

Chapter 2

Patentability of Biotechnology: A Comparative Study with Regard to the USA, European Union, Canada and India

Modern biotechnological advances have posed new challenges before the existing patent laws of countries as biotechnological inventions differ markedly from chemical and mechanical inventions that have been the traditional subject matter of patents. With the development of human genomics and success of the Human Genome Project, the gene becomes more important because of its informational content rather than its material qualities (physical attributes). Patent is a subject primarily concerned with questions inside a jurisdiction. Although the adoption and ratification of trade-related aspects of intellectual property rights (TRIPS) has brought a unified character to patent laws of member countries of the World Trade Organization (WTO) to a certain extent, these countries have adopted different approaches regarding biotechnology patents in tune with their national policies. As a result, the scope and coverage of biotechnology patents vary from country to country. Even in countries having similar patent laws such as the USA and Canada, interpretations of such laws by courts vary significantly. These variations among countries are important for the proper understanding of the trends in biotech patents. Therefore, the present chapter makes a comparative study of patent laws and practices relating to biotechnology patents in the USA, Canada, European Union and India in order to collate the common issues and the differences among and between them. The USA being a pioneer in biotechnology research exerts great influence upon other countries; the European Union reflects the unified approach of different member states in a politically diversified system; Canada makes a distinction between patenting of higher life forms and lower life forms and India represents the concerns of developing countries.

2.1 Biotechnology and Patent Law

Biotechnology and patent laws are not of recent origin; they have been present in our society for a long time. However, they became associated in recent years. This association became possible when biotechnology started creating commercial possibilities. Biotechnology, once primarily concerned with the academic field, has

been transformed into a commercial industry with an immense commercial potential. Recent bio-technological advances have presented unprecedented challenges before the existing patent laws, which have been slow to respond to technological challenges thus far.

2.1.1 Transformation of Biotechnology: From a Non-commercial Science to a Commercial Industry

Although the term ‘biotechnology’ gives an impression of modern, cutting-edge technology, its traces have remained present in early human settlements in the form of selective plant and animal breeding. Microorganisms have been employed for brewing and baking purposes for thousands of years. However, it was in early twentieth century, when the term biotechnology came into use. Karl Ereky, a Hungarian engineer, is said to have coined the term ‘to refer to science and methods that permits products to be produced from raw materials with the aid of the living organisms’.¹ He first used the term *Biotechnologie* in a 1917 article (written in German) describing his pig fattening plant.² Taking the analogy of chemical technology, he suggested the word *Biotechnologie* to cover the area of technology associated with the living beings.³

Technology was generally associated more with chemistry and physics and less with biology, however, with the great advancements in biological sciences, this trend has anomalously changed.⁴ Although from the 1880s analogies between physiological and technological structures did suggest a link between technological and biological evolution, however, biotechnology acquired a professional engineering dimension when the Americans took the biotechnics and biotechnology in the 1930s and 1940s.⁵ Swedes emphasised on microbiology and Germans gave it institutional strength. America became a pioneer in the integration of molecular biology and engineering.⁶

The major breakthrough in the field of molecular biology and genetics was the discovery of deoxyribonucleic acid (DNA) in 1953 by Francis Crick and James Watson. It was considered as the discovery of secret of life. The discovery had been a grand success as the modern biotechnological advances in DNA technology have demonstrated that ‘the DNA not only explains the very essence of every living cell but it promises great possibilities for future’.⁷

¹ Organisation for Economic Co-operation and Development (1999).

² Bud (1991).

³ *Ibid.*

⁴ *Id* at 444.

⁵ *Id* at 444–45.

⁶ *Ibid.*

⁷ Yelapaala (2000).

Before the 1970s, biotechnology was primarily concerned with the academic development, intellectual curiosity, and expansion of scientific knowledge and the propagation of ideas for the benefit of humanity. Since the 1970s, with the advent of modern biotechnological techniques such as recombinant DNA technology, and tissue culture, researchers, venture capitalists and business community in general realised that DNA technology held the promise of significant financial rewards if the science could be converted into products or services. This realisation, in part, led to the emergence of the modern biotechnology industry of today.⁸ Universities and research scientists once committed to the total openness were now interested in scientific discoveries that could be appropriated, protected within an intellectual property regime and eventually transformed into products and services in the market place.⁹ This commercial trend led to a paradigm shift in biotechnological research from openness and sharing of knowledge and ideas to acquisitiveness and exclusivity.¹⁰

2.1.2 Conjunction of Biotechnology and Patent Law: Challenges Posed by Biotechnology Before the Existing Patent Systems

The Biotechnology industry is primarily made up of small, single product start-up companies. There is a close relationship between basic and applied science in the biotechnology field, and the biotechnology industry has a highly educated workforce.¹¹ Due to the close association between academic laboratories and industrial laboratories, biotechnology companies developed a culture that borrows several features of university setting.¹² The highly skilled work force required for the biotechnology industry can only be made available when the industry continues to attract academic scientists to the industry. Here, it becomes pertinent for the biotechnology industry to maintain a university like atmosphere and provide good economic incentives to the researchers, encouraging them to maintain a high level of innovation.¹³ Further, due to the influence of academic research on biotechnology industry, the research ethos is encouraged with the encouragement of publication and sharing of results.¹⁴

Patents offer a viable option in this regard. Some form of economic incentive is *sine qua non* for the development of any start-up technological industry and patent offers such an incentive. Patents also encourage public disclosure of the invention so that society can be benefitted from that. Whether biotech patents fulfil the overall

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ *Ibid.*

¹¹ Boyd (1997).

¹² *Ibid.*

¹³ *Ibid.*

¹⁴ *Ibid.*

social goal for which patents are intended is still a debatable issue but there is no doubt that patents are critical for the protection of biotechnology industry.¹⁵ Due to the high level of uncertainty involved in biotechnology, investors are reluctant to invest into biotechnology ventures where the patent protection is lacking, or where the rights of patent holders are not clear.¹⁶ This necessitates the conjunction of biotechnology and patent law.

Though patents are seen as an effective protection for biotechnology inventions, however, concerns have been made in recent years that current patent laws do not adequately encourage continued growth and research in biotechnology industry. Arguments have been made that a patent system designed to accommodate older technologies produces undesirable results when applied to a new and radically different technology such as biotechnology.

The commercial potential of biotechnology has led to the existing patent systems to accommodate fairly new subject matters such as DNA sequences, microorganisms, plants and animals which were not intended at the time of the framing of patent laws. Since a very high economic incentive has been involved with these subject matters, biotechnology industries and patent community have persuaded courts and legislatures that these subject matters should be treated no differently from mechanical and chemical invention.¹⁷ In recent years, it has been realised that this analogy has failed to ensure a clear and adequate protection for modern biotechnology. Modern biotechnology differs significantly from chemical inventions with regard to structure and function and the manner and circumstances in which modern biotechnology and chemical inventions being created have been shown to differ markedly.¹⁸ Apart from subject matter, modern biotechnological advances have posed new challenges before the existing patentability criteria such as novelty, non-obviousness, utility etc.

2.1.3 Human Genetic Patents: A Special and Controversial Case of Biotechnology Patents

There are groups which see the patenting of life forms such as human gene plainly wrong; there are some others who do not consider it necessarily wrong but in terms of its consequences. Sometimes the problem does not lie in the availability of patents but the way that granted patents are being asserted by the ruthless corporations on to the detriment of the public and especially vulnerable people like patients.¹⁹ The opposition was driven by a variety of concerns including effects of such patenting on the environment, animal welfare, sustainable development, public health and

¹⁵ Burk (1991).

¹⁶ *Ibid.*

¹⁷ Dutfield (2009).

¹⁸ Pila (2003).

¹⁹ Dutfield, *supra* note 17, at 192.

patient's rights. One of the most fundamental objections regarding gene patents is based on religious conviction—the notion that humans are 'Playing God'.²⁰

As regards to patenting of gene, it is always contended that gene occurs naturally, hence is product of nature and not new. With rapid advancement in the field of molecular biology and genetics, gene sequencing once considered as a laborious manual task has become a highly automated and routine part of laboratory practice. This presents a great challenge to the inventive step/non-obviousness criterion. There is a significant challenge to the utility criterion as patents are being granted on gene fragments of unknown functions and gene sequences of limited or questionable utility. Since great uncertainty is involved in genetic technology, sometimes the description of an invention is not full. Many patents claimed far more than what the inventor actually discovered (e.g. claiming the sequence of a protein within the patent and then also asserting rights over all of the DNA sequences that encode that protein without describing those DNA sequences). The unique nature of science of genetics is the main reason for this failure.

Since a gene comprises a number of elements, therefore, it is possible that a number of patents could be granted in relation to one gene. For instance, in relation to a particular gene, patents could be sought for the full sequence of gene, an expressed sequence tag (EST), a single nucleotide polymorphism (SNP) or other variation of the gene, its promoter or enhancer, its individual exons or some other combination of the sequence.²¹ Furthermore, a gene may be the subject of a product patent, process patent and use patents. For example, a product patent would cover the sequence itself which may be a product sold as a diagnostic tool to determine whether a particular gene is present. There could also be a product patent asserting rights over a gene and its product protein. The scope of the product patent is relatively wide as it asserts rights over all the uses of that product.²²

A process patent may apply to some method of isolation and purification of a gene. As compared to product patents, process patent is unlikely to assert rights over the sequence of gene itself. However, if the gene or protein (which it encodes) is an element of a process or method that is used to produce some other product, the process patent may assert rights over the sequence of the gene.²³

The use patent relates to a specific use of a gene. It could take the form of the use of a gene or part of its sequence in the manufacture of a medicine. It could also be framed in terms of the use of a gene for the diagnosis of a disease. The use patents in relation to gene and genetic components are very controversial due to their broad scope.²⁴ Commenting on the 'use patent' practice of Myriad over BRCA 1 the Nuffield Council of Bioethics observed:

A broad use patent for a diagnostic test for BRCA1 that referred specifically to breast cancer would give the owner rights over all testing for that genetic susceptibility to breast

²⁰ *Ibid.*

²¹ Cain (2003a).

²² *Id.*, at 121.

²³ *Ibid.*

²⁴ *Ibid.*

cancer but not for other diseases. However, the effect of the patent owner having broad property rights over the diagnostic use of the gene for just one disease, would be that the patent owner has the monopoly over all ways of testing for that disease. This is because, even though the use patent does not include the sequence itself in the patent claims, in practice any other diagnostic test for the disease specified in a use patent would infringe that patent.²⁵

So, the actual scope of gene patents depends upon the extent of the analysis carried out by the examiner at the relevant patent office. In addition to this with recent advancement in the field of genomics, gene has become more important as information rather than as a tangible entity. This transformation raises issue of patent eligibility of information, which has been excluded from patenting as ‘scientific truths’ and ‘abstract ideas’.²⁶ Patenting gene as information has been viewed as departure from the long established patent practice.

2.1.4 Divergence in Biotechnology Patent Practices Among Different Jurisdictions

Although the minimum standards set out in international agreements brought some sort of uniformity in patent laws among member countries, however, the patent practices of these countries vary significantly. This is because the agreements provide considerable discretion to member countries in deciding how they choose to implement and operate their respective patent systems in tune with their respective needs.²⁷ The USA considers a much wider range of subject matter e.g. software, business methods and methods of medical treatment to be patentable as compared to Europe and Canada.²⁸ European patent law includes, for example, an ‘ordre public and morality clause’²⁹ in its legislation that allows the European Patent Office (EPO) to exclude biotechnology patents for inventions, the commercialisation of which violates fundamental moral norms in Europe.³⁰ This clause has been interpreted to prevent the patenting of human embryonic stem cells by the EPO.³¹ Indian patent law also contains a similar public order and morality clause.³² However, Canadian and US law do not contain such clause, which provides them similar discretion to exclude patents on the basis of public order and morality.³³

Patenting of whole animals and plants is another classic example of the discrepancies that exist between otherwise similar jurisdictions. These differences are

²⁵ Nuffield Council of Bioethics (2002).

²⁶ Merrill and Mazza (2006a).

²⁷ Gold (2009a).

²⁸ *Ibid.*

²⁹ Sec. 53(a) European Patent Convention, 1973.

³⁰ Gold and Knoppers, *supra* note 27, at 22.

³¹ *Ibid.*

³² Sec. 3(b), Patents Act, 1970.

³³ Gold and Knoppers, *supra* note 27, at 22.

explicit in the patenting of the Harvard College's genetically modified oncomouse, which received different treatments in the USA, Canada and Europe.³⁴ Further, three main patentability criteria—novelty, non-obviousness and utility—are applied more or less rigidly by different patent offices.³⁵ In order to understand the commonalities and differences in patent approaches of different countries regarding biotechnology inventions, a comparative study is pertinent. In this regard, the present study focuses on the patent approaches of the USA, European Union, Canada and India.

2.2 Patentability of Biotechnology in the USA

The USA has been a pioneer in the field of biotechnology and patent law. Initially, it has adopted relatively liberal approach while dealing with biotechnology patents but in due course of time it has developed its patent laws to fairly deal with the biotech challenges and the abuse of patent system in a matured way. It has therefore pioneered both the commercialisation of biotechnology applications and products and the development of patent law to protect them.³⁶

The authority to grant patent is provided under the constitution of the USA. Congress is authorised 'to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries'.³⁷ The basic requirement for obtaining a patent is set forth in Sections 101, 102, 103 and 112 of the Patent Act of 1952.

Section 101 prescribes the criterion for patentable subject matter as:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.³⁸

2.2.1 Biotechnology as a Patentable Subject Matter

Traces of Biotechnology Patents in the USA Before 1980: Product of Nature Doctrine to Exclude Life Forms from Patenting In the USA, patenting life forms was uncertain until 1980. Biotechnology products and processes were precluded from patenting and considered as product of nature. The product of nature doctrine implies that organisms or substances that occur in nature cannot be considered as

³⁴ *Ibid.*

³⁵ *Id.*, at 25.

³⁶ Dutfield, *supra* note 17, at 194–95.

³⁷ U.S. Constitution, Art. 1, Sec. 8, Cl. 8.

³⁸ 35 U.S.C. Sec. 101.

inventions and are therefore not patentable.³⁹ Very few patents were issued on ‘mixtures or compounds that included microorganisms in modified form’.⁴⁰ It was only Pasteur’s yeast culture product patent that exclusively covered living organisms.⁴¹ In 1873, Louis Pasteur was granted a patent by the USPTO, claiming ‘yeast free from organic germs of disease, as an article of manufacture’.⁴² Nevertheless, since the 1880s USPTO apparently disallowed the patenting on any further life forms by applying product of nature doctrine.⁴³ The patent attorney, Grubb, rightly mentioned: ‘In the USA, in spite of the precedent of the Pasteur patent...it has become practice of the Patent Office to refuse claims to living systems as not being patentable subject matter’.⁴⁴

The 1980s-Heralding a New Era of Wide Patenting of Biotechnology: Diamond versus Chakrabarty Case; Bayh-Dole Act 1980; Establishment of the Court of Appeal for Federal Circuit In the year 1980 and onwards, there had been a sea change in granting patents over life forms, heralding a new era of biotechnology patents. Three major developments have contributed to this remarkable change: the US Supreme Court’s decision in *Diamond versus Chakrabarty*⁴⁵ case; the Bayh-Dole Act; and the establishment of Court of Appeal for Federal Circuit (CAFC). The initial trend of USPTO to disallow patenting of life forms as a product of nature subsisted before the Supreme Court decision in *Diamond versus Chakrabarty*. Until the said decision, it was generally assumed within the emergent biotechnology sector that microorganisms could not be patented.⁴⁶ The Supreme Court decision in *Diamond versus Chakrabarty* allowed a patent on a new man made oil eating bacterium, paving way for biotechnology patents.⁴⁷

The 1980 Bayh-Dole Act encouraged universities to patent, and thereby commercialise, inventions arising out of government sponsored research.⁴⁸ It has allowed public institutions to own inventions resulting from federally sponsored research and exclusive license to those inventions. Further, it requires from the institutions to establish patent policies for its employees, enabling them to seek patent protection of their invention.⁴⁹ This Act has provided a great deal of discretion to the institutions, encouraging the growth of biotechnology patents.

³⁹ Dutfield, *supra* note 17, at 195.

⁴⁰ *Id.*, at 195–96.

⁴¹ *Id.*, at 196.

⁴² Rimmer (2008).

⁴³ Dutfield, *supra* note 17, at 196.

⁴⁴ Philip Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, 224–25 (Oxford: Oxford University Press, 4th edn., 2004), cited in Rimmer, *supra* note 42, at 24.

⁴⁵ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁴⁶ Dutfield, *supra* note 17, at 196.

⁴⁷ *Id.*, at 195.

⁴⁸ Klein (2007).

⁴⁹ Boettiger and Bennet (2006).

The third major development was the establishment of the Court of Appeal for Federal Circuit (CAFC) by the Congress in 1982. The establishment was backed by a large group of high technology firms and trade associations in the telecommunications, computer and pharmaceutical industries, believing that a court devoted to patent cases would better represent its interest. The US government was also one of the main actors in the creation of CAFC as it was interested to support its science-based corporations by strengthening intellectual property protection worldwide.⁵⁰ Other underlying reasons were that the early Supreme Court decisions seemed to reflect an anti-patent mentality and lower courts had issued extremely inconsistent decisions on patent issues.⁵¹ The CAFC has adopted a pro-patent approach which allows for the protection of biotechnology inventions. It has also issued decisions awarding high damages to patent owners in patent infringement cases, providing them additional protection.⁵²

Microorganisms as Patentable Subject Matter: Diamond versus Chakrabarty: a Case Study *Diamond versus Chakrabarty* was the landmark case on life forms as patentable subject matter. The Supreme Court's decision in *Diamond versus Chakrabarty* has opened the patent field for biotechnology, giving boost to biotech industries. This outcome was a case of forum management achieved by a firm General Electric unrelated to biotechnology or pharmaceutical research.⁵³ By the time of filing the case the scientist involved, A. M. Chakrabarty, was in doubt that his genetically modified microorganisms could be patentable but the company lawyer, Leo MaLossi, was confident regarding the grant of patent. He was aware of the changing atmosphere that by now scientists understood living matter, including bacteria to be chemicals and Chakrabarty's bugs were patent eligible as new manufactures and compositions of matter.⁵⁴ Daniel J. Kevles describes the changing atmosphere as:

By the time the case arrived at the court, it had become charged with the social and economic stakes that surrounded the swiftly accelerating commercialization of molecular biology. In the 1970s the new techniques of recombinant DNA were beginning to be exploited by adventurous start-ups such as Genentech. Companies were being founded at a rapid pace, while major pharmaceutical firms as well as several oil and chemical giants were plunging into recombinant DNA, initiating research programs of their own, letting research contracts to the start-ups, and even obtaining an equity interest in some of them.⁵⁵

Though Chakrabarty had not used recombinant DNA technology to produce his oil eating bacterium, however, his case raised the vital issue of patentability of living organisms—an issue which was directly related to the fate of biotechnology patents and ultimately the future of biotech industry. This was reflected in ten amicus briefs

⁵⁰ Dutfield, *supra* note 17, at 200.

⁵¹ Pila, *supra* note 18.

⁵² *Ibid.*

⁵³ Dutfield, *supra* note 17, at 195.

⁵⁴ *Id.*, at 196.

⁵⁵ Kevles (2011)

filed by various economically interested organizations including Genentech, the Pharmaceutical Manufacturers Association, the American Patent Law Association, the New York Patent Law Association and the American Society for Microbiology.⁵⁶ Most of the amicus briefs supported General Electric's position.⁵⁷

A. M. Chakrabarty filed a patent application in 1972 on behalf of General Electric, the abstract of the application titled, 'Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof'.⁵⁸ There were 36 claims asserted in the application related to Chakrabarty's invention of 'a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway'.⁵⁹

The abstract of the application states:

This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills.⁶⁰

There were three types of patent claims; first the process claims for the method of producing bacteria; second, claims for an inoculum that comprised a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves.⁶¹

The patent examiner at USPTO allowed the first two groups but rejected the claims directed to the bacterium as unpatentable under 35 US Constitution (USC) Section 101. The USPTO rejected the claim on the bacterium on two grounds; first, bacteria were 'products of nature' and second, bacteria as 'living things' cannot be patentable.⁶² Chakrabarty made an appeal against the rejection of these claims to the Patent Office Board of Appeals. The Board of Appeals reversed the first ground of rejection, mentioning that that the claimed bacteria were not products of nature, as they had been modified to produce a combination of plasmids that no known bacterium produced. It had, however, upheld the second ground that 'living things' could not be patented. While drawing the conclusion that Sec. 101 was not intended to cover living things such as these laboratory created microorganisms, the Board relied upon the legislative history of the 1930 Plant Patent Act, in which Congress extended patent protection to certain asexually reproduced plants.⁶³

⁵⁶ *Ibid.*

⁵⁷ *Ibid.*

⁵⁸ A. Chakrabarty, 'Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof', (1972) U S Patent No: 4,259,444.

⁵⁹ *Ibid.*

⁶⁰ 447 US 306 (*Chakrabarty*).

⁶¹ *Id.*, at 306–307.

⁶² 447 US 307 (*Chakrabarty*).

⁶³ *Ibid.*

Living and Non-living Distinction for Patentable Subject Matter In 1978, an appeal was made to the Court of Customs and Patent Appeals. The court overturned the rejection made by Board of Appeals stating that ‘the fact that microorganisms were alive was without legal significance for purposes of the patent law’.⁶⁴ Rich J. held that the claims were not outside the scope of patentable inventions merely because they were drawn to ‘live organisms’.⁶⁵

On reconsideration, the same court referred to its earlier decision in the *Application of Bergy*,⁶⁶ which involved patent claim relating to a biologically pure culture of the microorganism *streptomyces vellosus*.⁶⁷ Rich J. reversed the decision of rejection by the USPTO and held that it was in the public interest to include microorganisms within the terms of manufacture and composition of matter. Rich J. compared microorganisms with chemical elements, compounds and compositions of matter which are not considered to be alive despite their capacities to react and promote reaction to produce new compounds and compositions by chemical processes.⁶⁸ On remand, he upheld his previous stand that the claim cannot be rejected on the sole ground that it was for ‘living organism’.⁶⁹

The litigation reached to the US Supreme Court when Sidney Diamond, the Commissioner of the USPTO, sought and won a writ of certiorari from the said court.⁷⁰ Apart from the submissions from petitioners and respondents, the court received *amicus curiae* from different interested parties. The Supreme Court in this case held by a majority 5:4 decision that ‘A live, human-made micro-organism is patentable subject matter under Sec. 101. Respondent’s microorganism constitutes a “manufacture” or “composition of matter” within that statute’.⁷¹

In giving the wide interpretation of the terms ‘manufacture’ and ‘composition of matter’, the court looked into the prior decisions. *Perrin versus United States*⁷² guided that in making statutory interpretation ‘unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning’.⁷³ *United States versus Dubilier Condenser Corp.*⁷⁴ indicated that courts ‘should not read into

⁶⁴ *Application of Chakrabarty* 571 F.2d 40 Cust. & Pat. App. (1978) cited in Rimmer, *supra* note 42, at 28.

⁶⁵ *Ibid.*

⁶⁶ *Application of Bergy* 563 F.2d 1031 Cust. & Pat. App. (1977).

⁶⁷ M. Bergy, J. Coats and V. Malik, ‘Process for preparing lincomycin’, (1974) US Patent Application No: 477, 766 cited in Rimmer, *supra* note 42 at 29.

⁶⁸ *Application of Bergy* 563 F.2d 1031 at 1038 Cust. & Pat. App. (1977) cited in Rimmer, *supra* note 42, at 29.

⁶⁹ *Application of Bergy* 596 F.2d 952 Cust. & Pat. App. (1979) cited in Rimmer, *supra* note 42, at 29.

⁷⁰ Rimmer, *supra* note 42, at 30.

⁷¹ 447 U.S. 308–318. (*Chakrabarty*).

⁷² 444 U.S. 37 (1979).

⁷³ *Id.*, at 42.

⁷⁴ 289 U.S. 178 (1933).

the patent laws limitations and conditions which the legislature has not expressed'.⁷⁵ Based upon these judicial constructions Berger C. J. opined:

Guided by these canons of construction, this court has read the term, 'manufacture' in [Sec.] 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labour, or machinery'. Similarly, composition of matter' has been construed consistent with its common usage to include 'all compositions of two or more substances and... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids powders or solids'.⁷⁶

Scope of the Patent Laws: Anything Under the Sun Made by Man Regarding the scope of patent law, Berger C. J. held that 'In choosing such expansive terms as "manufacture" and "composition of matter", modified by the comprehensive "any", Congress plainly contemplated that the patent laws would be given wide scope'.⁷⁷ He added that the relevant legislative history also supports a broad construction and referred to the Patent Act of 1793, which embodied its author, Thomas Jefferson's philosophy that 'ingenuity should receive a liberal encouragement'.⁷⁸

The Act defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]'.⁷⁹ This broad language remained intact in subsequent patent statutes in 1836, 1870 and 1874. In 1952, when the patent laws were recodified, Congress replaced only the word 'art' with 'process', keeping the remaining Jefferson's language intact.⁸⁰ Berger C. J. had provided a much broader scope to the patent laws by referring to the Committee Reports accompanying the 1952 Act: 'The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man"'.⁸¹

Limitations on the Scope of Patentable Subject Matter While interpreting the scope of the statutory subject matter broadly to include 'anything under the sun made by man', the Supreme Court did not rule out limitations to such scope. The court recognized certain exclusions such as the laws of nature, physical phenomena and abstract ideas, which have been held not patentable in several cases.⁸² The court maintained:

⁷⁵ *Id.*, at 199.

⁷⁶ 447 U. S. 308 (*Chakrabarty*).

⁷⁷ *Ibid*

⁷⁸ *Id.*, at 308–309, quoting 5 Writings of Thomas Jefferson 75–76 (Washington ed. 1871).

⁷⁹ Act of Feb. 21, 1793, Sec. 1, 1 Stat. 319.

⁸⁰ 447 U.S. 309 (*Chakrabarty*).

⁸¹ *Ibid*, referring S Rep. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952).

⁸² 447 U.S. 309 (*Chakrabarty*), referring *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U. S. 63, 409 U. S. 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U. S. 127, 333 U. S. 130 (1948); *O'Reilly v. Morse*, 15 How. 62, 56 U. S. 112–121 (1854); *Le Roy v. Tatham*, 14 How. 156, 55 U. S. 175 (1853) *Le Roy v. Tatham*, 14 How. 156, 55 U.S. 175 (1853).

Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of... nature, free to all men and reserved exclusively to none”.⁸³

In the light of such exclusions, the court found Chakrabarty’s microorganisms plainly patentable:

Judged in this light, respondent’s micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity “having a distinctive name, character [and] use.”⁸⁴

In *Chakrabarty*, the Supreme Court did not concur with the then prevailing product of nature doctrine, propounded by it in the case of *Funk Bros Seed Co versus Kalo Inoculant Co.*⁸⁵ The court made a distinction between the Chakrabarty’s claims for the genetically engineered microorganism to *Funk Brothers Seed Co. versus Kalo Inoculant Co.*,⁸⁶ in which the claimant had discovered certain naturally occurring bacteria, useful for agricultural purposes, could be combined into a single package without adverse effects and sought a patent on the packaged bacteria. The court in *Funk Brothers’* Case ruled the packaged bacteria non-patentable by concluding that the patentee had discovered ‘only some of the handiwork of nature’.⁸⁷

On the other hand in *Chakrabarty*, the Supreme Court upheld the patent on Chakrabarty’s genetically engineered microorganisms because he had significantly manipulated nature. The court stated:

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under [Sec.] 101.⁸⁸

The Supreme Court rejected the argument made by petitioner that the passage of sui generis legislations, the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection, evidences congressional understanding that the terms ‘manufacture’ or ‘composition of matter’ do not include living things; if they did, neither Act would have been necessary.⁸⁹

After looking into the legislative history of the said Acts, the court observed:

⁸³ 447 U.S. 309 (*Chakrabarty*), quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U. S. 130 (1948).

⁸⁴ 447 U. S. 309–10, quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 121 U. S. 615 (1887).

⁸⁵ 333 U. S. 127, 333 U. S. 130 (1948).

⁸⁶ 333 U. S. 127, 333 U.S. 130 (1948).

⁸⁷ 333 U.S. 131 (1948).

⁸⁸ 447 U.S. 310 (*Chakrabarty*).

⁸⁹ *Id.*, at 311.

In enacting the Plant Patent Act... Congress thus recognised that the relevant distinction was not between living and inanimate things but between products of nature, whether living or not and human made inventions. Here respondent's microorganism is the result of human ingenuity and research. Hence the passage of the Plant Patent Act affords the Government no support. Nor does the passage of the 1970 Plant Variety Protection Act support the Government's position. As the Government acknowledges, sexually reproduced plants were not included under the 1930 Act, because new varieties could not be reproduced true-to-type through seedlings. By 1970, however it was generally recognised that true-to-type reproduction was possible and that plant patent protection was therefore appropriate. The 1970 Act extended that protection. There is nothing in its language or history to suggest that it was enacted because Sec. 101 did not include living things.⁹⁰

The petitioner argued that since genetic technology was unforeseen when Congress enacted Sec. 101, therefore the resolution of the patentability of inventions such as respondent's should be left to Congress.⁹¹ Rejecting the petitioner's argument, the court maintained:

The unambiguous language of [Sec.] 101 fairly embraces respondent's invention. Arguments against patentability under [Sec.] 101, based on potential hazards that may be generated by genetic research, should be addressed to the Congress and the Executive, not to the Judiciary.⁹²

Expressing the dissenting opinion on behalf of White J., Marshall J. and Powell J., Brennan J. emphasised that the courts should be differential to the wishes of the Congress, and extend protection no further than statute provides.⁹³ He maintained that in absence of legislative direction, 'the Court should leave the Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available'.⁹⁴

Referring to the Plant Patent Act 1930 (US) and the Plant Variety Protection Act, 1970 (US), Brennan J. noted: 'In these two Acts Congress has addressed the general problem of patenting animate inventions and has chosen carefully limited language granting protection to some kinds of discoveries, but specifically excluding others'.⁹⁵ He concluded: 'These Acts strongly evidence a congressional limitation that excludes bacteria from patentability'.⁹⁶ Brennan J. also maintained: 'It is the role of Congress not this Court, to broaden or narrow the reach of the patent laws'.⁹⁷

Implications of Diamond versus Chakrabarty on the Scope of Biotechnology Patents The Supreme Court decision in *Chakrabarty* received mixed reactions; while biotechnology industry groups and biotechnology advocates welcomed the decision, however, biotechnology patent opponents involving various non-governmental

⁹⁰ *Id.*, at 312.

⁹¹ *Id.*, at 314.

⁹² *Id.*, at 304, 314–18.

⁹³ Rimmer, *supra* note 42, at 42.

⁹⁴ 447 U.S. 319 (*Chakrabarty*).

⁹⁵ *Ibid.*

⁹⁶ *Ibid.*

⁹⁷ *Ibid.*

organisations and anti-biotech activists criticized the decision for extending patent protection to life forms. Cary Fowler, then an anti-biotech patenting activist, describes the situation:

The GE- Chakrabarty case was a major tactical victory for the industry. Not only did it secure the protection it has long sought, but it did so through a new arena, the court system. The courts were neither fast nor cheap, but they were faster and cheaper than the political process. They were also a foreign territory to most advocacy groups.⁹⁸

This decision of the Supreme Court galvanised opposition from individuals like Jeremy Rifkin and Pat Mooney and non-governmental organisations that continue to oppose patenting life in the USA and elsewhere.⁹⁹ Although Chakrabarty's patent claims were limited to genetically engineered mono-cellular living organisms and the Supreme Court in Chakrabarty never said that complex organisms were patentable, however, it took the position that the status of subject matter as living made no difference to its patentability. Therefore, a logical reading of Chakrabarty suggests that the Patent Act would seem to permit the patenting of any new, genetically engineered living organism.¹⁰⁰ Rebecca Eisenberg comments on the larger implications of Chakrabarty decision for patent jurisprudence as:

As predicted by both proponents and opponents of patents on living organisms, investment in biotechnology R&D has flourished in the wake of *Diamond v. Chakrabarty*. But the full consequences of the expansive approach to patent eligibility endorsed by the *Chakrabarty* majority continue to be felt far beyond the biotechnology industry. ...A quarter century ago it was unclear whether the subject matter boundaries of the patent system were expansive enough to embrace biotechnology and information technology. Today, it is not clear whether the patent system has any subject matter boundaries at all.¹⁰¹

Courts in the USA started giving wide interpretation to patentable subject matter criterion under the US Patents Act to extend patent protection to higher life forms in the light of *Chakrabarty* decision.

Plants as Patentable Subject Matter In a 1985 case, *Ex parte Hibberd*,¹⁰² the Board of Patent Appeals and Interferences reversed the USPTO's earlier rejection of a patent claiming corn plants and seeds as well as plant tissue cultures. The claims were related to plants produced through conventional cross-breeding but relied on new techniques such as cell culture and genetic analysis (but not recombinant DNA).¹⁰³ This case paved the way for patenting plants as by 1988, 42 patents on crop plants had been issued.¹⁰⁴

Animals as Patentable Subject Matter In 1984, Standish Allen and Sandra Downing of the University of Washington and Jonathan Chaiton of the Coast Oyster

⁹⁸ Fowler (1994), 150 quoted in Dutfield, *supra* note 17, at 198.

⁹⁹ Dutfield, *supra* note 17, at 198.

¹⁰⁰ Demaine and Fellmeth (2002).

¹⁰¹ Eisenberg (2006) quoted in Rimmer, *supra* note 42, at 44–45.

¹⁰² *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Interferences 1985).

¹⁰³ Dutfield, *supra* note 17, at 198.

¹⁰⁴ *Ibid.*

Company applied for a patent on the production of the triploid-sterile Pacific oyster. The inventor's lawyer, David Maki, sought to extend the claim to include the triploid oyster itself.¹⁰⁵ The oyster had been genetically modified to demonstrate increased growth and, to be edible throughout all stages of its life cycle.¹⁰⁶

The patent examiner rejected a number of claims in the application for lack of subject matter jurisdiction; by holding that polyploidy oyster was product of nature.¹⁰⁷ The examiner held that the animal produced by the method claimed was 'controlled by laws of nature and not a manufacture by man that is patentable'.¹⁰⁸ Further, the examiner had compared the claimed invention with the microorganisms claimed in *Diamond versus Chakrabarty* case and found that the claimed microorganisms were 'more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses'.¹⁰⁹ Along with the lack of subject matter, the examiner also held that a number of claims were obvious in light of a previous publication. The previous publication recommended polyploidy as a way to increase growth in cultured oysters.¹¹⁰

On the later stage, the Board of Patents Appeals and Interferences pointed out that relevant test was not whether the subject matter was 'controlled by the law of nature', but whether it was naturally occurring.¹¹¹ The Board observed that '[t]he examiner has presented no evidence that the claimed polyploidy oysters occur naturally without the intervention of man, nor has the examiner urged that polyploidy oysters occur naturally'.¹¹² The Board decided that 'the claimed polyploidy oysters are non-naturally occurring manufactures or composition of matters within the confines of patentable subject matter under 35 USC 101'.¹¹³ However, the Board agreed with the examiner's finding on obviousness of the claimed invention.¹¹⁴ On appeal, the CAFC affirmed the decision of the Board of Patent Appeals and Interferences, without disturbing the finding that animals could be patentable subject matter.¹¹⁵ The decision of the CAFC determined that Chakrabarty had opened the door to patents on genetic codes for multicellular animals that otherwise met the patentability requirements.¹¹⁶

In response to the decision of the Supreme Court of the USA in *Diamond versus Chakrabarty* and the ruling of the Board of Patent Appeals and Interferences in *Ex*

¹⁰⁵ Rimmer, *supra* note 42, at 84.

¹⁰⁶ Demaine and Fellmeth, *supra* note 100, at 318.

¹⁰⁷ *Ibid.*

¹⁰⁸ Rimmer, *supra* note 42, at 85, quoting *Ex Parte Allen* 2 USPQ 2d. P. 1425, 2) (1987).

¹⁰⁹ *Ibid.*

¹¹⁰ Rimmer, *supra* note 42, at 85.

¹¹¹ Demaine and Fellmeth, *supra* note 100, at 319, quoting *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. Appeals & Interferences (1987).

¹¹² *Ex Parte Allen* 2 U.S.P.Q.2d., 1425, 2 (1987).

¹¹³ *Ibid.*

¹¹⁴ Rimmer, *supra* note 42, at 85.

¹¹⁵ *Id.*, at 85–86.

¹¹⁶ Demaine and Fellmeth, *supra* note 100, at 319.

Parte Allen, the Commissioner of the USPTO, Donald Quigg, released a notice, announcing that animals could constitute patentable subject matter. The notice states: '[t]he Patent and Trademark Office now considers non-naturally occurring non-human multicellular organisms including animals, to be patentable subject matter within the scope of 35 U.S.C. 101'.¹¹⁷ The notice also made it clear that the Board's decision does not affect the principle and practice that products found in nature will not be considered to be a patentable subject matter under USC 101 and/or 102.¹¹⁸ It ensures that a patent will not be granted to an article of manufacture or composition of matter occurring in nature unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with the existing law.¹¹⁹

The notice issued by USPTO attracted a lot of opposition from various farming and animal rights groups. They filed a lawsuit in Northern District of California, challenging the notice, which recognises animals as patentable subject matter.¹²⁰ The District Court dismissed the challenge on the first instance, mentioning that the notice was supported by relevant legal and administrative case law.¹²¹ On appeal, the CAFC also dismissed the challenge from farming and animal groups. Nies C.J. ruled that the notice was consistent with the Supreme Court of the USA decision in *Diamond versus Chakrabarty*, and the USPTO rulings in *Ex parte Allen* and *Ex parte Hibberd*. He also made clear that the farmers, husbandry groups and animal rights organisations did not have standing to seek a declaration that animals are not patentable subject matter and an injunction against the issuance of animal patents.¹²²

Following the CAFC's decision in *Ex Parte Allen*, the USPTO issued a patent on the Harvard Oncomouse in April 1988 to two genetic researchers, Philip Leder of Harvard Medical School and Timothy Stewart of San Francisco, who assigned it to the president and trustees of Harvard College.¹²³ Since the mouse was created for the study of breast cancer, therefore called oncomouse. The patent claim directed to the mouse itself or any mammal with the mouse's genetic idiosyncrasies. Accordingly, the patent claim covered the activated oncogene sequence in the animal's germ cells and somatic cells because the scope of the claim included the offspring of any mammal having the oncogene. To put it in other way, the claim on the mammal entailed a claim on at least the portion of the mammal's genome that coded for its novel morphology or physiology.¹²⁴ Following Harvard Oncomouse, a number

¹¹⁷ United States Patent and Trademark Office (1987), 'Notice: animals-patentability', Official Gazette, United States Patent and trademark Office, 1077, 8, 21 April.

¹¹⁸ *Ibid.*

¹¹⁹ *Ibid.*

¹²⁰ *Animal legal Defense Fund v. Quigg* 710 F.Supp. 728, 9 U.S.P.Q.2d 1816 (N.D.Cal. 1889); *Animal Legal Defense Fund v. Quigg* 932 F.2d 920 C.A. Fed. (Cal.), 1991.

¹²¹ *Animal legal Defense Fund v. Quigg* 710 F.Supp. 728, 9 U.S.P.Q.2d 1816 (N.D.Cal. 1889).

¹²² Rimmer, *supra* note 42, at 87.

¹²³ *Id.*, at 90.

¹²⁴ Demaine and Fellmeth, *supra* note 100, at 318, citing U. S. Patent No. 4736,866 (issued Apr. 12, 1988).

of patents relating to animals had been issued and '[a]s of September 2003, about 454 animal patents has been granted in the USA, about half for disease models'.¹²⁵

The Wisconsin Democrat Robert Kastenmeir introduced the *Transgenic Animal Patent Reform Bill 1989* (US) into the United States Congress. The Bill was aimed to provide patent defences for farmers in respect of the reproduction, use and sale of a patented transgenic farm animal and its offspring. Although the Bill was passed in the House of Representative, it was not debated in Senate before the end of Congress. In 1990, Kastenmeir had lost his seat in the 1990 Congress elections and the Bill was never reintroduced into the USA Congress.¹²⁶

Human Chimera and Humanoid: Testing the Extent of Patentable Subject Matter and Morality

In order to test the extent of patentable subject matter and ethics of patenting, Professor Stuart Newman of the New York Medical College and biotechnology opponent, Jermy Rifkin, made an announcement in 1997 that they would seek a patent on methods to create a chimera, a human-animal hybrid. This initiative was titled as 'the Human Chimera Patent Initiative'.¹²⁷ Afterwards, an application was filed in the USPTO seeking a patent on a technique combining human and animal embryonic cells to produce a single hybrid mouse-human embryo (the so called 'humouse').¹²⁸ 'The embryo could then be implanted into a human or animal surrogate mother to develop into a being of mixed human and animal composition—a not-so mythological chimera'.¹²⁹ The applicants had no intention to commercially exploit the humouse but to test the reaction of USPTO in this regard.¹³⁰ It was an attempt to force the USPTO to clear its position over the ethical dimensions of patent law and to promote public debate about the ethics of biotechnology, particularly with respect to animal research and human cloning.¹³¹ Responding to this application, USPTO issued a media advisory by observing:

The Patent and Trademark Office is required by law to keep all patent application in confidence until such time as a patent may be granted. However, the existence of a patent application directed to human/non-human chimera has recently been discussed in the news media. It is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.¹³²

Consequently in 1999, the USPTO rejected the first application by Stuart Newman and Jeremy Rifkin because the invention 'embraces' a human being and failed the

¹²⁵ Dutfield, *supra* note 17, at 199, quoting Kelves (2006), 79.

¹²⁶ Rimmer, *supra* note 42, at 89.

¹²⁷ Rimmer, *supra* note 42, at 98–99.

¹²⁸ Demaine and Fellmeth, *supra* note 100, at 320.

¹²⁹ *Ibid.*

¹³⁰ *Ibid.*

¹³¹ Rimmer, *supra* note 42, at 99.

¹³² United States Patent and Trademark Office 'Media advisory: facts on patenting life forms having a relationship to humans', (1998) <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>, quoted in Rimmer, *supra* note 42, at 99–100.

moral utility test.¹³³ The USPTO believed that the Congress did not intend 35 USC to include the patenting of human beings.¹³⁴ Moreover any claim ‘directed to or including its scope a human being’ would not be considered patentable because treating a human being as exclusive property is unconstitutional.¹³⁵ The USPTO also pointed out that the application did not meet the enablement and best mode criteria.¹³⁶

Again in 2002, Newman and Rifkin refilled their patent application by arguing that the patent claims were not directed to a human being or human embryo, but rather a man-made chimeric animal developed from a chimeric embryo and the statute does not restrict patentability on the ground whether the claims embrace a human being.¹³⁷ However, the examiner at USPTO in 2004 rejected the application mentioning that the claimed invention was directed to non-statutory subject matter.¹³⁸ The examiner rejected the application for lack of specific and substantial utilities and not meeting the enablement and written description requirements.¹³⁹

Stuart Newman claimed the decision of the USPTO as a moral victory and observed that the action of the USPTO reflected the absence of an effective criterion in the patent system to determine the issue of relative humanity of a genetically engineered organism:

But if you could genetically engineer the chimera so that the human component will be a known percentage of the organism then the USPTO might be better satisfied. I don’t think that the rejection of this patent will impede research in the field. I do hope however, that it stimulates legislative guidelines. With commercial incentive alone it is only a matter of time before such an organism is made.¹⁴⁰

The human chimera episode made it clear that though the US patent law does not contain morality and public order provisions as grounds for rejecting a patent, however, it recognises its utility with regard to few serious issues. This concern has been echoed in an editorial in *Nature Biotechnology*, which noted that ‘no country’s patent system has yet found a way of extricating itself from the philosophical and political morass associated with patent applications that encroach on definitions of humanness’.¹⁴¹ Recently, the approach adopted by USPTO towards patenting

¹³³ Demaine and Fellmeth, *supra* note 100, at 320.

¹³⁴ Rimmer, *supra* note 42, at 100.

¹³⁵ Demaine and Fellmeth, *supra* note 100, at 320, quoting Donald J. Quigg, Statement by Assistant Sec’y of Comm. & Comm’r of Pat. & Trademarks, 1077 Off. Gazette U.S. Pat. & Trademark OFF. 24 (Apr.7, 1987) at 24.

¹³⁶ Rimmer, *supra* note 42, at 100.

¹³⁷ *Ibid.*

¹³⁸ *Ibid.*

¹³⁹ *Id.*, at 101–102.

¹⁴⁰ *Id.*, at 102, quoting Editorial, ‘Hybrid too human patent: case highlights lack of criterion for genetically modified organisms’, *Nature Review Drug Discovery*, (2005), <http://www.nature.com/news/2005/050328/full/nrd1710.html>, 31 March.

¹⁴¹ *Id.*, at 102 quoting Editorial, ‘Patenting pieces of people’, 21 *Nature Biotechnology*, 341, (1 April, 2003).

of human organism has been given the backing of law, by Leahy-Smith America Invents Act 2011 (AIA). Sec. 33(a) of the said Act reads: 'Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism'.¹⁴² This provision of the Leahy-Smith America Invents Act is in consonance with the long-standing policy of the USPTO that a claim encompassing a human being is not patentable, and the said Act does not bring any new change in the existing patent practice. However, it recognises the existing practice by conferring the effect of law. Sec. 33(b) mentions that Section 33(a) shall apply to patent applications filed on or after the date of enactment (i.e. 16 September 2011) of the Leahy-Smith America Invents Act 2011 and to the applications pending on the said date.¹⁴³ The words 'directed to' and 'encompassing' are not very clear and open for interpretation. It is to be seen how it would be interpreted in biotech patent cases.

Human Gene as Patentable Subject Matter Human genes have become a common subject matter for patents following Chakrabarty decision. One of the most common objections against the gene patents is that genes are naturally occurring entities that are there to be discovered but not invented. In the USA, although the patent statute states that both discoveries and inventions qualify as patentable subject matter, however, in practice the law does not permit the patenting of natural phenomena.¹⁴⁴

The USPTO and courts in the USA have long recognised that isolated and purified substances do not exist in nature, hence patentable.¹⁴⁵ This has been the general trend of the USPTO and courts regarding chemical products. This analogy has been applied to human DNA also by considering it a chemical. Before Chakrabarty, there were several cases in which the USPTO and courts recognised that isolated and purified chemical substances were patentable. First cited case in this series was *Park-Davis & Co. versus H.K. Mulford & Co.*,¹⁴⁶ where the applicant had patented adrenalin. The claim of the applicant states: A substance possessing the herein-described physiological characteristics and reactions of the suprarenal glands in a stable and concentrated form, and practically free from inert and associated gland tissue.¹⁴⁷ The court held that a substance derived and purified from nature could be patentable.¹⁴⁸ In a 1970 case, *In re Bergstrom*,¹⁴⁹ the inventors claimed 'naturally occurring', the prostaglandin compounds, PGE2 and PGE3, that they had extracted and purified from prostate gland. The court held that the 'sufficiently pure'

¹⁴² Sec. 33(a), Leahy-Smith America Invents Act (AIA) 2011, available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr1249enr/pdf/BILLS-112hr1249enr.pdf> (Visited on Sept. 27, 2011).

¹⁴³ Sec. 33(b), Leahy-Smith America Invents Act (AIA) 2011, available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr1249enr/pdf/BILLS-112hr1249enr.pdf> (Visited on Sept. 27, 2011).

¹⁴⁴ *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

¹⁴⁵ Goldstein and Gold (2002).

¹⁴⁶ 196 F.496 (2nd Cir. 1912).

¹⁴⁷ *Id.* 497.

¹⁴⁸ *Id.*, at 498.

¹⁴⁹ 427 F.2d 1394 (C.C.P.A. 1970).



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