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LACK OF PATENCY IN BIO-PATENTS: GREY AREAS WITHIN THE LEGAL PROVISIONS

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Abstract

While patency may mean non-obviousness and unobstructed in the literal translation, it is not quite so in the actual legal definition and procedure of the term – especially when it is in the context of biotechnical inventions. Even with the rapid development in the field of biotechnology and the innovations being made in the said field, the laws in many countries are yet to catch up to protect them.

And while there are attempts, the issue arises when that attempt leaves behind grey areas by not explicitly defining certain key terms. In this paper, we explore what is biotechnology and how its relevance has grown in the past few years along with the issues faced by the inventors of such biotechnical inventions when they try to opt for protection.

We further discuss various protections given by international conventions and agreements, based on which domestic patent laws are framed and how these domestic laws may vary based on different interpretations of such grey areas.

Lastly, the paper explores the Indian perspective on both the biotechnical inventions as well as the grey areas that may arise when one seeks the protection of bio-patent in the nation. Some steps and suggestions are also discussed in the conclusion while hoping that such matters be resolved at the earliest to avoid any obstruction that may result in the delay of our development just because of the unfounded prejudice against genetic engineering and biotechnology.

Keywords: Biotechnical Invention, Bio-patents, Patent law, Biotechnology and Genetic Resources.

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Introduction

With the rapid development in science, time as well as technology have been changing around us at an unprecedented speed. This could be especially observed through the scientific development made in the field of Biotechnology, where humans can now synthesize artificially modified food that can give us the required nutrients as per our needs and desires.

While life and living organisms were something that was previously believed to be strictly God-given, humans have finally come to a stage where we can modify even those God-given gifts; let it be for the purpose of food, medicines or even future experiments. This new development has caused quite a turmoil in the world since it challenges the views many people have harboured for so long.

Since human technology has advanced beyond what one may consider the boundaries of morality, the legal provisions helped to create a barrier for such developments from harming or indiscriminately exploiting any life form as well as resources while also providing them with a level of protection to foster the innovation that may help humanity to develop further. One such legal protection is the protection given under the Patent law. Patents, as one may already know, are a part of the intellectual property rights that are granted to a person in relation to the use or sale of a product/process that has been invented by them or assigned/licenced to them by the original inventor. In simpler terms, a patent gives the official title and rights of an invention to the rightful owner (inventor).

The protection given under patent law allows the inventor a monopoly over the commercial usage and distribution of their invention once the patent for the invention is granted. However, there are many catches to that single requirement of being granted a patent since the process itself is both complex and quite obstructing. Since the right of a patented invention is quite absolute in the context of commercial exploitation, the protection is granted after passing quite a few thorough procedures and eligibility criteria. And the main issue that arises is in the eligibility criteria itself rather than the straightforward procedures.

While the international minimum criteria of patent protection given in TRIPS is adopted by most of its signatory countries, the additional exclusion and protection to be given is left in the hands of the domestic legal system of the respective countries. This, unfortunately, has resulted in many grey areas not being defined or protected in the domestic arenas. Thus, making the protection

given under Patent law limited and ambiguous regarding some of the inventions; especially in the context of biotechnical inventions, which are often rejected protection due to the nature of the resources used for the making of the invention.

In this paper, we will cover the status of such grey areas in both the international and domestic legal arena in a detailed manner.

Growth of biotechnical inventions

Biotechnical inventions, as the term suggests, are inventions made in the field of biotechnology, which is nothing more than the usage of technology in a manner to manipulate and modify biological products and processes.[2] In simpler terms, inventions that are made from biological resources and modified in a manner to get the desired product or result are commonly known as biotechnical inventions.

And while many people may think that such inventions or even the application of biotechnology have been a recent advancement of humanity, it isn't quite so. In fact, biotechnology has existed since the beginning of civilization and is so common that we often are not even aware that the products we are using might be a result of it. From the brewing of wine to the curdling of milk to the making of yoghurt, all these processes are a part of biotechnology which would not have existed without human influence and desire for domestication. Other more relevant examples in the context of modified products would be crossbred plants like seedless bananas, orange carrots and lemons – most of which would not have existed without deliberate human intervention.

Many methods of crossbreeding animals and isolation of desired gene pools to get better animal products (milk, meat, leather, etc.) can also be accounted as biotechnology that humanity has been using since the dawn of civilization. The modern biotechnology that we see through vaccines, genetically modified or transgenic plants and medicines are more of the recent development that has brought some important breakthroughs in a lot of fields and has become as relevant to humanity as any other field of technology; maybe even more so in cases like health, medication and environment, where such inventions can stand unparalleled to any.

[2] Organisation for Economic Co-Operation and Development (OECD), "*Report on Genetic Inventions, Intellectual Property Rights and Licensing Practices*", Evidence and Policies (2002).

We can take the innovation of the biotechnical invention the 'liquid tree' as an example, which is helping to resolve the issue of excessive pollution in metropolitan cities with little to no carbon footprint of its own.[3] One can also take the example of the artificial insulin and hormones synthesized for disabled people whose bodies are lacking as such and need external dosage for survival. In addition, artificial pacemakers, lab-grown organs and other medical devices have also helped in increasing the life expectancy of humans indisputably.
However, while biotechnology is unparalleled in its growth and relevancy, there are still many hurdles and misconceptions that are yet to be cleared to give biotechnical inventions full legal protection.

While biotechnical products have been used by humans for quite a few centuries, the actual protection given to such products in terms of their commercialization is quite limited in scope. This is mostly because of the ideology that any and all life forms belong to the nature and cannot be claimed by any human as an invention. This mentality, however, was first challenged in 1980 when a genetically modified microorganism was patented in the USA.

It was the landmark case of *Diamond v Anand Chakrabarty*[4] which broadened the scope of legal protection of biotechnical inventions and lit the spark of innovation in the minds of many biochemical scientists. In this case, the respondent was a microbiologist who genetically modified a bacterium to be able to digest hydrocarbons like various types of oils. In a nutshell, the genetically modified microbe had the ability (as well as speed) to break down oils in the oil spill without any further adverse effects on the environment.[5]

At the time, not only was such an invention revolutionary but also had a dire need due to several oil spill incidents taking place frequently in the country as well as around the world. Keeping this fact in mind, the respondent had filed a patent application to the Patent Office where the Controller, the Appellant, had rejected the application on the prejudice that no life form could be claimed as an invention. However, this rejection was reversed in the appeal to the Appellant Board before moving further to the Supreme Court where it was held that the Patent application claimed a non-natural phenomenon that was genetically modified into the microbe by the respondent. Without the human

[3] S. Singh & Dr. M. Dake, 2023, "*Liquid Tree: the Future for Cleaner Air*", Dr. D. Y. Patil Biotechnology and Bioinformatics Institute, available at: https://biotech.dpu.edu.in/blogs/liquid-tree-the-dystopian-bush-is-here (Last visited: Aug. 10, 2023).
[4] (1980) 447 U.S. 303.
[5] Frank P. Darr, "*Policy Implications of Diamond v. Chakrabarty*", Patent Coverage, Ohio State Law Journal, Vol. 42:1061.

intervention as provided by the inventor, there would be no such microbe occurring in the natural domain. Thus, keeping this in mind, the first Patent for a genetically modified living organism was granted in 1980.

Before this case, the natural principle doctrine established in the case of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[6] was followed, which stated that a mere observation or isolation of any natural /biological process did not amount to invention or discovery within the scope of patent laws and thus would not be protected as such. However, after the *Chakrabarty case*,[7] this doctrine was denounced to some extent.

After this judgement, rapid growth of innovation was observed in the field of biotechnology as the scope of legal protection was finally extended to protect genetically modified or transgenic living organisms. However, despite such a ground-breaking new development, many nations were still on the fence regarding the allowance of granting such legal protection. Since genetic modification could lead to indiscriminate exploration of natural and biological resources, many developing countries scrutinized such landmark judgments for the fear that they would be exploited unhesitatingly. The other concerns of morality and fear of cruel experimentation on animals and plants along with such practices being against the religious views of many also led to prejudice as other nations speculated whether to grant protection to such inventions within their territories or not.[8] And since a Patent is a territorial law, without the domestic law allowing it, such inventions would get no protection.

This, in turn, resulted in biotechnical inventions becoming a grey area as many nations allowed them legal protection under Patent law while many didn't. The best way to explain this is through the case of *Harvard College v Canada (Commissioner of Patents),*[9] which is also commonly known as the 'oncomouse' case. In this case, the researchers at Harvard College developed one of the first transgenic animals, which was a mouse that was highly susceptible to cancer due to the introduction of an oncogene or tumour-causing gene in its DNA. Since many medicinal as well as food products often need to be tested on animals (mostly lab rats) to see whether there will be any adverse effects upon consumption, such transgenic mice could help in the easier detection of cancer-causing

[6] 333 U.S. 127 (1948).
[7] (1980) 447 U.S. 303.
[8] A. Jauhar & S. Narnaulia, "*Patenting Life the American, European and Indian Way*", Journal of Intellectual Property Rights Vol 15, pp 55-65 (2009).
[9] 2002 SCC 76, 219 D.L.R. (4th) 577, 21 C.P.R. (4th) 417, [2004] 235 F.T.R. 214.

ingredients or elements.[10]

In fact, such transgenic animals could also help further the research in the field of cancer with ease as their sensitive system could develop cancerous tumors quite easily. Thus, with such beneficial utilities, Harvard College sought patent protection in several countries including Canada, the USA and the European Union (EU) Patent Office.

While the USA Patent Office granted transgenic animal protection quite easily, observing how the patent claim explicitly focused only on animals and not humans, the EU patent office hesitated. After extensive consideration, the patent application in the EU patent office was also approved; though, not before making some minor amendments to the patent claims, which were narrowed down from the term 'animals' to only 'mice'.

However, in the case of Canada, the Patent application was rejected since it was held that 'higher life forms' such as animals and plants were not patentable and that the process of 'manufacture' in their patent laws was to be interpreted as a non-living process. Thus, this case highlights the different approaches taken by different nations in regard to the interpretation of grey area terms such as 'higher life forms' and 'manufacture.'

Despite such different approaches, a uniform system of protection was established by several international treaties and agreements, which we shall discuss in the next section of the paper.

Protection under international agreements

Since Intellectual Property (IP) law is still an evolving concept, there is a lot of ambiguity in its concepts which had previously led to varying laws around the globe with little to no uniformity. To resolve this issue, as well as to promote the protection and commercialization of intellectual property in developing and underdeveloped countries, several conventions and treaties were conducted with the aim of bringing standardization in IP laws around the globe by setting a minimum standard of protection.

[10]"*Bioethics and Patent Law: The Case of the Oncomouse*", WIPO Magazine, *available at:* https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html (Last visited: Aug. 13, 2023).

One of such major international agreements for IP law included the Trade Related Intellectual Property Rights (TRIPs), which established the basic minimum standards for the protection of intellectual property in all its signatory or member countries. However, TRIPs did not focus much on biotechnical inventions or even mention any scope of patency in the field of biotechnology. The main objective of the agreement, instead, was to prioritize the protection of the rights of an individual IP holder regardless of the nature of their intellectual property.

Article 27 of the TRIPs[11] Agreement lays down the scope of patentable subject matter, which is used as a guideline by many nations while framing their own patent laws especially developing countries like India. According to the aforesaid Article, patents shall be granted to any and all inventions (process or product) regardless of their fields of technology, given that they are eligible for the patent protection.

However, the Article also states the exceptions that cannot be patented in order to protect public order and morality, which includes the protection of human, animal and plant lives. Further exceptions were also provided under Article 27 (3), where sub-clause (b) explicitly talks about animals, plants and biological processes occurring in nature.[12] While the sub-clause states it in a manner not of compulsion but rather a suggestion, it still does not clarify the terms mentioned, resulting in a grey area due to varying interpretations in the respective domestic jurisdictions.

On the other hand, the United Nations Convention on Biological Diversity (CBD) focuses solely on biological and genetic resources and their usage as intellectual property around the globe. With the aim of the convention being to sustainably use the resources while conserving biodiversity and sharing access to all the genetic data relating to it, CBD does not directly address the topic of bio-patents. Unlike TRIPs, CBD mostly works towards forming an alliance among its member countries for collective development in the field of biotechnology – especially in the context of genetic resources.

There are two protocols under the CBD convention; the Nagoya Protocol and the Cartagena Protocol, in which the former deals with the legal framework of access and benefit sharing in regards to genetic resources while the latter deals with the regulation of transfer of Living Modified Organisms (LMOs) from one nation to another.

[11] Trade Related Intellectual Property Rights, 1995, Art. 27.
[12] Trade Related Intellectual Property Rights, 1995, Art. 27 (3) (b).

Both the Protocols, while dealing with biotechnical inventions, do not directly cover nor clarify the grey areas of bio-patents. And while Genetically Modified Organisms (GMOs) as well as LMOs are clarified and explained well under the Cartagena Protocol, none of the other grey area terms such as inventions, discovery, manufacturing, biological processes, etc., were explained explicitly.
The last convention that directly and indirectly deals with the field of biotechnology is the International Convention of the International Union for the Protection of New Varieties of Plants (UPOV), which deals with the protection of genetically engineered or transgenic plants. As its name suggests, the convention lays down the legal provisions to protect the rights of the breeders, farmers and researchers in the context of plants genetically modified through crossbreeding, hybridization or another method of biotechnology.

This convention covers the aspect of transgenic plants which cannot be protected under the patent law. However, since the main focus is only circled around the rights, many terms are left with an open interpretation, including the terms essential biological processes and plant variety.
There are many other treaties like the International Treaty on Plant Genetic Resources for Food and Agriculture of 2001 and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 1977 that also vaguely encompasses the field of biotechnology with its subject matters, such as plants (or seeds) and its genetic resources, which can often be used as references for bio-patent applications.

However, despite many such international conventions and agreements setting a baseline for IP protection, as discussed above, most of them do not explicitly define or even mention terms like life forms, biological processes or other grey areas which may result in different interpretations in different jurisdictions even when all the member countries followed the same guidelines and frameworks provided by the treaties.

Differing interpretation

As seen in the *oncomouse case,*[13] different jurisdictions or nations may interpret the same terms differently due to how broad the interpretation of such terms could be. These terms are often what causes grey areas to arise when filing for bio-patents since whether or not one may get a patent is not guaranteed.

[13] 2002 SCC 76, 219 D.L.R. (4th) 577, 21 C.P.R. (4th) 417, [2004] 235 F.T.R. 214.

As we noticed in the aforesaid case, the EU patent office granted Harvard College the bio-patent after some contemplation. However, in a similar case known as the *Upjohn mouse case,*[14] the EU patent office did not grant a patent to the transgenic mouse which was genetically modified to be susceptible to losing its hair for the conduction of more accurate and efficient tests for products to resolve human baldness and to explore fur production methods.
Such duality occurred due to the utilitarian approach taken by the EU patent office while considering such bio-patents. However, this approach was not opted by other jurisdictions' Patent offices, as seen in the context of the USA and Canada.

Moreover, unlike the developed countries as discussed above, developing countries have more rigid patent laws with even harsher barriers for bio-patents to avoid any harm to the public order and morality, let it be from a social or religious perspective. In countries like China and India, all living organisms except microbes are not patentable; even biological processes or other biological materials like organs, cells, tissues, etc., are not patentable even when artificially created or manufactured.[15]

One may wonder why there are so many irregularities or lack of consensus regarding bio-patents among the nations despite having the same base framework and that is because of how the international conventions only provide the minimum standards and leave the rest to the nations themselves to decide how much protection beyond the provisions they would like to provide.

And since Article 27 (3) of the TRIPs Agreement is not mandatory but rather discretionary, many nations opted to apply it to their legal provisions while others did not, with India and most of the other developing and underdeveloped countries being in the former category while the developed countries like the EU, USA and Australia being in the latter.

Due to this very reason, many aspects of biotechnology like transgenic plants and animals along with artificially manufactured organs, muscles, protein, meat, etc., have become a part of the grey area which is not defined whether to be patentable or not directly in the patent laws of many nations, leaving its Patent offices and judicial system to determine that on the basis of precedents and their interpretations of the provisions.[16]

[14] The *Upjohn Pharmaceutical Company* vs. *Akzo Nobel Pharma B.V.* [1999] ECLI: EP: BA: 1999:T079196.19991115.
[15] Debapriya Biswas, "*Protection of Bio-Technical Inventions: First Step to Sustainable Development*", ILE Intellectual Property and Corporate Law Review, Pg. 19-24 (2023).
[16] Jauhar & Narnaulia, *supra* note 7.

In a nutshell, this discrepancy regarding the patentability of biotechnical inventions from nation to nation and territory to territory has led to many grey areas that are often not clarified in the Patent laws itself and are only resolved when brought or appealed to the Judiciary.

Indian perspective

The quite interesting thing about the Indian Patent laws is that while the Patent Act of 1970 does clarify the eligibility criteria to be patentable, it does not specify exactly what is patentable. Instead, Sections 3 and 4 of the aforesaid Act[17] outline exactly what is non-patentable, giving a wider scope to those which are not mentioned in these exceptions.

Before the 2005 amendment of the Indian Patent Act, the scope was quite limited since all life forms and any related process and product to them were mostly garnered to be non-patentable. This only changed after the landmark case of *Dimminaco vs. Controller of Patent Designs,*[18] in which the Calcutta High Court granted a patent to Appellant for the process of preparation of a live vaccine for the Bursitis disease.

With the only reason for the patent application's previous rejection being that the end product produced a living organism, the Court granted the patent to the process of manufacturing the vaccine, drawing the conclusion that the invention meets all the eligibility of patentability and the process can be interpreted as 'manufacturing', as given under the (then) Patent Act.

However, even after the 2005 amendment, some issues still persisted since Section 3 (j) still restricts the patentability of any biotechnical product or process except in relation to microbes and genetic resources.[19] This limits the patentable subject matter in the field of biotechnology quite a bit considering how there is still an ambiguity when it comes to the explicit definition and meaning of the term 'microorganisms' or microbes in the Act.

And, although that is quite an obstruction in itself, further issues are created when many terms used under the Act regarding such restrictions are not clearly defined; for example, plant variety, manufacture, essential biological processes, etc. In fact, terms like inventions are not clearly defined

[17] The Patents (Amendment) Act, 2005, § 3 & 4.
[18] (2002) I.P.L.R. 255 (Cal).
[19] The Patents (Amendment) Act, 2005, § 3 (j).

either, beyond their basic eligibility for the grant of a patent – leaving the speculation upon the Patent Office's discretion as the applicants get trapped in the uncertainty of the scope of these terms.

Let us take an instance to get a better understanding; Biotechnology has many techniques, one of which is the cell-fusion technique in which two (or more) different types of cells are engineered to be combined in such a manner that a new cell is created.[20] It is most commonly seen to be used for the procedure of In-vitro fertilization (IVF) for the making of test tube babies.

The other examples can be taken from the studies being conducted on human antibodies by fusing them with the respective disease cells to create an even stronger batch of antibodies. This study was mostly conducted in relation to measles cells and their antibodies, before exploring the field of cancer cells as well to create such antibodies with its fusion that might have anti-tumor potency.[21]

Supposing that such an anti-body was created that could cure cancer even at its later stage, it would still not be patentable under the Indian Patent Act due to being in contravention of Section 3 (j). While some may argue that the substantial human intervention in the creation of such a cell or anti-body was akin to a manufacturing process since the scope of the term itself is ambiguous under the current laws, the above biotechnical invention would be left uncertain in its patentability still till it is brought in front of the judicial system.

Furthermore, such artificial antibodies can also be interpreted as non-inventions due to both the cells already existing in nature (or the human body) and the product formed being a mere fusion or 'mixture' of those two naturally occurring substance. This can lead to even further ambiguity and confusion. Such is also the case for the term 'plant variety', which is admittedly protected under a different Act altogether but leaves an uncertainty as to the scope regardless. The most common example of it would be the *Bacillus Thuringiensis* (BT) cotton, which is a transgenic plant genetically modified to be resistant to all kinds of pests and bacterial diseases.
As given in its very description, it is a genetically modified plant, which should be accounted as a non-natural organism that is artificially created by deliberate human intervention. Taking it as a 'plant variety', which should be occurring in nature whether as a mutation or by crossbreeding and hybridization leaves a lot to interpret. This was exactly why there was quite a conflict regarding this

[20] T. Nakamura, K.W. Peng, S. Vongpunsawad, M. Harvey, H. Mizuguchi, T. Hayakawa, R. Cattaneo & S.J. Russell, "*Antibody-targeted cell fusion*", Nature Biotechnology 22, pp 331–336 (2004).
[21] *Ibid.*

topic when BT cotton and other types of transgenic plants were first introduced in India.[22]

Such grey areas and limited subject matter scope for biotechnical inventions have left the status of bio-patents in India as a rather hit-or-miss concept except in cases of genetic resources and microbes.

Conclusion

With the rapid development of technology in all fields, biotechnology has been highlighted for the past few years due to its wide scope of utility and innovation. However, while many countries are accommodating in accordance with these new developments and innovations, there are also many nations reluctant to provide greater IP protection to biotechnical inventions for the fear of its potential misuse or contravention of morality and public order.

Especially in developing and underdeveloped countries, where the blanket of IP protection took longer to spread, such new developments are still a far thought to be caught up to, considering their conflicting position on the protection of an individual's (IP owner) commercial interest versus the State and public's moral as well as social interest.

Thus, the first step to establishing a balance between the two is to lessen the ambiguity caused due to the grey areas left by the legal provisions by bringing uniform and working definitions that can be abided by. The second step should be to address and dissuade the unneeded paranoia of the public concerning biotechnology and its products as well as processes.

Without these two steps, the obstruction to further development will only enlarge and may result in us being left behind in the changing times due to the ambiguity of the scope of the overtly complex provisions.

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[22] P. Ramasundaram, A. Suresh & R. Chand, "*Manipulating Technology for Surplus Extraction: The Case of Bt Cotton in India*", Economic and Political Weekly, vol. 46, no. 43, pp. 23–26 (2011).