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A Critical Analysis of Patent Law and Biotechnological Innovations in Intellectual Property Rights

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ABSTRACT

Over the past few decades, there has been a great deal of discussion and development about the relationship between biotechnology and patent law. With the rapid advancements in genetic engineering and biotechnology, the challenge of striking a balance between ethical considerations and intellectual property rights has grown more intricate. This abstract offers a succinct summary of how patent law has changed in relation to biotechnological advancements, emphasizing the difficulties, moral conundrums, and necessity of striking a careful balance between innovation and society concerns.

In the past, the purpose of patent law was to encourage innovation by giving creators temporary exclusivity on their inventions. This implies that genes, organisms that had been genetically modified, and genetic engineering techniques were patentable in the field of biotechnology. This strategy initially encouraged research and development spending, which resulted in ground-breaking biotechnology discoveries and breakthroughs. But as genetic engineering methods advanced, moral questions surfaced. Politicians, bioethicists, and the general public were concerned about the commodification of living forms, the possibility of genetic injustice, and the environmental effects of genetically modified organisms.

The development of biological patent law highlights the continuous conflict between encouraging innovation and taking ethical issues into account. To ensure that the advantages of genetic modification and biotechnology can be utilized while protecting from potential abuses and moral quandaries, it is imperative to strike the correct balance. A constant exchange of ideas among interested parties, such as scientists, legislators, bioethicists, and the general public, is necessary to create patent laws that encourage biotechnology innovation while adhering to ethical standards. This study sheds light on the ever-changing biotech patent law landscape and emphasizes the necessity for a balanced strategy that promotes innovation in the domain of genetic engineering while preserving ethical concerns.

Keywords: Biotechnology, Patent Law, Intellectual Property Rights, Biological Innovation, Invention

1. INTRODUCTION

Recent decades have seen amazing developments in the field of biotechnology, altering the field of genetics and presenting previously unheard-of chances for creativity and commercialization. Specifically, genetic engineering has become a potent technique for modifying and manipulating genetic material, resulting in the creation of innovative medicines, 'Genetically Modified Organisms' (GMOs), and ground-breaking discoveries. But this quick development has also presented intricate moral conundrums and difficulties that touch on patent law, a system of laws intended to promote innovation by giving creators the exclusive right to their inventions.

The broad definition of biotechnology is the use of biological concepts and techniques to the development of products and processes. It has revolutionized a number of industries, including environmental research, agriculture, and medicine. As a branch of biotechnology, genetic engineering enables researchers to work with and alter DNA in order to create creatures with desired properties, produce biopharmaceuticals, and create novel therapeutics.

Patent law has been essential in encouraging investment in biotechnology research and development as a response to these improvements. Traditionally linked with material innovations, patents now cover genes, living things, and genetic engineering techniques. The U.S. Supreme Court's famous *Diamond v. Chakrabarty*[1] ruling in 1980, which held that living things created by humans could be copyrighted, marked the beginning of this progression. This verdict initiated an expanded approach to biotech patent law and established the standard for the obtaining a patent of genetically modified organisms.

[1] 447 U.S. 303 (1980)

The fusion of patent law with biotechnology has not, however, been without controversy. The discussion has come to emphasize the importance of ethical issues. Concerns about genetic discrimination, the commoditization of living things, and the effects of genetically modified organisms on the environment have led to a re-examination of the consequences of biotechnology patenting by legal experts, bioethicists, and legislators.
With the determination of human genomes, biotechnology is set to have a major impact on clinical trials, drug distribution, diagnosis techniques, and the general way of life in human civilization. Biotechnological inventions are classified as biological, microbiological, genetic, medicinal, and agricultural innovations under the patent system. These innovations include substances made from bacteria, plants, insects, and mammals in addition to genetic engineering. The patenting of biological processes and living things is covered in Article 27 of the TRIPs agreement (Trade Related Aspects of Intellectual Property Rights). The WTO (World Trade Organizations) oversees TRIPs, which establishes baseline requirements for intellectual property laws among its member nations.

2. HISTORICAL DEVELOPMENT OF BIOTECHNOLOGY PATENT

The field of biotechnology emerged in the midst of intensive public scrutiny and discourse. In order to draw in investors, many of the new businesses established to take advantage of the scientific advancements that had been made during the previous 20 years produced publicity. Scientists expressed their worries in public regarding the potential risks or catastrophic outcomes of specific kinds of studies. Some were concerned that new infections would emerge and, if not carefully contained, spread throughout the environment. The Patent Act in India was passed in 1970. Since biotechnology wasn't invented in India at the time, it makes no mention of biotechnological invention. The biotech industry's growth and evolution led to the United States and the European Union granting patents for various biotechnological inventions. This demand for adoption of the same methodology and significance extended throughout the world, including India. It also altered the course of patent law history and cleared the way for the ratification of international agreements such as the TRIPs Agreement. The TRIPs agreement's Article 27 requires member governments to grant patent for biotechnology inventions, covering the patenting of live things and living processes. India modified its patent and intellectual property rules to allow for biotechnological inventions once TRIPs were ratified.
After a first amendment in 1999, Patent Act, 1970 underwent a second amendment in 2002. Significant modifications were brought about by this second amendment, which permitted the patenting of products related to chemistry, biochemistry, biotechnology, and microbiology. India enabled the depositing of biological inventions once it recognized the Budapest Treaty. Furthermore, section 5 of the Act, which restricted patents to industrial processes-was eliminated in the third amendment of 2005. As a result, biotechnology processes and goods were both eligible for patent protection. This covers innovations like genetically modified animals and plants, microbes, and methods for working with living things.

3. COEXISTENCE OF IPR AND BIOTECHNOLOGY

The introduction of biological techniques such as cell culture, recombinant DNA technology, and technology for genetic engineering in the 1970s marked the beginning of the biotechnology industry's ascent. In 1973, Cohen and Boyer[2] provided evidence that it is feasible to combine DNA extracted from many species and then incorporate it into an existing organism. One refers to the process of constructing DNA as recombinant DNA technology. One refers to the process of constructing DNA as recombinant DNA technology. Put another way, genetic engineering is the process of fusing genes from completely unrelated species in order to give a host organism new characteristic. Beginning in the early 1980s, studies on recombinant human insulin led to the commercial manufacturing of human insulin by the insertion of the human insulin gene into bacteria. Bacteria multiply quickly, therefore inserting a gene and expressing it there might result in a high insulin production rate. Somatostatin, a human growth hormone-regulating protein, was initially produced in bacteria and was announced as such by the US pharmaceutical firm Genetic Inc. in 1977. The finding of stem cells in 1998, which could differentiate into any organ in the body or into fully formed living organisms, surpassed all expectations in the field of genetic study.
Researchers worldwide are delving into the fundamental secrets of the biological process and the natural world via the use of bioinformatics tools, inventive approaches, and genomes of living organisms. This exploration might lead to the development of novel medicinal treatments, increased yield, and other benefits. Computers and related software are utilized in high-throughput test performance and assessment, combinatorial chemistry design and manufacture of chemical libraries, sequencing of fragments of DNA and their association with known sequences, and molecular modeling. These days, the inconvenient process of physically designing pharmaceuticals using chemicals and test tubes may be avoided by developing drugs on a computer.[3] We can determine which medications are most appropriate for the active spots on a protein surface by turning and examining the three-dimensional representation of the protein's structure on the computer screen.

[2] Herbert Boyer was a genetic engineer and biochemist at the University of California, San Francisco, and Stanley Cohen was an assistant professor in medicine at the University of Stanford in California.
[3] NS Sreenivasulu, Law Relating to Biotechnology 4-5 (Oxford University Press, New Delhi) Ed. 1st 2016.

The result of applying human intelligence, understanding, and knowledge to biological processes is biotechnology. These creative endeavors by humans are worthy of preservation. Because of the potential for biotechnological advancements to yield financial benefits, biotechnology and IPR, have come together, with businesses and IPR producers looking to new biotechnological discoveries for protection against infringement.[4]

4. DEVELOPMENT OF BIOTECHNOLOGICAL PATENT BY GENERATIONS

Biological or biotechnological patent is not the innovation that is made in a sudden practice. But it has been a part of human life for a long time and also got development with the need of society. If it is possible to make it categorized by the means of generations, so it can be summed up as: First Generation (Stone Age Era), Second Generation (Before 19th or 20th Century) and Third Generation (20th and 21st Century)

- ***First Generation****:* This is the very basic and initial development of the biotechnology. It was the development during the Stone Age. In that era use of enzymes, cross-breeding and alcohol fermentation were some biotechnological developments. For instance, 7000 BC ago, China used to ferment the rice wine.
- ***Second Generation****:* In this generation the development of the biotechnology got more creativity. It was during the 20th Century in which many kinds of invention developed like vaccines, single cell protein, antibiotics etc. For instance, the first vaccine was developed by Edward Jenner in 1796, but in 19th century some more vaccines were developed.
- ***Third Generation****:* The third generation of biotechnology is more common as genetic engineering. More development can be noticed here in this era. Every modern technology with a blend of biological innovation is the third generation. E.g. plant biotech, animal biotech, medical applications, chemical applications etc. are propounded during this era.

5. CRITERIA FOR PATENT

- Novelty is the first prerequisite. The Indian Patent Act's Section 2(1)(j) states that an invention needs to be original and separate from 'prior art'. An invention is no longer regarded as novel if it has been publicized in whatever manner anywhere prior to the filing of a patent application. The Supreme Court ruled in *Bishwanath Prasad Radhe Shyam v. Hindusthan Metal Industries*[5] that an invention can only be allowed if it is novel. Since genes & gene products are chemical substances that can be copyrighted once they are separated and processed from their original state, achieving the originality criteria for them is frequently simple.
- The Patent Act's section 2(ja) deals with non-obviousness. An innovation must be commercially significant, include a technological advance over previously known information, or both, and be difficult for a skilled individual in the field to duplicate. For instance, '*covaxin'*, a vaccine invented for the lethal coronavirus. It was never existed before and not previously known.
- Utility is a requirement for patentable inventions. The product must to be useful for a certain industry and able to carry out a certain kind of task. According to economists, an invention passes the utility test if it can be sold for a profit. For example, partly complementary DNA sequences that were previously unknown may be patentable if the method employed to separate them satisfies the usefulness criteria.

6. PATENTABILITY AND USA

For many years, the United States has been the global leader in biotechnology research. It has not only led the world in biotechnology but also significantly contributed to maintaining stringent intellectual property regulations around the globe. Important advances in US patent law portend a potentially significant shift for nations like India. Countless of households in underdeveloped nations are influenced by American precedents regarding patentability. An example of this kind of paradigm shift in the scope of human gene patenting is the *Association of Molecular Pathology v. Myriad Genetics case*[6]. The conditions under which human genes can be patent eligible were lowered by this historic case. In the end, the United States Supreme Court distinguished between separated genomic DNA and material that is naturally derived from that DNA. The Court ruled that isolated human genes are not patentable, and that producing synthetic versions of naturally occurring elements or separating a gene off its environment does not make DNA patentable due to a lack of creative step.

7. PATENTABILITY AND EUROPE

Even if they are defined, European patent rules and regulations regarding human gene patents are somewhat archaic. While certain European nations, such as Germany and France, are enacting more stringent regulations, isolated genomic DNA patent claims are still permitted throughout the continent. Regulation of gene sequence and stem cell patents is based on EU Biotech Directive (98/44/EC) Articles 5 and 6. Both Rule 29(2) of the *s* and Article 5(2) of the Biotech Directive

[4] Archana K, "Do We Need Patent Protection to Biotechnology Inventions" 3 IJSPR 2 (2013)
[5] AIR 1982 SC 1444
[6] (2013) 569 U.S. 576

state that isolated or naturally occurring gene sequences can be patentable upon disclosure of their industrial use. Therefore, as long as the applicant can provide evidence of the gene sequence's industrial use, the EPO will award patents to human gene sequences.
This is not how things are done in the United States. Human genes cannot be patented in the US due to the Myriad Genetics case since DNA is seen as a '*product of nature*'. Global repercussions resulted from the *Myriad case*[7], and nations that had previously granted human gene patents more liberally started to recognize the legal difficulties associated with this loose use of patents.

8. AUSTRALIA AND PATENTING

The legal and regulatory changes pertaining to gene patents in Australia have generated a great deal of discussion. The Australian Law Reform Commission (also known as ALRC) had a discussion on gene patentability. Similar to "patentable subject matter" in the US, the *'manner of manufacture'* test is used in Australian patent law to determine if a product is patentable. Apparently, the biological procedure used for their generation is not a patentable innovation, despite the fact that humans are expressly excluded from the patentability definition under *Section 18(2) of the Patents Act, 1990*[8]. However, prior to the *Myriad Genetics case*[9], patents on human genes were prohibited since humans were not included in the patentability definition down to the molecular level. The APO mentioned that the isolated erythropoietin was deemed to be patentable because the DNA sequences had been purposefully removed from their natural environment, making the gene sequence more than a mere discovery. This issue of the patentability of isolated genes was raised in the patent dispute arguing erythropoietin sequences in the *Kirin-Amgen case*[10].
However, following the historic Myriad Genetics case, Australia's patent rules underwent a change with regard to patents covering human genes. After a protracted legal fight, it was first decided that even isolated human genes qualify for patent protection in the Myriad Genetics case in Australia. But in a majority ruling on appeal, the High Court of Australia determined that isolated genes and nucleic acids do not qualify as patentable subject matter.26 This is consistent with the ruling in the Association for Molecular Pathology v. Myriad Genetics, Inc.[11] held by U.S. Court.

9. PATENTING AND ANIMAL SUFFERING

A common moral defense of biotechnology is that using animals in genetic engineering experiments is unethical as the agony the animals endure is for purposes that, in comparison, seem trivial. Such an argument is hard to support since it is founded on an absolutist perspective that upholds just one value—animal protection—while moral decision-making necessitates the ongoing accommodation of competing values.
The Directive's[12] Article 6(2)(d) enumerates specific processes that alter an animal's genetic identity and are likely resulting in them suffering without providing significant medical benefit to humans or other animals, as well as the animals that result from such processes, as being unpatentable due to *ordre public* or morality. It is interesting to observe that the clause makes no mention of flora. This implies that it is allowed to modify plants genetically, and this will probably be decided based on standard patentability standards. This suggests that inventions pertaining to animals are subject to a higher moral standard than inventions pertaining to plants.
An animal in the Harvard Oncomouse was filed for patent for the first time in European history.[13] The method for creating a transgenic non-human animal with oncogenes and a transgenic mammal that is cancer-susceptible was claimed by the inventor. According to the EPO Technical Board of Appeal, the innovation in question does not violate public decency or order.[14] The board believed that the patent may be denied on the basis of "public order" and "morality" if the invention's risks outweighed its advantages. When new technology involves higher living forms, it is important to take into account both the danger and the potential for harm to those higher life forms.
Different interests needed to be balanced in the current situation. On the one hand, humankind's fundamental interest was in finding a cure for common and dangerous diseases. On the opposing side, the environment was in need of protection against the unchecked spread of undesirable genes, and animal cruelty needed to be curbed. Patents would be denied for reasons of public order and morality if the innovation resulted in any type of environmental instability or animal suffering.

[7] 569 U.S. 576
[8] Legislation related to Patent in Australia.
[9] Supra Note 2
[10] Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd., (2004) UKHL 46
[11] Supra Note 2
[12] EU Directives on the Legal Protection of Biotechnological Inventions, 1998
[13] Oliver Mills, Biotechnological Inventions: Moral Restraints and Patent Law 127 (Routledge, New York, USA 2016)
[14] EPC under Article 53(a) prohibits patent protection for invention the exploitation of which is contrary to public order and morality.

10. MORALITY ISSUES AND PATENT LAW IN US

Since moral standards were frequently upheld in court by virtue of Section 101 utility requirement—which stipulates that a procedure, machine, manufacturing, composition of matter, or improvement thereto be "useful"—US patent law does not, in and of itself, have a morality clause.[15] An innovation may only be considered valuable if it has some positive social use. Justice Story stated in *Lowell v. Lewis*[16]: *"The invention must not be worthless or detrimental to the welfare, sound policy, or morals of society. That is the whole thing the law requires." Therefore, the term "useful" is included in the Act to contrast with "mischievous" or "immoral."*
Justice Story mentioned several instances of immoral innovations, such as a novel way to poison people, enable covert assassinations, or encourage revelry. The US courts have usually followed the Story's definition of usefulness in refusing to grant patents for two categories of innovations that they deemed immoral: devices used to deceive consumers and gambling machines.
But later, in the case of *Juicy Whip Inc. v. Orange Bang Inc. and Unique Beverage Dispensers Inc.*[17] , the CAFC, represented by Judge Bryson, pointed out that the requirement of utility is not a command to the PTO or the courts to arbitrate cases involving deceptive trade practices when other State agencies have been tasked with this responsibility. This suggests that inventions used to deceive consumers, whether or not they are morally wrong, can no longer be deemed ineligible for patentability for that reason. *Judge Bryson* said, "It has not been used widely in recent years that innovations are defective if their primary goal is to fulfill immoral or criminal ends. For instance, it is no longer legal for courts to reject gambling equipment patents on the grounds that they are immoral."
The US Supreme Court rejected the idea that there are *'grave risks'* connected to genetic research in case of *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*[18], holding instead that the granting or refusing of a patent is unlikely to stop the study or the related risks. The decision we are encouraged to render is of high policy for settlement within the framework of legislation following the type of research, analysis, and analysis that legislative bodies can offer, and judges cannot, the court declared. *"We are no competent to entertain these arguments."* This shows that there was no attempt to reject patents in the US based on moral grounds at the relevant time.

11. MORALITY ISSUES AND PATENT LAW IN INDIA

India acknowledges the exclusion of public order and morality from patentability, just like Europe does. A morality clause exists in Indian patent law according to the clause (b) of Section 3 in the Indian Patents Act 1970. This clause states that an invention that could be used or intended to be used in a way that could be against public order or morality, or that could seriously harm human, animal, or plant life, health, or the environment, is not eligible for patent protection. More precisely, any biological material and method of producing it that could seriously harm human, animal, or plant life or health, or the environment, including the use of those that would be against public order and morality, are not patentable. Examples of such materials and processes include terminator gene technology[19]. This is stated in the Manual of Patent Practice and Procedure (2005).
A few instances of non-patentable biotechnology products that violate public order and morals are given in the Guidelines for Examination of Biotechnology Applications for Patent, published by the Office of the Controller General of Patents, Designs, and Trademarks in March 2013:
The following practices are prohibited:
(a) cloning humans or other animals;
(b) altering a human's germ line;
(c) changing an animal's genetic makeup in a way that will likely cause suffering for it without providing significant medical or other benefits to humans or other animals;
(d) creating seeds or other genetic materials that contain components that could have a negative impact on the environment; and
(e) using human embryos for commercial purposes.
In India, deeply ingrained moral, cultural, and religious convictions provide a bar that must be met for innovations relating to genes to be eligible for patent protection. Therefore, in India, the patentability of ideas based on genes is heavily influenced by public morals and order. A similar worry is expressed in the Indian Patent Manual of 2011 when it states, *"An invention, the primary or intended use of which is likely to violate the well accepted and settled social, cultural, legal norms of morality, e.g. a method for cloning of humans."*[20]

[15] Supra Note 9 at 45
[16] 15F Cas 1018 (No. 8568), Circuit Court, Massachusetts 1817.
[17] 185F 3d 1364 (1999)
[18] 206 USPQ 193 (1980)
[19] The Manual of Patent Practice and Procedure (2005), Annexure I, Page 142, Para 7.0.
[20] Manual of Patent Practice and Procedure (2011), Chapter 8.3.5.f P. 82

12. CONCLUSION

Biological processes are used to use and manipulate living things or biological systems in the course of developing or producing a product or in providing a technological solution to the real world. Biotechnology is the synergistic fusion of the natural sciences and technology-driven industrial art. Karl Erkay, a Hungarian engineer, came up with the term *'biotechnology'* in 1919. Although an all-encompassing description is impractical due to the changing dynamics of biotechnology, writers, experts, and organizations have attempted to describe biotechnology as closely to perfection as possible.

India only controls single gene products at the moment. Only Bt cotton, which is worm-resistant, has emerged as the only genetically modified crop to yet to be approved for commercial production in India. If permission has previously been granted for just one trait products and the characteristics are discrete, it is not required in the USA to provide additional security details on multiple trait goods developed using traditional breeding. Moreover, US patent law lacks the ordre public and morals clause. The human chimera incident showed that even though US patent law does not have morality or public order requirements to regulate the granting of patents, the US nevertheless views the law as useful for a few key concerns. However, India acknowledges that morality and public order are excluded from patentability. The Patent Act, 1970 makes it clear that the country sympathically prohibits patents for genomes and gene-based technologies that violate public morals or order. A method for human cloning is an example of an invention whose primary or intended application is likely to breach established social, cultural, and legal standards of morality. This is echoed in the Indian Patent Manual, 2011, which states the same worry.