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Critical Analysis of Patenting of Life Forms

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Patent protection has been an essential need in the developing world for securing one's invention and further helping the inventor in isolating the invention in order to serve the general public in the long run by satisfying the criteria of acquiring a patent. In the last few decades, with the rapid growth in biotechnology, it has become a much-debated and controversial topic as to how fair it is to grant patents to life forms. The stance of India on patenting of life forms has changed over the years. There are various issues ranging from legal to social issues revolving around this topic. This article aims at providing clarity on the history and evolution regarding the rules of patentability of life forms, and also the status of the same in India and other countries. It also discusses in detail the lacunae left behind by international treaties regarding bio-patenting.

Keywords: *patent, biotechnology, intellectual property, bio-patenting, lifeforms.*

INTRODUCTION

A patent is an exclusive intellectual property right granted to a person for an invention, which could be a product or a specific process of doing something, or presents a new and an entirely different solution to an existing problem. Acquiring a patent over such an invention allows the patentee to monopolize the invention to the exclusion of others. In order to be awarded a patent for that invention, the patentee must provide full disclosure, involving all technical and

any other related aspects, to the public. It is pertinent to highlight that the invention must-have qualities to be classified as an industrial application. A patent is provided for a limited period by the Government. After the patent is awarded, others, excluding the patentee cannot make use of the invention in any manner which might include the selling or importing of the patented product, or the process of production of the product. The concept of patentability of living organisms or life forms became a controversial topic around the late 1900s with the rapid and apparent growth of biotechnology. Hence, patents demanded products that were produced from existing life forms that were beneficial to society. This paved the way for the introduction of bio-patenting or patenting of life forms. The patentability of life forms involves a series of issues ranging from legal to moral issues as even under current provisions laid down under the Patent Act, 1970, various terminologies revolving around bio-patenting have not been defined, and since these kinds of patents involve industrial and commercial usage of life forms. In addition to that, the rules regulating these are not definite under the current laws.

STANCE OF INDIA PRIOR TO THE AMENDMENTS MADE IN 2003 AND 2005 TO THE PATENT ACT, 1970

Although India was a signatory to the TRIPS (Trade-Related Aspects of Intellectual Property Rights)¹ agreement, its stance on granting patents to living organisms was not clear and highly disputed. TRIPS agreement had previously laid down provisions that allowed granting of patents to micro-organisms along with interpreting the ambit of the term micro-organisms widely.

TRIPS AGREEMENT

The TRIPS agreement, administered and regulated by the WTO² set guidelines and mandatory standards for all its member countries to comply with. The agreement was negotiated under the consensus of WTO member countries at the Uruguay Round of General Agreement on

¹ 'Overview: the TRIPS Agreement' (WTO) <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 12 April 2022

² Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994

Tariffs and Trade (GATT)³ in 1994. It allowed the patentability of micro-organisms, but due to its lack of providing a proper definition of micro-organisms, the member countries interpreted the definition of micro-organisms arbitrarily and unequally. Amounting to this, various researchers were denied patents on genetically modified organisms made from existing life forms. It was argued that it was a product of skill rather than a product of the invention. To resolve this issue, there was a requirement for the enlistment of naturally existing organisms and genetically modified organisms under the ambit of this agreement.

Article 27⁴ of TRIPS Agreement: It mandates the allowance of patents of any kind of invention, regardless of it being a product or a process, in all fields of technology. The main and only requirements are that the product or process should be new, involve an inventive step, and must be capable of industrial application. It also has a provision for its member countries to exclude any such invention which is exploitative of natural life forms and affects the morality of the general public.

India and TRIPS Agreement: India being a signatory to the TRIPS⁵ agreement was mandated to follow all the provisions enshrined in the agreement. But due to the vague scientific definition of micro-organisms, applications for patents for the processes and products related to micro-organisms were rejected. The reasons behind the rejection were mostly given that since these processes involved an already existing organism, the scope of innovation and invention stood disqualified as required by Section 2(1)(j) of the Patent Act, 1970⁶ which defines an invention as a new product or process involving an inventive step and capable of industrial application.

ISSUES IN PATENTING OF LIFE FORMS

Legal Issues

³ General Agreement on Tariffs and Trade, 1994

⁴ Agreement on Trade-Related Aspects of Intellectual Property Right, 1994, art. 27

⁵ Overview: the TRIPS Agreement (n 1)

⁶ Patent Act, 1970, s 2(1) (j)

Around the world, prior to the 1980s, the patentability of life forms was considered unimaginable as it was viewed as merely a discovery rather than an invention. In the USA, in the case of *Funk Bros. v Inoculant Co.*,⁷ a patent application for a mixed culture of Rhizobia which were capable of immunizing seeds of plants belonging to cross-vaccinating groups was rejected. The court held that it was nothing more than a discovery of an unknown phenomenon and hence, a patent could not be granted for some mere discovery of a life form that already exists in nature. It was concluded by the court that a product obtained through the advancement of skill is not patentable. There must exist inventiveness, which it lacked. In another case in the USA, which is considered a landmark case for the patentability of life forms, *Diamond v Ananda Chakraborty*,⁸ the Supreme Court took a liberal approach and granted the patent to a genetically modified bacterial species. The main focus of the court was given to the “inventive step” which included the change in the composition of the bacteria which originally existed and the inventive process of manufacturing the modified bacteria. It was also taken into account that the final and modified product was capable of being utilized in a better and more useful way than the original bacteria. It was observed that “composition of matter” and “manufacture” gave way for the inclusion of various inventions which were previously rejected on the grounds of being manmade. Hence, the discovery was stated as a work of its own and not a product of nature.⁹ After this judgment, several applications were filed for claiming the patent protection over higher life forms like plants and animals. In subsequent cases, patent rights were extended to plants¹⁰ and then to animals¹¹. These decisions were based on the degree of interventions made by humans as a test of making the product. The usefulness of the product to society at large was a major influencing factor for the grant of patent. In India, it was still a disputed topic as to whether or not a patent should be granted to living organisms as it was in contravention of the exclusion clauses stated under Section 3 of the act¹². The use of living organisms such as micro-organisms to create genetically

⁷ *Funk Brothers Seed Co. v Kalo Inoculant Co.* [1948] 333 [US] 127

⁸ *Diamond v Chakraborty* [1980] 447 [US] 303

⁹ Patent Act, 1970, s 101

¹⁰ *In Re Hibberd* [1994] 227 [USPQ] 443

¹¹ *In Re Allen* [1962] 846 F.2d 77

¹² Patent Act, 1970, s 3

modified species was viewed as business propaganda and a way of exploitation of naturally occurring life forms for private usage.

Varying decisions of courts and unclear guidelines as to what constitutes sufficient human intervention for it to be classified as patentable created a confusing atmosphere around the patentability of life forms. In the year 2002, the Calcutta High Court gave a decision in favour of granting patents to life forms in the case of *Dimminaco A.G. v Controller*.¹³ Patent protection was requested against the Bursitis vaccine created by the involvement of a live virus. The application was initially rejected by the Patent Office Examiner under the grounds defined in Section 2(j)(i), which stated that there had to be some sort of invention. An appeal was made to the Controller of Patents and Designs who delegated authority to the Assistant Controller of Patents and Designs under Section 73(3)¹⁴ of the Patent Act, 1970. The decision of the Examiner was upheld, which led to further appeal to the Calcutta High Court under Section 116¹⁵ of the Act. The final decision by the Calcutta High Court was passed in the favour of the appellant. The Court observed that the patent application successfully met both the criteria of novelty and usefulness. It used a specific process subjected to particular conditions which were utilized to create the vaccine to prevent Bursitis disease in poultry.

Moral and ethical issues

These kinds of issues came into play when living organisms were used as biological tools to further scientific development and advancement. There are various religious, spiritual, and philosophical issues regarding the patenting of living organisms. One of the main objections to patenting of micro-organisms and animals is the path that it might lead to as its subsequent result. The religious argument revolving around bio-patenting is that all life forms, including micro-organisms, animals, and plants are works of God, and the interference of humans by modifying them and making use of them as industrial and commercial tools for private gains is blasphemous and similar to defying God and its creations. Another major issue regarding patenting of micro-organisms and animals is the subsequent path it follows which is the

¹³ *Dimminaco AG v Controller of Patents and Designs* (2002) IPLR 255 (cal)

¹⁴ Patent Act, 1970, s 73(3)

¹⁵ Patent Act, 1970, s 116

patenting of humans, themselves. Humans are at the top of the ecosystem and have the highest intellectual capacity, hence the mere idea of patenting any part of the human body, including genes or human DNA, and utilizing that for commercial gains is considered disrespectful and demeaning to all humans and their dignity. Their contention is that it would reduce humans to mere tools used for technological advancement.

THE CASE OF RELAXIN

In the case of obtaining a patent for a human hormone called Relaxin which relaxes and puts the uterus at ease during childbirth. It was to be used for medical purposes in order to figure out its therapeutic usage. The Howard Florey Institute in Australia isolated and determined the chemical structure of a human form of the hormone. Further research led to the revelation of an unknown form of human insulin. Finally, it was observed that the structure of human relaxin differed from other species and for the desired results, only human relaxin could be used in the process of the required experiments. Hence, it required the manufacturing of large amounts of synthetic relaxin by gene cloning. The Howard Florey Institute filed for patenting the unknown form of relaxin and the synthetic relaxin produced by gene cloning. After the patent was granted, it was faced with huge opposition by the members of the Green Party in the European Parliament. The contentions of the Green Party were that there was no new invention and the process used was a conventional one. It also argued that it was immoral and affected the dignity of pregnant women as it included the dismemberment of women. In rebuttal, the European Patent Office (EPO) responded that the gene sequence was novel and the unknown form of relaxin did not exist in nature till it was isolated by the inventor. Regarding the process, it argued that since the final product was unknown and did not previously exist, the process of producing it was immaterial. As for the dismemberment of women, it contended that the patent was for synthetic relaxin and hence it had nothing to do with the hormone produced by women during pregnancy.

THE CASE OF ONCOMOUSE

Another case for obtaining a patent for a transgenic mouse called the *oncomouse* became a controversial topic in many countries. The patent application was filed by Harvard Medical School. The researchers produced a genetically modified mouse that was severely susceptible to cancer. The process included the introduction of an oncogene that triggered the growth of tumors. This was done in accordance with furthering cancer research for the benefit of human society. Subsequently, Harvard College sought patent protection in various countries like the US, Canada, etc. Various approaches were used by different countries to arrive at conclusions regarding the patentability of the *oncomouse*. The stance taken by the US was in favour of granting the patent as humans were excluded from the patent application and it only included transgenic animals, created by recombinant DNA sequencing. The EPO weighed the benefits against the harm through a balancing process. It came to a conclusion that the benefits far outweighed the harms for it was being done in furtherance of cancer research, but with an amendment made to the application which now only limited the patent to mice. Canada initially rejected the patent application as its laws did not classify transgenic animals as inventions but allowed claims on the process of obtaining the *oncomouse* but on the body of the mouse. Finally, the Supreme Court held that the scientific achievement of altering the genetic material of an animal and creating an animal with a changed composition that previously did not exist, amounted to the invention as it included an “inventive step”, which came within the ambit of the definition of the Patent Act.¹⁶

Ownership issues

The main factor and reason for patenting life forms are for the greater benefit of society. Patent protection helps in the accumulation and production of the final product which could be highly beneficial to the society in terms of healthcare and treatment of the people who are a part of this society. If these commodities are not protected, their reckless use could result in the failure of the production of a far more beneficial product. The main aspect of providing the ownership of a patent is the objective of serving and promoting the interest and needs of the public. Research is only encouraged when a fair award is given for the same. Hence,

¹⁶ *Harvard College v Canada (Commissioner of Patent)* 2002 SCC 76

temporary monopolization over an item is too less a price to pay for the greater benefit in the future.

THE CASE OF JOHN MOORE

John Moore had a rare kind of cancer called hairy-cell leukemia. It occurs when a person's body produces too many defective lymphocytes. It was diagnosed at the University of California, Los Angeles, or UCLA. During his subsequent visits to the hospital for his treatment, large amounts of blood, sperm, and skin were withdrawn from Moore's body. In line with his treatment, his physician David W. Golde recommended the removal of Moore's spleen to slow down the growth of his leukemia. Moore's written consent was taken for the removal of his spleen, but he wasn't informed of the further research plans on his spleen by the hospital. Later studies on Moore's spleen revealed that his defective T-lymphocytes were unique and were a subtype of white blood cells. Golde further wanted to study more on these lymphocytes to unfold why they had been overproduced and utilize them for medical technologies. The Regents of the University of California later applied for a patent on the Mo cell line, made from Moore's spleen, which had now reached an economic and commercial value of 3.01 billion US dollars. Moore, in retaliation, filed a counter patent and asked to be a part of the patent holder as the Mo cell line was made from his body and hence, his property. The Supreme Court in its final decision held that patients did not have any right over the tissues or cells which are removed from their body during surgeries and they cannot demand monetary benefits generated from these tissues and cells. The judgement was a four-to-three decision ruled in favour of the Regents of the University of California. The Supreme Court ruled that Golde did not provide Moore with acceptable informed consent but Moore's suit for conversion failed as the Court opined that such confirmation from every willing donor would only hinder the process of research and researchers would be discouraged from conducting their medical research. It is also observed that patients cannot be a party to receive monetary gains from their donated organs because the value only increases after due experimentation and research which is the sole work of the researcher. The final observation by the Court was that Moore could not be granted a patent on his cells because his cells were natural and living

materials. A patent was granted to UCLA on the Mo cell line which was the manipulated cells replicated outside of Moore's body.¹⁷ Hence, the patent is granted for the development of the whole of society and not for the purposes of private gains.

Environmental Issues

Apart from the other issues regarding bio-patenting, there are several environmental issues with granting patent protection to GMOs.

Firstly, GMOs are created with the intermix of DNAs, which lead to the creation of an organism that originally did not exist. And if such organisms are unleashed accidentally or otherwise to the environment, could cause serious harm to the natural-born animals. This causes imbalance and turbulence in the setting of nature. And these transgenic organisms if handled carelessly, could create various new kinds of diseases in plants, animals, and even human beings. Further mutation of these transgenic organisms could lead to the creation of certain kinds of diseases that cannot even be solved by the experimenting researchers since they are also in the learning and knowing stage of these transgenic organisms. The laboratories where these experiments are conducted could expose the researchers and nearby residents to several kinds of harmful byproducts of the experiment which might cause numerous diseases. A very important point to be taken into consideration is that intentional misuse of GMOs or transgenic animals could unleash unfavorable and undesired troubles for indefinite periods.

Even if GMOs are patented, some set and clear standards must be made mandatory to be followed. Each country should have strict laws regarding the creation and utilization of these GMOs or transgenic animals so that they are not misused and only made for the benefit of the whole society. It is also recommended that all countries formulate similar laws regarding bio-patenting in order to reach a consensus on the controversial and much-debated topic of obtaining patents on living organisms.

Social Issues

¹⁷ *Moore v Regents of the University of California* [1990] 51 Cal. 3d 120

Humans have lived together whilst sharing all their resources with each other and helping by giving away one's own resources to another in times of need. The whole concept of patent protection came into being very late in human civilizations and since then, restrictions have been put on various commodities which were prior to the patent protection, available freely to the general public and they made use of it in their daily lives.

Many foreign and tribal cultures, even now do not believe in the idea of individual innovation and ownership of any commodity. They believe in the idea of public enjoyment and availing of all the resources and innovations as according to them, everything available in the environment is a gift of nature and should be available to everybody. The concept of patent protection is contradictory to this idea of community enjoyment of innovation, hence putting restrictions on the usage of products available freely in the environment. Although the restrictions are put in order to safely use the resources to convert them into products that are for the benefit of the general public and the greater good. Another angle surrounding the social issue is that when life forms of any kind are patented, it paves way for the further patenting of other life forms, and eventually it might lead to patent protection for human beings. This implies that all life forms including human genes, tissues, cells, or DNA are tools for private gains and commercial benefit. Anything and everything can be patented according to the theory of future benefit of the general public. This ideology questions the entire value of living organisms; Are all life forms just gene machines whose meaning of existence is to be exploited and used for commercial and industrial benefit? Around the world, several human rights activists and organizations have protested against the patenting of life forms. Some countries and their courts have ruled in their favour, while others have not. Many worldwide protests have been witnessed against patenting of life forms. In Washington, in September 1995, around 200 or more organisations from 35 countries filed a petition at the US Patent and Trademark Office against the patent granted to W R Grace company to use a pesticide extract from the neem tree. In Switzerland, the Swiss Supreme Court, in a landmark decision ruled that the Manzana variety of the chamomile plant may not be patented. It revoked the patent that the Swiss patent Office had granted in 1988 to the German Pharmaceutical company Degussa/AstaMedica on its Manzana variety.

In India, farmers' movements led by M D Nanjundaswamy of the Karnataka Farmers' Union campaigned against the patenting of seeds and plants and the operation of foreign grain companies in the country.¹⁸

STANCE OF DEVELOPING AND DEVELOPED COUNTRIES ON BIO-PATENTING

Canada, a developed Country

In a landmark case in Canadian Patent Law, the Supreme Court of Canada ruled in favour of granting Harvard College which filed an application for acquiring patent protection on a genetically modified mouse called the *Oncomouse*¹⁹. But a decade later, the Supreme Court gave a judgment contrary to its previous decision and denied patents in cases of the end results, but patents were granted for the alteration process. The reasoning behind this was that higher lifeforms could not be patented. In another case, the Canadian Supreme Court granted patent protection to a genetically modified plant cell which required the usage of canola plants that contained the patented gene²⁰. The stance of Canada on patenting of lifeforms has been fluctuating and unclear in reference to the various judgements given by the Canadian Supreme Court. In some cases, judgements have been given in favour of granting patents to lifeforms, even the higher ones. And in other cases, decisions have been against granting patents to lifeforms due to moral issues and predicted public disruptions and outcries. In addition to that, the definition of innovation²¹ has been unclear and ambiguous. The current requirement is for the revision and amendment of the section which lays down clear rules regarding the controversy.

The US, a developed country

Various decisions made in US Supreme Courts have indicated that new higher lifeforms, animals, or plants can be patent. The two requirements that it needs to meet are, first; they

¹⁸ Sandy Tolan, 'Against the Grain : Multinational Corporations Peddling Patented Seeds and Chemical Pesticides Are Poised to Revolutionize India's Ancient Agricultural System. But at What Cost?' (*Los Angeles Times*, 10 July 1994) <<https://www.latimes.com/archives/la-xpm-1994-07-10-tm-14043-story.html>> accessed 08 April 2022

¹⁹ Harvard College (n 16)

²⁰ *Mosanto Canada Inc v Schmeiser* (2004) 1 SCR 902

²¹ Patent Act, 1970, s 2

have to be non-naturally occurring, and second; they must not be human, in the case of animals.

EPO

It has laid down various exceptions in rules 28 and 29 of Article 53(a).²²It denies patent protection to any process which clones human beings²³, modifies the germ line genetic identity of human beings²⁴, uses human embryos for industrial or commercial purposes²⁵, or any such process which modifies the genetic identity of animals by causing them suffering without any substantial benefit to man or animal.²⁶

India, a developing country

The stance of India on patenting of life forms has changed over the years. Initially, the Patent Act prohibited patents to any and all living organisms, after the amendment made in 2003, following various decisions of the Calcutta High Court along with the landmark judgment given in the **Dimminaco A.G case**²⁷, it was held that micro-organisms could be patented. The amendment was made in accordance and alignment with the provisions laid down in the TRIPS agreement and Section 3(j) was so provided which expressly allowed the patentability of micro-organisms. Prior to this amendment, micro-organisms were categorised under the exceptions to patentability. This amendment was the initial step of patentability of micro-organisms but it was limited to only the processes and method of manufacture by virtue of Section 5 of the Act. Later in 2005, Section 5 of the Act was abrogated which then allowed the patentability of the products of these processes and methods as well.

²² European Patent Convention, 1973, art. 53

²³ European Patent Convention, 1973, art. 53(A) r 28(1) (a)

²⁴ European Patent Convention, 1973, art. 53(A) r 28(1) (b)

²⁵ European Patent Convention, 1973, art. 53(A) r 28(1) (c)

²⁶ European Patent Convention, 1973, art. 53(A) r 28(1) (c)

²⁷ Dimminaco AG (n 13)

CONCLUSION

With all the issues analysed in detail, it is pertinent to understand that there is still a requirement for proper laws regarding the patenting of all forms. Also, there must be uniformity in the laws of most countries regarding the same. The global laws must be made clear and all ambiguity should be removed that arises from the unclear definitions in the agreement²⁸. The definition of “micro-organisms” must properly state all the life forms that it includes within its ambit. Other issues regarding the moral and ethical issues revolving around this need to be understood and properly explained to the masses. Patenting of life forms should not be seen as an intervention of humans in the work of God, but rather they must be weighed for their benefits that humans could avail in various sectors such as healthcare. As for the issues of ownership, it is important to understand that these inventions are being done in furtherance of the benefit and requirement of the general public. The monetary value attached to these inventions reduces their value to commercial and industrial tools manufactured for economic and private gains. Hence, there is a clear need to separate the two. Even though these inventions are of great economic value, the main purpose behind these inventions needs to be seen and highlighted. The main purpose is inventions made to serve humanity and improve the healthcare conditions of the people. If all these inventions get tangled in suits of ownership, it will severely hinder the process of research and in the long run, no benefit can be acquired from these incomplete inventions. To address the environmental issues, it is observed that no imbalance is being caused to the environment as the innovations are regarding Genetically Modified Organisms (GMOs), and not with naturally existing animals. In addition to that, no such invention is granted a patent that solely causes immense suffering to any animal without any benefit derived from it to man, animal, or the animal part of the experiment.

In spite of all these arguments in favour of granting patents to lifeforms, there is a significant issue that needs to be addressed. Developing countries are still improving and developing their technology, unlike first world countries which have already perfected these techniques as

²⁸ TRIPS Agreement, 1994, art. 27

they possess all essential technologies to make such inventions. So, patenting such genetic resources available in the third world countries by the first world countries robs these countries of their chance to make such inventions and hinders their growth, economically and strategically. To summarise all of these arguments, is it essential for a global consensus to be reached on laws governing bio-patenting. Such provisions must be made keeping in line with all the issues addressed in the article. Also, respective countries and their legislatures should make clear and unambiguous laws regarding the patenting of life forms, which must expressly state all the lifeforms that it includes within its ambit, higher or lower. It must also clearly lay down all the life forms that cannot be patented, no matter at what stage of development.