administered by the WTO[2], is an international agreement for laying down minimum fixations and standards for trade forms of intellectual property regulation and is applicable to WTO members. He given agreement was negotiated under consensus of WTO members at the Uruguay Round of GATT.[3] TRIPS set the basic standard requirement for patentability and obliges to patent microorganisms[4] to its members. Hence, the term "microorganism" requires an understanding to constitute its essential. Lack of a scientific definition creates unforeseen stigmas and restrictions in research. TRIPS agreement makes it mandatory to grant patents of microorganisms, but at the same time fails to define the term "microorganisms". Therefore, creating a vague standard which can be interpreted by nations unequally and differently. A clarity on inclusion of naturally occurring substances and genetically modified organisms was required.

Issues in patenting life forms:

Traditionally patenting requires inventive step and disclosure of new invention with the requirement of proof whereas when it comes to inventions in biotechnology the subject matter already exists in nature. In patent law, it's a well-accepted principle that naturally available matter is excluded as it doesn't contribute anything new. Conversion of natural material into private property as done in biotechnology invention is rather considered as against public interest and unethical. Such deliberations raise ethical and moral issues to convert god made natural

[1] Ammen, J. and Swathi, N. Patenting life the American European and Indian way. Journal of Intellectual Property Rights 15: 55–65 (2010).

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

[3] General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994)

[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

material to mere private objects using advanced technology. This further created difficulties for biotechnological inventions to be granted patents due to the test of inventive faculty. Another issue was the written description as a practical requirement of production of samples and invention. However, developments and advancements in biotechnology helped in searching solution for the mentioned issues.

Legal issues:

The centered around legal problem on patentability of life form is whether it should be considered under the existing criteria or not. According to the legal interpretations in 1980s in USA, the patent rights eligibility denied all life forms as it was a mere discovery rather than an invention. The given decision was in Funk Bros. v. Inoculant Co. The claim of patent in this case was regarding the mixed culture of Rhizobia which were capable of immunizing seeds of plants belonging to cross-vaccinating groups. The Court held that "he who discover a hither of unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery it must come from the application of law of nature to a new and useful end. Even though it may have been the product of skill, it certainly was not product of invention."[5]

In the case of Diamond v. Chakrabarty[6], the Supreme Court of USA granted patent to bacteria which was genetically modified useful for clean-up of oil spills. The ratio decidendi centered on the inventiveness to modify the bacteria. The liberal interpretation according to the Court for the term "composition of the matter" and "manufacture" contemplated the wide scope of patent law to include thing made by man. It was held that the new bacteria had different characteristics than that found in nature and had potential utility in various fields. Hence, the discovery was stated as work of own and not of nature's hand in Section 101, 35USC.

The case of Diamond v. Chakrabarty had opened gates to numerous applications to claim patent protection over higher life forms like plants. In the Judgement of In Re Hibberd[7], the patent right was fully extended and granted to plants and in the Judgment of ex parte Allen[8] the same to the animals. These decisions were purely based on the degree of interventions made by humans as a test of making the product and the constitutional mandate of protection for non-naturally occurring.

The differentiating line between invention and discovery has been a major difficulty especially considering DNA technique which isolates genetic materials. After the decision of Diamond v. Chakrabarty, the USA patent office granted patent for Onco-Mouse for cancer drug study. In these terms morality or public order wasn't taken up as a criterion since human intervention was all that was needed.

Moral and Ethical Issues:

[5] Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S., 127 (1948)
[6] Diamond V. Chakrabarty, 447, U. S, 303 (1980)
[7] In re Hibberd, 227 U.S.P.Q. 443
[8] In Re Allen, 846 F.2d 77 (Fed. Cir. 1988)

Patent grant on higher life forms such as genes, human cells, mice etc. has provoked and invoked a lot of various ethical objections to life forms being patented. Religious institutions claimed that patent of life forms mere reduction of God's creature to material objects which degrades the dignity of life by making it as a private property. Considering human beings were playing god using advanced technological development and patents. The European Court addressed this issue in the Relaxin case[9]. In this case, Relaxin encoded human gene patenting was being claimed. It was held that patenting of an individual human gene isn't the same as patenting of human life and has nothing to do with it considering that it would be impossible to recreate an entire human being out of human gene cloning. And given that no individual human being confers such right of a patent. Under gynecological operations and consent the tissue is taken. Such substances are lifesaving ones and are applicable in industrial technical solutions to technical problems. Hence, it's patentability is evident. A synthetic Relaxin was produced using the cloning DNA technique gene. Relaxin is a hormone which can relax uterus in events of child birth. It was held to be not a mere discovery as Relaxin's isolation was necessary for gene coding.

In case like Green Peace[10], PGS[11], the transgenic plant patent was contested on the ground of morality and public order under the European Patent Law. For the first time, the technical board of appeal laid down definitions for "morality" and "order public," and its applicability to be individual as opposed to together. Morality was defined as behavior considered acceptable and right in the European society and order public as the protection of environment and public security. Any other behavior not considered moral by the European Society was considered as wrong, and the given was framed on the standard inherited by the European Society and Civilization which were conventionally accepted. Any and every surveys and opinion polls presented by Green Peace were rejected by the board despite their relevance.

It can be said that inventions are propelled by necessity. In the era of advancements in biotechnology, inventions are being fueled by necessities but at the same time protect of rights is a responsibility as well. Transplantation of organs is considered a moral issue for biotechnological inventions. Organ transplantation is facilitated through biological inventions as opposed to religious faith and their intellectuals.

Claim to human body or its parts like organs is said to be unclaimable property under the Common Law due to the ethical and social concerns prevailed in Commonwealth society. A directive on biotechnology and its inventions was passed with the emergence of genetic material patent claims in 1998. The provision in the given Directive provided definitions on biological process, biotechnological inventions etc. and non-patentability of cloning human beings, including modifying genetics of humans and human embryos for commercial and industrial purposes. That being said, only discovery and isolation of that to the process can be patented. In Europe, many social activists mounted successful challenges

[10] Oliver Brüstle V Greenpeace., E.V C-34/10 (2011)

against biotechnological patents, including genetically engineered plants like steam cell lines.

The European Patent Office considered that the rules laid down after the 2004 decision are more than interpretive in nature due to its large ambit. Further, new guidelines were provided pertaining to the pending decision on stem cells patents. This was given in Article 53(a) of EPO and the new rules[9].

Environmental issues:

The potential adverse effects are some of the concerns about new technology especially its effects on biological diversity and risks to human wellbeing and health. With GMO's attaining risk to environment and human health, it has also remarked considerable uncertainties like impact on environment. Complete documentation as well precautionary measures are advised when there's reasonable ground of concern. Without vital knowledge availability about the safety and commercial usage of GMO's, countries should refrain from allowing patents considering the safety of GMO's. The Court considered the purpose of the Onco-Mouse invention in respect to the possible risk to environment. As stated by the Court, the usage of the invention was to be exclusively under controlled laboratories with qualified staff. Onco-Mouse invention was in regard to providing animal test models with no release to the general environment. Blatant ignorance and intentional misuse of the qualified staff at such laboratories is the only uncontrolled release as a potential risk to the environment at large. The deciding factor whether patent should be granted or not can't be decided on a mere fact of such acts being conceivable in near future without any substantial evidence to support otherwise.

Thus, executive and legislature should be responsible to frame environmental standards. Environmental, health and safety standards are to be set by the parliament according to the desires reasonable to getting GMO's patented.

Patenting Standards of Biotechnological inventions in UK and US:

It is a complex task to apply the same set of parameters of the patent standards with the evolution of newer technology. In the situations of biotechnological inventions, the originality and subtle requirements are applied differently when compared to inventions relating to machinery or pharmaceuticals. The following can be sought with enlisted cases:

In the case of Amgen v. Chugai[12] pharmaceuticals, the issue of conflict was between two patents - one which was asserting for the gene or DNA sequence concealing a protein and another claimed that the protein in itself an extremely purified form. Amgen patent was in consideration with a purified and lone DNA sequence which encoded the human Erythropoietin and host cell alteration, with the help of which the potential treatment of chronic anemia could be possible. Amgen was the one who got its patent in October of

[12] Amgen, Inc. v. Chugai Pharmaceutical Co., 808 F. Supp. 894 (D. Mass. 1992)

year 1987 whereas Chugai got in in the June of 1987. However, Amgen was the one who conceived the DNA sequence of the protein while in the production of purified EPO. But the inventive concept regarding the isolation was present before but there were no signs of DNA sequence until Amgen made it. The Court held that examination and reviewing method taken up by the Plaintiff is factor which differentiated between the invention from the previous art and held Amgen's invention as novel and credible.

As a result, the test of obviousness in Graham's case[13] was weakened. The prima reason was that there was a level of predictability when we talk about this case. It is a fact that there wasn't a need for absolute predictability to exist under the condition mentioned in Section 103 of Patent Act, 1952. Thus, undetermined predictability in the case of biotech inventions can harm and meddle the non-obviousness standard which are generally followed. This is observed from the Court in Chugai's contentions that other method could have been used to clone and regenerate the EPO gene as mere theorizing. "Obvious to try" was certainly not the code of standard in order to determine the obviousness under Section 103 of US Patent Act, 1952. An invention is obvious when both the suggestion as well as expectation of success is found in the previous art and not in applicant's revelation. If there is a certain degree of reasonable expectation of positive outcome then test of non-obviousness must be contended. With reference to the biotech invention inventive concept means an absolute mental conception of the purified and lone DNA sequence forming the EPO and the method of preparation. Hence it can be concluded that the standard of skill accredited to a hypothetical person skilled in art i.e. Graham's test becomes absolutely unrealistic in the field of biotechnology. These certain high standard of skill of a hypothetical person for evaluating the inventive step adds to the difficulties for granting a particular patent in biotech inventions.

In the case of Biogen v. Medeva[14] one can witness the approach followed by the court of UK.

The Plaintiff in this case got a patent for DNA molecules which encoded Hepatitis B Virus Antigen. When the date of patent application came, the said DNA was not sequenced. Biogen was the first person to present the protein of Hepatitis B Virus Antigen in the prokaryotic cell. The inventive step is the solution that someone had discovered in order to solve the problem and not the goal itself or any other general method of attaining it. Also, inventive idea could be understood as doing a new thing which is the idea of using an already existing thing in order to do something new which others have not thought of or an inventive idea might be similar to achieving solution to a problem. In this case, the Court held that "even though Biogen had taken the initiative something uncontemplated by others; it used available techniques and methods in research. They had not developed a new inventive process or had not discovered anything about those processes and it was only a business decision to carry out research to pursue an identifiable goal by known means". As a

[13] Graham v. John Deere Co., 383 U.S. 1 (1966)
[14] Biogen Inc v Medeva Plc, FSR 4 (1995)

result, the biogen's patent was held invalid It can be concluded that both in Amgen and Biogen case issue is almost similar. But the Courts applied the different standards of inventive steps and non-obviousness. In both the cases inventive concepts was known to the world of science but in Amgen case when using probing and the screening technology resulted in wanted result it not succeeded for the very first time and the Court claimed that it is non-obvious. But in the case of Biogen even though the prior art goal was known to scientific world as the technique used is already known to the users it was held that 'it was obvious to person skilled in art" and hence it followed a higher standard than what was applied in the US Court in Amgen. Another point to be noted that the claimed invention in Biogen was extremely broad, not due to the inability of teaching to produce desired results, but to the fact that the similar results could be produced by other different means and one might not be allowed to monopolies every way of doing obvious needed and desirable product.

This method is followed in the case of Kirin-Amgen Inc. v. Roche Diagnostics GmbH[15] too. In this case, it was proclaimed that "the law of patents is ultimately concerned with practicality," therefore a prior art experiment which, when is performed, reliably produced a result "for more than 99 per cent of the occasions on which it is conducted" would be treated for the aim to disclose as "inevitably" leading to the result which is in question. It is followed that a claim which defines the "invention" by acknowledgment of the standard parameters, for instance, of a process or a certain product, is anticipated by a disclosure, which when is applied into practice would surely fall within the ambit of the claim, even if the disclosure is not in context with the parameters.

The Privy Council had followed the same way of dealing in the case of Ancare New Zealand Ltd.'s[16] Patent and held that scientific view or opinion is out of accord with reference to what is done in the market. In the above case, the patentee argued that an inventive step laid in including the tapeworm agent because there was a certain kind of scientific hostility against treating tapeworms in sheep. However, it was very usual practice for New Zealand farmers to treat their lambs for tapeworm at the date of priority. The Privy Council, upholding the Judgments of the New Zealand High Court and Court of Appeal, which was to repeal the patent for obviousness and not to involve any inventive step on what was earlier used and known before the date of priority of the claim in New Zealand, held that the fact that scientific opinion may have thought of it as something not needed and useless or didn't mean to practice it or have an idea to prepare it, was the inventive step. Otherwise, anyone who had adopted an obvious method for doing certain thing which was widely in the practice but to which the best scientific view thought was pointless could gain a patent.

In a recent case of KSR Intl' Co. v. Teleflex Inc.[17] the honorable United States Supreme Court changed the way of analyzing the patent claims by the courts and the examiners, hence creating a brand new

[15] Kirin-Amgen Inc v Roche Diagnostics GmbH, [2001] EWHC 518 (pat)

[16] Ancare New Zealand Ltd v Cyanamid of NZ Ltd, 3 NZLR 299 (2000)

[17] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)

multi factor approach for the method of determination and to find the invention was obvious or not and to find that the it can be given a patent or not. According to the Court if some sort of motivation or suggestion existed in order to combine the prior art, then the new invention, is obvious and hence cannot be patented. The Court further stated that "the diversity of inventive pursuits and of modern technology counsels against confining the obviousness analysis by a formalistic conception of the words teaching, suggestion and motivation or by overemphasizing the importance of published articles and the explicit content of issued patents." The Court further observed that “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense"[18]. The plethora of US judicial decisions from Graham to KSR and the landmark decisions of UK's Courts from Wind surfing to Kirin Amgen, A person can observe fluctuations in the standards and methods of patentability. it is quite evident that the Court is applying the common concept of obviousness and inventive step in the field of the new era of technology which may not be predicted when the statute was made. Therefore, there are different standards are being read into non- obviousness. Hence, it is the want of the definite criteria to judge the non-obviousness requirement in the case of biotech inventions which lead to much confusion.

It can be concluded that balancing and comparing the standards followed in the US and UK and in matters of patenting biotechnology inventions, it could be observed that in US the private interests are given more priority to alter the speed of technological advancement in the disguise of promotion of science and technology thus lessening the space of public domain. But when we talk about the recent decision of US Supreme Court in KSR Intl' Co. v. Teleflex Inc, it gives a clear sign of change in their way of attitude by setting a much higher standards of patentability. It is also come to a realization that granting patent protection to advances that occur in a very usual course without any real innovation retards progress and it may, for patents combining earlier known elements, deprive the prior inventions of their utility and deserving value.

Whereas in UK such flexibility could not be seen through the cases and their priority seems to be more towards the public interest over the private so that they could keep a balance between private monopoly as well as public interest therefore keeping up the underlying philosophy of the very intellectual property. One can witness that Europe is experiencing more turbulence in the recent years over the matters of patents of genetically modified organisms. The ongoing fashion in United States is more likely to see an accelerating increase in challenges in the matters of biotech patents as advocacy groups are raising broad questions about the role of the public and the role of public interest in science and technology policy-making.[19]

[18] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)

[19] Sekar, S. and Kandavel, D. Patenting microorganisms: Towards creating a policy

Comparative analysis between Australia and China

AUSTRALIA – According to the Australian Patents Act (s18(1)(a))[20] claims that an invention which is patentable should be a "manner of manufacture." Similar to that, the schedule to the Act defines the "invention" as any "manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention." The formative case that provides some inner view is National Research Development Corp (NRDC) v Comm. of Patents.[21]

It was discovered that if, on its frontal, a specification states an invention that cannot present any particle of inventiveness; it is not a "manner of manufacture" and is not patentable. In such certain cases, a court need not to go on to view the novelty and inventive step differently and separately. If it actually meets the basic sill, provided that it meets the other patent needs, the invention will be patentable.

With the respect to this, there is no certain "test" to determine whether or not any specific patentable manner of manufacture. However, certain few good rules of thumb are: (a) the invention must produce an artificial state of affairs (i.e. it must be a production of a human and not natural cause), and it must have a very wider commercial significance or (b) "the invention must involve the production of some commercially useful effect."[22]

CHINA – The article 25 of the Chinese Patent Law enlists the subject matter which are excluded from patent protection. The standard for applying Article 25(1) of the Chinese Patent Law is in consistence with listed international standards, which is, an object which is a mere discovery of living persona/nature is not patentable but might be given patent protection in case if it has been secluded or purified from its very own natural environment and has been characterized.[23]

The article 25(3) of the Chinese Patent Law has various similarities to article 52(4) of the European Patent Convention. The similarities between both jurisdictions exclude the process and methodology of surgery, therapy, as well as diagnosis which is practiced on the human or animal body, all of which are quite commonly allowed in the United States. Certain examples of the excluded subject matter in China comprises, methods of treatment such as immunization, acupuncture and radiotherapy. The non-comprised ones are certain prominent methods of disease diagnosis such as the endoscopic and ultrasonic methods. To add to this, prophylactic treatment methodology of treatment of diseases or treatment of wounds or any method of contraception or the artificial insemination method, as well as embryo transfers are also completely excluded from patent protection in the country of China. These exclusions of patentability do not apply to methods not directly applied on the human or animal body. Therefore the methods of treatment and

framework. Journal of Intellectual Property Rights 7: 211–221.

[20] Patents Act 1990 (Cth) (AUS act)

[21] 102 CLR 252 (Dwyer, Dufty, Lahore and Garnsey, 1996)

[22] Balachandra Nair, R., Ramachandranna, P. *Patenting of microorganisms: Systems and concerns*. J Commer Biotechnol **16,** 337–347 (2010)

[23] Jacqueline Lui. *Patenting biotechnology inventions in China.* Nat Biotechnol 19**,** 83–84 (2001

diagnosis which is applied to tissue and certain other biological materials which are separated and kept away from the body are patentable subject matter. The methods of analysis, treatment along with data collection to be applied to the body for purposes which are not relating to disease matters are also allowed, and so are the products and compounds which are used for the therapy and diagnosis of certain diseases.[24]

Certain instances of patentable subject matter in China also include (1) the non-therapeutic hair treatment (cosmetic) methods. For example giving permanent waves or hair colouring/dyeing; (2) methods of sterilization. Which is not immediately or directly applied to animal or; (3) the method which is used in order to store the dead bodies; and (4) methods of estimating physiological parameters only for the purpose of perfecting a medical implementation units. Article 25(4) of the Chinese Patent Law excludes the varieties of flora and fauna from patent protection. This barring is mainly directed toward living organisms mainly, hence the methods of reproducing and the outcomes which are derived from these organisms certainly remain patentable.[25]

Patenting of Life forms – The Indian Stand

Patent Act of India, 1970, Section 2(1)[26],primarily defines invention as a contemporary, modern and useful method/ manner of manufacturing or a substance produced by a manufacturer. No such specific definition of method of manufacturer or substances were given in the act per se. Therefore, the Patent Office approved a more reformed practice of interpreting a "manner of manufacture" as a patentable subject matter on the grounds if it results in a tangible non-living substance. Section 3, clause (j), of the said Act stated that plants and animals at entirety, or in parts comprising of seeds, varieties and vital biological processes for the production of plants and animals are excluded. Statutory obstacles created by the Indian Patent Act,1970 are for fulfilling the patentability requirement criteria which are inventiveness, industrial application and novelty. Although there are numerous exclusions of some inventions given as well in Section 3 of Indian Patent Act, 1970.

The existing system of Indian patenting marked its amendment after India joined the Budapest Treaty[27] on 17th December, 2001 and further strengthened its hold by acquiring the status of an IDA on 4th October, 2002 in Microbial Type Culture Collection (MTCC) and Gene Bank of the Institute of Microbial Technology, Chandigarh. Furthermore, the position was made more substantial after the 2002 amendment of Indian Patents Act, 1970, in which it was stated that microorganisms can be patented provided they fulfil the other imperative requirements.

The Patent Amendment Act, 2002[28], came into effect in May 2003, including

[24] Id.

[25] Jacqueline Lui. *Patenting biotechnology inventions in China.* Nat Biotechnol 19, 83–84 (2001)

[26] The Patents Act. (1970) No. 39, Acts of parliament 1970 (India).

[27] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or Budapest Treaty, is an international treaty signed in Budapest, Hungary, April 28, 1977.

[28] Patents (Amendment) Act 2002. No. 38, Acts of Parliament 2002 (India)

microorganisms within the domain of patentability. Section 3(j) was formulated in terms of Article 27(3) (b). It stated that plants and animals in whole or any part henceforth should include seeds, varieties and species and essential biological processes for production or propagation of plants and animals should not be considered inventions other than microorganisms, in the context of the Act. It excluded microorganisms from the exceptions to patent protection and allowed patenting of 'processes' pertaining to microorganisms as well as all sorts of non-biological and microbiological processes.

Subsequently, Patents Act, 1970 was again amended in the year 2005 to construct consistency with TRIPS. The latest amendment deleted Section 5 of the Act, which included only process patents. The provision covered inventions where only method or processes of manufacturing were patentable. Thus, the omission of this section paved way for product patents which was in complete opposition to the US approach that argued patenting of life forms can have immense advantages involved.

Despite the concerns against the patenting of microorganisms, this stance can be termed revolutionary for the biotechnology industry as it can help in its advent at an inevitable pace.

There was no patent protection on inventions of life forms in India before 2002. Calcutta High Court in a landmark judgement of Dimminaco A.G v. Controller[29], covered the ambit of the term "manufacture" even to living organisms in terms of patentability of a vaccine with live virus used in its process of preparation. Hence, the Court stated that an end product might be an invention even if it requires the containment of a live virus in the process of creating the final product which was a vaccine. Though there was not been even a single decision in India relating to the required standards and steps considered as inventive to the biotechnological patents.

The Section 3 of Patent Act,1970 had been amended in light of the TRIPS agreement, Article 27 specifically. The definition of "inventive step," "new invention," and "invention" showcased a somewhat restricted portal for legal protection of life forms material. The patent office has to make crucial interpretations of terms like "animal," "plant," "non-biological process," "essentially biological process," "microorganisms" since there is an absence of definitions for the same. There is a safer reliance upon the rules and guidelines provided in the provisions of the TRIPS agreement since terms like microorganisms have various definitions including genetic material.

The establishment of burden of proof under Indian standards of patent grant of life forms states that the burden of proof is on the party which is supposedly claiming infringement on their invention. Whereas in other countries like the United States, the burden of proof is reversed.

Standard of patentability of biotechnology becomes lowered if inventive step is interpreted by considering only economic

[29] Dimminaco AG v Controller of Patents and Designs (2002) I.P.L.R. 255 (cal)

significance and technical advance which is another concern in Indian spectrum.[30] Technical advance or economic significance of biotechnology has always been the primary considerations and never as a secondary consideration as well as for a basis of creating inventive step.

The patent office incorporated provision in a patent manual in 2008[31] which formed the basis of guidance to interpret provision of the patent act. In the draft manual of patent practice and procedure, 2008, certain indicators of inventive step were considered such as surprising effect, commercial success, distance, failure of others, standing problems and a more economical product as a technological solution. Setting up of higher standards is decided by the patent office as well as implement certain objectives.

Conclusion:

Various dimensions of intellectual property rights are related in patenting of life forms in the world of industrialization with aspects of ownership, transfer, use and rights on knowledge. Globally, the TRIPS agreement states a mandate for the provision of patent protection of non-biological, microorganism and microbiological production associated with plants and animals. Biotechnology as a category is difficult to be excluded as inventions in developing countries due to such reasons and limiting the scope of such provisions should be a strategy.

Definitions of the word "microorganism" is not including under the TRIPS agreement and is considered a concern for patent protections of microorganism. Hence, it is necessary of for the parliament of a country to define the term "microorganism" by including virus, algae, fungus and bacteria as a part of it.

There is also a lack of the concept-based definitions of discovery and invention for the patent protections of biological material and is an important limitation. It is due to microorganism occurring in nature and its discovery cannot be stated as an invention. It's the human input in genetically modifying such microorganisms which falls in the invention category. Patenting of a specific genetically modified microorganism results into the blocking of any external or further research on that microorganism as different genetically modified microorganism perform different number of activities.

To resolve the various concerns made over the patentability of microorganisms, the term "microorganism" shall be addressed by defining it in a more scientific and precise manner; substantiating the difference between invention and discovery; and granting patents exclusively to inventions which involve human involvement or substantial intervention like genetic engineering.

From TRIPS to Diamond v. Chakrabarty and beyond, the biotechnological industry is responsible for constant endeavor and innovation, with the aim to increase inventions for human welfare. The rationale of patenting life forms is deeply in embedded

[30] Mittal, D.P. (1999) Indian Patent Law. New Delhi: Taxmann Allied Services.

[31] The Patent Office. (2008) Draft Manual of Patent Practice and Procedure, 3rd edn. India: The Patent office.

as the criterion of utility, whether it is useful for treating oil spills, vaccine to fight life-threatening diseases or infectious diseases. Without an effective patent protection, the enormous pool of vital information may stay as a trade secret, with low chance of being showcased into public domain. Thus, a substantial and sheltered patent protection system is much needed for protecting research on life forms and microorganism.

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