

MORALITY AND ETHICS EMBRACING BIOTECHNOLOGY PATENTS

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ABSTRACT

A technology in itself is neither good nor bad rather it is its use which determines its character. The morality comes into picture when the acceptability of biotechnological invention has to be determined on the basis of the weightage of its propitious and detrimental uses. The aspect of ethics also comes into picture when patenting biotechnological inventions, since biotechnology has the power of manipulating even the natural attributes and incorporating novel ones, thereby hitting directly at the inherent dignity, and natural integrity of living beings, besides challenging nature itself. A moral argument against biotechnology is that animal testing for genetic engineering purpose is wrong because pain and suffering are inflicted upon animals for ends that appear frivolous in contrast. Another criticism frequently received by biotech patents is that allowing patenting of new human or animal traits means condoning the commercialization of life which is considered morally unacceptable. Moreover, cloning is being looked upon across various corners of the globe as highly unethical. But whether such moral and ethical concerns have strong footing or not has to be deciphered.

Keywords: *Animal Suffering, public abhorrence test, patent, morality, cloning*

“Biotechnology- A science that manifests life”

1. Introduction

It is rightly said that a technology in itself is neither good nor bad but it is its use which determines its character. In the context of biology, when Recombinant DNA technology (rDNA) was first introduced back in 1970s it was considered a revolutionary technology. At that point of time, it was hard to describe whether this rDNA technology was good or bad which rested much upon its immediate use. With its immense power to redesign life; on one hand it can be utilized to tweak a gene sequence to make a protein that prevents a human disorder, on the other hand it can also be utilized to know-how to produce one that's viral and deadly. Similarly, with its tremendous power, biotechnology can be used to make algae capable of producing energy, yet with its aid, it is possible to introduce some tailored life-form capable of interrupting natural cycles of the environment with unimaginable consequences. Here comes the morality to decide the acceptability of biotechnological invention on the basis of the weightage of its propitious and detrimental uses. [1]

Of all the natural, human, and fundamental rights, the right to self-dignity and integrity is the foremost right of any living being. This right of self-integrity of any being includes within its ambit the self-preservation

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of the features attributed to it by the nature. However, since biotechnology has the power of manipulating even the natural attributes and incorporating novel ones, it is often looked as hitting directly at the inherent dignity, and natural integrity of living beings, besides challenging nature itself. Moreover, these days “cosmetic genetics” is gaining much popularity for its ability to pack our children with physical and perhaps intellectual and emotional traits, like athletic and intellectual prowess, of our choosing. Here, comes the aspect of ethics in shaping the man’ behaviour while developing biotechnological invention, considering the fact that such inventions hits directly at moral principles of society. [2]

Very recently, a Chinese scientist He Jiankui has claimed to have made the world’s first “genetically edited” babies, a pair of twin girls, by removing a specific CCR5 gene from the embryos using the CRISPR-Cas9 technique [3] which would make them naturally resistant to the human immunodeficiency virus (HIV). [4] The said groundbreaking claim [5] has received strong condemnation from various quarters across the globe. For instance, “It is unconscionable ... an experiment on human beings that is not morally or ethically defensible,” said Dr. Kiran Musunuru, a University of Pennsylvania gene editing expert and editor of a genetics journal. [6] The moral and ethical concern here is that the feat could open the door to “designer babies.” [7]

There is great uncertainty in patent law at international level so far as the application of morality and ethics to biotechnology is concerned. Both these terms carry different connotations in different jurisdictions. Since, in many jurisdictions across the globe, morality and ethics play a major role in forming the ground for rejection of patent applications, a thorough and deep analysis is necessitated.

This research paper is a humble attempt to examine the significance of aspect of morality and ethics specifically in relation to patents claimed on biotechnological inventions.

2. Illuminating ‘Morality’

In its etymological term, morality is actually a belief according to which a particular behaviour is said to be right and acceptable while other behaviour is deemed wrong. Judging right and wrong must be done according to the accepted values deeply rooted in the culture inherent in the society and civilisation. [8] While capability of scientists extends only to identifying the benefits of biotechnology, it is only the general public, which is in a better position to settle on the importance level to be assigned to the benefits, the hazards and their impact. [9] To determine whether an invention is contrary to morality, a fair test also famously known as “*public abhorrence test*” is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of a patent right would be inconceivable. [10]

3. Animal Suffering evoking Morality

It often comes as a moral argument against biotechnology that animal testing for genetic engineering purpose is wrong because pain and suffering are inflicted upon animals for ends that appear frivolous in contrast.

For the first time in the history of Europe, an animal “oncomouse” was claimed for patent. [11] The invention was a transgenic non-human mammal [12] susceptible to cancer. The EPO Technical Board of Appeal rejected the contention that the present invention was against morality. [13] It opined that if the invention caused any

kind of environmental imbalance or suffering to animals higher than its benefits, denial of patents would be justified on the grounds of morality. It took note of the fact that invention was intended to be used exclusively in the laboratory under controlled conditions by qualified staff; there is very little chance of environmental imbalance. Further, it opined that cancer being one of the deadliest diseases of the world, the usefulness of present invention to humankind could not be denied. In short, *usefulness to humankind outweighed animal suffering*.

4. Morality and the US Patent Law

As rightly pointed out, one would hardly find statutory morality requirements under U.S. patent law, for the patent system is one of “patent first, ask questions later.” [14]

If we try to find out morality clause under US Patent law, we may not be successful straightaway, but that does not mean that US grants patents even on immoral innovations. Morality in such inventions is often inquired into by the courts as a measure of utility requirement wherein the patent claim must be ‘useful’. And to be useful, an invention must be capable of some beneficial use in society.

In *Diamond, Commissioner of Patents and Trademarks vs. Chakrabarty*, [15] the US Supreme Court refused to consider the ‘grave risks’ associated with genetic research, on the pretext that grant or denial of patents is not likely to put an end to the research or its attendant risks. It seems that there is no attempt in the US, at the relevant time, to deny patents on the basis of moral concerns.

As 13th amendment to the US Constitution prohibits slavery in human beings, the US judiciary believes that cloning of human beings and patenting the same are grossly violative of human rights and unethical and are totally excluded under the US Constitution as well as under the patent law. In the US cloning for both “reproductive” and “non-reproductive” purposes is prohibited. A sole exception is made with regard to allowing stem cell research on “existing stem lines”.

5. Morality and the Indian Patent Law

Unlike US, India contains morality clause under Section 3(b) of the (Indian) Patents Act, 1970. [16] More specifically, the *Manual of Patent Practice and Procedure, 2005*, provides that any biological material and method of making the same which is capable of causing serious prejudice to human, animal or plant life or health or to the environment including the use of those that would be contrary to public order and morality are not patentable, such as terminator gene technology. [17] The Guidelines For Examination Of Biotechnology Applications For Patent, issued by the Office of the Controller General of Patents, Designs and Trademarks in March 2013 provides a few examples which are not patentable as they are against morality: (a) a process for cloning human beings or animals; (b) a process for modifying the germ line of human beings; (c) a process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or other benefit to man or animal, and also animals resulting from such process; (d) a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact; (e) uses of human embryos for commercial exploitation. [18]

In India the presence of deep-rooted moral, cultural and religious beliefs often set a litmus test for gene related inventions in order to pass the patentability criteria. So morality plays a significant role in determining patentability of gene-based inventions in India. [19]

India is opposed to reproductive cloning [20] since India believes it as unacceptable and violative of human values and dignity, but supports research on stem cells [21] saying that the new technology could be used to fight certain deadly ailments.

6. Overhauling Moral & Ethical concerns in the context of Biotech Patents

One moral argument against genetic engineering is that it involves great risk since its consequences as yet are largely unknown. This argument does not seem legitimate as safety concerns, which need to be addressed on individual terms, are not unique to the field of genetic engineering but rather extend to all fields of technology.

In *Plant Genetic Systems N.V. et al.*, [22] it was held that that plant biotechnology *per se* ought not to be regarded as more contrary to morality than traditional selective breeding.

Another criticism frequently received by biotech patents is that allowing patenting of new human or animal traits means condoning the commercialization of life which is considered morally unacceptable. However, no one seriously disputes that a dairy farmer owns his cows and can sell them at will, therefore 'owning life'. The criticism rests on the 'slippery slope' premise, i.e., once patents are granted over animals, it is only a matter of time before they are granted over humans.

Another ethical consideration often put forward against biotech patents is that at times, they hold exclusive interests in lifesaving therapy which makes the treatment pricier. This consideration must be measured against the potential that had there been no patent incentive, no enterprise would have ventured to bring such therapies into existence. Moreover, compulsory licensing and negotiation by respective national governments with the service provider can mitigate such concern.

7. Conclusion

It must be borne in mind that that economic policy lies at the heart of, and has been advanced by means of, patent law. In contrast, the aims of moral policy (if any, in certain terms) are unclear and cannot be achieved, or achieved adequately, through the patent system. It must be pondered whether or not a policy designed to advance economic interests can adequately accommodate moral concerns.

Finally, if we comprehend thoroughly the entire set of moral and ethical objections against each category, it appears that the arguments against patenting of human genes tend to justify genetically related property rights in bacteria more readily than in plants, in plants more readily than in animals, in animals more readily than in chimeras, and in chimeras more readily than in humans. [24] But, in actuality, there seem no justification in lending support to such arguments. [25]

This research paper subsumes the responsibility of streamlining the concept of morality and ethics in application to biotech patents. It may provide useful insight to budding researchers in understanding the concept more

clearly which may be utilized to define the scope of morality and ethics, in specific terms in relation to biotech patents, which otherwise depending upon the contemporary societal norms, extends to infinity.

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- [11] T 19/90 (1990) O.J. EPO 476, Tech. Bd App; (1991) E.P.O., R.525, Ex. D.
- [12] A mammal is a living being that breastfeeds its offspring. As such, human being is also a mammal.
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- [18] http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf.
- [19] Manual of Patent Practice and Procedure (2011), Chapter 08.03.05.02.f, Page 82.
- [20] Reproductive cloning requires prior destruction of the embryo.
- [21] Stem cell research in India is regulated from the human rights and ethical perspectives by the guidelines issued by the ICMR and the DNA Safety Guidelines brought out by the Government of India. The National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and an Institutional Committee for Stem Cell Research and Therapy (IC-SCRT), registered under NAC-SCRT, would analyze the scientific, technical, ethical, legal, and human rights issues in embryonic stem cell research.
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