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Biotechnology Patenting with the Ethics and Morality Issues

PRIYANKA GEHLOT¹

ABSTRACT

With the advancement of the technology everything in this world are changing with the passage of time and with this there is also emerged a technology called biotechnology which means to produce the healthcare related to products using the living organism and molecular biology and now the patent of this biotechnology has been debating topic in the society in the regime of intellectual property right as how it is right to give someone complete control over the novel beings. The prime focus of the paper on that how there are certain ethical issues related to this patent and how it affects the society at large and it becomes extremely difficult for law to join hands with protecting the intangible property vested in biotechnology patents.

Keywords: *Biotechnology, Patenting, Organism.*

I. INTRODUCTION

Biotechnology is a new concept which come into picture in recent times as in this the technology is used to made health related products or modify products or processes for specific use by using the genome sequencing, biological processes or systems to improve the health of the human beings. It is a technology driven system which use DNA or genes of the organism or the cell to develop or modify the product which used in pharmaceuticals and also for the improvement of the human life. And patent of biotechnology means to bar other person or organization from using, selling, importing of patent organism or products, which formed from technology and there is essence of novelty in it, for twenty years. And according to the article 27 of TRIPS, *patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.*² And there is one more things which says that an invention would not be harmful and does not against the morality or the public health order and safety. And along with it there is article 27.3(b) of TRIPS which talks about granting patent to the micro-organism, it excludes animals and plant varieties. The issue that affects or concern the society while giving the patent to the biotech methods is the ethics and morality as it is there right to live freely which are

¹ Author is a student at Symbiosis Law School, Pune, India.

² https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#fnt-5

provided to every living organism and it give free control to the hands of private individuals and other issue is non obviousness as everything is present in the nature for example DNA, genes or any living organism and by creating them from it is quite non obviousness as there is novelty features in this which is important clause of it.

(A) Literature review

<p>Arif Ali, Human stem cell research in the Europe and the USA: post Brustle and Sherley, ethics issue and patent Quagmire.³</p>	<p>This paper analyses the importance of biotechnology and also did the comparative study of cases of Europe and USA such as the case of Brustle and Sherley. It laid down that how biotechnology is a progressive step and along with it, the patenting of the same raise the concern about the ethical issue.</p> <p>RESEARCH GAP: in this paper, Arif Ali failed in giving a solution to the proper implementation in such technology as he did comparative study and suggested that progressive steps are taken but failed to give reasonable explanation regarding the method through which we can keep check on the immoral activities and also promote and give protection for the invention.</p>
<p>Gagan Krishna Das, patenting of living organism: policy issues and concern – International trends</p>	<p>This paper highlights the issue associated with references to judgement of Diamond vs Chakrabarty⁴ of Supreme court of USA and list out with regards to the patent of living organism the ethical and social issues arising out of this. In this Gagan Krishna das also referred to the article 27(1) of TRIPS agreement.</p> <p>RESEARCH GAP: In this paper the author pointed out the art 27 of TRIPS and also the concern but it failed to point out the clause which is itself present in the agreement such as art 27.3(b) which exclude the plant, animals and macro organism so there no issue of human genes and higher</p>

³ Arif Ali, human stem cell research in the Europe and the USA: post Brustle, Sherley, ethics issue and patent Quagmire, 145 NTUT journal of IP law& Management. (2013)

⁴ Diamond vs chakarborty, 447 U.S. 303(1980)

	organism involved and this research if patent will give encouragement only.
Rameshwari Rao, Patenting in Biotechnology-an overview, National law University, Jodhpur.	<p>According to Rao, he stated various examples wherein he gave the example of patent granted to different micro-organism and also in same case for higher life forms patent is granted such as in Harvard Onco Mouse in which patent is granted on non-human mammal and also to polyploid oysters so author pointed out that this lead to way that slowly patent will be granted to higher living organism even which will be included human clone and which give monopoly to a person or organization over life of another living organism which is against the ethics.</p> <p>RESEARCH GAP: The author in this article fails to recognise the different aspects of laws which are made in the developed countries which is used to check the patent on the life forms. For example in European Union there is article 52(2) EPC which excluded the animals and plants from this, there is also similar law in Australia also which set some thumb rules regarding patenting of biotechnology.</p>
Rujitha T.R, Conceptual issues in biotechnology patenting, Manupatra.	<p>The author in this paper tried to analyze that patenting of the life forms attract many ethical objections, many peoples connected it to the religious beliefs as according to them the patent on life forms means considered living beings as a commodity and degrades the life forms made by the god by giving other person an authority, in this paper it also raised questions on the decision that had taken by European union on Relaxin case where the patent claim was on the single human gene.</p> <p>RESEARCH GAP: The author of this article failed to recognised that the patent of single human genes will not lead to give full control over the life of individuals, even</p>

	single gene is cloned it is impossible to make human beings out of it.
Dr Aisling McMahon, gene patenting and marginalization of ethical issues.	<p>The author tried to conclude that with the advance of the technology there are certain patent laws which are developed and there are different judgements and jurisdiction of the laws in biotechnology patenting. In this research paper author tried to compare the rules of different countries like the USA, Australia, and Canada and concluded that the Canadian approach is best where a solution outside patent law is developed in which compulsory licensing is provided for the benefit for public at large.</p> <p>RESEARCH GAP: As author pointed out that there is marginalisation of the ethics involved in it so in order to prevent this Canada come up with the agreement called Canadian public health license agreement in which for the benefits of the public licensing is provided for the diagnosis but this licensing practice hamper the innovation and also discourage the company and individual to do further research.</p>

(B) Issue addressed by the research paper

- Whether patent should be given in the biotechnology which involved multi cellular organism in wake of ethics and moralilty concern with it?
- Should permission be given for patenting of the organism, gene sequencing and cloning for the interest of the public at large?
- Will patent to life form: a morality issue or detternce to an invention?

(C) Objectives

The objective of this paper to identify the issue of the patent of biotechnology and the living forms and also how it raises concern regarding the ethical and moral factor and also raised question of the monopoly or control of the private individuals over the life forms and how will

it lead to be exploitative in future and also this paper aims to highlights the fact that we need to make the balance between the right of individuals and public at large as in the situation like Covid recently we need vaccination for the mankind to save the life so we also need to encourage the research and development both but it should not be done with the cost of ethics ground.

(D) Research methodology

In this research outline the method used by the author is the doctrinal method in which we read the different primary and secondary sources available and analyses according to the context and do interpretation by applying our reasoning. Followings are the things that come under different methods of doctrinal research methodology.

- This methodology involved reading journals, articles and newspapers and news and basically it involves secondary sources.
- In this research paper I also used the legal database for reading of the research paper provided by the college it includes SCC online, Hein online and jstor law etc.
- And I also read primary source like Indian Patent act 1970 and TRIPS agreement for the research in this research outline.

II. CONCLUSION

In this age of information and technology, new inventions and innovation are one thing which we cannot ignore and it is also unavoidable and biotechnology is the most advance form of technological development which if we can use in the positive way it will help in saving the various life forms such as in the case of BRCA 1 and BRCA 2 which is regarded the identifying mutation in genes regarding breast cancer so such innovation if we provide patent it encourage further research but at the same time patenting of this give monopoly to one person and it against the ethics also so the need of the hour is balanced law which not only promote inventions but also at same time look at the interest of the public at large.

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