CHAPTER-IV
NUANCES OF PATENT PROTECTION WITH MODERN TECHNOLOGIES: BIOTECHNOLOGY

As long as there have been people, there has been technology. Indeed, the techniques of shaping tools are taken as the chief evidence of the beginning of human culture. On the whole, technology has been a powerful force in the development of civilization, all the more so as its link with science has been forged. Technology-like language, ritual, values, commerce, and the arts-is an intrinsic part of a cultural system and it both shapes and reflects the system's values. In today's world, technology is a complex social enterprise that includes not only research, design, and crafts but also finance, manufacturing, management, labor, marketing, and maintenance.

In the broadest sense, technology extends our abilities to change the world: to cut, shape, or put together materials; to move things from one place to another; to reach farther with our hands, voices, and senses. We use technology to try to change the world to suit us better. The changes may relate to survival needs such as food, shelter, or defense, or they may relate to human aspirations such as knowledge, art, or control. But the results of changing the world are often complicated and unpredictable. They can include unexpected benefits, unexpected costs, and unexpected risks—any of which may fall on different social groups at different times. Anticipating the effects of technology is therefore as important as advancing its capabilities.

Science for All Americans

4.1 Introduction

Technology is a broad concept that deals with a species' usage and knowledge of tools and crafts and how it affects a species' ability to control and adapt to its environment. It refers to human activities such as agriculture or manufacturing and even to processes such as animal breeding or voting or war that change certain aspects of the world. Further, technology sometimes refers to the industrial and military institutions dedicated to producing and using inventions and know-how. In any of these senses, technology has economic, social, ethical, and aesthetic ramifications that depend on where it is used and on people's attitudes toward its use.

Technology is a term with origins in the Greek "technologia," i.e., systematic treatment of an art. However, a strict definition is elusive; "technology" can refer to

material objects of use to humanity, such as machines, hardware or utensils, but also encompass broader themes, including systems, method of organization and techniques. The term can either be applied generally or to specific areas such as construction technology, medical technology, engineering technology, nano-technology, biotechnology etc.

Human race recognized the value of technology and began with conversion of natural resources into simple tools. The pre-historical discovery of the ability to control fire increased the available sources of food and the invention of the wheel helped humans in traveling in and controlling their environment. Recent technological developments, including software technology, biotechnology, engineering technology and nano-technology have improved the standards of living of individuals in all respects and at the same time, benefited the society in overall perspective and made the world as global village. Technology particularly biotechnology helped the society in a number of ways. It helped in identifying the DNA structure, genetic engineering, cloning, medicines, gene transplantation etc., which helped to develop the human health, agricultural sector etc., But various implementations of technology influenced the values of a society and new technology often raises new ethical questions such as patenting of gene and living organisms, cloning of animals and human beings, using human beings in clinical trails.

Technology particularly biotechnology helps the mankind in many respects. In the areas of health sector and agricultural sector due to the inventions made by the Biotechnology firms, the human life, standard of living particularly in the field of medicine has improved alarmingly. The other edge of biotechnology is worsening the human life than improving. In the modern intellectual property era, where it gives exclusive right to inventor to use the invented technology, it is becoming a cost affair concept and it is not in the hands of a common middle class man. Before looking in deep about the biotech patents it is required to analyze the understanding of technology and about biotech patents.

http://mw1.merriam-webster.com/dictionary/technology

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4.2 Definition of technology

In general, technology is the relationship that society has with its tools and crafts, and to what extent society can control its environment. The Oxford Dictionary offers a definition of the term, “the scientific study and use of applied sciences”. The Merriam-Webster dictionary offers a definition of the term: “the practical application of knowledge especially in a particular area” and “a capability given by the practical application of knowledge.” Ursula Franklin, in her 1989 “Real World of Technology” lecture, gave another definition of the concept; it is “practice, the way we do things around here”. Bernard Stiegler, in his article ‘Technics and Time,’ defines technology in two ways: as “the pursuit of life by means other than life”, and as “organized inorganic matter”. The term is mostly used in three different contexts: when referring to a tool, a technique, the cultural force or a combination of the three.

Technology can be most broadly defined as the entities, both material and immaterial, created by the application of mental and physical effort in order to achieve some value. In this usage, technology refers to tools and machines that may be used to solve real-world problems. Tools and machines need not be material; virtual technologies, such as computer software and business methods, biotechnology and genetic engineering, etc., fall under this definition of technology.

4.3 Technology and Society

The relationship of technology with society is generally characterized as synergistic, symbiotic, co-dependent, co-influential and co-producing, i.e., technology and society depend heavily one upon the other. It is also generally believed that this synergistic relationship first occurred at the dawn of humankind with the invention of

4 http://mww1.merriam-webster.com/dictionary/technology
5 Franklin, Ursula, Real World Technology, http://www.anansi.ca
simple tools, and continues with modern technologies today. Today and throughout history, technology influences and is influenced by such societal issues / factors as economics, values, ethics, institutions, groups, the environment, government among others. Studying the impacts of science, technology and society and vice versa is an essential exercise need to be done regularly, then only the balance can be maintained between nature and technology.

4.4 Broad Classification of Modern Technologies in view of patents

4.4.1 Nano technology

Many describe nanotechnology (nano-tech) as the science that will usher in the next industrial revolution. Literally nano-technology means "technology on the nanometer scale", nanotechnology has been alternately defined as the application of science at the nano-scale, from 1 to 100 nanometers and "the research and development of materials, devices, and systems that exhibit physical, chemical, and biological properties that are different from those found at larger scales." One can find myriad other definitions in legal, patent, and scientific literature.

Firms currently develop golf balls and space elevators and market them as nanotechnology along side more traditional nano-tech pursuits, such as nano-tubes and nano-particles. In fact, published applications pertaining to nanotechnology rose over 40% between 2003 and 2004. Many of these applications are drawn towards the fundamental principals of nanotechnology research and development. As a result, some feel that these patents generate a patent thicket, through which researchers must wade to advance the science. That thicket may deter the critical innovation still required to bring nanotechnology to fruition or to the market.

4.4.2 Information Technology

Information Technology (IT), with regard to the IT sector, there is considerable debate about the need for exclusive rights to promote development of software and business methods and whether patent protection is the appropriate regime to use. Unlike copyrights and contractual rights, patents create claims that are good even against independent inventors. For cumulative technologies or in instances where interoperability is an important goal, the need to sift through prior patents and negotiate rights arguably creates a high tax on innovation and a drag on development.

Other untoward consequences may flow from the decision to permit patenting in this area. For example, the risk of debilitating suits motivates participants to acquire multiple patents, hoping that with enough potential counterclaims, they can fend off or negotiate their way out of difficulty. The result is a vicious cycle: thickets of rights that are expensive (or nearly impossible) to clear, requiring an ever-larger arsenal of defensive protection. Furthermore, many IT products involve multiple inventions and, accordingly, multiple licenses. In that environment, holdout possibilities are numerous and, as the Blackberry case\textsuperscript{10} nearly demonstrated, can potentially undermine the investments of producers, other patentees, and the public. All of this patenting activity fosters so many potential lawsuits that, as economists James Bessen and Michael Meurer have concluded the cost of litigation has begun to exceed the profits from patents by all measures in this sector.

In addition, some IT products are characterized by strong network effects and standard setting, which may make switching costs high and lock consumers into inferior products. Those holding patent rights in products toward which a market has tipped receive awards out of proportion to the technical contributions of the inventors. When these patents also dominate their fields, they allow right holders to prevent entry by competitors.

\textsuperscript{10} NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).
4.4.3 Biotechnology

While the term "biotechnology" was coined early in the twentieth century, the use of biotechnology processes dates back almost as far as the beginning of humankind. Not until the nineteenth century, however, did scientists begin to understand the chemical and biological bases for these developments. Specifically, the nineteenth century marked several important scientific breakthroughs, including Louis Pasteur's discovery of yeast in the fermentation process, Gregor Mendel and Charles Darwin's work on heredity, and Schleiden and Schwann's discovery of the cell, all of which helped open the door for modern biotechnology. Today biotechnology is a booming industry, generating billions of dollars and producing innovations ranging from new antibiotics to cloned animals and genetically modified food products.

The commercialization of biotechnology has led researchers and corporations to seek patent protection for their biotechnological innovations. As the courts and the Patent and Trademark Office increasingly have allowed patents for these inventions, the biotechnology industry has demanded enhanced patent protection. USA made certain specific legislations such as The Biotechnology Process Patent Act, 1995.

4.5 Development of Biotechnology

Biotechnology has become a new and challenging technique for established industries and for specialist entrants. Crops may genetically manipulated at every level from the specific variety to the genus or species, in order to improve their commercial qualities or to make them resistant to insects or diseases or herbicides which can then be used on surrounding weeds.\(^{11}\)

Classical biotechnology may be defined loosely as the production of useful products by living microorganisms, and as such it has been with us for a long time. The production of ethanol from yeast cells is as old as history, and over fifty years ago the production of various industrial chemicals such as acetic acid and acetone by

fermentation processes was well known. Indeed, even the word biotechnology is not recently coined. In 1920, a Bureau of Bio-Technology was established in Leeds, and published a journal dealing with fermentation technology and related topics. Back in 1873, Louis Pasteur obtained a US patent claiming ‘yeast, free from organic germs of disease, as an article of manufacture’, an early case of a patent for living organisms.

More recently, the antibiotics industries were based upon the isolation of products from selected strains of microorganisms, and although the majority of antibiotics are now produced synthetically, are still made from micro-organisms either found in nature or artificially mutated. Not only antibiotics but also other drugs – for example, the immunosuppressant cyclosporine – are produced by fermentation of a microorganism.

The modern biotechnology, as distinct from the classical fermentation technology, began in the 1970s with the two basic techniques of recombinant DNA technology and hybridoma technology. These are also referred to as gene splicing or genetic engineering, that it causes the production of a desired protein by the cell; secondly producing monoclonal antibodies. More recently, the techniques of genetic engineering have been applied to higher organisms to produce transgenic animals and plants, and even to humans (gene therapy) for example to replace missing or defective genes coding for a protein required by the body, or to introduce genes into cancer cells which will render them easier to kill.

The genomic era has started. The concept of Genomics was developed in a high speed by the sequencing of DNA fragments and has led to the completion ahead of schedule of the Human Genome Project, and the identification of many human genes, and this science of genomics can be used to find genes which could make useful protein products, which could be applicable in gene therapy, and which might be useful in elucidation of disease mechanisms, in diagnostic kits, and in screening for new drugs.
There are also many research tools and techniques making use of biotechnological processes.\textsuperscript{12}

\textbf{4.6 Biotechnology in Science}

Biotechnology is an interdisciplinary enterprise, a scientific melting pot whose language of communication and expression is that of chemistry. It draws, not only upon a wide range of life sciences, but also on other less obviously related sciences like computer science and chemical engineering. Biotechnology also brings together a diversity of industrial sectors that benefit from using it.

For \textit{Arthur Kornberg}, a Nobel laureate for his pioneering research on DNA synthesis, 'the most rational understanding of life' is 'its reduction to the molecular details of chemistry' This conceptualization of life as essentially chemical, embodied in and promoted through the discourse of biotechnology, is undoubtedly appealing to those who esteem modern science for its progressiveness and rationality.

Modern biotechnology is very much a late twentieth-century phenomenon; it is the result of scientific advances that go back well over a century. \textit{Gregor Mendel}, whose findings were rediscovered in 1900, had worked out the basic rules of heredity in the 1860s. \textit{Chromosomes} had been discovered, also in the 1860s, and were found to behave in a systematic manner during cell division.

The molecular biology emerged in the next decades. The term was actually coined by a scientists working at the Rockefeller Foundation, an important source of research funding and scientific guidance in this area between the 1930s and the late 1950s. \textit{Linus Pauling}, the renowned American biochemist, working at the California Institute of Technology, \textit{Maurice Wilkins} and Rosalind Franklin at King's College, London, and \textit{James Watson} and \textit{Francis Crick} at Cambridge

University elucidate the structure of the DNA macromolecule. Watson and Crick were first to come up with the double helix model, which was announced in 1953 in *Nature*.

Unlike rDNA and hybridomas, the polymerase chain reaction (PCR) technology came out of a corporate laboratory. Kary Mullis, a scientist working for the California-based Cetus Corporation (like so many of the early Dedicated Biotechnology Firms (DBFs)), was credited with the invention, which is usually dated to 1985.

During the 1980s and 1990s, genetic engineering became increasingly sophisticated, with genes being transferred not just to microorganisms but also to plants and animals. A cancer-causing gene was inserted into a mouse, resulting in the controversial Harvard Onco mouse that was patented in 1988.

Another new technique developed during this period was animal cloning based on nuclear transfer, i.e., the insertion of a cell nucleus into an egg cell that has had its nucleus removed. In 1996, the world famous sheep called Dolly was cloned by Ian Wilmut and Keith Campbell at Roslin Institute in Scotland from a cell taken from a mature sheep's udder. It was not the first cloned animal but the first to be cloned from an adult mammal.

The Human Genome Project was launched in 1990 as an international public consortium with the objective of sequencing every one of the three billion nucleotides within the 23 chromosome pairs found in human cells, and publicly disclosing the data for the benefit of science. Given that genes take up only about 3-5 per cent of the genome, this was a much more ambitious task than just decoding the then estimated 1,00,000 or so genes, which in itself would have been
a huge undertaking. Human Genome project was finished and published in February, 2001.  

Initially, two techniques were adopted for the mapping part of the work; physical mapping and gene mapping. Physical mapping involves breaking DNA into multiple fragments using bacterial enzymes called restriction enzymes, inserting them into bacteria or yeast cells, and then matching the overlapping pieces.  

In spite of being an international project, the USA has made an extremely large contribution in terms of funding and the actual sequencing work. The United Kingdom has made the second biggest overall contribution, ahead of France, Japan, Germany and China, which all participated. The Wellcome Trust, a UK medical foundation, was one of the biggest single funded organizations for the Project, and the Sanger Center near Cambridge sequenced a total of eight chromosomes. In fact, the Sanger Center was the only non-American among the five institutions responsible for 85 per cent of the sequencing achieved by October 2000.  

There were many controversies between the scientists regarding to priorities. In 1991, a scientist at the NIH expressed to Craig Venter, eager to sequence and map protein-coding regions of the genome, adopted a short cut method of identifying genes using 'expressed sequence tags (ESTs). The EST method takes advantage of the established principle that mRNA can be converted back to DNA using an enzyme called reverse transcriptase. mRNA is the chemical that relays the genetic code form the nucleus to the site in the cell where it is translated for the assembly of the protein-forming amino acids. The result of applying reverse transcriptase is a substance called complementary DNA (cDNA). Essentially, cDNA has the same sequence as the gene but without the non-coding  

nucleotides sometimes referred to as 'junk DNA' but more formally as 'introns'. By sequencing the ends of these pieces of cDNA, one obtains partially encoded gene fragments called ESTs. When stretches of RNA are extracted from specialized cells, such as brain cells, the ESTs derived from them can help to identify genes that are useful in the functioning of that particular cell or the organ of which it forms a part. But the lacuna in the technology of EST is that they do not provide the full gene sequence and also enough information to indicate the function of the related gene.

The successful sequencing of the human genome has significantly expanded the global pool of medical and scientific knowledge. Scientists are currently studying the functions of individual genes in our bodies and how they interact with one another (otherwise known as genomics). Though this study is still in progress, genomics is already speculated to have the potential to revolutionize health care delivery. Such genomic prophecy, however, may be counterproductive if it generates indifference to reforms of existing, conventional, and workable methods of health care delivery. For instance, legitimate concerns have been raised as to the potential of genomics to distract attention from the funding of research on well-tested conventional methods of medical delivery. C.F. Curtis similarly observed that while molecular/genomic means of controlling mosquitoes that transmit malaria parasite might be helpful, they are not necessarily or practically superior to currently available non-molecular methods that have proved successful in the past. Nevertheless, genomics is an important phase of health biotechnology and promises significant health gains if properly harnessed with conventional methods.

Health biotechnology seems to enjoy considerable global support. Contrast with the general public attitude towards products of agricultural biotechnology some of which entail genetic modification. For instance, some people fear that products of agricultural biotechnology could harm the environment or jeopardize human health. These concerns were the subject of a recent scientific investigation undertaken by the United Kingdom GM Science Review, which confirmed that there is no verifiable scientific evidence
underpinning the alleged health and environmental hazards of agricultural biotechnology. The GM Science Review Report cautions, however, that the absence of evidence of harm does not translate to absence of harm, and recommends that regulation of genetically modified organisms should keep pace with new developments. These tools include polymerize chain reaction techniques, micro-arrays, bioinformatics, pharmaco-genomics, and proteomics. Moreover, the public seems to be satisfied with existing oversight mechanisms for the products of health biotechnology, such as the framework of a Food and Drug Administration existing in many countries. It seems that health biotechnology has benefited immensely from public support in the form of a favorable investment climate, patent protection and early commercialization of innovation. For instance, in the U.S.A. alone, hundreds of drugs were brought to the market in less than three decades and about three hundred new drugs are in "late-stage" development. Though similar positive results could easily be confirmed for other developed countries, the position in many developing countries is dismal.

Some years ago, Hiroshi Nakajima, a former World Health Organization (WHO) Director-General deployed a powerful metaphor of "silent genocide" to describe the unacceptable situation where millions of people in developing countries die every year from disease conditions for which there are available vaccines and treatments in the North. Nakajima observed that the silent genocide was "a preventable tragedy because the developed world has the resources and technology to end common diseases worldwide," but lacked "the will to help the developing countries." Health care delivery in many developing countries is still rudimentary and basic health care infrastructure is patently lacking. This situation has forced about 80% of Africa's population to rely on traditional medicine. Accordingly, the diseases and particular health situations in many developing countries such as India demonstrate the relevance and necessity of health biotechnology. But how have genomics, or health biotechnology, responded or planned to respond to the critical health situation in many developing countries.

The application of genomics by the pharmaceutical industry to drug discovery and the development process has frequently been claimed to promise better drugs and improved healthcare. The establishment of the Human Genome Project in 1990 quickly led to the first generation of genomics firms using high speed sequencing technologies to identify genes. In fact, at least 60 percent of the biotechnology firms in the USA and Europe are engaged in human and animal health. The types of products being developed include so-called ‘biopharmaceuticals’ such as genetically engineered therapeutic proteins and vaccines. Other common types of product are diagnostic kits for diseases linked to genetic defects. Genomics technologies are precipitating major changes in the pharmaceutical industry that may impact profoundly on the development of health services, yet there has been little social science research into these issues. In investigating what impact the commercial development of genomics technology has had on innovation processes within the pharmaceutical industry and competitiveness of the world biotechnology sector, this study uses a novel analytical framework that brings together insights from social studies of science and technology, and innovation and management studies.

The potential of new genetic technologies to improve therapeutic and commercial success has led all major pharmaceutical companies to embrace genomics and has seen their reinvention from predominantly chemistry-based firms to enterprises led by the life sciences. Heavy investment has been made in industrializing R&D methods to improve the effectiveness of drug discovery.

The largest pharmaceutical companies are increasing their technological capabilities in genomics faster and more extensively than medium-sized pharmaceutical companies and large biotechnology firms. Over 300 small and medium-sized genomics firms were profiled. Most corporate collaborations are between small genomics firms and large integrated pharmaceutical companies. Leaders in Europe are Germany, UK and France. Very few genomics companies have the financial and technical resources to develop drugs on their own, but from part of a highly dependent knowledge supply chain.

15 Graham Dutfield, p.146
Specialized informatics and technology platform providers have proved commercially unsustainable and the failure rate of genomics firms generally has been high.

The world genomics sector was far smaller than claimed by policy-makers and other industry analysts, and is less focused on gene discovery and the commercial opportunities this has offered. Genomics technology will not produce radical changes in drug discovery, medicine and healthcare or give quick results in economic development. Rather it is following a well-established pattern of slow incremental changes that are only now beginning to improve productivity. Health biotechnology is used not only to develop new types of drugs but also to enhance the efficiency of the drug discovery process. In fact, this has become the main objective of health biotechnology research.16

4.7 Field biotechnology

The successful application of biotechnology tools has had and is having dramatic effects in some areas of agriculture. These effects were being felt throughout the world in academic, government and industrial communities. The result is the rapid development of a multi-million dollar industry. In the present scenario, it is evident that genome science has already revolutionized pharmaceutical discovery and is now certain to change the nature and structure of most biologically based industries including agriculture, health and food.

Agricultural biotechnology is considered as the second important field. Much of this research is geared towards the development of new seed products with introduced traits providing mainly agronomic benefits such as disease resistance, pest resistance, and herbicide tolerance and also extended shelf life of harvested produce. Genomics has showed significant impact in agriculture with genetically engineered plants comprising ten percent of the current U.S. corn crop. Similar, or greater, acreage of genetically engineered crops are anticipated for cotton and soybean. So, there was growing need of the development of the area of plant genomics because the total number of plant traits that have been genetically engineered is few and need is there for more study.

16 Graham Dutfield, p. 146
Scientists from Japan started the Rice Genome Programme (RGP) in 1991. However, in 1998, a second phase of RGP was launched with the objective of complete sequencing of the genome and also of functional analysis of genes. Presently, ten countries are participating in this International Rice Genome Sequencing Programme (IRGSP). A new database known as the INE (Integrated Rice Genome Explorer) has also been established (pronounced I-ne, and refers to the rice plant in the Japanese language). The rice genome is estimated to comprise ~ 430 Mbp of DNA, which is about three times the amount of DNA in Arabidopsis. Later, Monsanto, a multinational company, in 2000 produced a draft of rice (Oryza sativa) genome. But sequencing of entire genome is not possible in most of the cases. A rapid way to establish an inventory of expressed genes is to determine partial sequences of cDNA called expressed sequence tags (ESTs). Thus genomic technology is being used to develop ESTs, which provide a cost-effective and rapid approach for describing all the genes of an organism. Thousands of sequences can thus be determined with a limited investment. There are more than 1,30,000 plant ESTs available in public databases from 19 plant species including Arabidopsis, rice, tomato, maize, soybean, potato, brinjal and cotton.

Compared to other higher plants, the genomes of Arabidopsis and rice are small, making whole genome sequencing of these two plants a readily achievable goal. Arabidopsis and rice can become reference or model genomes for two major classifications of plants, dicots and monocots, respectively.

4.8 Commercial Biotechnology

The biotechnology and genomics revolutions have created completely new commercial opportunities, and spawned four types of business. These are (i) the technology providers who manufacture the DNA sequencing machines and other equipment (for example, Applied Biosystems and Amersham Biosciences); (ii) the information providers (companies such as Incyte and Celera) that collect and organize sequencing information; (iii) the research firms, consisting mainly of the DBFs(Devoted Biotechnology Firms) that generally do the upstream research...
but lack the resources or the ambition to do the downstream product
development and marketing; and (iv) the health, agricultural and industrial
biotechnology firms. These include the larger vertically integrated DBFs (for
example, Amgen and Genentech) and much longer established businesses, which
are mostly pharmaceutical, chemical and life science corporations. These business
types are not necessarily discrete. Millennium Pharmaceuticals and Human
Genome Sciences are also involved in drug discovery and development.

Commercial biotechnology is far from being the preserve of small research-
intensive biotech 'boutiques'. This is not only because pharmaceutical companies
increasingly do biotechnological research and development themselves, but also
because of the recent emergence of a type of integrated business enterprise called
the 'life science corporation'. Such corporations, which include Monsanto,
DuPont, Novartis, Astra Zeneca and Aventis, among others, are so large that they
hold dominant global positions in two or more industrial fields that were
previously considered to be completely separate.

Essentially, they emerged out of a wave of mergers, acquisitions, joint
ventures and strategic partnerships involving companies in a wide range of fields
such as chemicals, seeds, processed foods, dietary supplements and
pharmaceuticals.

4.8.1 Structure of Biotechnology Industry

Whereas a large segment of the pharmaceutical industry is made up of a
relatively small number of multinational companies, the biotechnology industry is
very much more fragmented, and presents a different picture in USA, Europe,
Japan and India. In USA the industry is characterized by a large number of small
companies set up using venture capital. It is difficult to obtain reliable figures
about the total number of biotechnology companies, since different sources use
different definitions of the term and some small companies have only a transient
existence, or exist only on paper. In the early days of biotechnology, most small companies had the ambition to become a fully integrated pharmaceutical company, but only Amgen and Biogen have really achieved this aim while remaining independent, whereas other successful biotechnology companies such as Genetech have been acquired wholly or in part by larger companies.

The emerging biotechnology industry in Europe has been disadvantaged by comparison with USA because of the difficulty in raising venture capital (the main source of initial funding in Europe has in the past been banks, who, as is well known, will lend money only to someone who can prove he does not need it) and because of excessive governmental regulation. The Gene movement in Europe, with its strong bias against anything to do with gene technology, has also been a negative factor.

In EU the major biotechnology companies are at UK, such as Celltech, which was set up with the help of government investment, and British Biotechnology. After a brief period in which in terms of market capitalization it was one of the biggest companies in the country, crashed spectacularly when its lead products failed in clinical testing, and there were accusations that early bad results had been concealed. More recently, Celltech itself has been taken over by the Belgian Company UCB. The company PPL Therapeutics, best known for its production of Dolly, the first cloned sheep, is currently struggling for existence and has been acquired for a near-nominal price. There are still supposedly about 500 biotechnology companies in the UK, most of which are very small. Investors seem to have been scared away by the British Biotechnology fiasco, and the prospects for the UK biotechnology industry do not look good.

In Europe there are still relatively few pure biotechnology companies are there, although some medium-sized companies are in Germany. The major European Pharmaceutical companies are either active in the field themselves or
else involved in licensing or research co-operation agreements with US biotechnology companies or academic research centers.

In India there are few biotechnology companies, heavy investments in biotechnology were made both by government agencies and by large established firms. After 1990 of Indian liberalization there is a recognizable move started in India with regarding to biotechnology industry growth and research.

4.8.2 Commercial biotechnology in USA

The first company biotechnological applications Genetech, founded in 1976 by a venture capitalist called Robert Swanson, with Herbert Boyer, co-inventor of the rDNA technology, acting as an independent consultant. Genetech, whose name is short for ‘genetic engineering technology’, and is now owned by Hoffman LaRoche, raised considerable funds with its first public offering in 1980, its successful launch encouraged other university researchers to move into this emerging sector or to launch new firms themselves.

In 1982, genetically engineered human insulin became the first biopharmaceutical product to reach the market. The product was developed by Genetech but marketed by Eli Lilly, an established pharmaceutical company, which has had an interest in this product. At that time, the insulin on the market was extracted from grown-up pig and cow pancreases and could cause allergic reactions in some diabetes sufferers. Claims that human insulin is better for diabetes sufferers despite its higher price have been widely accepted. Later Genetech managed not only to develop but also to market two genetically engineered human proteins as pharmaceutical products. These were human growth hormone, which was approved in 1985 and marketed as protropin and tissue plasminogene activator (tPA), a ‘clot-buster’ drug for heart attack patients approved in 1987 and sold as Activase. Amgen followed in Genetech’s footsteps two years later with Epogen (erythropoietin), a hormone used to treat anaemia caused by kidney failure.
By the end of the decade, biotechnology had succeeded in developing over 75 FDA-approved drugs, vaccines and diagnostic tests, with hundreds more undergoing clinical trials. Amgen and Genetech are among the few DBFs that have become integrated pharmaceutical corporations, although in Genetech's case this came at the cost of sacrificing its independence.

4.8.3 Commercial Biotechnology in Europe

Europe has been less successful when compared with USA in putting together the downstream linkages from fund raising for basic research all the way to commercialization. The most successful countries in commercial biotechnology are the UK, Germany and France. The first two countries have a significant number of DBFs, many of which are university spin-offs, but in France and the rest of continental Europe the existing large science-based pharmaceutical and chemical firms have from the start been responsible for virtually all the private sector biotechnology research and development. Like their US counterparts, they tended to be quite cautious about biotechnology and were thus rather slow to set up in-house biotech research and development programs.

Since 1980s the EC countries have been preoccupied with catching up with the USA. Both the EC and the national governments have sought to stimulate biotechnology research and development through industrial policy and more business-friendly product and IP regulation.

4.9 Biotechnology and the Patents

At global level, the growth and consolidation of the US biotechnology sector is closely linked to the expansion of patent law into the protection of life forms and their structural and functional components. The reason behind the regulatory changes taking place in different countries is the huge importance of
patent protection in the biotechnology field. Biotechnology was and continues to be a high-risk and extremely research-intensive activity, and for DBFs especially, it has always been crucial to be able to secure large amounts of investment capital just to stay in business. Patent portfolios are the main magnet for outside investors – which also include larger science based firms and the larger the portfolio, the greater the interest from investors.

Research decision in many companies can depend as much, if not more, on the advice of patent lawyers as on the opinions of the scientists. Naturally, companies have a strong interest in securing patents that encompass the broadest possible scope and whose claims are drawn in ways that seek to anticipate future scientific developments.

At the same time, the strength of competitor’s patent positions helps companies to decide which research not to pursue. The extent of biotechnology patenting has increased tremendously in the last two decades. If only DNA sequences is taken Giles Stokes of Derwent Information, a company that provides patent and scientific information, explains that they ‘first began appearing in patents in 1980, just 16 sequences all year. By 1990 that figure had risen to over 6,000 sequences. Throughout the 1990s the growth in the patenting of sequences expanded exponentially, and this continued. In 2000 over 3,55,000 sequences were published in patents, a 5000 percent increase over 1990 -2000.17

It is not just the companies that are doing patenting, the US Department of Health and Human services was also one of the biggest applicants for patents claiming human gene sequences. In the agro-biotechnology field, six companies are responsible for three-quarters of all the US patents granted to the top 30 patent-holding firms. These are Monsanto, Du Pont, Syngenta, Dow Aventis and Grupo Pulsar.

17 http://www.derwent.com/ipmatters/2001_01/genetics.html
In Europe, it is estimated that more than 5,000 applications were made to the EPO in 2000, and a 50 percent increase of Biotech application during 2000 to 2005 of which 40 per cent were for microorganisms, plants and animals, while 60 per cent were for human and animal DNA sequences or for new gene therapies and medicines, or for both.

4.9.1 Biotechnology patenting in USA

USA pioneered both the commercialization of biotechnology applications and products and the development of patent law to protect them. Before the 1980s, the patent situation with respect to biotechnology processes and products was highly uncertain. While clearly non-biological process technologies such as rDNA could be patented in the USA, the product of nature doctrine was assumed by the Patent and Trademark Office, and by most scientists entirely to preclude the patenting of life forms and their structural and functional components. The meaning of the product of nature doctrine is that organisms or substances as they occur in nature cannot be considered as inventions are therefore not patentable. And, at this time, the new DBFs were yet to organize themselves into a single trade association to further their collective legal and regulatory interests. For better understanding of patenting regulation development case study is the best way.

4.9.1.1 Vitamin technologies case

A landmark case in early history in US relating to biotechnology is the Vitamin Technologies vs. Wisconsin Alumni Research. The suit involves the validity and infringement of three patents issued to Dr. Harry Steen bock of the University of Wisconsin, who transferred his interest in them to the plaintiff, Wisconsin Alumni Research Foundation of Madison, Wisconsin, a non-profit affair, which was organized in 1925 for the purpose of promoting scientific research at the University in

18 146 F.2d. 941, Oct 1941.
assisting the development of inventions and discoveries made by the faculty and students of the University. The defendant Vitamin Technologists is a corporation organized under the laws of the State of California, and the defendant H.F.B. Roessler is a director and officer of the defendant corporation.

The first patent entitled ‘Antirachitic Product & Process’ was issued August 14, 1928, on an application of Harry Steen bock on June 30, 1924. The second patent entitled ‘Antirachitic Product Essence and Process’, was issued August 9, 1932, upon an application of Harry Steen bock, filed December 27, 1926, and is stated therein to be a continuation in part of the first patent, and the third patent entitled ‘Anti-rachitic Product and Process,’ was issued October 13, 1936, on application of Harry Steen bock filed May 14, 1932. The first patent contained claims directed to the process of imparting anti-rachitic properties to organic substances of dietary value which comprises subjecting the same to the action of ultra violet rays such as are produced by a quartz mercury vapor lamp for a period sufficient to effect anti-rachitic activation but seems to be so limited as to avoid subsequent substantial injury to the anti-rachitic principle.

The second patent contains claims directed to the process of producing a concentrated anti-rachitically activated substance from substances rich in unsaponifiable lipoids which comprises separation and irradiation of unsaponifiable lipoids, such irradiation being effected by subjecting the lipoids before or after separation to the action of the ultra violet rays such as emanate from a quartz mercury vapor lamp for a period sufficient to effect antirachitic activation and claimed to be limited so as to avoid subsequent substantial injury to the antirachitic principle. It also contains claims directed to an activated edible compound comprising an unsaponifiable lipoidol extract activated antirachitically in accordance with the process stated in claims, compounded with an inactivated edible substance. The third patent contains claims directed to a process which comprises antirachitically activating yeast by subjecting it to the action of artificially produced ultra violet rays for a period sufficient to render the yeast antirachitically active.
The 9th Circuit Court of Appeals mentioned that it is a general rule that the last step taken under a claimed discovery, which turns failure into success, is an invention and is that which is sustained.19 Dr Steen bock's discoveries concerned with the effects of sunlight followed them up by inventing a new method by which to accomplish through artificial means what sunlight could not do. The court ruled that prior to the Steen bock discoveries and invention it was not known that it was possible to treat edible products with ultra violet rays so as to make such product a preventive or cure of rickets, and such process was practical through the use of sunlight, or that the ultra violet rays of the sun could not antirachitically process medicine or food with any distinction as to selection of substances, or of intensity, or of time, or that ultra violet rays of the sun could not practically impart the antirachitic principle to medicine or foods as the only then recognized edible, antirachitic substance was cod liver oil. It seems clear as the evidence demonstrates that the rays of the sun are not of the intensity of rays such as are produced by a mercury vapor lamp and that it was man who made use of artificially produced ultra violet rays which supplied the practical mechanical contrivance that sunlight had not given, and no product is shown to have been activated by the sun left to itself. Under most circumstances the scientists seem to realize that the amount of sunshine is inadequate for the prevention or treatment of rickets and it becomes necessary to supplement the diet of the infant with some special sources of vitamin D, so that such supplements of one kind or another must be given in order to be assured of protection against the disease of rickets.

The principle of law is settled that if one has gone beyond the domains of discovery and laid hold of a new force and connected it with some mechanical contrivance through which it acts, it is entitled to secure control of it, for the existence in nature of a force that can be and is used by man does not argue against invention unless the invention consists simply in adopting the type of nature, unaided. It is the use that during patentability, the utilizing of a law of nature by means of a method. The process covered by the patent is patentable if it is one where, as said by Judge Lacombe of the

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Second Circuit Court of Appeals: 'The process is one which puts a force of nature into a certain specified condition and then uses it in that condition for a practical purpose.'

The court also recognized the principle that a natural force is not the product of inventive skill, but points out the distinction in method for its direction as the patent there did not follow up the discovery by inventing some new process or method that contrived for its direction, but recognized the principle urged by plaintiff that 'not until some new instrument or method is contrived for its direction towards ends which it cannot naturally accomplish does his creative genius manifest itself.' The Court there reached the conclusion that the invention covered a process of nature, the facts are distinguishable from the present inventions as the present discoveries which concerned with effects of sunlight were followed up by the use of artificial means for producing ultra violet rays which sunlight did not and could not perform, patent protection allowed.

4.9.1.2 Bergy case

In re Begy case, however, United States Court of Customs and Patent Appeals held that a living microorganism was patentable under Section 101. The applicant in Bergy sought a patent for a pure strain of the microorganisms *Streptomyces vellosus* produced under controlled laboratory conditions, which was utilized in a process for preparing the antibiotic lincomycin. Although claims relating to the process were allowed by the patent examiner, the claim for the microorganism itself was rejected on the ground that it was a "product of nature" and hence non-statutory subject matter.

The rejection of the claim for the micro-organism was affirmed by the Board of Appeals of the United States Patent and Trademark Office, not on the ground that the micro-organism culture was a product of nature, but because it was a "living organism" and, as such, not "within the realm of statutory patentable subject matter" under section 101. The Board expressed the concern that if it were to adopt a "liberal interpretation" of

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20 Cameron Septic Tank Co. v. Village of Saratoga Springs et al., 2 Cir., 159 F. 453, 463
21 Wall v. Leck, 9 Cir., 66 F. 552, 558
22 563 F.2d. 1031 (C.C.P.A. 1977).
section 101, "new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable."

On appeal, the Court of Customs and Patent Appeals addressed the single issue of whether the mere fact that a microorganism is alive removes it from the coverage of section 101. Answering to the question the court rejected that living microorganisms were not patentable. The majority’s analysis was two fold. First, it observed that processes are patentable subject matter notwithstanding their use of microorganisms. Noting that the patent law makes no distinction between "manufactures" and "compositions of matter" on the one hand and "processes" on the other, the court concluded that it would be "illogical" if the existence of life in a manufacture or composition of matter removed it from these patentable categories while the utilization of life functions in a process could be patented.

Second, the court reasoned that the pure cultures of microorganisms are "much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses." The court concluded that there is no reason to deprive the creator of the microorganism culture of a patent solely on the ground that the microorganisms are alive, when both microorganisms and patentable chemical compositions perform similar functions as "industrial tools."

The legislative histories of both the Plant Patent Act and the Plant Variety Protection Act were cited as further evidence that section 101 provided patent coverage for nonliving subject matter only. Bergy is not the first instance in which a court has considered a patent claim for a living organism under section 101 has rejected in previous cases, courts have rejected these patent claims on the ground that one of the express statutory requirements was not met. For example, claims for living organisms have been rejected because the living subject matter could not be regarded as having been invented by the applicant,\(^\text{23}\) the subject matter of the patent claim could not be considered new or nonobvious, or the patent application did not describe the subject of the patent claim in

terms precise enough to comply with the specification requirements. In contrast, the *Bergy* case court acknowledged at the outset that the pure microorganism culture was novel, sufficiently described, and properly regarded as having been invented by the applicant. The court, however, erred in not adequately considering whether the terms "manufacture" and "composition of matter" was intended by Congress to encompass living organisms.

Since patents are granted only pursuant to express statutory authorization, there being no common law of patents, only those subjects or classes of inventions that are specifically enumerated in the statutes can be given patent protection. In determining whether an invention can be patented, courts should consider whether Congress intended to include such an invention in the classes of patentable subject matter, since the bare statutory language provides little guidance. In *In re Arzberger*, a patent for a new strain of bacteria was sought under the "plant" category of the predecessor of section 101. The court denied the patent claim on the ground that there was no evidence that Congress intended the term "plant" to cover bacteria. Although the court recognized that bacteria were scientifically regarded as plants, it concluded "Congress, in the use of the word 'plant,' was speaking 'in the common language of the people,' and did not use the word in its strict, scientific sense."25

Similarly, living organisms cannot reasonably be considered to be "manufactures" or "compositions of matter," as those terms are commonly used, and thus must be viewed as un-patentable in the absence of evidence that Congress intended the terms to be used in other than their everyday sense. Actually, the precise issue, which the court should have addressed, was not whether section 101 encompasses living organisms *per se*, but rather whether that section authorizes patents for the *modification* of a living organism. Still, it is the presence of life in the organism that is determinative of the issue of patentability. the applicant has modified the organism's form; no new life has been created. The modification, as in *Bergy*, may be sufficient to remove the organism from the category of "products of nature," but because the applicant has not created the

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24 112 F.2d 834 (C.C.P.A. 1940).
25 112 F.2d. at 838.
organism's life itself, it must be concluded that no new manufacture or composition of matter has been invented.

In the Bergy case court offered no evidence that the statutory classes of patentable subject matter were intended to include living organisms. In fact, the enactment of the Plant Patent Act in 1930 provides evidence that Congress did not intend to include living organisms within the scope of section 101. If that section is construed as covering living organisms, including plants, then the Plant Patent Act would appear to have been unnecessary, and it is a basic principle of statutory construction that Congress does not enact useless law. The legislative history of the Plant Patent Act strongly supports the conclusion that the general patent provision does not include living organisms.

Finally the court decided basing on more practical consequence of the decision will be that processes that utilize new strains of micro-organisms will receive greater protection than if only the process were patentable, since process patents are notoriously difficult to police against infringers. A patent on the microorganism itself will allow the patentee to recover royalties on the mere use of the microorganism by another party, without the patentee has to prove that the process in which the other party uses the microorganism infringes upon his own process. In view of the considerable commercial importance of microbiological processes in the production of chemicals, drugs, and food, this increased protection might prove to be a major incentive to the development of new, industrially useful microorganisms. the extension of patent coverage to higher forms of life could be avoided, if such an extension is considered to be undesirable. Congress, rather than the courts, is the proper forum for the extension of patent protection to living organisms.

Nevertheless, as a practical matter, it is likely at present that only microorganisms could be successfully patented under section 101. More complex life forms may well be unpatentable because they cannot be made the subject of precise written descriptions in patent claims, as is required by section 112. With regard to the patentability of living microorganisms, this obstacle is presumably overcome by the Patent Office requirement
that a deposit of the culture be placed in an established repository. Complete descriptions of morphological and serological characteristics, not to mention identification of genetic composition, would presumably be necessary to identify clearly the subject matter of a patent claim for a higher life form. In the absence of a comparable system for depositing samples of the patented organism, the requirements of precise specification may, at present, prove to be an insurmountable obstacle to the patenting of higher forms of life.

Compliance with the statutory requirements may eventually be achieved, however *Bergy* must be regarded as precluding the rejection of a patent claim on the sole ground that the subject matter is alive, regardless of whether that subject matter is a culture of bacteria or a new breed of racehorse.

4.9.1.3 Chakraburty case

This situation began to change in 1980 with the US Supreme Court decision in *Diamond Vs. Chakrabarty* to allow the patenting of a new man-made oil eating bacterium. Microbiologists have made great advances in modifying gene structures to create new forms of life. In *Diamond v. Chakrabarty*, the Supreme Court addressed for the first time the patentability of a living microorganism. In a 5-4 decision that has been condemned as heralding the advent of Aldous Huxley's *Brave New World*, the Court held that the living nature of a microorganism is no bar to patenting it.

Skepticism about the patentability of living organisms was to be expected. At around the time that General Electric filed its patent in 1972, of the four million US patents issued since 1790, only 70 had protected 'mixtures or compounds that included microorganisms in unmodified form'.

Only Pasteur's yeast culture product patent exclusively covered living organisms. The product of nature doctrine had since the 1880s apparently precluded the patenting of any further life forms. At least that was the view of the

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26 100 S.Ct. 2204 (1980).
USPTO when it rejected the application’s claims directed to the microorganism itself. Within the emergent biotechnology sector it was likewise generally assumed that microorganisms could not be patented.

General Electric’s patent lawyers had a different attitude, working as they did for a long established industrial corporation whose use of the patent system dates back to its formation in the 1890s. So while the scientist involved, Anand Chakrabarty, doubted that his microorganism could be patented, the company lawyer assigned to the case, Leo MaLossi, saw no logical reason why it could not. ‘To MaLossi, aware that by now scientists understood living matter, included bacteria to be chemicals, Chakrabarty’s bugs were manufactures, new compositions of matter and, hence, patentable.

In 1972, Dr. Ananda M. Chakrabarty filed a patent application relating to bacteria capable of degrading oil compounds into useful byproducts and of potentially great value in combating oil spills. The patent examiner allowed claims for the process by which Chakrabarty had combined four strains of oil-eating bacteria into a single bacterium. Claims to a floating carrier (such as straw) inoculated with the bacteria were also allowed, but claims to the bacteria themselves were rejected. The Patent and Trademark Office Board of Appeals affirmed the examiner's ruling.

The US Patent and Trademark Office initially rejected the patent. But the Court of Customs and Patent Appeals overturned this decision. In hindsight this was the most likely outcome. A few months earlier, Judge Rich of the Court had made the following statement when delivering the majority opinion at the conclusion of a similar case, ‘we think the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance’. He also opined that microorganisms ‘are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses’.
When the same court ruled again a year later on the patentability of the Chakrabarty and Bergy microorganisms, Rich argued that there is "no legally significant difference between active chemicals which are classified as "dead" and organisms used for their chemical reactions which take place because they are "alive". There is no question that this life as chemistry conceptualization inherent to Manlossi and Rich's arguments is a powerful one. Indeed, it is now recognized by other patent offices, including the EPO.

The sole issue it addressed was whether Chakrabarty's microorganism "constituted a 'manufacture' or 'composition of matter' within the meaning of" section 101 of the patent law.

The majority found that the statutory language supported a broad interpretation of patentable subject matter. Referring to legislative history, the majority concluded that "Congress intended statutory subject matter to 'include anything under the sun that is made by man." Notwithstanding its broad characterization of patentable subject matter, the Court recognized that the patent laws do not cover every discovery. The Court gave as an example the "products of nature" exception, which prevents an individual from obtaining a patent for the discovery of elements that already exist, but found this exception inapplicable to the Chakrabarty organism. Stating that "the patentee had produced a new bacterium with markedly different characteristics from any found in nature," the Court concluded that Chakrabarty's microorganism "plainly qualified as patentable subject matter."

As a matter of statutory construction, the majority's position makes sense given the purpose of the patent system. Although the creation of new life-forms has been condemned by some, it is an area of rapidly evolving technological development with vast commercial and industrial potential. Furthermore, it involves the development of new elements, rather than the mere discovery of elements previously existing in nature. While microbiological research certainly was not foreseen when Congress enacted the first patent statute in 1790, the purpose for patent protection stated in the Constitution - to
"promote the Progress of Science and useful Arts" applies nonetheless.

The *Chakrabarty* rationale, however, encompasses all living organisms, including microorganisms produced through recombinant DNA techniques (gene splicing), as well as multi-cellular and higher organisms. If a new organism meets the normal requirements of the patent system - such as novelty and usefulness - and if it truly is developed rather than discovered by man, under *Chakrabarty* it is patentable.

The court expressed that the parties and amicus curiae provided considerable discussion of social, technological, and commercial issues. The Court, however, wisely refused to examine the potential implications of its ruling, suggesting instead that final resolution of these issues must rest with Congress. Whether microorganisms should be patentable is a policy judgment that must be considered in light of the efficacy and purpose of the patent system itself. Because even the important patent issues arising in connection with microbiological research are ancillary to far broader scientific, social, and ethical issues, they should await comprehensive congressional review of microbiological and genetic research.

Congress does review the matter, it should consider separately issues of patent law and issues of regulation. Genetic research is potentially dangerous. Institutions receiving government funding generally are required to follow National Institutes of Health (NIH) guidelines on recombinant DNA research; but further formal government regulation is desirable, particularly with respect to private industries, which need not comply with the NIH standards. Apart from considering the traditional patent issues - whether patent protection is necessary and appropriate to encourage invention - Congress may determine that changes in the patent law are desirable as a means of regulating research and development. But such indirect regulation is of questionable efficiency and should be used, if at all, only in conjunction with direct regulation. The courts should not be left to fashion regulatory policy through patent decisions.

The decision in Diamond Vs. Chakrabarty was the first success in a campaign by
industry to clarify patent rules in the biotechnology field in ways that suited their interests. General Electric did not pursue this affair because the invention in question had commercial promise but because the company was seeking to ensure that the barrier to the patenting of microorganisms would henceforth be lifted. Not surprisingly, Generic Electric attracted support from pro-patent interests with several amicus briefs filed by companies and organizations such as Genetech, the Pharmaceutical Manufacturers Association and the American Patent Law Association. 27

4.9.1.4 Ex parte Hibberd case

Five years later, to chakraurty case the USPTO’s Board of Patent Appeals and Interferences in ex parte Hibberd reversed the PTO’s earlier rejection of a patent claiming corn plants and seeds as well as plant tissue cultures. The plants were produced through conventional crossbreeding, but relied on new techniques such as cell culture and genetic analysis. The applicant was a DBF called Molecular Genetics Research and Development.

A maize tissue culture capable of generating a plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed is capable of germinating into a plant capable of producing seed having endogenous free tryptophan content of at least about one tenth milligram per gram dry sec 1 weight. 28

There are no rejections based on prior art; certain claims are rejected solely under nonobviousness. Examiner’s decision regarding to seeds and plants, subject matter which is inappropriate for protection under nonobviousness because the subject matter of plants and seeds is within the purview of the Plant Variety Protection Act of 1970 administered by the U.S. Department of Agriculture. The examiner’s decision with respect those claims of tissue cultures is that such subject matter is inappropriate for

27 Graham Dutfield, p. 156.
28 www.iplawusa.com/resources/227_USPQ_443.pdf
protection under 35 USC 101 because it is within the purview of the Plant Patent Act of 1930, 35 USC 161. The examiner asserted that, to the extent that the claimed subject matter can be protected under the Plant Variety Protection Act (PVPA) or the Plant Patent Act (PPA), protection under section 35 USC 101 is not available.

On appeal, Supreme Court interpreted the scope of 35 USC 101 in the recent case of Diamond Vs. Chakrabarty,29 which involved a rejection of claims to a micro-organism under 35 USC 101 on the ground that Section 101 was not intended to cover living things such as microorganisms. In determining the scope of Section 101 the Supreme Court began with the language of the statute, interpreted words as taking their ordinary, contemporary, common meaning unless otherwise defined, and was careful not to "read into the patent laws limitations and conditions which the legislature has not expressed.” The Court noted that the use of the expansive terms "manufacture" and "composition of matter" modified by the comprehensive "any" indicated that Congress "plainly contemplated that the patent laws would be given wide scope," to "include anything under the sun that is made by man." Thus, the Court held at Chakrabarty’s case that the involved microorganism plainly qualified as patentable subject matter.

This case opened the way for the patenting of plants. By 1988, 42 patents on crop plants had been issued. Till 2007, there are more than 4000 patents with claims to plants, seeds, or plant parts or tissues.

4.9.1.5 Oncomouse case

In the following year, the first-ever animal patent was granted for 'a transgenic nonhuman mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence'. The patent is commonly referred to as the oncomouse patent, since it describes a mouse into which a gene has been inserted which induces increased susceptibility to cancer.

29 447 US. 303, 206 USPQ 193 (1980)
Harvard University and Philip Leder moved to take advantage of the patent opened by Chakrabarty case. A distinguished biomedical scientist, Leder was appointed in 1981 to the faculty of the Harvard University Medical School. In conjunction with his recruitment, the DuPont Corporation gave Harvard $6 million for support of Leder’s research. The principal quid pro quo was simple: Although Harvard would own any patents that might arise from Leder’s research; DuPont would be entitled to an exclusive license on any and all such patents. Over the next two years, Leder and his collaborator Tim Stewart developed a so-called oncomouse—a mouse genetically engineered to be highly susceptible to certain types of cancer. They accomplished this feat by exploiting the then-recently developed transgenic technology to insert the myconogene, tied to a mammary-specific promoter, into the new embryo of a normal mouse. Leder wondered whether his mice might be eligible for patent protection because they formed a man-made model system for the study of cancer, including the testing of its causes and therapies.

Harvard University, filed an application for a patent on Leder and Stewart’s invention. The main utilities claimed were straightforward, including the use of such animals as sources have malignant or proto-malignant tissue for cell culture and as living systems on which to test compounds for carcinogenicity or—in the case of substances such as Vitamin E—for the ability to prevent cancer. The claims extended to any transgenic mammal, excluding human beings, containing in all its cells an activated oncogene that had been introduced into it, or an ancestor, at an embryonic stage. In April 1988, a U.S. patent was awarded to Harvard University on any nonhuman mammal transgenically engineered to incorporate in its genome an oncogene tied to a specific promoter. It was the first patent on a living animal in the history of the world’s patent systems.

4.9.1.6 Pioneer Hi-bred International Inc., Case

Respondent Pioneer Hi-Bred International, Inc. (Pioneer), holds 17 utility patents issued under 35 U. S. C. section101 that cover the manufacture, use, sale, and offer for

30 http://www.nap.edu/catalog/11487.html
The District Court granted Pioneer summary judgment. Relying on this Court’s broad construction of section 101 in Diamond v. Chakrabarty, the District Court held that section 101 clearly covers plant life. It also held that in enacting the PPA and the PVPA, Congress neither expressly nor implicitly removed plants from section 101’s subject matter. In particular, the District Court noted that Congress did not implicitly repeal section 101 by passing the more specific PVPA because there was no irreconcilable conflict between the two statutes.

The Court also opined that Neither the PPA’s original nor its re-codified text indicates that its protection for sexually reproduced plants was intended to be exclusive. The 1930 PPA amended the general patent provision to protect only the sexual reproduction of a plant. And Congress’ 1952 re-vision, which placed plant patents into a separate chapter 15, was only a housekeeping measure that did not change the substantive rights or the relaxed requirements for such patents. Plant patents under the PPA thus continue to have very limited coverage and less stringent requirements than section 101 utility patents. Importantly, chapter 15 nowhere states that plant patents are the exclusive means of granting intellectual property protection to plants. The arguments that petitioners advance for why the PPA should preclude assigning utility patents for plants
are unpersuasive because petitioners fail to take account of the forward-looking perspective of the utility patent statute and the reality of plant breeding in 1930.

As for animals, because no alternative IP system was created specifically for them, such an argument cannot be tried anyway. And since no other convincing arguments have been forthcoming to persuade courts or legislators that non-human animals are a special case, the situation for animal related patents seems to be quite secure for the present time.32

4.9.1.7 Bayh-Dole Act

Before 1981, both government and university researchers and scientists working under government contracts had virtually no ownership right to any invention created with the aid of federal money. Contractors and universities did not want to participate in government funded research for fear of losing the patent rights to commercially valuable inventions that would result from the research. In view of losing participation of private industry, Congress declared a policy of cooperation between government laboratories and private sector industries and universities.

At its inception the Bayh-Dole Act created a dichotomy in federal policy between small business firms and nonprofit organizations, on one hand, and enterprises not qualifying either as a small business firm or a nonprofit organization, on the other hand, in that The Bayh-Dole Act allows small business and nonprofit organizations to elect to take title to inventions made with federal funds, subject to certain conditions and restrictions. In 1987, the Act was expanded to cover businesses of any size so that at present the Act benefits virtually everyone receiving federal funding for research.

after Bayh-Dole Act was establishment by Congress of the Court of Appeals for the Federal Circuit (CAFC) to hear all patent appeal cases. The CAFC is widely acknowledged to have a strong tendency to uphold patents. This should not be surprising.

given that 'a very large group of large high technology firms and trade associations in the telecommunications, computer and pharmaceutical industries was essentially responsible for the creation of the CAFC. The group believed that a court devoted to patent cases would better represent its interests'.

4.9.1.8 Amgen Inc., case

Erythropoietin (EPO) is a protein consisting of 165 amino acids, which stimulates the production of red blood cells. It is therefore a useful therapeutic agent in the treatment of anemia or blood disorders characterized by low or defective bone marrow production of red blood cells. The preparation of EPO products generally has been accomplished through the concentration and purification of urine from both healthy individuals and those exhibiting high EPO levels. A new technique for producing EPO is recombinant DNA technology in which EPO is produced from cell cultures into which genetically engineered vectors containing the EPO gene have been introduced. The production of EPO by recombinant technology involves expressing an EPO gene through the same processes that occur in a natural cell.

On June 30, 1987, the United States Patent and Trademark Office (PTO) issued to Patent entitled "Method for the Purification of Erythropoietin and Erythropoietin Compositions". The patent claims both homogeneous EPO and compositions thereof and a method for purifying human EPO using reverse phase high performance liquid chromatography. The claims of the patent cover purified and isolated DNA sequences encoding erythropoietin and host cells transformed or transected with a DNA sequence.

On October 27, 1987, the same day that the patent was issued, Amgen filed suit against Chugai and GI. It alleged that GI infringed the patent by the production of recombinant EPO (rEPO) and by use of transformed mammalian host cells containing vectors with DNA coding for the production of human EPO, and that Chugai, as a result of a collaborative relationship with GI, had induced and/or contributed to the direct infringement of the patent by GI. Amgen further sought a declaration that GI's patent is

33 927 F.2d.1200
invalid under 35 U.S.C sec 102,103, and 112 or, in the alternative, that Amgen does not infringe the claims of the patent, and a declaration that GI and Chugai's future activities in the production and sale of rEPO will infringe the patent.

GI and Chugai answered and counterclaimed, asserting several affirmative defenses, including invalidity under 35 U.S.C sec 102,103 and 112; non-infringement; failure to make deposits at a public depository of biological materials allegedly necessary for enabling the best mode of practicing the invention; and unenforceability of the patent because of Amgen's alleged inequitable conduct before the PTO. GI also counterclaimed, alleging that Amgen infringed the patent, asserting unfair competition, and seeking a declaratory judgment that the patent was invalid and not infringed.

GI and Chugai then filed a joint motion for a partial summary judgment that Amgen infringed the claims of the patent. Chugai also filed its own motion for summary judgment. On February 24, 1988, the district court granted GI's and Chugai's motion for partial summary judgment and, on January 31, 1989, the court granted Chugai's motion for partial summary judgment only to the extent of ruling that the patent does not contain a process claim.

The court determined that Amgen could not assert its patent to prevent Chugai from importing EPO produced in Japan through the recombinant DNA technology. This was because previous court decisions had determined that the scope of Amgen's patent covered only the cDNA coding for EPO and host cells transformed by the EPO expressing gene. It did not cover the recombinant EPO itself, or the process, which had of course been invented earlier by Cohen and Boyer. Chugai was in the advantageous position of having licensed a patent owned by Genetics Institute that covered the rEPO itself. This allowed it to produce the EPO using the cDNA patented by Amgen and the same technique as long as its production was carried out abroad, with the EPO then exported to the USA. 34

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34 Graham Dutfield, p. 158.
4.9.1.9 Biotechnology legislative development

For lawmakers, the experience of AMGEN, INC., Plaintiff/Cross v. CHUGAI PHARMACEUTICAL CO., LTD., and Genetics Institute, Inc., pointed the need to change the law to protect an emerging industrial sector considered vital to the future of the US economy. Some legal commentators further worried that this increased uncertainty in the patent law would have a detrimental effect on the biotechnology industry. This concern spread to biotechnology companies who then lobbied Congress for greater patent protection.

In the congress senator Deconcini introduced the biotechnology patent protection Act, 1990, failed to make an Act and again introduced as biotechnology process patent Act, 1995 in that also could not turn in Act form finally the congress came out with biotechnology guidelines 2001.

4.9.1.10 USPTO Biotechnology Guidelines, 2001

US passed the Biotechnology Guidelines, 2001 to allow the patenting of genomic inventions in the United States. A specific requirement with regard to the utility of inventions has been formulated as a reaction to the rising number of gene-related patent applications. Guidelines were published in 2001 for patent examiners in the US Patent and Trademark Office concerning the requirement of utility of inventions.35 In contrast to r.23e (3) EPC, the Utility Guidelines apply to all areas of technology. However, the USPTO noted about the Guidelines "they are particularly relevant in areas of emerging technologies, such as gene-related technologies, where uses for new materials that have not been fully characterized are not readily apparent". Prior to publication of the Guidelines, interim Guidelines were published in 1999, which provoked comments by several individuals and organizations

If the only described utility of an EST were as a probe to search for an unknown gene that hardly would seem adequate to fulfill the criterion of being a specific, substantial and credible utility. Homology-based function is not a priori excluded from patentability; the reasonable assignment of a new protein to a class of sufficiently conserved proteins would impute the same specific, substantial and credible utility to the assigned protein. Finally, according to the Guidelines the utility of a claimed DNA sequence does not necessarily depend on its biological function, since the sequence might for instance also serve as a specific hybridisation probe.

4.9.1.11 Raghunath Lalgudi case


The claimed invention relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants. The claimed sequences are commonly referred to as "expressed sequence tags" or "ESTs." The application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via micro-array technology to provide information about gene expression; (3) providing a source for primers for use in the polymerize chain reaction ("PCR") process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms. In a final rejection, dated September 6, 2001,

36 421 F.2d. 1365
the examiner rejected claim 1 for lack of utility under Sec.101. The examiner found that the claimed ESTs were not supported by a specific and substantial utility. Fisher filed a notice of appeal with the Board.37

The Board considered each of Fisher's seven potential uses but noted that Fisher focused its appeal on only two: (1) use for the identification of polymorphisms; and (2) use as probes or as a source for primers. As to the first, the Board found that the application failed to explain why the claimed ESTs would be useful in detecting polymorphisms in maize plants. The Board reasoned "without knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage." Thus, the Board concluded that Fisher's asserted uses for the claimed ESTs tended to the "insubstantial use" end of the spectrum between a substantial and an insubstantial utility:

The Board also concluded that using the claimed ESTs to isolate nucleic acid molecules of other plants and organisms, which they had no known utility, is not a substantial utility.

4.9.2 Biotechnology Patenting in Europe

The situation in the EPO is less clear-cut because of the prohibition in the EPC against the patenting of plant and animal varieties.38 The history of the Harvard Oncomouse application in the EPO is a depressing saga, which has been going on since the filing date in 1985, and was concluded only in July 2004. The Examining Division initially refused the application on the basis that it claimed an animal variety, contrary to Article 53(b). The refusal was appealed, and the Board of Appeal considered both parts of Article 53 in a decision39 which held that Article 53 (b) prevented the patenting of certain categories of animals, but not of animals as such, but returned the application to

37 421 F.2d. 1365.
38 Art.53(b), EPC.
the Examining Division with instructions to consider Article 53(a) and weigh the possible suffering of the animal against the possible benefit to humanity.

The Examining Division went through this exercise as best it could and granted the patent, whereupon it was opposed by a motley group of green organizations and individuals. After long delays, oral proceedings were held in Munich in 1995. In 1989, the European Commission, concerned about the legal uncertainties which, it was felt, could be prejudicial to the future of biotechnology in Europe, and fearing that some European countries might respond to mounting controversy by banning patents on living organisms and genes, drafted a Directive on the Legal Protection of Biotechnological Inventions. The aim was to harmonize patent law relating to biotechnology around high minimum standards, while preventing member states from ‘backsliding’.

However, it took nine years for the Directive to be approved by the European Parliament and to enter into force. Opposition throughout was stiff, from within the Parliament, which rejected an earlier text in 1995, and outside from several environmental, development, religious and anti-genetic engineering civil society organizations, and even a group representing indigenous peoples of the Amazon. Some European governments were unhappy with the Directive even after its approval. The Dutch government brought an action against the European Parliament and the Council of the European Union before the Court of Justice of the European Communities in October 1998 to have the Directive nullified, and subsequently gained the support of Italy and Norway. The grounds for the action included allegations that the Directive has an incorrect legal basis, breaches obligations under international law and violates human rights.

Second oral proceedings of Oncomouse case were held in 2001, and a written decision was issued early in 2003, which upheld the patent with claims limited to species such as rodents suitable for use as experimental animals. By the end of 2001, only four countries, the UK, Ireland, Finland and Denmark had fully incorporated the Directive.
into their national law one year after the deadline by which all EU members were supposed to have done so.

The exclusion of plant varieties from patent protection was construed in a limited way in a case decided in 1984. In this case, which related to chemically treated seeds, not transgenic plants, it was held that if the claim covered plant genera without claiming individual specific varieties it did not contravene Article 53(b). However, in a later case in which transgenic plants were claimed, the decision was essentially that a transformed plant, having a characteristic phenotype stably transmitted, was by definition a plant variety, and the prohibition of Article 53(b) was not avoided merely by using broader claim language. Claims to plant cells were granted, but not claims to plants or seeds. It was also held that although the first step in the process, the transformation of the plant cell, was ‘microbiological’, this did not make the final plant the product of a microbiological process.

This decision was strongly attacked by the seeds industry, and the President of the EPO referred the matter to the Enlarged Board of Appeal on the basis that there were conflicting Board of Appeal decisions on the same point of law. The Enlarged Board of Appeal, in a decision, which many users of the EPO saw as a complete abdication of its responsibility, held the referral inadmissible because it did not consider that there was indeed any conflict between the cited decisions, and refused to decide the point.

4.9.2.1 Howard Florey/Relaxin Case

In this case, the patentee filed an application for Human H2-relaxin. Human H2-relaxin had no previously recognized existence. The patentee had developed a process for obtaining H2-relaxin and the DNA encoding it, had characterized these products by their chemical structure and had found a use of the protein.

The Opposition Division while rejecting the oppositions held that it was common ground among the parties that, until a cDNA encoding H2-relaxin and its precursors had

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40 Art.112(1)(b), EPC.
41 [1995] EPOR 541
been isolated by the patentee, the existence of this form of relaxin was unknown, the novelty of the granted claims was assured. The opponents' argument as to lack of inventive step failed for the reason that the gene was novel. In isolating the DNA encoding human H2-relaxin the patentee was therefore not preparing a known substance by conventional means but instead providing to the public for the first time a product whose existence was previously unknown. The opponents' argument that the subject matter of the patent represented a mere discovery was wrong. The consequences asserted by the opponents as to the patentability of such discoveries as the moon (after the Americans landed on it in 1969), Otzi (a mummified, around 5,000-year-old man found in the Italian/Austrian Alps) or a new animal found in some remote area, did not follow. In relation to the objection under Article 53(a) (morality), the opponents' arguments as to slavery and the dismemberment of women betrayed a fundamental misunderstanding of the effects of a patent.

The argument that human life was being patented was also unfounded, DNA not being 'life' but instead a chemical substance, which carries genetic, information and which can be used as an intermediate in the production of proteins which may be medically useful. Pending the final formulation of the EU Directive on the legal protection of biotechnological inventions, it was inappropriate for the EPO to impose a moratorium on the patenting of human genes. Nor was there any legal mechanism in the EPC for doing so. The opponents' request that the EPO carry out a referendum as to the public's view in Contracting States on what should be patented was misconceived. The burden of proof lay with the opponents. It was for them to carry out such survey, if they considered that it would assist their case. The Article 53(a) exclusion on the grounds that an invention is contrary to morality was limited to the limited class of case where there was an overwhelming consensus that the exploitation or publication of an invention would be immoral.42

42 [1995] EPOR 541
4.9.2.2 Plant Genetic Systems NV Case

In 1995, the EPO Technical Board of Appeal in *Greenpeace Vs. Plant Genetic Systems NV*\(^4^3\) ruled on an appeal against the upholding of a plant-related patent. In this case, patent for transgenic plants were claimed. The decision was essentially that a transformed plant having a characteristic phenotype stably transmitted, was by definition of a plant variety, and the prohibition of Art.53 (b) was not avoided merely by using broader claim language. Claims to plant cells were granted, but not claims to plants or seeds. It was also held that although the first step in the process, the transformation of the plant cell, was 'microbiological', this did not make the final plant the product of a microbiological process.

Greenpeace succeeded in having six of the 44 claims deleted from the patent. But perhaps the most important aspect of the case is that the TBA was challenged to apply the morality and ordre public exclusions. The TBA concluded that an invention is 'immoral' if the general public would consider it so abhorrent that patenting would be inconceivable. But it provided no clarification on how 'abhorrent' should be interpreted, nor how opponents of a patent should demonstrate that the general public regards the invention is immoral. The TBA rejected the evidence of surveys and opinion polls provided by Greenpeace as inadmissible, arguing that 'surveys and opinion polls do not necessarily reflect... Moral norms that are deeply rooted in European culture'. With respect to ordre public, the TBA placed the burden of proof on the patent's opponents by requiring convincing evidence that exploitation of the patent would be seriously prejudicial to the environment. The TBA's rather narrow interpretations of the exceptions led them to reject their application to this case.

Subsequently, the same TBA that decided the Plant Genetics Systems case\(^4^4\) referred to the Enlarged Board a series of questions on the interpretation of Article 53(b) arising out of a specific appeal. This referral could not be evaded, and the EBA finally decided that transgenic plants were patentable subject matter. The EBA did not, as some


had expected, decide the issue on the basis that at the time the EPC was written, the only way to make plant or animal varieties was by traditional breeding methods which are non-technical in nature and not reproducible. Transgenic plants or animals are made by a technical, reproducible process and therefore should fall outside the exclusion.

4.9.2.3 Transgenic Plant Case

In this case, the questions on the patentability of certain transgenic plant varieties were referred to the Enlarged Board of Appeal. The principal issue was whether the prohibition in the European Patent Convention 1973 Art. 53(b) on the grant of patents in respect of plant varieties or mainly biological processes for the production of plants applied to a claim relating to plants but not to specific plant varieties and whether Art. 53(b) applied to a plant variety produced by recombinant gene technology. Further, whether under Art. 64(2) process claims could be allowed when the product directly obtained by the claimed process was or included a plant variety.

The Board held that (1) according to Art. 53(b) a patent was "in respect of plant varieties" if the claimed subject matter was directed to plant varieties and a claim that did not refer to specific varieties was not excluded; (2) Art. 64(2) was not to be taken into account when examining a claim to a process for the production of a plant variety, and (3) the prohibition on patentability in Art. 53(b) applied irrespective of the way varieties were produced, including the use of recombinant gene technology.

Instead, the rationale of the decision was that at the time the EPC was ratified, most contracting states were members of the UPOV Convention in a version that prohibited dual protection of plants through UPOV and through patents. Therefore, plant varieties were excluded from patent protection only to the extent that they could be protected by plant breeder's rights under UPOV, which transgenic plants generally could not. A claim which does not individually claim specific plant varieties is not

unpatentable merely because it may embrace plant varieties. This decision is perfectly logical as applied to plants, but cannot be easily applied to animals, as there is nothing corresponding to UPOV for animal varieties.

4.9.2.4 Oncomouse case

Consequently, for the next four years, the EPO stopped accepting claims on plants per se. Similarly, the oncomouse patent was initially rejected on the grounds of being for an animal variety. This situation, a victory for Greenpeace, was of course highly unsatisfactory in the view of the life science corporations. But things changed in a more favourable direction in December 1999 when the EPO Enlarged Board of Appeal decided that, while genetically modified plant varieties are unpatentable, ‘a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), EPC even though it may embrace plant varities’.

Opponents of biotechnological patenting, such as Greenpeace, have sought to make use of the morality and ordre public exclusions in Article 53(a) of the EPC and try to expand their application. But they have not been successful. In the famous Oncomouse case, the EPO’s Examining Division responded by formulating a balancing test for this particular case that would take into account the following: (1) the interest of mankind in providing remedies for dangerous diseases; (2) protection against uncontrolled dissemination of unwanted genes; and (3) prevention of cruelty to animals.

In earlier proceedings the Board had overturned the Examining Division’s original rejection of the application but had remitted the application for further prosecution in relation to the issues of (a) whether the subject-matter (oncogenic test animal, particularly rodent) constituted an animal variety within the meaning of Article 53(b), and (b) whether the subject-matter was contrary to ‘ordre public’ or morality within the meaning of Article 53(a).  

On remittal, the Examining Division decided both issues in the applicant’s favor and, exceptionally, provided written reasons to accompany the Rule 51(4) communication as to intended grant. As regards issue (a), rodents and mammals constituted taxonomic classification units much higher than species, whereas an animal variety ranked even lower than a species. As regards issue (b), it was necessary to weigh in the balance the three different interests of (i) the remedying of widespread and dangerous disease; (ii) protection of the environment against uncontrolled dissemination of unwanted genes; and (iii) avoidance of cruelty to animals. The balance here lay in favor of the applicant. Since the invention would lead to a smaller number of test animals being required, there would be an overall reduction in the extent of animal suffering.47

On this basis, the Examination Division determined that, since the potential benefits of the invention outweighed the negative factors, the patent should be granted, and the EPO consequently did so. However, this patent remained controversial among environmental and animal welfare groups, and opposition proceedings have continued ever since.

4.9.2.5 Biotechnology Patenting Directive (BPD)

It has for many years been a project of the European Commission to harmonize the national laws of EU Member States on the question of the patent protection which should be given to biotechnological inventions, including genes, plants and animals. Although when the discussion was started in 1988 the status quo was that living organisms and DNA were patentable, or at least not stated to be unpatentable, in all Member States, there was a fear that individual states might change their law so as to ban such patents. It was also felt that the situation in Europe as compared with the USA was uncertain enough to cause disadvantage to European research. Accordingly, in 1989 the Commission adopted a draft Directive on the Legal Protection of Biotechnological Inventions, which if adopted would enforce certain minimum standards of protection upon all Member States, and prevent any subsequent weakening of protection in this area.

However, this first version was rejected by the European Parliament in 1995, mainly because the Parliament considered that there were insufficient ethical controls on the patenting of human body and its parts. After this rejection some industry representatives considered that the whole idea should be allowed to die, as it was feared that any version to which the Parliament would agree would be less favourable than the status quo. However, the Commission persevered, and a new version, which even after the incorporation of the large number of amendments proposed by the Parliament was considered acceptable by industry, was adopted by the Council as its common position, and was finally approved by the Parliament on 12 May 1998, and entered into force on 6 July 1998 as Directive 98/44.

EU enacted the European Patent Convention ("EPC"), based on the EPC, the European Patent Office ("EPO") grants patents in Europe. This Convention was an initiative of the Council of Europe, and therefore is not part of EU law; the EU as such has no jurisdiction over the EPC. The EU Biotechnology Directive is addressed to the national laws of the EU Member States. In an attempt to bridge the gap between the EU Biotechnology Directive and the EPC, the Administrative Council of the European Patent Organization decided to use the Directive for the purpose of providing a supplementary means of interpretation of the EPC. In September 1999, changes were made to the Rules in the EPC Implementing Regulations in order to incorporate the provisions of the Directive.

Paragraph 1 of Art. 3 of the Directive provides "For the purposes of this Directive, inventions which are new, involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used." According to Art. 2 of the Directive, "biological material" is defined as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system".

48 Art. 18 of Directive 98/44
Thus biotechnology inventions such as genes and gene fragments that meet the standard patentability criteria of novelty, inventiveness and industrial applicability in principle are patentable subject matter. The second paragraph of Art.3 of the Directive further clarifies that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature". This confirms the current practice in which purified and isolated natural products are patentable subject matter.

Article 5 of the Directive addresses more specifically the patenting of sequences or partial sequences of genes. Paragraph 1 of Art.5 provides "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." This, however, is immediately qualified in the second paragraph of the Article, which provides, as in Art.3, that isolated substances, or substances otherwise produced by means of a technical process are not excluded from patentability "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." Finally, the third paragraph of Art.5 of the Directive expands the criterion of industrial applicability by providing "The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

In the EPC, the general criterion for industrial applicability of inventions is provided by Art.57 EPC "An invention shall be considered capable of an industrial application if it can be made or used in any kind of industry including agriculture." The provision of r.23e (3) EPC distinguishes genomic inventions from other inventions, for which it is sufficient if the invention "can be made or used" to fulfill the requirement of industrial applicability under the EPC.

The new requirement that the industrial application of a sequence or a partial

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49 Arts 54, 56, 57 EPC
sequence of a gene must be disclosed in the patent application would appear to stem from
the concerns expressed about the many patent applications that were filed for gene
elements of totally unknown biological function. Indeed, Recitals 23 and 24 of the
Directive provide further explanation: "(23) Whereas a mere DNA sequence without
indication of a function does not contain any technical information and is therefore not a
patentable invention; (24) Whereas, in order to comply with the industrial application
criterion it is necessary in cases where a sequence or partial sequence of a gene is used to
produce a protein or part of a protein, to specify which protein or part of a protein is
produced or what function it performs;"

In order for the industrial application of a genomic invention to be disclosed in the
patent application, it would appear that information should be available concerning the
function of the gene or gene element, or the product that it is coding for. With respect to
industrial applicability, the Directive provides a new and specific requirement not to be
found for inventions in other technical fields. It has been noted that the new requirement
does not necessarily imply that experimental evidence per se should be available to
support the function of the gene or gene product. Furthermore, it has been concluded that
r.23e (3) EPC read in conjunction with Art.57 EPC implies that in order for genomic
inventions to satisfy the Art.57 requirement the invention must reside in the "usefulness"
of the product, not in the fact that it can be "made". This implication, however, may be
flawed since a rule in the Implementing Regulations to the EPC cannot take precedence
over an Article of the EPC. Here, the hybrid structure of European patent law becomes
apparent: patentability is governed both by an intergovernmental treaty (the EPC) and by
Community Law (the Biotechnology Directive). Thus, although r.23e (3) EPC does not
take precedence over Art.57 EPC, the similar provision in the Directive does constitute
substantive law and is binding as to the result to be achieved upon the Member States⁴⁰.

The Netherlands challenged the Directive before the European Court of Justice
and the ECJ upheld the Directive in October 2001. Nevertheless, not only the
Netherlands, but also a number of other Member States, including Germany, France and

⁴⁰ Art.249 EC Treaty
Austria, has not implemented the Directive as of 2004. Austria is as of writing considering whether or not to implement the Directive, and it is said that there must be public debate on the issue first.

Thus germ-cell gene therapy is regarded as unethical, and the BPD provides that it is un-patentable. If a couple may pass on to there offspring hemophilia or sickle cell disease, and it were possible to eliminate this possibility by germ-line gene therapy. There is no moral reason why this should not be done. The real reason for this exclusion is the fear that germ-line intervention could be used not to prevent disease but for eugenic reasons; a valid ethical concern, but one which has nothing at all to do with patents. A more pragmatic reason not to attempt germ-line gene therapy at present is that, the normal public does not know enough about human reproduction and human genomics to be sure that it could be done safely.

As justification for this approach it is sometimes suggested that genes are not merely chemical substances, but are primarily carriers of information. It is also argued that the same gene may code for more than one protein product, and a patent for a gene based on its coding for one protein should not cover the production of a different one. The problem with this is that it is impossible to clearly distinguish this situation from that of a low molecular weight compound which may have a number of different and unrelated uses, but for which it has been settled patent law for decades that absolute product protection covering all possible uses is available.

Another area of controversy is that of the patenting of human cell lines. The BPD clearly states that cells isolated from a human body may be patentable, but problems arise when the cells are human embryonic stem cells (hESCs) derived from early stage embryos (blastocysts). Human ESCs were claimed in US patent of Wisconsin Alumni Research Foundation, although in view of the Eli Lilly case it must be questioned whether these patents meet the written description requirement. Many more US patents claim methods for the culture or selection of hESCs or their differentiation into lineage-

51 USP 5,843,780 and 6,200,806.
specific cell lines, but in Europe there was a major controversy over one such patent granted to Edinburgh University and generally referred to simply as the ‘Edinburgh Patent’. The problem arose initially because the patent covered animal cloning processes without disclaiming human cloning. But in opposition proceedings, the Opposition Division went much further than this and held essentially that any invention (for example that of a differentiated cell line) deriving from the use of hESCs was cyst and was therefore ‘industrial or commercial use of a human embryo’.

This decision is based on a number of questionable premises. It assumes that a blastocyst which will never be implanted into a uterus is indeed an embryo, which is by no means self-evident. More seriously it makes no ethical distinction between a blastocyst generated for the purpose of supplying ESCs and one which is surplus from in Vitro Fertilization and would be destroyed in any event. The decision deliberately differs from the position of the European Group on Ethics, although this is the body specifically charged by the BPD with giving guidance on such matters. It is a perfect illustration of the folly of making patent office examiners judges of morality.

4.9.2.6 Modified animal case\textsuperscript{52}

In this case, the patent related to a modified animal, exemplified as an immune compromised mouse implanted with human hematopoietic tissue and hence constituting an animal-human chimera. The production technique involved taking cells and tissue from aborted foetuses or children below the age of three years. The potential medical benefits of the invention in transplantation were not in dispute among the parties. In addition to objections as to lack of novelty, lack of inventive step and sufficiency, it was asserted that the patent contravened Articles 52 (4) (surgical method), 53 (a) (contrary to morality) and 53 (b) (animal variety).

The decision of the German Federal High Court that surgical methods were not to be considered systematic processes and hence were unpatentable did not apply since (a) a

\textsuperscript{52}R. v. LELAND STANFORD [2002] E.P.O.R.2
product, not method, was involved here and (b) a decision of such a German court was in any event of no relevance to proceedings before the EPO. The claims were directed to a taxonomic group higher than an animal variety. The implementation of the E.U. Biotechnology Directive 98/44 into the EPC via Rules 23 (b) to (e) could not be questioned by the Opposition Division. So long as a claimed invention has a legitimate use it cannot be the role of the EPO to act as a moral censor. The controversial nature of the technology did not in itself debar the subject-matter from patentability. The sufficiency objection failed because the burden of proof lay here on the opponent and there was no evidence on file to suggest that animals other than mice could not be successfully used. The amended Claims possessed novelty and inventive subject-matter patentable.

4.9.3 Biotechnology patenting in India

India follows the method of pre-grant opposition unlike the USA and the European Union, in granting biotech patents. The patents Act, 1970 (as amended up to 2005) governs the law on granting of biotechnology patents in India. India is a party to the Paris Convention and also to the TRIPs agreement. Hence the patent law of India is commensurate with the above international agreements. In India patents applications can be filed at any branch office at Chennai, Mumbai or Delhi or at the head office in Kolkata. Any person claiming to be the true and first inventor of the invention, his assignee, or his legal representatives can file an application for the grant of patent claiming a biotechnology invention. There is also the possibility of joint applications by two or more inventors in case all of them have worked for the same invention.

In India only inventions are patentable but not discoveries. There is a clear distinction between inventions and discoveries as the law specifies that only inventions constitute patentable subject matter. Indian patent law defines invention under section 2(j) as ‘a new product or process involving an inventive step and capable of industrial application’. Here inventive step means a feature that makes the invention not obvious to a person skilled in the art. Indian patent law does not provide for subjects that are not
patentable, instead it does provide what is not patentable. Indian patent law provides for
an illustrative list where it has mentioned, which doesn't fall within the preview of the
illustrated list, does constitute a patentable subject matter. The list has been updated and
modified to comply with the provisions of the TRIPS agreement. The Indian Patent Act,
1970 did not give the information of what can be patentable, section 3 gives the
information of what cannot be patentable that indicates the Act is giving the
understanding in negative form as follows

1. invention against natural laws
2. inventions contrary to public order and morality
3. discovery of a living thing occurring in nature.
4. a claim for a duplication of an earlier work
5. methods of treatment for human beings or animals
6. Plants and animals in whole or in part, and essentially biological processes for the
production of plant and animals.

However, micro-organisms and such other inventions of biotechnology, both
products as well as processes, do constitute patentable subject matter. In extension of the
same meaning to biotechnology the understanding would not include the following

1. discoveries
2. inventions against public order and morality includes
   a. human body, discovery of its elements and genes in natural form, processes
      for cloning human beings;
   b. Processes for modifying the germ line genetic identity of human beings;
      Uses of human embryos for industrial or commercial purposes; and
      processes for modifying the genetic identity of animals which are likely to
      cause them suffering without any substantial medical benefit to man or
      animal, and also animals resulting from such processes.
3. Plants, animals, and essentially biological processes.

After Chakraburty's case decision in the USA, throughout the world living beings
were recognized as patentable subject matter. As a biotechnology industry progressed
and engendered modern-day miracles of enormous human values, there was a strong demand to include biotechnology invented living matter within the realm of patentable subject matter. Due to the enormous impact of the field of biotechnology on the society and on the day-to-day life of human being, it was considered necessary to include biotechnology inventions within the gamut of patentable subject matter. This proposal has got a strong back push from the decisions of the law courts of the United States and Europe as well as from the practices of the EU and USA. India, yet to experience with such type of cases prior to The Patent Amendment Act, 2005 there is no scope for bringing such type of cases later to that it provided an opportunity and later to it only started moving the things. There are a few universally accepted requirements such as novelty, inventive step, industrial application, and written description on satisfaction of which biotechnological inventions are patentable.

Essentials of Patent in Biotechnological inventions

4.9.2.1 Novelty

Novelty is not defined in the patent law of India under section 2(1) (j). But invention is defined as new product or process involving an inventive step and capable of industrial application. The Indian Patent Act, defines inventive step under section 2(1) (j) (a) but it does not defines the term novelty. Still the understanding of the term can be extracted with the help of anticipation under chapter VI of Patent Act, 1970 according to section 3 also few subject matters are not novel or new, such as discoveries and findings of a living or substance occurring in nature are considered as not new and do not constitute an invention. Further plants, animals, and essentially biological processes are not considered new and do not constitute an invention.

However micro-organisms are considered new and can be patented. Human genetic material in isolated and purified form is also considered new invention. For the first time in the history of Indian patent law a living process was claimed for patent in
Dimminaco A.G. V. Controller of Patents.53 The process was useful in preparation of a vaccine against infectious disease in poultry. The applicants contended that the process was new and was patentable. The patent office initially rejected the patent on the ground that it was a living process, which was not new and the same did not constitute invention. In appeal the kolkata high court held that there is no bar in the patent law to patented a new living process or living product. The High court accepted the contention of the applicant that the claimed living process is new and directed the patent office to grant patent on the invention.

In the light of the TRIPs agreement considering biotechnological inventions as new, India being a signatory to the agreement, amended its patent law to implement the agreement. Now with the amendments to the patent law biotechnological inventions, both product and processes are considered new. There was no strong debate in India unlike in the USA on the novelty of biotechnological inventions. As the matter is settled in developed countries like USA and EU that biotechnological inventions are novel over and above the pre-existing biological products there was no difficulty for India to follow suit.

4.9.3.2 Inventive step

Patents are granted for inventions involving an inventive step was defined as 'a feature that makes the invention not obvious to a person skilled in the art'. Any new product or process that involves an inventive step is patentable in India. The patent law provides that when an application for patent is made, the patent examiner will have to conduct an investigation to find the relevant prior art. If in the investigation it is found that the invention has been anticipated by publication in India or elsewhere before the date of the applicants filing of the complete specification, the patent shall not be granted. In such circumstances the invention falls within the realm of prior art, the knowledge in the public domain involving no inventive step. Such knowledge in the public domain

being obvious to a person skilled in the relevant art shall not be given patent. The requirement is no different with reference to biotechnology inventions. However, there is no substantive case law development with regard to inventive step in the biotechnology inventions in India.

For the first time in India inventive step involved in a biotechnology invention had come before the courts in Dimminaco A.G. V. Controller of Patents\(^4\). The Kolkatta High court was confronted with a question whether the claimed invention relating to a process for preparation of infectious bursitis vaccine did involve inventive step and whether the claimed subject matter constituted invention under the Indian Patent Act. the vaccine was useful for protecting poultry against contagious bursitis infection. The inventors contended that the process claimed involved certain chemical steps under specific scientific conditions. The patent office initially rejected the patent application by stating that living virus or living process did not constitute invention under the Indian patent Act. However, the Kolkatta High Court held that there was no statutory bar to patent living processes or product that involved inventive step.

In the instant case the process claimed did involve certain inventive step, as it required certain chemical steps to be taken in the production of the Vaccine. The High court directed the patent office to grant patent on the claimed process. There fore as per the decision of the Kolkatta High Court a biotechnology invention involving a new process or product could be patented if it involved an inventive step. Further, as per the patent law if the invention was anticipated in the prior art or is published, used, or patented, it did not involve an inventive step. In case of biotechnology inventions also the claimed invention did not constitute an inventive step if it was anticipated or published or used or patented earlier or in any way formed part of the prior art.

However, nowhere in Indian patent law the term ‘prior art’ is used or defined; the situation is same in USA also. The EPC used the term ‘state of the art’ which is

equivalent to prior art and states that state of the art comprises every thing that is made available to the public by means of a written or oral description or by use in any other way before the date of filing of the European patent application. The USA patent law, the EPC and the patent law in India state that any invention which is known or published or patented, being part of the prior art, is obvious and does not involve inventive step. Therefore, an invention, which is part of the prior-art, does not involve inventive step and is not patentable. The invention shall be a leap forward from the state of the art or it shall be a step forward from the already existing knowledge that is prior art. It shall be an advancement of existing knowledge in the public domain. It implies that courts while determining the obviousness of any invention shall have to consider the scope of the prior art. In fact, law courts have taken into consideration the knowledge in the public domain or the state of the art in deciding the obviousness of an invention. The presumption is that on the basis of prior art, it an invention becomes obvious to the person having skill in the relevant art, such invention does not constitute an inventive step and must not be patented.

4.9.3.3 Utility

The patent law states that any new product or process involving inventive step and capable of industrial application does constitute an invention and is patentable. The expression 'capable of industrial application in relation to an invention' means that the invention is capable or being made or used in an industry. The requirement of industrial application of inventions in India is no different from the industrial requirement of Europe or USA or else where of the globe. However is no substantial case law development with regard to the industrial application of biotechnology inventions in India as the industry is in an infant stage. In Dimminaco AG Vs controller of patents for the first time, utility of a biotechnology invention was demonstrated. The invention related to a process for preparation of infectious bursitis vaccine. The vaccine was useful for protecting poultry against contagious bursitis infection. Initially the patent office rejected the patent application on the ground that the claim did not constitute an invention. But the utility of the invention was not disputed.
The inventions of biotechnology are very much useful in different sectors, specifically and substantially. Biotechnology is being vastly used in different sectors such as agriculture, medical, chemical industry, animal husbandry, and many others. Biotechnology has brought innovative medical treatments and surgical procedures that are useful to the society. Biotechnology inventions are useful in treating pollution, poultry, fisheries, forestry and others. The technology is gaining enormous importance in present day life.