

INTERNATIONAL JOURNAL OF LAW
MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 4 | Issue 6

2021

© 2021 International Journal of Law Management & Humanities

Follow this and additional works at: <https://www.ijlmh.com/>

Under the aegis of VidhiAagaz – Inking Your Brain (<https://www.vidhiaagaz.com/>)

This Article is brought to you for “free” and “open access” by the International Journal of Law Management & Humanities at VidhiAagaz. It has been accepted for inclusion in International Journal of Law Management & Humanities after due review.

In case of any suggestion or complaint, please contact Gyan@vidhiaagaz.com.

To submit your Manuscript for Publication at International Journal of Law Management & Humanities, kindly email your Manuscript at submission@ijlmh.com.

New Dimensions of Bio Tech Patents

MS. T. DERIFA¹

ABSTRACT

This research paper deals with the birth of patents and traces the nature of biotech patents. The idea of issuing monopoly to an invention is not a novel concept. Patent law has a rich and extensive history that began as early as 500 BCE, where chefs in Sybaris had the opportunity to enjoy a year of monopolized profit for a unique dish that they had created². Although, the earliest origins of patents are ancient and obscure, growing populations, rising disposable incomes and progressive urbanization across the world have spurred rapid growth in the research of biotechnological inventions. Right from the Chakrabarthy to Chimeras, the research and development in biotechnology has crossed the ocean. An attempt has been made in this paper to discuss the history of patents and the concept of growing nature of biotech patents.

I. INTRODUCTION

The term biotechnology was used for the first time by Karl Erkey, a Hungarian Engineer, in 1919³. He considered biotechnology as the technology which includes all such work by which products are produced from raw materials with the aid of living organisms. The first official broad definition given by the US Office of Technology Assessment which states that “biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses” is also considered now void⁴.

Biotechnology can be traced back to various stages of its development. The first generation biotechnology can be based on the traditional knowledge in various tribes like preparing fermented foods, medicinal distillates, etc. Second generation of biotechnology may be considered when the utilization of microorganisms started on industrial scale during the Pasteur era which involved mass production of alcohol, fermentation of antibiotics, development of classical vaccines like for cholera, typhoid, yellow fever, etc. This generation can be considered

¹ Author is an Assistant Professor, India.

² The Origin, History, and Development of Patents, 3 Forum 1 (1875)

³ Aashish Swarup Varma, Shishir Agrahari, Shruthi Rastogi, Anchal Singh, Biotechnology in the Realm of History, Journal of Pharmacy and BioAllied Sciences, 2011 Jul-Sep; 3(3): 321–323., <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178936/#>

⁴ K.K. Tripathi, Biotechnology and IPR Regime: In the Context of India and Developing Countries, July 2004, https://ris.org.in/sites/default/files/article1_v7n2.pdf

as the longest one as the mass production of vitamins, amino acids, organic acids as well as plant tissue culture and animal breeding methods were also developed. The third generation of biotechnology can be called “modern biotechnology” when the rDNA techniques, hybridoma technology, polymerase chain reaction (PCR) and cloning methods emerged during post-Second World War advances in molecular biology⁵. The fourth generation of biotechnology would see further advances where interdisciplinary techniques like information technology and nano-technology would get involved in further advancement of this discipline, especially utilizing the bioinformatics, which is the foundation of modern biotechnology⁶. Rapid advances in information technology, particularly in the area of bioinformatics, have played a critical role in breakthrough applications of modern biotechnology in medicine and agriculture. Thus the evolution of biotech patents can be divided as post and pre Chakrabarty era based on technological developments.

II. PRE DIAMOND V. CHAKRABARTY ERA

The development of biotech patents can be traced back to 1600, where traditional technologies like beer brewing and bread making were invented. These go back to the Sumerians who introduced baking technology with Yeast and the Egyptians who introduced the wine Brewing technology by fermenting grape juice. These techniques were passed on from generation to generation. Baking and wine making were considered to be normal household works until the technological process involved in it. Advanced science techniques like biotechnology proved that the process of fermentation occurred due to the presence of microorganisms in nature. Reports state that This is the discovery which received the first patent in life forms in Finland during the 16th century. For the process of isolation of Yeast, Louis Pasteur was granted patent in 1873. Both these technologies were mere discovery rather than invention but patent was granted in order to stimulate inventiveness.

Later, the introduction of microbial applications discovered by Louis Pasteur, developed to a greater extent and led to greater discoveries like genes, chromosomes, transferable genetic material in DNA and RNA, codon, isolation and purification of genes, sequencing DNA, and synthetic insulin's were made. Humans started to apply for patents to these methods and the courts denied protection on the concept of discovery. Law distinguishes between invention and discovery. The basics of discovery are new knowledge of something already existing in nature. Whereas, invention is a new product or process with no previous existence. The concept of

⁵ David E. Adelman, A Fallacy of the Commons in Biotech Patent Policy, 20 Berkeley Tech. L.J. 985 (2005)

⁶ Id.9

invention with respect to biotechnology is evolved through judicial decisions. The products of nature are generally considered invention when some human intervention has been necessary to make them available.

The first decision which broadens the concept of invention was the 1969 red dove case⁷ in the German federal Supreme Court. A process of cross breeding selection of birds by humans is claimed as an invention. It is purely a biological process which as such does not occur naturally. The argument made in this case is that the method is not natural. The court held that “for an animal breeding method considered as an invention, if it shows a controllable natural force to achieve a casual, perceivable result”⁸.

While this situation persists in 1980, there arose a query of patentability of microorganisms. Prior to 1980 the answer was no. Microorganisms are considered as "products of nature" and therefore they were not patentable. However, the era of manipulating DNA between organisms changed that.

In *Funk Bros Seed Company v. Kalo Inoculant co*⁹, the Supreme Court was faced with the question whether a mixture of naturally occurring bacteria fixing nitrogen was a subject matter? It is held that the bacteria were all naturally occurring and nothing is new. They are the manifestation of nature¹⁰. For an invention from discovery it must come from the application of the law of nature to a new and useful end. Later in *Diamond v. Anand Chakrabarthy*¹¹, the issue is whether a genetically engineered bacterium capable of degrading crude oil? Here the question of when discovery changes into invention is answered. Putting together a single organism CDNA that coded for four different enzymes each of which could degrade different types of oil made the invention. The court held that a non naturally occurring manufacture or composition of matter – a product of human ingenuity having a distinctive name, character and use. It amounts to invention. The court also added that anything under the sun that is made by a man amounts to invention. Distinction between invention and products of nature was not between living and inanimate things but between products of nature and manmade invention. This decision of the US Supreme court made a change in the history of patents that biological invention as patentable subject matter.

⁷ Red Dove Case IIC 138 (1970)

⁸ Li Westerlund, *Biotech Patents: Equivalency And Exclusions Under European And U.S. Patent Law* 10 (2002), Kluwer Law Publications

⁹ *Funk Bros Seed Company v. Kalo Inoculant co* 333 US 127 (1948)

¹⁰ Li Westerlund, *Biotech Patents: Equivalency And Exclusions Under European And U.S. Patent Law* 10 (2002), Kluwer Law Publications

¹¹ *Diamond v. Anand Chakrabarthy*, US 303, 100 S.CT 2204 (1980)

III. POST DIAMOND V. CHAKRABARTHY ERA

After these alarming decisions many patent applications related to biological inventions were flooded in the patent office. From microorganisms, scientists started their research in animals and human beings. In 1988, a biologist from Harvard University was granted a patent¹². The patent is for a mouse that had been engineered for increased susceptibility to cancer. The “Harvard Oncomouse” is the first animal considered as an invention by the U.S. Patent and Trademark Office. It marked a precedent within patent procedures for patenting genetically modified animals. Though this research was intended to benefit human health, the issue in this patent lies with the ethical issues of patenting complex living beings. In this case a transgenic mouse was made by transfer of DNA. The issue in this case is whether the injection of one or some genes in the body of the mouse where already 50,000 to 1, 00,000 genes are present amounts to invention? The court held that from the invention perceptive the animal has definitely been given new qualities not present in the original mouse as it existed in nature.

Similarly, in 1988 an invention related to oyster’s reproduction was filed for patent and the US Supreme court rejected it based on Diamond case. In Oyster’s case¹³ Oysters reproduce by discharging their gametes (sperm or eggs) into the water, where the eggs are fertilized (at which time they are called "zygotes"). The zygotes develop into larvae and then grow to become oysters. Two of the most important species of edible oysters in the United States are the Atlantic (or American) oyster found generally in the Atlantic Ocean and the Pacific oyster (*Crassostreagigas*) found in the cooler waters of the Pacific Ocean. The main difference between the two species is the percentage of body weight that is involved in producing gametes during the breeding season. The Atlantic oyster devotes up to 40 percent of its body weight to gamete production; the Pacific oyster expends up to twice that amount. The Atlantic oyster is edible throughout the year whereas the Pacific oyster is soft and unsuitable for human consumption during its reproductive phase. The appellants' application discloses

(1) A method of producing sterile Pacific oysters, which are edible year round, by inducing polyploidy in the oysters, and

(2) The oysters produced by that method.

Most cells are "diploid" or have two sets of chromosomes. "Polyploid" cells possess three or more sets of chromosomes. Appellants induce polyploidy by fertilizing oyster eggs under controlled temperatures and applying hydrostatic pressure to the zygotes. The zygotes are then

¹² *Harvard College v Canada (Commissioner of Patents)* [2002] 4 SCR 45, 2002 SCC 76

¹³ *In Re Allen* 846 F.2d 77 (Fed. Cir. 1988)

cultivated using known techniques until they develop into adult oysters. The claimed process is used only on Pacific oysters. The examiner allowed the process claims but rejected the product claims as not disclosing patentable subject matter under 35 U.S.C. Section 101 and as obvious under 35 U.S.C. Section 103. The Board reversed the section 101 rejection because "the Supreme Court made it clear in its decision in *Diamond v. Chakrabarty*¹⁴ that Section 101 includes man-made life forms." The Board affirmed the section 103 rejection in light of a prior art publication by Stanley et al., which discloses a method of chemically inducing polyploidy in more than half of the Atlantic oysters so treated. Since it is obvious to the Person having ordinary skill in the Art, the product claim is rejected.

By 1997, over forty animals had been patented, including turkeys, nematodes, mice and rabbits. Hundreds of other patents are currently awaiting approval, including patents on pigs, cows, fish, sheep and monkeys. Tracey the sheep has had human genes introduced into her mammary glands so that she produces a human blood-clotting agent called alpha-1-antitrypsin in her milk. The patent is held by Pharmaceutical Proteins Ltd. (PPL)¹⁵. Their spokesperson described sheep like Tracey as "furry little factories walking around in fields." Tracey's success was said to provide "a strong impetus to the further exploitation of transgenic sheep as bioreactors for the production of large amounts of pharmacologically active proteins".¹⁶

IV. CHANGING DYNAMICS OF PATENT TOWARDS HUMAN GENES

A most alarming aspect of patenting life is the patenting of human genes, cell lines and tissues. Corporate patent attorneys have lobbied the Patent office that these "products of nature" are patentable once they have been isolated to produce a form not found outside of a laboratory.¹⁷ In 1976, a leukemia patient, John Moore had a splenectomy surgery at the University of California to remove his cancerous spleen. The University later claimed and it was granted a patent for a cell line called "Mo," removed from the spleen, which could be used for producing valuable proteins. The commercial value of the cell line was expected at over one billion dollars. Mr. Moore demanded the return of the cells and control over his body parts, but the California Supreme Court decided that he was not entitled to any rights to his own cells after they had been removed from his body¹⁸.

In Relaxin case¹⁹ The Green Party Opposed patent granted to the Howard Florey Institute of

¹⁴ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

¹⁵ Eklavya Gupte, *Biotech's Biggest Blockbuster*, *Managing Intell. Prop.* 54 (2008)

¹⁶ *Ibid*, 20

¹⁷ *Association of Molecular Pathology v. Myriad Genetics* 133 S.Ct 2107 (2013)

¹⁸ *John Moore v. Regent University of California*, 793 P.2d 479 at 490 (Cal. 1990)

¹⁹ *Relaxin case*, EP- B1 112 149(1995)

Experimental Physiology and Medicine for a gene sequence coding for human relaxin, a hormone involved in reproduction. The gene was isolated from ovarian tissue removed in the treatment of an ectopic pregnancy. This is challenged on the ground of not being an invention and opposes it as discovery. The court analyzed this case as, ‘to find a substance freely occurring in nature is a discovery. If however a substance found in nature first had to be isolated from its surrounding or a process for obtaining it was developed, the process was patentable.’, if the substance could be properly characterized by its structure and was new in an absolute sense, then the substance per se could be patentable. The human H2 Relaxin had no previously recognized existence, it was characterized and a new use for the protein is found. A hormone which relaxes the uterus during childbirth and hoped it will reduce the need of c-sec delivery. Relaxin from pigs was first described in 1926, but then until 1975 Howard Florey Institute in Australia isolated and determined the chemical structure of a human form of the hormone. It is found that only human relaxin is used for medical purposes. Though it occurred naturally in the human ovary, a synthetic form was needed for therapeutic use. The court held that, “by isolating the nucleotide sequence coded for the relaxin recombinant DNA techniques were used to clone the gene making it possible for producing synthetic relaxin.” The patent was issued.

In *Genentech Inc’s Patent* (1989)²⁰, Mustill LJ favored the view that there must be an ‘invention’. In this case the description of the genetic construction of a known naturally occurring substance a human protein t-PA did not accord with Mustill LJ’s view of invention as being the creation of a product or a process for the production of a product.

The issue of invention and discovery was raised again in *Biogen Inc v. Medeva plc* (1997)²¹. The claim is related to the synthetic molecule of a naturally occurring virus hepatitis B, which enabled the construction of diagnostic kits for its detection. Hobhouse LJ applied to the Mustill LJ test and held that choosing a method of research did not constitute invention. In the House of Lords Mustill LJ stated that there might be cases where a conceptual analysis of the nature of the invention might be necessary. Subsequently the patent was granted for this human genetic material.

Since then there have been numerous instances where cell lines have been patented across the world. It is now a settled matter in the US and in EU that the human genetic material is patentable. But there were no standard provisions in many countries which support gene patenting. There are also countries which strongly oppose the kind of patenting as it is against public order, morality and ethical concerns and legal issues. Beyond the contradictions the

²⁰ *Genentech Inc’s Patent*, [1987] RPC 553

²¹ *Biogen Inc v. Medeva Plc*, [1997] RPC 1, [1996] UKHL 18, (1997) 38 BMLR 149

biotech patents are applied in various fields.

V. APPLICATIONS OF BIOTECH PATENTS

Advances in the life sciences and pharmaceutical sector have had an impact on life expectancy and the quality of life. Most modern medicines are based on biotechnology. One of the earliest biomedicaments was insulin, a life-saving drug for diabetics. Over the years many improved forms of insulin have been developed, and this continuous innovation has been supported by patents granted for the new compounds. Other patented medical inventions have provided breakthroughs in DNA fingerprinting, paternity testing and blood transfusions, where patented tests to check donated blood for the presence of deadly viruses have improved patient safety²².

Many anti-cancer drugs based on patented human gene sequences are prolonging the lives of cancer patients, such as Herceptin for breast cancer and Avastin, for colon and other cancer. Humira, a patented medicament based on human gene sequences used to treat auto-immune diseases such as arthritis, was the world's best-selling medicine in 2014. Eight out of the top 10 best-selling medicaments were biological in origin and covered by patents. It is enormously expensive and time-consuming to develop a new drug and obtain market approval, and the necessary funds are largely provided by venture capital supplied by investors. Drug companies would not be able to fund costly clinical trials and research without being able to claim exclusive rights to recoup these investments. Patents are also an effective barrier to illicit copying of medicines and the health risks associated with unauthorized imitated versions.

Patents constitute a limited exclusive right only: Once the patent has expired (after a maximum of 20 years), the invention falls in the public domain and can be used by anyone without paying royalties. National authorities work with pharmaceutical companies to negotiate lower prices for medical products, and after the patent has expired, cheaper generic copies may enter the market. These are the few notified applications amongst the umpteen numbers of applications of bio tech patents. The recent development in biotech patents have also led to many legal and ethical issues.

VI. CONCLUSION: RECENT DEVELOPMENTS IN PATENTING OF BIOTECH PATENTS

Growing populations, rising disposable incomes and progressive urbanization across the world have spurred rapid growth in the research of biotechnological inventions. Right from the Chakrabarthy to Chimeras, the research and development in biotechnology has crossed the

²² Lisa Larrimore Ouellette, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 Stan. Tech. L. Rev. N1 (2010)

ocean. In July 30, 2019 Japan approved the ground breaking experiment bringing Human-Animal hybrid to term which many countries around the world have restricted, defunded or outright banned these ethically fraught practices. The microbiologists favor this human-animal hybrids with a strong view that this could be a vital first step towards eventually growing organs that can then be transplanted into people in need. Due to the dramatic organ shortage for transplantation, there is an indisputable need for such a transgressive practice. The possible types of human-animal embryos are cytoplasmic hybrid embryos where the embryos are created through cell nuclear replacement using animal eggs, hybrid embryos where embryos are created by mixing human sperm and animal eggs or human eggs and animal sperm, human chimera embryos which have animal cells added to them during early development, animal chimera embryos where animal embryo which have human cells added to them during early development, and transgenic human embryos where human embryos which have animal genes inserted into them during early development. In these entire techniques one could easily understand that manipulation of genes was attempted. Patenting of this technology leads to ethical and legal issues.
