Université de Montréal

The Patentability of Human Genetic Material in China:

A Comparative Analysis

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For my father, Xueguang Li, who first awakened my interest in the intellectual life, and for my mother, Qingzhu Wang, who taught me what dedication to ideals means.

In particular, I would like to extend my sincerest thanks to Mme. Bartha Maria Knoppers, who gave me a great help in the preparation of this paper.

Sommaire

Les mots-clés : biotechnologie, brevetabilité, droit de brevet, matériel génétique humaine, et chine.

Durant la dernière décennie nous avons assisté à une explosion de données génomiques séquentielles provenant de projets publiques et privés. Le séquence complète du génome humain à été publiée ainsi que la localisation certains gènes a été tracée pour des chromosomes individuels.

Avec l'accroissement de l'information séquentielle, l'industrie de la biotechnologie s'est sérieusement établie. Le brevets octroyés en regard des gènes à joué un rôle important dans cette industrie, aussi il y a eu une augmentation dans la demande de brevets dans le domaine du matériel génétique humaine. Cependant après plusieurs controverses publiques et la créations de règles internationales certains doutes ont été soulevés à propos de la « brevetabilité »du génome humain, mais impact. Il sera question dans notre étude ces inquiétudes, de la réponse à ces inquiétudes par les bureaux des brevets différentes juridictions, ainsi que des divers moyens utilisés pour de ces problèmes tout en avançant le présent débat en utilisant les structures légales existantes.

Summary

Keywords: biotechnology, patentability, patent law, human genetic material, and china.

The past decade has seen an explosion in the availability of genome sequence data from public and private genome projects. Most notably, the complete human DNA genome sequence has been published and the locations of some of the genes have been mapped to individual chromosomes.

Commensurate with the growth in sequence information, the biotechnology industry has become firmly established. Gene patents have played an important part in this industry, and there has been a marked increase in patent applications filed in the field of human genetic resource. However, concerns have been raised over the patentability of human genetic material through public protests and international statements, but to little effect. Discussed here are some of these concerns, the patent office's response to them in different jurisdictions, and ways in which to address these issues and to move the debate forward within current legal structures.

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Introduction

In the early 1980s, biotechnology was applied commercially in producing diagnostics and therapeutics. Biotechnology companies were created specifically to exploit the commercial potential of biotechnology. Ever since the Chief Justice of the U.S. Supreme Court, Warren Earl Burger ruled that "everything under the sun made by man"[i] was patentable, genetic engineering has been fuelling the growth of the biotechnology industry. Public markets recognized the potential benefits of biotechnology and money flowed into biotechnology companies. However, the concomitant patenting of the resulting products, especially human based products, has stimulated debates.

During the past twenty years, patent law has struggled to keep pace with the rapid growth of research and developments in the field of biotechnology. Not surprisingly, science has outpaced the law, which is playing catch-up when it comes to providing patent protection for biotech inventions. Facing increasing debates and issues around patenting of biotech inventions involving human genetic materials, international communities and nations have tried to harmonize patent law.

In the United States of America, the United States Patent and Trademark Office's (USPTO) policy has been more lenient on patenting scopes and standards than other countries. It conferred very extensive protection on patents on human genes, with

[i] *Diamond v. Chakrabarty*, 447 U.S.303, 206 U.S.P.Q. 193 (1980).

exceptions granted only for ' laws of nature, physical phenomena or abstract ideas'.[ii] Nevertheless, while early U.S. patents on biotech inventions often included seemingly broad, "prophetic" claims, for 20 years now, the Court has gradually narrowed the scope of biotech patents.[iii]

In Europe, a legal framework has been created by the European Patent Convention (EPC) and European Union Directive for the Legal Protection of Biotechnological Inventions (E.U. Directive) for applicants in the field of biotechnology. Most European countries have now grasped the nettle of implementation of the Directive, and are drafting legislation to incorporate its provisions into national patent law. The EPC and the Directive ensure that biotechnology patent law is both strong and consistent across Europe. In this way, European consumers and biotech companies are not disadvantaged with respect to their American and Japanese counterparts.

Canada takes an intermediate stance on patentability of human genetic materials. The Canadian Patent Office is reluctant to grant patents on life forms. As we will see, there have only been a handful of judicial cases dealing with genetic materials in Canada. Neither human beings nor their organs are patentable, but products derived from the human body, including cell lines, genes, and DNA sequences are patented.

[ii] USPTO interpreted the Court ruling of Diamond v. Chakrabarty, which defined a number of elements in order to test patentability under section 101. See "This Opinion Was Not Written For Publication" by USPTO (1997), online: http://www.uspto.gov/web/offices/dcom/bpai/decisions/fd970777.pdf, at 5.

[iii] See *Amgen Inc v. Chugai Pharmaceutical Co. Ltd. and Genetics Institute*, 927 F. 2d 1200, 18 U.S.P.Q. 2d 1016 (Fed. Cir. 1991). The ruling prevented a company from getting very broad-based claims on all DNA sequences that code for a protein or analogs of that protein. See also *Fiers v. Revel*, 984F.2d1164,25 U.S.P.Q. 2d 1601 (Fed. Cir. 1993); See also *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q. 2d 1398(Fed. Cir. 1997), in which the Court repeated: "Accordingly, an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."

As the only member from the developing countries in the human genome project (HGP) consortium, China faces the same issue of patentability on human genetic materials. In contrast to the broad patent scope of U.S.A., China is extremely strict in examining gene patent applications. So far, there is no re-examination of board decisions or court decisions relating to the novelty, utility and inventive step of gene-related inventions. This is because there is also no related provision in the Examination Guidelines of the Chinese Patent Office. However, China seems inclined to patent human genetic materials in the immediate future.

This paper will start with a preliminary chapter on an introduction of the molecular biology of genes, followed the legal status of human genetic material is described in chapter II. Next, the controversy and the requirements of patenting of genes will be respectively discussed in chapter III and chapter IV. The detailed overview of the international law on the patenting of genes will be exposed in chapter V. This will be followed by chapter VI, which outlines the legal framework in the U.S.A., Europe, Canada, and China, as concerns the patentability of biotech inventions derived from human resources. Last but not least, a comparative study on the requirements for patenting human genetic material will be examined in light of current American and Chinese national laws in chapter VII. The concluding remarks provide a suggestion that China should adopt patent protection on biotech inventions related to human genetic materials.

I. Preliminary Chapter: Scientific and Socio-Economic Issues

An understanding of how the patent system differentially treats the patenting of human genes necessitates an understanding of the molecular biology of genes. This preliminary chapter explains the evolution and the biology behind genes, describing what a gene is and what a gene does.

i. Evolution and genetics

The publication in 1859 of The *Origin of Species* by Charles Darwin ushered in a new era in intellectual history. It radically changed our conception of the universe and our place in it. Darwin completed the Copernican revolution by drawing out for biology the ultimate conclusion from the notion of nature as a lawful system of matter in motion. The adaptations and diversity of organisms, the origin of novel and highly organized forms, even the origin of man himself could now be explained by an orderly process of change governed by natural laws.

In the *Origin of Species*, Darwin proposed that evolution occurs by natural selection: individuals in a species differ in their heritable fitness for a particular environment. The fittest have more surviving progeny.[1] These steps, accumulating in successive generations, eventually led to the formation of new species. But while Darwin presented a mass of evidence for this theory of natural selection, he barely discussed an equally important part of his theory: the requirement for a continuous supply of heritable novelty for natural selection to act on. The reason for his neglect is that the

[1] As discussed in B. D. Davis, *The Genetic Revolution* (Baltimore and London: The Johns Hopkins University Press, 1991) at 13.

mechanism of this postulated variation was entirely unknown, for there was not yet any science of genetics.[2]

Until about the mid-twentieth century, modern biology corroborated Darwin's view of biological evolution and added depth and infinitely more detail to our understanding of the processes. Darwin's theory of natural selection assumes that hereditary variation is pervasive. It is genetics that eventually filled the gap accounting for the origin of hereditary novelty.

Since 1950s, developments in molecular biology have made biologists able to research biological evolution at the molecular level. Because the molecular structure of the different species is not identical, their relationships can be determined by means of analyzing the molecular structure. Take the example of the comparision of the arrangement of the amino acid of the peptide chain in the hemoglobin molecules between three species: human, ape and horse; human and ape are identical on the arrangement of amino acid, however, there are 86 differences between that of the human and the horse.[3] Cytochrome *c* molecule is the protein molecule necessary for the oxidization food. Scientists have determined and compared the molecular structure of cytochrome *c* among hundreds of species. The results indicate that the more familiar the molecular structure is, the closer the species relationship is.

This molecular evolution is greatly enriching evolutionary biology. Biologists have found that all living things use deoxyribonucleic acid (DNA) to pass traits on to their

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[2] Ibid., at 13.

[3] Z.L. Chen and D. Ming, *Copying Lives: Human Beings and Clone* (Beijing: Popular Science Press, 1999), at 51.

offspring.[4] The DNA structure is referred to as the double helix and resembles a spiraled ladder. Each rung of the ladder consists of a pair of nucleotide bases. These bases are the structural unit of DNA, and are as follows: Adenine, Thymine, Guanine and Cytosine (A, T, G and C respectively). On this ladder, "A" may link only with "T" to form a rung, and "G" may only link with "C". While an entire DNA molecule consists of only four types of nucleotide bases, the vast diversity and complexity of life is achieved through the extreme length and exact sequencing of the rungs.[5] The human DNA complex may consist of as many as 3 billion base pairs.[6]

The path from the DNA code to the expression of the corresponding genetic trait is complex. DNA is organized into units called genes. A gene typically codes for a single protein, and it is this protein that effects the genetic traits. For instance, many genes code for proteins that function as enzymes, which facilitate biochemical reactions in the human body. These biochemical reactions ultimately result in the expression of a genetic trait, and in the case of defective genes, disease.

ii. Genetic Manipulation

All living things are made up of cells that are programmed by the same basic genetic material, called DNA. Genes are working portions of DNA and the biological units of heredity. DNA is the chemical database that carries the complete set of instructions for making all the proteins a cell will ever need, which in essence, determine every detail

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[4] M. S. McBride, "Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification", (2002) 34 in K. B. Tripp, ed., *Intellectual Property Law Review* (New York: Clark Boardman Co.), at 251.

[5] K. Gerald, *Cell and Molecular Biology* (New York: John Wiley & Sons, Inc., 1996), at 410 – 411.

[6] L. Walters and J. G. Palmer, *The Ethics of Human Gene Therapy* (New York: Oxford University Press, 1997), at 5.

about an organism. Specific genes code for specific traits that are found in a given organism. For example, one gene may code for eye color while another one may code for shoe size.

DNA is an extremely complicated biological system. The many thousands of proteins coded for by the DNA must work precisely with other proteins in order to insure the sound health of a person. This precise interaction of proteins in turn dictates such things as physical appearance, general health, and metabolism. In past twenty years, physicians and geneticists have made a great progress on treating genetic disease based on the development on molecular genetics. Increasingly, genetic manipulation is used in clinical medicine and the life sciences.

Genetic manipulation has many meanings, depending on who is using the term. It has also been called genetic engineering, biomanipulation, and biological engineering.[7] Engineering can be defined as the application of scientific principles to practical ends. The modern era of genetic engineering began in 1973 with the first successful experiment to recombine DNA from one organism with that of another by Dr. Herbert Boyer and Stanley Cohen.

a. Genetic Mutations and Disease

Many diseases stem from a defect in the genetic code. Mutations upset the delicate balance of proteins in the human body. There are two ways to receive a genetic defect or mutation. A mutation can be inherited from one or both parents. In this case, every cell in this person will have the mutation in its DNA. Or a genetic mutation can be

[7] A. S. Moraczewski, eds., *Genetic Medicine and Engineering—Ethical and Social Dimensions* (St-Louis: The Catholic Health Association of the United States and The Pope John XXIII Medical-Moral Research and Education Center, 1983), at 145.

acquired, in which case only the cells which arise from the originally affected cell will have the mutation.[8] Acquired mutations can occur for a number of reasons, possibly as a result of carcinogens or toxins. Acquired mutations occur largely during DNA replication. Sometimes the cell's safeguards against mutations grow less efficient with age. In any event, a minute change in DNA may have disastrous repercussions.

b. Gene Therapy

Gene therapy is the process by which cells are supplied with healthy copies of missing, flawed, or desirable genes. Gene therapy holds the promise of curing disease and improving the quality of life, target indications for gene therapies include genetic and metabolic diseases, cancer, acquired diseases such as AIDS, and cardiovascular disease.[9] The first clinical trial was initiated in 1990.[10] Current gene therapy is considered as a novel approach in its very early stage and is primarily experimentation based, with a few early human clinical trials. The field of gene therapy continues to focus its efforts on patients with severe and life-threatening diseases who usually have few treatment options or who have failed all available therapies.

There are two types of gene therapy: somatic and germ line. Somatic gene therapy treats specific types of target cells and alters the DNA of these cells. For example, somatic gene therapy may be used to treat some sort of genetic defect in the lung.

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[8] Chen and Ming, supra note 3, at 190 to 196.
[9] Davis, supra note 1, at 144 to 145 .
[10] On September 14, 1990, the first officially sanctioned human somatic-cell gene-therapy experiment began on a 4-year-old girl. See Walters, supra note 6, at 17.

Somatic gene therapy however has to be done continually, since cells will eventually die, and the treatment won't necessarily spread. [11]

Germ line therapy might eventually permanently and heritably treat some diseases by modification of the genes in fertilized egg and sperm cells. The process has already been carried out, albeit with some technical difficulty, in lower mammals.[12] If this approach were to become technically and ethically feasible in human beings, a single genetic modification might prevent disease not only in specific individuals but also in all of their offspring. However, germ line therapy has been criticized more than somatic cell therapy, on both technical and moral grounds.[13]

c. Xenotransplantation

The demand for human organs for transplantation continues to far outstrip the available supply. The United Network of Organ Sharing (UNOS) in U.S.A. found that, from 1988 to 1994, the waiting list of patients in the United States for organ transplants grew from 16,026 to 37,609, increasing at a rate of 22.4 percent per year.[14] By the end of 1998, about 60,000 people were registered on transplant waiting lists. Unfortunately, each year, less than one-third of the listed people received solid organ transplants.[15]

However, modified organs from other species are believed to be promising sources for

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[11] J. M. Wilson, "Human Gene Therapy: Present and Future."(1999) online: Human Genome News < http://www.ornl.gov>.

[12] Davis, supra note 1, at 146.

[13] For example, germ line therapy has the potential to affect not only the individual being treated, but his or her children as well. Germ line therapy would also change the genetic pool of the entire human species and future generations would have to live with that change. On ground of ethics, public think that we are not wise enough to know which human traits can be modified without dire social or evolutionary consequences.

[14] Institute of Medicine, Committee on Xenograft Transplantation, "<setting the stage> in Xenotransplantation : Science, Ethics and Public Policy, in B. M. Knoppers, ed. *Droit, Biotechnologies et Societe (Medecine Moderne)* (Montreal : COOP DROIT, Universite de Montreal, 2002)863, at 865.

[15] Biotechnology Industry Organization (BIO), Encouraging Development of the Biotechnology Industry: A Best Practices Survey of State Efforts (2000), online: BIO <http://www.bio.org/govt/ethics.html>.

donor organs for humans. This practice is called xenotransplantation. The transplantation has been found to be an especially effective, cost-efficient treatment for severe, life-threatening heart, kidney, lung and other diseases. The first xenotransplant experiment was conducted in 1905. Between late 1963 and early 1964, a team at Tulane University led by Keith Reemtsma transplanted kidneys from chimpanzees into six patients, one of whom lived for nine months.[16]

The most significant obstacle to xenotransplantation is the human body's immune system protections against infection. When tissue not recognized as human is introduced into the body, hyperacute rejection occurs -- the body cuts off the flow of blood to the donated organ. The most promising method for overcoming hyperacute rejection is believed to be genetic modification. By inserting human genetic material into other donor animals, it is believed that the human body will recognize the new organ as human and begin to use it as its own.[17] Several biotechnology companies are working to overcome hyperacute rejection and other obstacles to xenotransplantation.

d. Human Genetic Project

Genetic material is housed on chromosomes. In humans, there are 23 pairs of chromosomes. Genes are located in a definite position on a particular chromosome. When a doctor suspects that a certain gene may be the reason for a problem, obviously this gene must be located, before any problem can be remedied. Such is the goal of the Human Genome Project (HGP). The HGP that was initiated in 1990 is a world wide

[16] Supra note 14, at 864.
[17] Supra note 15.

research activity and many countries are playing a role in mapping the gene.[18] It was expected to take between fifteen and twenty years. The goal of the HGP is to map and sequence the 24 different human chromosomes (22 autosomes and the two sex chromosomes, X and Y). This project is so important because it is "major or 'revolutionary' impact", such a database will have great influence "on health care and disease prevention."[19] Knowledge of the 30,000 human genes will provide a vast therapeutic repertoire with which the pharmaceutical industry can attack fundamental aspects of human disease. Upon completion in 2001, the infrastructure of biology was enriched, and the revolution of biology and clinical medicine accelerated.

The success of genetic manipulation may result in a better quality of life for people. Some diseases may potentially be cured. As a result of genetic testing, risk prevention and life style changes are possible. Or, if one knows of a recessive gene for a disease, it will affect reproductive decisions. In a nutshell, the benefits of genetic manipulation may be longer lives, less disease and perhaps "tailored" children.

It goes without saying that there are many ethical and religious arguments against gene technology. Many people say that it will be an invasion of one's genetic privacy. Others feel that genetic technology will have organizational problems. [20] For example, the practice will be poorly regulated with the result that people can do as they please with

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[18] Included hundreds of scientists at 20 sequencing centers in China, France, Germany, Great Britain, Japan and the United States.

[19] K. Evelyn Fox, "Nature, Nurture, and the Human Genome Project"(1992), in Daniel J. Kevles and L. Hood, eds., *The Codes of Codes: Scientific and Social Issues in the Human Genome Project* (London, Cambridge: Harvard University Press, 1992) 281, at 294.

[20] Darryl R. J. Macer, "Attitudes to Genetic Engineering" (1992), online: Eubios Ethics Institute <www.biol.tsukuba.ac.jp. >

developing genetic technologies.[21] People also fear the fact that genetically engineering humans will decrease the diversity of the human species, and make the human population susceptible to diseases.[22] This is a far-fetched notion, but a possibility nonetheless.

Nevertheless, whether people like it or not, science does not stop. Like all new technologies, genetic manipulation has its pros and cons. The potential for reward and for disaster are both great. It is undoubted that with sufficient regulation and responsibility, the benefits of genetic manipulation can far outweigh the drawbacks.

iii. The role of biotechnology in the modern economic development

The discovery of the structure of DNA in 1953 and the identification of DNA as the genetic material in all life created a great leap in our understanding of life-forms from bacteria to plants to humans. Armed with a better understanding of how organisms "work," we are now able to engineer life to suit our needs through biotechnology.

Biotechnology is not an industry, but a set of biological techniques operating on living organisms. As an area of science, biotechnology is often defined as a combination of advances in our understanding of molecular and cellular biology, plant, animal and human genetics. In short, Biotechnology is the integration of the natural sciences and engineering to obtain the use of organisms, cells, parts of cells and molecular analogues for products and services; Environmental biotechnology is the application of these processes to the protection and restoration of environmental quality.

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[21] Ibid.

[22] M. Millar, "Human Genetic Manipulation and Society" (1999), online: Technology and Culture <http://www.loyala.edu/dept/philosophy/techne/gentech.htm.>

Developed through decades of basic research, biotechnology is now being applied to producing new, improved, safer, and less expensive products and processes used in health care, food and agriculture, industrial processes and environmental cleanup, among other applications.

Since the 1980s, biotechnology has been applied to commercially producing diagnostics and therapeutics. Biotechnology companies thus were created specifically to exploit the commercial potential of biotechnology. The biotechnology industry has grown rapidly in recent years. The industry clearly makes substantial current economic and fiscal contributions to the global economy.[23]

The United States has led the world in the commercial development of biotechnology because of its strong research base—most notable in biomedical sciences—and the ability of entrepreneurs to finance their ideas. During the early 1980s, a combination of large-scale federal funding for basic biomedical research, hype surrounding commercial potential, and readily available venture capital funding led to the creation of hundreds of dedicated biotechnology companies (DBCs).

In 1988, the Office of Technology Assessment of U.S.A. verified that there were 403 DBCs in existence and over 70 major corporations with significant investments in biotechnology.[24] On Wall Street, biotechnology is recognized in some business reports as a portfolio of stocks—in much the same manner as other technologies and industrial sectors are so recognized.

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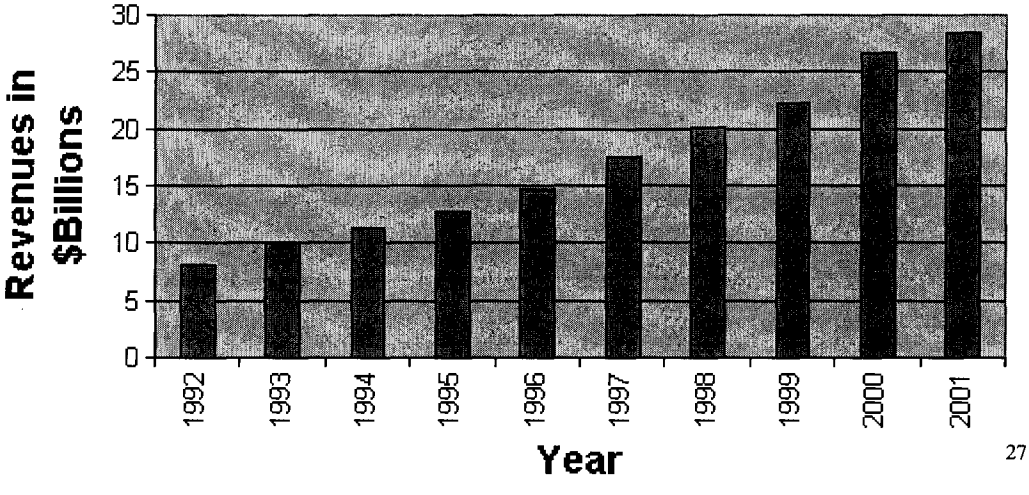
[23] Biotechnology Industry Organization (BIO), "Biotechnology Industry Statistics" (Spring 2002), online: <http://www.bio.org.>

[24] U.S. Congress Office of Technology Assessment, *Biotechnology in the Global Economy* (Washington: U.S. Government Printing Office, 1991).

In 1999, over US$300 million was available through NIH for Small Business Innovation Research Program (SBIR) grants. The biotechnology industry received approximately 50 percent of these awards.[25] As a sequel to the enormous investment, American biotechnology companies obtained tremendous profits. Currently, there are 1,457 biotechnology companies in the United States, of which 342 are publicly held. The total value of publicly traded biotech companies at market prices, was $224 billion as of early May 2002.[26] According to a recent report of BIO (Biotechnology Industry Organization), prepared by Ernst & Young, the biotechnology industry has more than tripled in size since 1992, with revenues increasing from US$8 billion in 1992 to US$ 27.6 billion in 2001.

U.S. Biotech Revenues 1992-2001



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[25] See supra note 15.
[26] Biotechnology Industry Organization (BIO), "Biotechnology Industry Statistics". (December 2002), online: < http//www.bio.org/ Biotechnology Industry Statistics. html>.
[27] Ibid.,

Based on the experience of the U.S. biotech industry, European companies are striving to achieve significant benchmarks believed necessary for accomplishing sustainability, including the ability to reach significant market valuations, develop a product focus, gain access to technologies capable of producing multiple products, and develop a complete pipeline.

The rate at which new companies are being created throughout Europe is astounding, increasing by 173 in 2000 to 1,351. Germany, where the number of biotechnology companies has risen more than 150 percent in the past three years, now claims the largest number of European biotech companies. In Europe, industry revenues have leapt forward over 2000, increasing by about 45 percent to 5.4 billion Euros. This is approximately the level of U.S. industry seven or eight years ago, with a similar number of companies.[28]

Canadian biotechnology first started some years after their American competitors, but is proportionately comparable to the US field. According to the Figures of Statistics Canada, in 1999 Canada's biotechnology sector generated C$1.9 billion in revenues including C$718 million in exports (see the following figure). These revenues exceeded C$5 billion in 2002. The total market capitalization of these firms was about C$ 12,9 billion by the end of May 1999. At the same time, the Canadian venture capital market developed very rapidly in the last decade. In 1998, the total pool was estimated at C$ 10 billion, and that year more than C$ 1.66 billion was invested in some 1200 companies, sixty of them active in biotechnology.[29]

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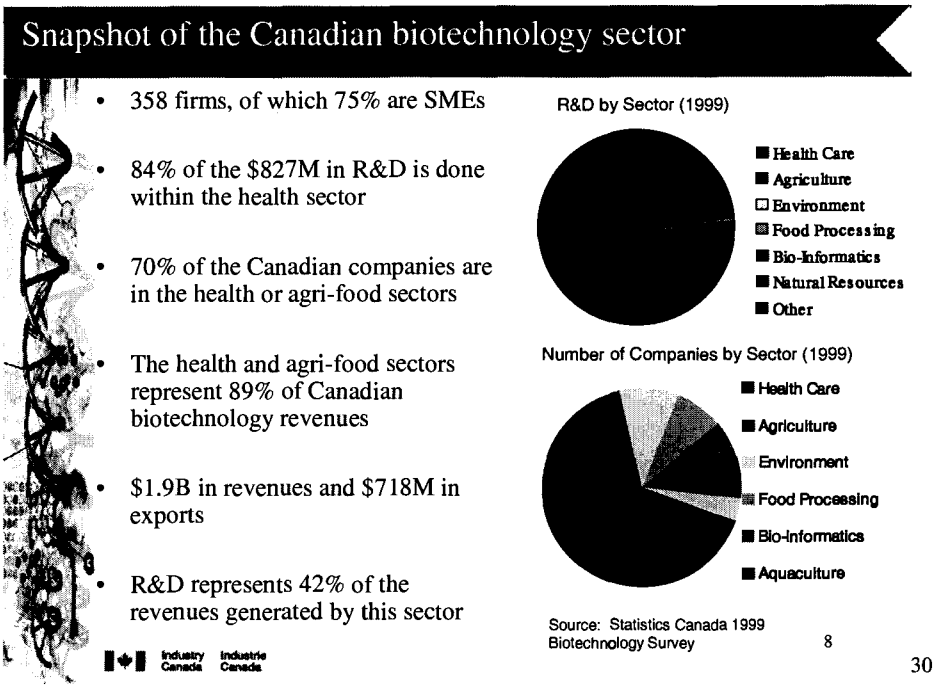
[28] Ernst & Young, "Convergence: Ernst & Young's Biotechnology Industry Report, Millennium Edition" (2000]), online: Ernst & Young <http://www.ey.com/industry/health>, at 68.

[29] J. Niosi and Tomás G. Bas, "The Competencies of Regions Canada's Clusters in Biotechnology"(1999), online: <http://www.wabio.com/industry/econ_dev/CanadaClusterStudy.pdf>.

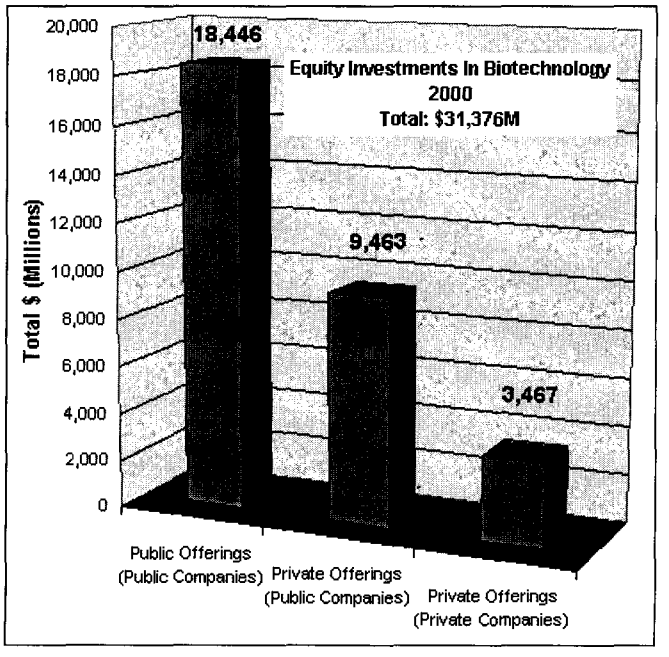


This industry has attached much attention in developing countries. In China, the government believes that biotechnology will help to solve the most urgent problems, such as in population, food supply, health care and environment protection. The funding from government for R&D has been increasing continuously during the past over 20 years. There are more than 400 universities, research institutes and companies and a total of over 20,000 scientists and researchers involved in biotechnology. The total sales of biotechnological products in China have increased by 50 times during the past 10 years. In 1997, it was about 13 billion RMB (US$ 1.6 billion). In the year 2000, it reached more than 20 billion RMB (US$2.5 billion).[31]

[30] Industry Canada. "Innovation Agenda and Biotechnology". (September 25, 2001), online: industry canada <http://www.strategis.ic.gc.ca>.

[31] Jin Ju. 2001, "Life Science and Biotechnology in China". (June 2001), on line: Chinagate < http://www.chinagate.com.cn/DEVELOPMENT china GATEWAY.htm>.

Biotechnology is likely to be seen as a national asset by more nations—both as a way to develop a high-technology base and to increase market share in several international industrial sectors. As commercial biotechnology expands in size and scope, its effect on the international economy is obvious. Biotech companies raised more money in 2000 than they had in the previous six years combined. From 1994 through 1999, the biotech sector raised a total of US$30.9 billion (excluding payments, fees and revenues from partnerships). In 2000 *alone*, the sector raised almost US$31.4 billion on a global basis. (See the following figure) [32]



Of that, public offerings held nearly US$18.5 billion, equivalent to 59 percent of all funds going into biotech companies. (See the following figure)[33]

[32] J. V. Brunt. "A Superlative Year" (2001), online: Signals Magazine <http://www.signalsmag.com>.
[33] Ibid.,

Biotechnology is one of the world's fastest-growing industries, with global demand expected to more that double from US $20 billion in 1995 to US $50 billion by 2005.[34] Undoubtedly, the biotechnology industry is a key to global technological future, when biotech companies obtain product approvals, growth can be dramatic, boosting job levels and tax revenues. In the new 21st Century, the biotechnology industry holds great promise to help the world meet its growing needs for innovative medicines, better agricultural products and preservation of the environment. It is increasingly becoming an important economic development strategy around the world as regions and communities try to capture the economic benefits of this promising industry. Encouraging and facilitating research will help bring these new technologies to fruition and at the same time contribute to the economic development of global economies. However, many biotechnology uses create legal issues, one of the most important issues involving biotechnology and the law is the patenting of human genetic materials. It is important that there be certainty in the law so that companies endeavoring to invest large sum of money in research and development are secure in the knowledge that they can protect their costly invention.

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[34] Canadian Biotechnology Advisory Committee. *Patenting of higher life forms and related issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee.* (Ottawa: Canadian Biotechnology Advisory Committee, 2003) at 2.

II. The Legal Status of Human Genetic Material

Owing to the tremendous potential benefits of biotechnology, the key to investment by both the public and private in human genomics is the issue of intellectual property—in particular, patent protection on biotech inventions. Some patents on biotech inventions related to human genetic materials are hotly argued. The issue of patenting in this field first appeared in 1991 when Graig Venter was identifying and sequencing hundreds of small expressed genes in his research. Although the function of these expressed sequence tags (ESTs) were not known, the NIH decided to file patents on the ESTs. Many scientists and patent attorneys were appalled at this preemptive claim on bits of human genes, since their functions were unknown and it was presumed that these applications would not meet the requirement for utility. [35]

When the project to map the Human Genome Working Draft was made public on June 2000, debates around patenting of such material began. The issue has resulted in the controversy in the legal world since it has touched the basic principle of the patent law, in addition to moral and ethics issues.

Many Western countries have laws dealing with the donation of human organs and tissue for purposes of transplantation and medical research, such as Canada and its common law provincial Human Tissue Gift Acts.[36] Generally, these laws are

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[35] J. V. Brunt, "Biotech Patent Fights"(October 2002), online: Signals Magazine <http://www.signalsmag.com>.

[36] Human Tissue Act, RSNB 1973, c. H-12; Human Tissue Gift Act, RSS 1978, c. H-15; Human Tissue Gift Act, RSBC 1979, c. 187; Human Tissue Gift Act, RSA 1980, c. H-12; Human Tissue Gift Act, RSYT 1986, c. 89; Human Tissue Act, RSM 1987, c. H180; Human Tissue Act, RSNWT 1988, c. H-6; Human Tissue Act, RSNS 1989, c. 215; Human Tissue Act, RSN 1990, c. H-15; Human Tissue Gift Act, RSO 1990, c. H20; and Human Tissue Donation Act, SPEI 1992, c.34. In Quebec, there is article 22 of the Civil Code which states "A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purpose of research." Furthermore, under the Civil Code, a person has the right to decide what happens to his or her body after death. (The note is continued on the next page.)

ambiguous, however, with respect to genetic material, such as DNA, cells, and derivative cell lines. These provincial laws successfully protect against the exploitation and sale of organs, blood, etc., but do not address the ownership or possible patenting of genetic material. Such material, as a biological entity, is unique and different from other human tissues such as organs or blood. For this reason, the issue of patenting of human genetic materials cannot be answered without having examined the status of such material.

In general, genetic material is defined as a segment of DNA that codes for a protein. The biological definition in terms of a stretch of DNA brings out both the physical and informational aspects of genetic material: the stuff of DNA and the coded information contained in DNA. Both the physical material itself and the information it contains have immense research and therapeutic value, as well as economic and social significance. However, the legal status of both the material and the genetic information it contains, have not yet been settled in law.

i. Genetic Material

A gene is a sequence of DNA that constitutes the coded information for manufacture of proteins and other key substances in cells. This genetic material is copied and passed on between generations and copied to all cells of an organism. The substances produced are responsible for the organization, development and maintenance of structure and life possesses. Though genetic material is invisible to the naked eye, it has both a tangible and intangible nature. Since almost all tangible things, other than human being, are

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36 Continued....
Article 43 of the C.C.Q. state "A person of full age or a minor fourteen years of age or over may, for medical or scientific purposes, give his body or tissues therefrom." This act, however, is not designed for human genetic materials.

properties. Human genetic material could seemingly be considered as property. However, genetic material emanates from, and is integral to the human being. It is certainly for the law to regard such material as an extension of its human source, even if it is not *per se* a human being. Then, what legal definition is used in practice?

Some cases have judged human genetic materials to be an object *"sui generis"*. In *Hect v. Superior Court (Kane)*, the California Court of Appeal concluded that cryogenically preserved sperm was a "unique" category of "property", which properly formed part of a decedent's estate and over which the decedent had an interest in the "nature of ownership". [37] Even if the sperm was not governed by the general law of personal property, it occupied an "interim category" of "property" that was subject to the jurisdiction of the Probate Court. [38] In contrast, the case of *Davis v Davis*, the Supreme Court of Tennessee concluded that pre-embryos are neither person nor property and entitled them to special respect because of their potential for human life."[39]

In *Moore v. The Regents of the University of California*, the majority of the California Supreme Court refused to characterize Mr. Moore's interest in his surgically removed spleen as *sui generis*. According to Justice Rothman of the California Court Appeal, Mr. Moore's property right did not include the right to sell his spleen, even absent legislation, which prohibits such a sale. Such interests could be described as "quasi-property". This means that the object in question is in part property, but does not spawn the whole array of property rights ordinarily associated with property.[40] In other words,

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[37] M. Litman, "The Legal Status of Genetic Material. "In B. M. Knoppers, C. M. Laberge and M. Hirtle, eds., *Human DNA: Law and Policy* (Kluwer Law International: The Hague/London/Boston, 1997) 17, at 26.

[38] *Hect v Superior Court (Kane),* 20 Cal. Rptr. 2d 281-283. (Ct. App. 1993).

[39] *Davis v. Davis*, 842 SW 588 (Tenn.1992)

[40] Litman, supra note 37, at 26.

such material is legally unique or *sui generis*. Accordingly, at some point in the jurisprudential development of a *sui generis* right, it is appropriate to refer to it as "quasi-property."[41]

Under classical civil law principles, the human body is outside of legal commerce. Despite its material existence, the body is not considered a thing with pecuniary value. Moreover, in accordance with general civil law principles and, more precisely, with notions of morality and public order, the human body may neither be the object of contract, not be sold, leased, or in any way alienated.[42]

In a 1991 opinion on the application of genetic tests to individual studies, family studies, and population studies, the French National Ethical Consultative Committee for the Life and Health Sciences took a firm position stating that an individual's genome may not be the object of commercial transactions.[43] It further affirmed this principle in another opinion on the non-commercialization of human genome by asserting that "all information contained in the human genome belongs to the common heritage of mankind; it is a field of knowledge that cannot be subjected to monopoly."[44] This principle of non-commercialization of human body, its organs, tissues, cells and products, was embodied in legislation in the French bioethics laws of 1994.[45]

Additionally, a report on the use of human tissue by the Health Council of the Netherlands emphasized the right to self-determination over one's body, rejecting all

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[41] M. Litman and G. Robertson, "The Common Law Status of Genetic Material", in B. M. Knoppers, T. Caulfield, and T. D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery Publications Limited, 1996)51, at 70.

[42] M. Hirtle, "Civil Law and the Status of Human Genetic Material," in B. M. Knoppers, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery Publications Limited, 1996) 36, at 85.

[43] Ibid., 113.

[44] Ibid., 113.

[45] Ibid., 113.

notions of property rights over the human body as a whole.[46]

These two European sources, largely influenced by similar civil law traditions, seem to tend toward a "personality rights" basis for the legal regime for the human material.[47] Several articles of the 1994 Civil Code of Quebec relevant to the disposal of body parts or corpses are found under the title *Certain Personality Rights* and more specifically in the chapter *Integrity of the Person.* This seems a clear indication of the legislator's intention to opt for a personality rights approach to personal control over human genetic material.

ii. Genetic Information

Genetic information is highly personal information. This information is encoded by gene sequences that perform a variety of functions, most of which have not yet been discerned. However, genetic information is qualitatively different from other types of medical information, since not only is it highly personal but also it may impact significantly on interpersonal, familial and social life.

Under the Common law, genetic information can be considered as either part of the person or as property.[48] However, the concept of ownership is very rarely used in practice. Information tends to be protected by existing guidelines or through specific legislation. The issue is, should it be protected in the same way or differently from other medical information? In practice, most countries apply concepts of confidentiality

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[46] Health Council of the Netherlands, *Committee on Human Tissue for Special Purposes, Proper use of Human Tissue* (The Hague: Health Council of the Netherlands, 1994) 32.
[47] Hirtle, supra note 42, at 116.
[48] B. M. Knoppers, "Status, Sale and Patenting of Human Genetic Material: an International Survey"(May 1999) *Nature Genetics* 23, at 24.

and privacy to genetic information, but some want to give it special protection. In Canada, the U.K. and to a much greater extent of U.S.A., there are some cases, which regard genetic information as confidential information, namely, as property. These cases suggested characterizing genetic information as confidential information protected by relational wrongs such as breach of fiduciary duty and the law of informed consent, as well as the law of breach of confidence. The Supreme Court of Canada has recognized that persons have privacy interests with regard to medical information.[49] China has classified "the human genetic resources and the relevant information or data" from an international scientific cooperation as "State scientific or technological secrets".[50] It considers genetic information as property.

As concerns the patenting of human genetic material, one of the arguments centers on the patenting of genetic information, acquired through manipulation of genetic material itself. Genetic information is so private that some courts are unlikely to grant a broad discretion to physicians to disclose genetic data to biological relatives or to reproductive partners. The courts are even less likely to impose liability on physicians and others for refusing to disclose this information.[51]

Genetic material itself is truly unique because it has profound and far-reaching social, psychological, scientific, and economic implications. These implications are best regulated through the collective efforts of a variety of areas of law. Though the legal

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[49] *McInerney v. MacDonald (1992),* 93 D.L.R. (4th) 416. The Court held that a patient has a sufficient property interest in the photocopy of documents prepared by other physicians to request an additional photocopy from his or her physician without having to go back to the other physicians to obtain a photocopy of the original.

[50] See article 5 of the Chinese Interim Measure for the Administration of Human Genetic Resources, 1998. This Measure aims to prevent Chinese genetic resources from leaking. No articles relating to human genetic materials were found in Chinese Civil Code.

[51] Litman, supra note 37, at 27.

status of genetic material is far from settled, case law will play an important role. Legally characterizing this material as *sui generis,* as a prerequisite, should be an appropriate legal rule to resolve this disputes on a case by case basic. In deed, as concluded by Litman and Robertson concluded: rather than focusing on the legal characterization of genetic material and information, and trying to assign to them specific juridical categories such as property or person, courts should view them as legally unique and use the flexibility of a *sui generis* approach to fashion whatever rights, obligations, and remedies that policy demands in the particular context and circumstances of each case.[52] However, the *sui generis* approach, to some extent, is ambiguous for patent law, because it creates a quasi property right but not complete property. In this case, how could patent laws define the patentable requirements for some *sui generis* "object"?

[52] Litman, supra note 41, at 84.

III. The Patenting of Human Genetic Material

In 1999, an article entitled "who owns our genes" in Time magazine stated: "in recent years researchers have flooded the USPTO with application for thousands of genes and gene fragments," the applications in fact are "a general idea of what specific strands of genetic coding do, often it's just that-general..."[53] Much of the controversy surrounding the patenting of genes stems from these applications. Who can or should own human genes? Should it be considered as the common heritage of humankind at the level of the genome or as a patentable subject matter at the level of individual genes? This enquiry has created an ongoing and intense international debate.

Background

Since 1992, international bodies have repeatedly argued against granting patents on naturally occurring DNAs, or cDNAs and ESTs of unproven utility or function. As already mentioned, the controversy was sparked by the initial filing in June 1991 for patent rights on 337 genes, and a second filing in February 1992 on 2,375 more genes by Craig Venter. Venter's research at NIH's National Institute of Neurological Disorders and Strokes aimed at locating and sequencing the 30,000 or so complementary DNAs. cDNAs are clones made from messenger RNAs; thus, they represent the coding regions of all the genes expressed in a tissue. By sequencing a short stretch of cDNA clones, about 300 to 500 bases, Venter created ESTs. ESTs are short sequences of DNA; they can be generated automatically by machines. Though they are extremely useful in locating a full-length gene to predict the protein that gene

[53] J. Kluger, "Who Owns Our Genes" (January 1999), TIME, at 35.

makes, by their very nature, ESTs cannot disclose anything about their function. The patent application for protection of this new knowledge has generated a number of questions, some hotly debated. An USPTO ruling in 1992 denied the applications on the grounds that gene fragments cannot be patented with an unknown function. [54]

i. Controversies over the Patenting of Human Genes

Do ESTs, cDNA Sequencing and other early gene findings count as decisive knowledge about the genes themselves? Venter was the first to admit that, even though he could tag a cDNA, he still had no idea what it does, unless it is a sequence from a gene whose function is already known. James D. Watson, who opposed this rush to patent, decried this move. Members of the Gene Patent Working Group, an interagency committee set up by the White House Office of Science and Technology Policy (OSTP), meeting in May 1992, said that ESTs are merely research tools. [55] French geneticist Daniel Cohen said there were two problems with the patenting of genes: "The first is moral. You cannot patent something that belongs to everyone. It's like trying to patent the stars. The second is economic. By patenting something without knowing its use, you inhibit industry. This could be catastrophe." [56] So, the patenting of genes at this stage was premature. Three years later following the first patent application on ESTs, the NIH abandoned those original applications.

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[54] L. Roberts, "Rumours Fly Over Rejection of NIH Claim" (1992) 257 Science, at 1855.
[55] T. Peters, "Intellectual Property and Human Dignity" in Mark S. Frankel and Albert H. Teich, eds., *The Genetic Frontier: Ethics, Law and Policy* (Washington: American Association for the Advancement of Science, 1994) 215.
[56] Ibid., 215.

With respect to the issue of ESTs. Vast regions of the human genome lack genes and harbor (only) highly repetitive sequences with questionable functions. In order to hunt for DNA sequences that encode for proteins, researchers use ESTs. Obviously, an EST can be used as a probe to identify the full-length gene of which it forms just a part.[57] The hundreds of thousands of ESTs present in databases allow the search for other ESTs whose sequences overlap and align them to give the nucleotide sequence of the coding region or a substantial part of it.[58]

Even in Europe, where applicants also tried to obtain patents by providing just the unspecific indication of an EST for use as a probe to obtain the remainder of the coding region of the gene, they were not enough to fulfill the requirement of inventiveness (and industrial application).[59]

Generally, there are important arguments against the granting of patent on human genes.

Firstly, when examined critically, the claims made by industry for the benefits of the patenting process are exaggerated. It is not true that patenting necessarily encourages early and beneficial dissemination of knowledge which, without such protection, might be kept secret. This is a widespread mythology about patenting, but in practice it is only a half-truth. Patenting can indeed lead to the dissemination of information, but there is also much information which remains secret. Many companies regard some things as too sensitive even for patent protection, and some may be secret "in the national interest". The high cost and lengthy timescale of seeking patent protection can often be

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[57] S. Huldebrand, "Patenting of Human Genes in Europe; Prerequisites and Consequences" (September, 2001), online: NDS Intellectual Property < http://www.ndsge.ethz.ch.>
[58] Ibid.
[59] In respect of art. 5 (3) and recital 24 of the Directive 98/44/EC.

a deterrent for research institutes or small and medium enterprises, when compared with a relatively short market advantage. Once a patent application is put into the hands of patent lawyers, the questions asked – for example to widen the application of a viable but narrow patent – inevitably divert a company's effort and personnel, which may set back the company's ongoing research programs, and lose its competitive edge in the next potential area of discovery. The litigation that can result from rival companies claiming "prior art" can make patenting a doubtful and even more expensive business.

Secondly, patents of partial and uncharacterized cDNA sequences will reward those who make routine discoveries but penalize those who determine biological function or application (inappropriate reward given to the easiest step in the process). Such patent applications may also lead to so-called submarine patents, claims that are made today and then vanish, only to reappear when some unsuspecting scientist finds something useful to do with genes hidden in the patent.[60] The patent applicants may seek a broad scope of so as to prevent anyone else from developing and using them. On occasion, patenting is abused by companies as a strategy deliberately to block a competitor from developing potential products in a field which might rival an existing product, but have no intention of ever bringing it to market. In such cases, public knowledge is reduced by patenting.

And third, patents could impede the development of diagnostics and therapeutics by third parties because of the costs associated with using patented research data. Patent stacking (allowing a single genomic sequence to be patented in several ways such as an EST, a gene, and a SNP) may also discourage product development because of high

[60] Kluger, supra note 53, at 35.

royalty costs owed to all patent owners of that sequence; these are costs that will likely be passed on to the consumer.[61] Costs increase not only for paying for patent licensing but also for determining what patents apply and who has rights to downstream products. In addition, because patent applications remain secret until granted, companies may work on developing a product only to find that new patents have been granted along the way, with unexpected licensing costs and possible infringement penalties.[62] It is also noted that private biotechnology sectors who own certain patents, can monopolize certain gene test markets.

Finally, patenting human genes could be wrong because of public harmful consequences. For example, it will enable patent holders to reap monopoly profits from lifesaving therapies or diagnostic techniques. Patent holders are being allowed to patent a part of nature --a basic constituent of life; this allows one organism to own all or part of another organism. Ownership of life, or property rights in portions of human genome, is inherently wrong.[63]

ii. The Partisan Position

Some arguments in favor of patenting genetic material can be identified. The first was stated by Philip Leder, the co-inventor of the Harvard mouse. In the course of the 1989 Congressional hearings on proposed U.S. legislation to restrict the patenting of transgenic animals he stated: "The great and costly engine for invention can only be effectively driven with the support from the private sector, motivated to serve a public

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[61] Oak Ridge National Laboratory, "Genetics and Patenting"(2001), online: Oak Ridge National Laboratory <http://www.ornl.gov.>
[62] Ibid.
[63] Huldebrand, supra note 57.

need. The patent system offers the only protection available for the intellectual product of this research, and thus, the only hope of a fair return against the great financial risks that investment in biotechnology entails."[64]

This argument can be interpreted as an appeal either to the inherent fairness of compensation of those who take the risk, or to the assumption that patent protection provides an incentive without which beneficial scientific and technological development will be delayed. Dr. Leder argued that the Harvard mouse had great potential for public benefit "as a vehicle for the development of further therapies" as well as "an early warning system for the detection of carcinogens and mutagens" in chemical testing. He pointed out that: "In the past few weeks, the gene for cystic fibrosis has been identified and the ability to replace this gene, for example, in a mouse, with the defective human cystic fibrosis gene would constitute an extremely powerful model system for the development of an effective treatment. For individuals and families at risk for this and other diseases, this would represent a priceless asset."[65]

Similarly, Bernadine Healy, then Director of the NIH, argued during the 1992 Congressional hearings on the patent application policy of the Human Genome Project that: "the success of Government-funded human genome research is of critical importance to our Nation's public health" as the basis for "understanding the genetic basis for health, disease, and life functions" as well as for developing therapies. "The supportive and symbiotic relationship must be assured between emerging scientific

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[64] T. Schrecker, C. Elliott, C.Barry Hoffmaster, E.W.Keyserlingk, and M. A. Somerville, "Ethical Issues Associated with the Patenting of Higher Life Forms" (May 17, 1997), online: Industry Canada < http://www.strategis.ic.qc.ca/>, at 25.

[65] Ibid., 26.

developments and the intellectual property system."[66] She went on stating: "[P]atent protection for biotechnology and pharmaceutical industries is critical, bringing new therapies to the public is a lengthy and expensive process. Not surprisingly, companies are reluctant to invest the resources and take risks unless some market protection can be obtained."[67]

A second argument is based on considerations of economics. Patenting a gene does not grant ownership of genetic information; on the contrary, it actually encourages the publication and sharing of that information. It confers rights to the researcher to commercially exploit that information, in defined ways, for a limited period. If there were no protection of intellectual property rights, competitors could supply a beneficial product at a much lower price, as they do now on the expiry of patents. This would mean that industry would not invest in the research and development needed for new medicines and diagnostics. Patent protection can establish a product's virtual monopoly in the market place, one last long enough for the company to recoup the enormous of cash that it poured into developing the product in the first place.

The third positive aspect is the consideration of fairness: people deserve the fruits of their intellectual accomplishment.[68] Because biotech companies or research institutions depend on private investments, patents are the first and most important benchmarks of progress in developing a new biotechnology product. If such a patent is negated, investments will be reduced and more participants will withdraw from the research. Less and less competition will bring about the rising costs of products. Patents facilitate transfer of technology to the private sector by providing exclusive rights to preserve the

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[66] Ibid., 26.
[67] Ibid.,26.
[68] Ibid., 27.

profit incentives of innovating firms. Researchers are rewarded for their discoveries and can use the monies gained from patenting to further their research. As Leon Kass wrote, "justice requires protecting the labor of the imaginative and industrious against theft by the sly and lazy".[69] It should be noted that although the vocabulary is similar, there is a difference between this argument and Philip Leder's invocation of the beneficial consequences for society that can arise only if inventors and investors retain the "hope of a fair return".

Finally, concerning the question that patenting of early gene findings would impede the development of downstream products. Supporters argue that if further developing of products is demanded by the society and is profitable, patentees, of course, would develop it themselves. Even if patentees would not do it, others have the right to do it. Since the patent law entitles one to use others' patent as long as it is done legally. [70] If an improved technology is not subordinate to the early-patented product, it will not constitute the infringement of patent. Furthermore, patents avoid wasteful duplication of effort, as well as encourage research into new and unexplored areas.

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[69] L. Kass, *Toward a More Natural Science: Biology and Human Affairs*. (New York: The Free Press, 1985) 112, at 135.

[70] See article 72 of the Chinese Patent Law, and art. 31 (b) of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs), both of them regulate other use of the subject matter of a patent without authorization of the right holder, including use by the government or third party authorized by the government.

IV. Requirements For the Patenting of Human Genetic Material

During the past thirty years, patent law has struggled to keep pace with the rapid a growth of research and development in biotechnology. Not surprisingly, science has outpaced the law, which is playing catch-up when it comes to providing patent protection for biotech inventions involving genetic material. Difficulties remain over the patenting of human genetic material under the traditional patent system. Much of the controversy surrounding the patenting of genes stems from a misunderstanding of the limitations of patent law. Numerous media sources often refer to "gene patents." This term is imprecise and can lead to the belief that it is possible to file for a blanket patent covering all the possible uses of a gene, or even a patent on the sequence itself. For this reason, a review of patent law in general is necessary before discussing the issue of patenting of human genetic materials.

Background

In each jurisdiction, patent rights are determined by reference to various national statutes and to international treaties. Under patent law, a patent grants the patentee the exclusive commercial proprietary right over a new, useful, and inventive creation. The patentee may, for a limited period of time, prevent anyone else from making, construction, emulating, using, or selling the patented invention, or any other invention that achieves substantially the same result in substantially the same manner.[71] In return for granting a limited term of commercial exclusivity,[72] the patentee must disclose his

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[71] T. Caulfield, K. Cherniawsky, and E. Nelson, "Patent Law and Human DNA: Current Pratice" in B.M. Knoppers, T. Caulfield, and T. D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery Publications Limited, 1996) 117, at 119.

[72] Canada's Patent Act, the Chinese Patent Law and the U.S. (The note is continued on next page)

or her intellectual achievement. This enables others to replicate the invention for experimental purposes and to freely use it once the term of exclusivity has expired. In this way, patents are a dynamic compromise between undesirable market monopolies and the broader social need for increased useful technological advancement. Essentially, the rationale for a patent system is to provide an advantage to society as a whole by rewarding the development of new inventions. Thus, the patent system has two basic purposes: to promote the advancement of technology, and to protect the inventor.

The legal threshold criteria of patentability and the rights encompassed in grant of patent are quite similar in all jurisdictions. As a patentable subject matter, it must be novel, inventive (non-obvious) and capable of industrial application (utility). Together these three criteria ensure that only certain types of inventions can be protected and that patent protection is commercially meaningful. The U.S. Patent Act § 101 defines patentable subject matter or "inventions" as: any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement.[73] Some subject matters, by their very nature, cannot be patented, such as naturally occurring organisms, laws of nature, natural or physical phenomena and abstract ideas. But, some patentable inventions are excluded from the scope of patent protection based on public policy. For instance, most countries, like China, Canada and the member states of the European Union, prohibit the issuance of patents over plant and animal varieties, and have adopted special laws to protect them. In addition, most national (not Canada) and

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[72] Continued..
Patent Act provide a 20-year protection period for a granted patent.

[73] Canada's Patent Act, RSC 1985, c P-4, s.2., or Chinese Patent Law, 2001, art. 2, both have similar definition of invention.

international laws include a general prohibition against the patenting of illicit or immoral inventions.[74]

The utility, novelty and inventiveness criteria are necessary before an invention is classified as patentable subject matter. These three criteria are often difficult to achieve when filing an application. Thus inconsistent case law has developed along side a particular technology further compounding the problem of separating patentable from non-patentable inventions on human genetic material. In essence, the debates focus on whether a finding of a gene is an *invention* or a *discovery*; and whether it possesses an industrial application.

i. Utility

Debates on *discovery v. invention* are closely related to the issue of the utility. Proof of utility consists of two parts: an invention must possess industrial application and must actually achieve the stated utility. This requirement guards against the granting of undeserved or premature monopolies. A product that can be used as an intermediary may not be adequate to establish legal utility, a useful end product or result must be known. Moreover, the utility criterion distinguishes basic research from applied research. The former has been traditionally considered as knowledge belonging to the public domain that can be freely used, while the latter is regarded as an appropriate subject matter for exclusivity.[75] Although patenting of basic research would facilitate the development of other subject matter into widely available commercial products,

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[74] Caulfield, Cherniawsky and Nelson, supra 71, at 122. See also article 5 of the Chinese Patent Law, which "prohibits the issuance patents over subject matters with an illicit or immoral object".
[75] Ibid., 132.

such a practice might inhibit progress by discouraging the free exchange of materials for fear that a competitor will invent around the protected subject matter.

A biotech invention involving human genetic materials must satisfy the utility requirement by providing a clear application (such as a diagnostic test). But if the invention contains a gene of unknown function, the invention does not possess the requisite utility. Practically, the patent authorities in most nations accept that human genetic materials and related processes fall within the sphere of patentable subject matter and have applied tradition patent law maxims to these inventions. It should be noticed that the technical character of the process of isolating a gene constitutes an argument in support of the patentability only of the processes themselves, but not of the elements that were isolated through these processes.

A typical case involving the patenting of human genetic material ESTs was the NIH filed application in 1991 mentioned above. Although neither the structure nor the functions of the ESTs were known, the NIH applied and pursued the patent application to ensure that subsequent licensed innovators would be guaranteed adequate commercial rights and the accompanying incentive to develop commercial products. The NIH claimed that the ESTs satisfied the utility requirement since people could use them for several purposes: to obtain full coding mosomes; to assist in forensic identification; and to prepare items used in molecular biology such as vectors and probes.[76] However, opponents argued that the patent claim was overly inclusive and that the premature issuance of a patent over such basic subject matter could secure undeserved proprietary rights for the patentees, effectively transforming patents from a system of rewards for the successful development of inventive commercial products

[76] Ibid., 134.

into institutions into a lottery based on luck.[77] Ultimately, the USPTO denied the claims for several reasons; one of them was lack of utility.

ii. Novelty

Novelty determines the scope of patent protection. Perhaps a difficult question for the layman to understand is how a natural substance like a gene can have no previously recognized existence since it is found in nature? The answer lies in the fact that a gene is not necessarily part of the state of the art, which means accessible to the public in the sense in which this term is used in patent law. To make a gene available to the public, it needs to be isolated, purified, classified and identified from its natural surroundings. The novelty arises now because the underlying technical processes for putting a gene - preexisting in a complex mixture of natural origin - into practice requires human intervention and cannot be accomplished by nature alone.[78]

Some who argued against granting patents on gene insist that genes and DNA are natural parts of the body belonging to products of nature, and unsuitable for patent protection.[79] Products of nature are only discoveries that cannot be invented. Granting patent protection over such discoveries improperly results in removing these pre-existing human genetic materials from the public domain.[80] However, if a new method of production of a known product is discovered, then only the specific method can be

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[77] Ibid., 134.

[78] See recital 21 of the Directive 98/44/ on the Legal Protection of Biotechnological Inventions, which states: "Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself."

[79] M.S. Greenfield, "Recombinant DNA Technology: A Science Struggling with Patent Law" (May 1992) 44, Stanford Law Review 1075, at 1078.

[80] Caulfield, supra note 71, at 136.

protected. Thus, novelty is not a key barrier to the patenting of genetic invention, since isolated and purified products are patentable if their new form is substantially different from their natural form.

iii. Non-Obviousness / Inventiveness

The test of non-obviousness attempts to determine whether a person skilled in the relevant art would have been inexorably led to the invention without research, on the basis of common knowledge and other specified prior information.[81] If publications in the prior art collectively provide both the means to carry out the objective of the particular invention, plus a reasonable expectation of success, then the invention is obvious and not patentable. The following three factors should be considered when determining whether the test of non-obviousness has been met: the scope and the content of the prior art, the differences between the prior art and the invention, and the level of ordinary skill of a worker in the art who lacks any imagination. [82]

Inventions involving genetic materials, including the isolation and expression of DNA sequences, are legally obvious if the prior art supplies a reasonable expectation of success and thereby creates the motivation to produce the invention. Nevertheless, such inventions will not be obvious if the prior art either offers no suggestions about which of the experimental parameters are critical to achieving the desired result, or provides only general guidelines in a promising area. Inventiveness may be derived from the process used to achieve a result rather than the result itself. The requisite level of

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[81] R. W. Marusyk and A. I. Athanassiadis, "Patenting of Human Genetic Sequences In Canada", in B. M. Knoppers, C. M. Laberge, and M. Hirtle, eds., *Human DNA: Law and Policy* (Hague/London/Boston: Kluwer Law 1997)343, at 347.

[82] Caulfield, supra note 71, at 137.

inventiveness may be reached if the materials essential to the invention are not "available to the public" at the time of the invention.

In practice, it is very difficult to evaluate and determine the inventiveness of a claimed invention in specific situations. That is why each patent office tends to examine the inventiveness through the whole process of examination of patent application. Actually, in the case of gene patenting, it is the very scope and quantity of claims that has generated controversy. Since the initial patent on human genetic materials was issued. Over 20 years ago, we have seen the courts continue to narrow the scope of biotech patents on human genetic materials.

V. Patentability of Human Genetic Material Under International Law

This chapter will analyze the legislation and recommendations adopted internationally on the patenting of human genetic material. At the international level, the most relevant texts are WTO's Agreement on the Trade Related Aspects of the Intellectual Property Rights (TRIPs)[83], and the Convention on Biological Diversity (CBD)[84] adopted within the framework of the United Nations system, as well as the Universal Declaration on the Human Genome and Human Rights by UNESCO.[85] At the regional level, Directive 98/44 on the legal protection of biotechnological inventions, adopted by the European Union, is the only international instrument expressly regulating human genome patenting.[86]

i. The World Intellectual Property Organization and the World Trade Organization

The World Intellectual Property Organization (WIPO) is the specialized United Nation agency responsible for the promotion of intellectual property worldwide. It administers 20 conventions and treaties in the field of intellectual property. Four key conventions concern patents: the 1883 Paris Convention[87] for the protection of intellectual property;

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[83] *WTO's Agreement on the Trade Related Aspects of the Intellectual Property Rights*, WTO, April 15 1994, online: WTO <http://www.wto.org/English/tratop_e/trips_agmo_e.htm.>

[84] Convention on Biological Diversity, U.N.T.S., June 5 1992, online:<www.biodiv.org.>

[85] *Universal Declaration on the Human Genome and Human Rights*, U.NT.S., September 9 1998, online: United Nations Education, Scientific and Cultural Organization< www.unesco.org.>

[86] Division of Human Science, Philosophy and the Ethics of Science and Technology of UNESCO, *Intellectual Property in the Field of the Human Genome,* SHS/HPE/2001/CONF-8-4/3, December 19, 2000, at 63.

[87] *Paris Convention For the Protection of Industrial Property,* World Intellectual Property Organization, March 20 1883, online: WIPO<www.wipo.int>

the Patent Cooperation Treaty [88]signed in Washington in 1970, 115 Member States by the end of 2001; the Strasbourg Convention [89]adopted in 24 March 1971, which established the international patent classification; and the Budapest Treaty [90]on the international recognition of the deposit of microorganisms for the purpose of patent procedure in 1977. In the past 30 years, with its unprecedented developments in the field of biotechnology, these treaties may be too old to answer the questions surrounding the patentability of human genetic material. The lack of protection and the acts of "bio-piracy" denounced by holders of biological and genetic material both seem to stem from inappropriate regulation. WIPO established its Global Intellectual Property Issues Division (GIPID) in 1997, to deal with the challenges facing the intellectual property system in a rapidly changing world.

The World Trade Organization (WTO) was established January 1, 1995, in Geneva. The organization was formed through a series of talks between major economic countries based on the Global Agreement on Tariffs and Trade (GATT).[91] The WTO provides a forum for negotiating trade agreements, handling trade disputes, and monitoring national trade policies.[92] The WTO appoints panels to assist in settling trade disputes and in reaching agreements amongst Member States. The WTO adopted the Trade Aspects of Intellectual Property Rights Agreements (TRIPs) in 1994. TRIPs

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[88] *Patent Cooperation Treaty, World Intellectual Property Organization*, June 19 1970, online: WIPO http://www.wipo.int.

[89] *Strasbourg Agreement Concerning the International Patent Classification*, World Intellectual Property Organization, March 24 1971, online: http:// www.wipo.int.

[90] *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, World Intellectual Property Organization, April 28 1977, online: http://www.wipo.int.

[91] *General Agreement on Tariffs and Trade*, October 30 1947, 58 U.N.T.S. 187, online: http://www.wto.org.

[92] See World Trade Organization, http://www.wto.org

provisions are directly complementary to the international treaties administered by the WIPO Secretariat. This Treaty is called the milestone of intellectual property because of its exceptionally broad scope. This system has been described by the United Nation Development Program (UNDP) as "introducing an enforceable global standard by linking intellectual property rights with trade, making them binding and enforceable through the WTO processes."[93]

The scope of patentability under the TRIPs is quite broad. The only inventions that can be excluded from patentability are those that are contrary to *ordre public* or to *morality*.[94] It does not exclude patentability of human genes, no more than it excludes biomedical technologies such as cloning. Furthermore, there are no waivers for chemicals or pharmaceutical products. This can have serious repercussions on the rights to health and the rights of indigenous people. So far, the national laws of many developing countries, such as China, Egypt or India have intentionally excluded drugs from product patent protection (allowing only process patents) to promote local manufacturing capacity for generic drugs and to make drugs available at lower prices. The move from process to product patents introduced under the TRIPs dramatically reduced the possibilities for local companies to produce cheaper versions of important life-saving drugs, such as those for cancer and HIV/AIDS.

The TRIPs has caused controversies and is being revised. While the United States of America has requested the elimination of waivers under article 27, developing countries

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[93] United Nations Development Program, *Human Development Report*, 2000, box 4.9. online: http://www.undp.org/ reports/global/2000/en/pdf.

[94] See art. 27 paragraph 2 of the TRIPs, which states: Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public or morality.*

are seeking a broadening of exemptions concerning the patentability of living organisms.[95]

ii. The Convention on Biological Diversity

The Convention on Biological Diversity (CBD) was adopted in 1992 in Rio de Janeiro and came into effect in 1993. The CBD has three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources.[96]

Developing countries feel that the CBD enhances their control over their genetic resources. Under the Convention, contracting parties have a sovereign right over their genetic resources, but should endeavor to facilitate access to those genetic resources.[97] The CBD states that where the genetic resources are the subject matter of patents, such access is to be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. However, contracting parties are obliged to ensure national patent rights are supportive and do not run counter to the objectives of the CBD.[98]

However, the CBD does not clearly identify its material application scope: it contains no specific reference to human genetic material, be it to include it or exclude it from its scope. Indications may be derived from the definitions given under Article 2:

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[95] UNESCO, supra note 86, at 73.
[96] H. Smith, "Challenge to the Biotechnology Directive," (March 2002) 24 European Intellectual Property Review (London: Sweet & Maxwell Ltd.) 150, at 153.
[97] Art. 3 and art. 15 of the CBD.
[98] Art.16 (2) and 16(5) acknowledged in recital 55 of the preamble of the CBD.

Genetic material: means any material of plant, animal, microbial or other origin containing functional units of heredity.

Biological resources: includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Genetic resources: means genetic material of actual or potential value.

The Convention does not seem to rule out the patentability of human living organisms, but its lack of specificity regarding the subject matter protected by intellectual property rights, and its scope does not contribute to defining the perimeter of patentability protected under the Convention. It should also be noticed that the CBD does not establish whether genetic resources, including the human genome, can be subject to rights of ownership. The CBD explicitly rejected the common heritage approach. It favored the prerogative of individual, sovereign states. This offers a form of protection for developing countries, but the legal status of human genetic resources remains undefined. It clarified however in 1995 that "human" genetic resources were not covered by the CBD.

In addition, under the Convention, individuals are dependent upon policy decisions made by their states. Companies using intellectual property rights to gain control over genetic resources such as sequences of human genome DNA would not be going against any legal obligation arising from the CBD if the state where said resources were located agreed to this and it was in agreement with international law (TRIPs, etc).

Thus, the only rights actually mentioned and acknowledged are intellectual property rights, which are to be provided with 'adequate and effective protection'.[99] Although the rule seems to provide for access to resources and the sharing of knowledge, with intellectual property rights presented as an exception to this rule, (limited to those cases where patents have been granted), intellectual property increasingly covers everything related to plants, animals, and human beings. The exception shall no doubt soon become the rule.

iii. UNESCO and HUGO

UNESCO

In line with its Constitution, UNESCO has long been engaged in standard setting in its fields of competence, with the particular aim of maintaining, increasing and diffusing knowledge with regard to human rights and fundamental freedoms. UNESCO is one of the first international organizations to have attempted to frame bioethical principles for genetics. The Universal Declaration on the Human Genome and Human Rights of 1997 is a major achievement.

Since the initiation of the HGP, a group of scientists, ethics, attorneys and politicians approached UNESCO and proposed a new international statement to the HGP. In 1993, Mr. Mayor, the then Director-general of UNESCO, created the international Bioethics Committee (IBC) to be responsible of the preparation of an international instrument on

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[99] CEAS Consultants (Wye) Ltd Center for European Agricultural Studies, Geoff Tansey, and Queen Mary Intellectual Property Research Institute, "Study on the Relationship Between the Agreement on TRIPs and Biodiversity Related Issues." Online: http://europe.eu.int/comm/trade/pdf/ceas_final.pdf: Essentially, article 16 of the CBD preserves the entitlements of intellectual property owners as they are defined in international law, such as TRIPs.

the protection for the human genome. The IBC created a Legal Commission, chaired by His Excellency Mr. Hector Gros Espiell. At its eighth meeting (November 1996), the Legal Commission approved a Revised Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights. On November 1997, the General Conference of UNESCO adopted the Declaration. The following year, the Declaration was endorsed by the United Nations General Assembly and became the first international normative instrument specifically on the human genome research. China has actively supported and signed it.

The Declaration is composed of four major parts:

- Human dignity and the human genome;
- Principles for the human genome research;
- Solidarity and international cooperation;
- Promotion and implementation of the Declaration.

Article 1 states that the human genome is the 'heritage of humanity' in a "symbolic sense". The idea is to emphasize the fact that research on the human genome and the applications that may stem therefrom bring into play the responsibility of humanity as a whole in the interests of present and future generations. The expression 'common heritage of humanity' was subsequently changed to 'heritage of humanity', so as to avoid any interpretation which would consider that human genome as possibly open to collective appropriation, and a fortiori, to individual or private appropriation.[100]

[100] UNESCO, supra note 86, at 76.

This obviously leads to ruling out patentability of the human genome at the level of the species. Article 4 of the Declaration confirms this assertion, insofar as it states: "The human genome in its natural state shall not rise to financial gains."[101]

Yet, at the level of the genes of individuals, UNESCO, in accordance with its calling to further the sharing of knowledge, feels that the simple knowledge of human genes, or partial gene sequences, in their natural state, cannot be subject matter to patent, and that it must be freely accessible to all those involved in research worldwide. This does not rule out the fact that research results on individual genes may be covered by intellectual property rights.[102]

As to the scientific cooperation, article 18 suggests that States should attempt "to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research... particularly among industrialized and developing countries". In general, the Declaration is not a binding instrument, but to quote Mr. Mohammed Bedjaoui: [T]he formal adoption of a Declaration on the protection of the human genome can only be the starting point for an in-depth study, followed by effective practical measures worldwide to ensure that this heritage is respected in all circumstances and transmitted intact to future generations.[103]

HUGO

Even before UNESCO, the Human Genome Organization (HUGO) has been closely watching patenting developments in the area of genomics and has analyzed its possible impact specifically on further genome research. In 1997, after the decision of the

[101] Ibid., 76.
[102] Ibid., 76.
[103] Ibid., 77.

USPTO to grant patents on ESTs based on their utility as probes to identify specific DNA sequences, HUGO urged the USPTO "to rescind these decisions and, pending this, to strictly limit their claims to specified uses, since it would be untenable to make all subsequent innovation in which EST Sequences would be involved in one way or other dependent on such patents."[104] On April 2000, HUGO issued the Statement on Patenting of DNA sequences. In that statement HUGO emphasized that DNA molecules and their sequences, be they full-length, genomic or cDNA, ESTs, SNPs or even whole genomes of pathogenic organisms, if of unknown function or utility, in principle, should be viewed as part of pre-competitive information. According to HUGO, those ESTs without having found balanced solutions for the previous problem of arising dependencies should not be patented, and SNPs should also remain unpatentable.[105] Additionally, a mere DNA molecule and its sequence without indication of a function does not contain any technical information and cannot constitute an invention. Contrary to many critics of the E.U. Directive,[106] HUGO supports the Directive's regulation on such issues as patentable subject matter, specific patentability requirements, scope of protection and ethical aspects of patenting in the area of human genomics.

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[104] HUGO Intellectual Property Rights Committee, "*HUGO Statement on Patenting of DNA Sequences—In Particular Response to the European Biotechnology Directive*", April 2000, online: HUGO<http://www.hugo_international.org>

[105] The reason is that SNPs cannot be meet the requirement of inventiveness, also see HUGO statement on Patenting of DNA Sequences.

[106] For example, the Biotech Directive was unclear, in terms of when biotechnological inventions would be ineligible for patent protection on ethical grounds; and historically could be seen to allow patents to be obtained over isolated parts of the human body, which was offensive to human dignity from an ethical point of view. See D. Curley and A. Sharples, "Patenting Biotechnology in Europe: The Ethical Debate Moves on"(2002) 12, *European Intellectual Property Review* (London: Sweet & Maxwell Ltd.) 555, at 571.

On the specific procedure to patent biotech invention involving human genetic materials, the 2000 Statement on patenting of DNA sequences underscored that an unambiguous indication and enabling disclosure of the function must be provided when examining the requirement of industrial application of the claimed DNA molecules and their sequences; and the patent offices and courts should "rigorously examine the indication of functions or the function disclosed."[107]

Then in 2000, HUGO Ethics Committee published its Statement on Benefit-sharing. It considered that the field of human genetics goes beyond the individual, the family, or the population, a common shared interest in the genetic heritage of mankind. Therefore, "we all share a common genetic heritage".[108]

Although both UNESCO and HUGO have considered the human genome at the level of the species as the heritage of humanity, how our genetic heritage is to be protected is unclear. There is international consensus on the need to prohibit the more extreme possibilities of human genetics. [109]

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[107] See HUGO Statement on Patenting of DNA Sequences—In Particular Response to the European Biotechnology Directive, April 2000.

[108] HUGO Ethics Committee, "Statement on Benefit-Sharing", April 9 2000, online: HUGO<http://www.hugo_international.org/hugo/benefit.html.> This common heritage approach is also found in all of HUGO's Ethics Committee Statements since 1996.

[109] B. M. Knoppers, *Human Dignity and Genetic Heritage* (Ottawa: Law Reform Commission of Canada 1991), at 74.

vi. The European Patent Convention and The E.U. Directive

a. European Patent Convention

Patenting in Europe is governed by the European Patenting Convention (EPC) issued on October 5, 1973, also known as the Munich Convention of 1973. This Convention provides for a patent which is valid within 20 States (including 15 member States of E.U.) and requested by the applicant in accordance with a unique and centralized procedure which is carried out at the European Patent Office (EPO). In general, the patentability of human genetic material had never raised any controversies in EPO before the issue of patenting of ESTs. According to the article 52 of EPC, the invention to be patentable must, 1) be an invention; 2) be novel; 3) present an inventive activity; 4) have an industrial application. However, those inventions whose commercial exploitation could be "*contrary*" to morality or "*ordre-public*" can be opposed.

According to the EPC, there are product inventions; procedural inventions; and inventions for the use of a product and for the use of an apparatus to initiate a procedure. In these categories of inventions, product inventions have raised issues around the patenting of human genes in Europe. The patentability of procedures and methods is less criticized, such as--inventions for the use of a product or apparatus.[110] But this does not mean that any procedural inventions dealing with human genes can be patented. Rather, article 52(1) of EPC provides: "Methods of treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body shall

[110] J. C. Galloux, "The Patentability of The Human Genome: A European Perspective" in B.M. Knoppers, eds., *Human DNA: Law and Policy* (The Hague/London/Boston: Kluwer Law International) 361, at 363.

not be regarded as inventions which are susceptible to an industrial application within the meaning of (1)".

An invention may be carried out on living matter in European patent law. The EPC has no provisions excluding such objects from the scope of patentability. As to human genes themselves, in accordance with the article 52(2)a) of EPC, they are not patentable because discovery by definition is not invention. However, the gene sequences are regarded by the Opposition Division of the EPO as "a chemical substance carrying genetic information, which substance may serve as an intermediary in the production of proteins usable in the medical field".[111] Further, as concerns the patentability of genetic material "*per se*", one must patent not only the procedures for obtaining a product by means of a genetic engineering method, but also the initial product and the result achieved. That is, in so far as the product invention is concerned, one must have identified and isolated the human genetic sequences.

Additionally, article 56 of the EPC stipulates that "an invention is considered as having the attribute of an inventive activity if, for a person knowledgeable within the field, the invention does not obviously follow form the state of the art". Since the rapid development of knowledge and technique in the field of biotechnology, it is difficult to anticipate the practical criteria for inventive activity in the field of DNA sequences. It is likely that developments will be parallel to that within the field of chemistry.[112] For this reason, the difficult isolation of a gene, the fact that it codes for an "inventive" protein, the advantageous qualities which are as yet unknown or unanticipated when a gene is

[111] Ibid., 363.
[112] Ibid., 365.

inserted into a new organism: these are all means for determining an inventive activity. Inventive activity is often confused with novelty.

Industrial application is also an important factor for determining an invention under the EPC. Article 57 of the EPC provides that: "an invention is considered as having an industrial application when its object may be manufactured or used in a some field of industry, including agriculture." This provision poses certain problems in Europe. For example, as to DNA sequences, the use as such of an intermediary product in obtaining a final product fulfils the requirements for an industrial application. By contrast, the mere use of a research tool yielding the possibility of an industrial application does not appear to fulfill this condition. As a result, a claim applying for EST sequences without indication about the function of the corresponding genes would not be considered as having an industrial application. On the basis of the aforementioned objective conditions for patentability, as of 1998, the EPO has granted 300 patents on genes coding for human proteins out of 2,000 patent applications in biotechnology. [113]

The Diplomatic Conference of the Revision of the EPC on November 2000 did not address the patentability of biotechnological inventions. According to the States Parties to the Convention, and in view of the current EU Directive on Biotechnology, and the conformity of the EPC with its provisions, no further initiative is called for.

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[113]Greenpeace, "Facts about the European Patent Office" May 1999, online: Greenpeace: <www. greenpeace.org/reports>.

b. The European Biotechnology Directive

A draft European Directive was first presented by the Commission in 1988. In the 10 years following, the European Parliament and the European Union Council as well as the European Union Commission strived to harmonize this proposal for the Legal Protection of Biotechnological Inventions. On May 12, 1998, the European Parliament did vote in favour of the Directive for the Legal Protection of Biotechnological Inventions, which had been adopted by the EU Council of Ministers earlier in the year. The text was then formally accepted by the European Council, and published in the Official Journal of the Communities on July 30, 1998.

The Directive had immediate effect on the way in which existing law on the legal protection of biological invention was construed by the courts of the Member States. Under article 15 of the Directive, member States had until July 30, 2000 to bring their national patent law, regulations and administrative provisions into line with the Directive. Although the Directive has no legally binding effect on the European Patent Office, it was believed that the necessary amendments to, or an appropriate interpretation of, the EPC enables it to comply with the provisions of the Directive.

The Directive is divided into five chapters, with each chapter dealing with separate issues such as: Patentability; Scope of Protection; Compulsory Cross-Licensing; Deposit, Access and Re-deposit of Biological Material. Contrary to much comment in the press while the draft was going through the legislative process, the Directive did not make major changes to the law of patentability in biotechnology. The most significant feature of the Directive are the provisions pertaining to the patentability of biological

material, including inventions relating to plant and animal varieties, the human body and sequences or partial sequences of genes.

The Directive confirms that products consisting of, or containing, biological material and processes producing or processes using, biological material are patentable if they fulfill the requirements of novelty, inventive step and industrial application.[114] Also biological material isolated from a natural environment, or produced by a means of technical process, is patentable, even if it previously occurred in nature.[115] The human body, at various stages of its development, including germ cells, is not patentable. This includes a sequence or a partial sequence of a gene. An element isolated from the human body or otherwise produced by a technical process, including a sequence or partial sequence of a gene can be patentable, even if the structure of the sequence is identical to the natural occurring form. Industrial applicability of the claimed sequence must be disclosed in the patent application.[116]

Patentability

As set out in Article 2, the Directive is dealing with "biological material" in general, i.e. any material containing genetic information and capable of reproducing itself or of being reproduced in a biological system. As further stipulated in Article 3&2, even biological material which is isolated from its natural environment (and which is used for whatever purpose) may be regarded as a patentable invention under the Directive. Thus, the Directive placed emphasis on the distinction between discoveries and

[114] Art. 3(1) of the Directive/98/44/EC.
[115] Ibid., art. 3(2).
[116] Ibid., art. 5.

inventions.[117] The fact that the biological material already occurs in nature does not support the finding that it is allegedly a discovery. Further, the Directive relates to microbiological processes [118] i.e. any process involving or performed upon or resulting in microbiological material. Although the Directive contains no definition of a microbiological material, one may infer that smaller constituents of biological systems are contemplated, e.g. DNA, vectors, cells etc.

The human body and its elements

According to article 5, the human body and a simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. Thus, article 5 addresses two separate problems. Firstly, article 5 addresses the issue as to whether the human body as such may be the subject matter of a patent. The answer to this question is clearly no and as further stipulated in recital 20, any rights conferred by a patent do not extend to the human body and its elements in their natural environment.

As to DNA sequences, it was pointed out that a mere DNA sequence in the absence of any indication as to its function is not a patentable invention.[119] Moreover, the Directive explicitly requires that the industrial application of a sequence or a partial sequence of a gene[120] must be disclosed in the patent specification. As further elaborated in recital 24, whenever a sequence or partial sequence of a gene is used to

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[117] Such distinction provided by Directive has been criticized for it eliminates the distinction between discovery and invention in traditional patent law.
[118] Ibid., article 2, paragraph 1 (b)
[119] Ibid., recital 23.
[120] Ibid., article (3).

produce a protein or part of a protein, it is necessary to specify which protein or part of a protein is produced, or which function it performs.

The other issue pointed out in article 5(1), relates to the distinction between inventions and discoveries. Most importantly, article 5(2) of the Directive clarifies that an element which is isolated from a 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 (i.e. the sequence has not been made available to the public before the invention), even if the structure of that element is identical to that of a natural element.

Ethical Issues and Morality

The Directive pointed out that a patent does not authorize the patentee to implement the invention but merely entitles him to prohibit third parties from doing so. Thus, the purpose of patent law cannot be to impose restrictions or prohibitions, notably from the point of view of the requirements of public health, etc., or of compliance with certain ethical standards.[121] Article 6 of Directive stipulates that inventions shall be considered unpatentable if their commercial exploitation would be contrary to *ordre public* or *morality*. In this regard, the following examples are given:[122]

(a) Processes for cloning human beings,

(b) Processes for modifying the germ line genetic identity of human beings,

(c) Uses of human embryos for industrial or commercial purposes,

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[121] Ibid., recital 14.
[122] Ibid., article 6 (2).

(d) 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.

Recitals 37 to 42 further elaborate on any such inventions that are contrary to *ordre public* or *morality*. In this context it has to be noted that recital 42 clarifies that the exclusion which concerns the use of human embryos does not affect inventions for therapeutic or diagnostic purposes that are applied to the human embryo, and that may be useful in that respect.

Deposit, access and re-deposit of a biological material

Articles 13 and 14 of the Directive provide particulars on the depositing of biological material. Such regulations have become necessary since there is no law concerning the deposit of a biological material other than the EPC. The article 28 of the EPC, in its new version, takes account of the provisions of the Directive.

In short, a legal framework has been created by the EPC and Directive in Europe for applicants in the field of biotechnology. The Directive ensured that biotechnology patent law is both strong and consistent across Europe, so that European consumers and biotech companies are not disadvantaged with respect to their American and Japanese counterparts. However, the Directive has been much criticized after its entry into force by professional associations.

c. The Criticisms of the Directive

The E.U. Directive has been much criticized for it does open the door to the patenting of human genes. On October 19 1998, the Dutch government filed an opposition in the European Court of Justice to the Directive, requesting the annulment of the Directive under the Article 173 of the European Convention Treaty. The Dutch argued that it had the wrong legal basis, as well as failing to respect the principles of human rights and conflicting with international treaty obligations. This move was welcomed predominantly by the Greens, who remain opposed to the patenting of biological inventions and who were calling upon Belgium, Germany and Italy to join the action. On July 6, 2000, the Netherlands further launched an application for interim measures seeking the suspension of the Directive until the European Court of Justice had ruled on the action for annulment.

In addition, UNESCO gave the most controversial points on the Directive in its report of 2000.[123] They maintained that the distinction between discovery and invention in the Directive is blurred, and that article 5 (2) contradicts the principles of patent law. It also held that article 5(2) contradicts 5(1), since 5(2) considers genes to be inventions on the sole grounds that they have been isolated or produced using a technical process, while 5(1) stipulates "human body, at the various stages of its formation and development (...) cannot constitute patentable inventions."

The UNESCO held that the Directive eliminates the distinction between a product patent and a process patent. The Directive extends the effects of a process patent to a

[123] UNESCO, supra note 86, at 80.

product patent. It thus, confers to patents covering processes used to identify, purify, classify or reproduce outside the human body (§ 21, preamble) the effects of product patents. According to the Dutch, patents under the Directive not only cover the process by which genes are isolated and reproduced, but also the gene itself and all its possible uses: all in all they grant exclusive rights to produce, import and market the gene. Finally, UNESCO also criticized the adoption of an approach that human beings are reduced to an assembly of cells and DNA sequences. This commercial view of the human body and its elements being regarded as spare parts offends the dignity of human beings.

On the issue of disclosure of the industrial application of genes and the extension of protection conferred, article 5(3) requires that the industrial application of a sequence or a partial sequence of a gene be disclosed in the patent application. Requiring disclosure of this type is not the same as requiring a demonstration through experimental evidence.[124] In practice, function is simply deduced by companies on the basis of computerized comparisons, and industrial function is then concretely presented, whereas in actual fact it is only induced. By way of illustration, HGS patented the gene CCR5.[125] Years later, scientists discovered that this gene plays a crucial role in the intracellular penetration of the HIV virus. All therapeutic developments based on this gene will however be dependent on the HGS patent, as the company may oppose the use of the sequence, or require the payment of a fee.[126]

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[124] Ibid., at 80.
[125] HGS is Human Genome Science; CCR5 is a cell surface protein, now called an HIV co-receptor essential for viral entry into cells.
[126] Ibid., at 80.

Whatever the pros and cons of the E.U. Directive, most of the Member States have now grasped the nettle of implementation of the Directive, and are incorporating its provisions into national patent law. While in the regulation of the use of biotechnology, ethics and morality, are not a matter of primary concern within the patent system, the European Commission has learned, polices in this field need to be developed in a responsible way, in harmony with ethical values and societal goals. With these values and goals in mind, it is hoped that the debate in Europe can move on and the objectives of the European Commission for the life sciences and biotechnology sector fulfilled.

VI. Patentability of Human Genetic Material under Comparative Law

This sixth chapter focuses on outlining the legal framework in U.S.A., Europe and Canada, as well as China as concerns the patenting of biotech inventions derived from human sources. This section begins with the U.S. patent system. Chief Justice of the Supreme Court warren Earl Burger set the stage 20 years ago when he ruled "everything under the sun made by man"[127] was patentable, the patentability of living organisms has been non-stop. Companies and intellectual property lawyers have been trying to pin down just exactly under what circumstances they could obtain an unassailable patent on a biotech invention. Following a discussion of the American requirements for the patenting of genes, comes an examination of current European, Canadian and Chinese laws. A comparison will be made on the objective conditions for obtaining a patent among these different countries.

i. The United States of America

In the United States of America invention patentability is determined by the United States Patent and Trademark Office (USPTO), within the Department of Commerce, in accordance with relevant regulations. Patents are regulated by US Code Title 35, last amended in 1999 by the American Inventors Protection Act. America's legislation on patenting of biotechnology inventions is the most advanced in the world, and its biotech patent cases have also had a far-reaching influence on other jurisdictions.

The U.S. Patent Act, § 101 defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful

[127] See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 U.S.P.Q. 193 (1980)

improvements thereof."[128] Until quite recently, this Act was interpreted by the U.S. Courts as excluding living organisms such as plants or bacteria, as well as human genetic materials. For example, in the 1948 case of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,[129] the U.S. Supreme Court ruled that a patent could not be held on a mixed culture of bacterial used for inoculating plant roots. Even though the patentee had isolated the bacterial so that they could be more easily used in agriculture, he had not created any new bacteria. Since the bacteria were a "phenomenon of nature," "part of the storehouse of knowledge of all men," and not a new invention, they were not patentable.

This interpretation of the Patent Act changed dramatically in 1980 in the case of *Diamond v. Chakrabarty.*[130] This is a starting point for addressing the interface between biotechnology and patent law. In this case, the U.S. Supreme Court held that an oil-slick-swilling, man-made microorganism is patentable. A patent was issued on a genetically engineered living microorganism (it had naturally occurring bacterial plasmids introduced into it) that was designed to digest and break down crude oil. The patent was initially rejected by the patent examiner on the grounds that bacterial were products of nature and non-patentable. The Supreme Court, however, cited records accompanying the Patent Act of 1952 and said that "...Congress intended statutory subject matter to include anything under the sun that is made by man." According to the Court, judged in this light, *Chakrabarty's* microorganism could qualify for patent protection. Even though it had been derived in part from naturally occurring material,

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[128] 35 U.S.C. §101,1988.
[129] *Funk Brothers Seed Co. v. Kalo Inoculant CO.,* 333 U.S. 127, 1948.
[130] Supra note 127.

the crucial difference between *Funk Brothers* and *Chakrabarty* was that in the first case, the patentee had not altered the function of the bacteria, whereas in *Chakrabarty*, a new bacterium (and thus a new invention) had been created.

The impact of *Chakrabarty* has been profound, since it opened the doors to a flood of patent claims on plants, animals, and human genetic materials. 'Products of nature' are no longer barred from patenting so long as the item in question is new, useful, and non-obvious. For example, a human DNA sequence incorporated into a recombinant bacterial host cell could be the subject of patents, as neither the recombinant DNA nor the modified host cell occur in nature. It might even be possible to argue that purifying and identifying a certain DNA sequence allows for patent claims as the new recombinant DNA is an extract from DNA in its 'impure' form in the chromosomes.

In 1988, the Patent Office granted Harvard University a patent for a transgenic cancer mouse (U.S.4,736,866). This is the first patent on a living animal, also know as the Harvard Onco-Mouse. This announcement marked a turn point in the debate about the patenting of living organisms.

In 1997, the Clinton Administration announced that the PTO would begin allowing patents on ESTs based on their utility as probes. Yet, faced with the increasing contradictions between the patent law and the rapid development of biotechnology, on December 21, 1999, the USPTO published a revised set of guidelines for the written description requirement. Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. Section 112, 1, "Written Description" Requirement, 64 Fed. Reg. 71427, supersede the 1995 Utility Guidelines. Under the Revised Interim Guidelines, the emphasis is on whether the utility of an invention is credible, specific

and substantial. In addition, "throw-away" utilities, such as the use of a complex invention as landfill, have been distinguished as nonspecific and insubstantial utilities and therefore do not satisfy the utility requirement. Now, specificity and substantiality of an asserted utility have been incorporated into the utility analysis to address concerns regarding the patentability of ESTs.

Patentability

Under 35 U.S.C.101, an invention must be "useful" to be patentable. This is commonly referred to as the utility requirement in patent law. According to the Revised Interim Guidelines, to satisfy the utility requirement, the invention must have a specific and substantial utility that is credible. An application can comply with the utility requirement if the invention has any well-established utility. In addition, 35 U.S.C. 101 states that the specification should contain enough information to enable one to make and use the inventions. There is a close relationship between the utility requirement of section 101 and the enabling disclosure requirement of section 112. Indeed, in 1966, the Supreme Court defined the standard for utility as a "specific benefit in currently available form."[131] The Court of Appeals of the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals, have interpreted this as a minimal requirement of practical utility. All that is needed is some form of real-world value or practical utility.[132] Thus, nearly any use for an invention should satisfy section 101 as

[131] *Brenner v. Manson*, 383 U.S.519, 534-35, 148 U.S.P.Q. 689,685 (1966).
[132] *Nelson v. Bowler*, 626 F.2d 853,856,206 U.S.P.Q. 881,883 (C.C.P.A. 1980).

long as it is credible and does not violate a law of nature, such as the laws of thermodynamics.[133]

According to the Court, the essential criterion of novelty and non-obviousness establishing invention patentability is the proof of "human intervention" or "manufacture" (in section 101) on the matter to be patented, be it living or inanimate. The USPTO interpreted the Court ruling in *Diamond v. Chakrabarty* that the Court did not want to limit its ruling to genetically modified living organisms and opted for a very broad interpretation of the term 'manufacture'. The Court in *Diamond* defined a number of elements in order to test patentability under section 101:

- laws of natures, physical phenomena and abstract ideas are not patentable,
- compositions of manufactures which do not occur in nature, are the products of human ingenuity, and have a name, a character and specific use are patentable,
- the development of useable products using raw materials prepared in such a manner as to give them new shapes, qualities, properties or combinations, be it by hand, or by machines is a 'manufacture' under section 101.

[133] See, e.g. *Newman v. Quigg*, 877 F. 2d 1575, 1581,11 U.S.P.Q. 2d 1340, 1345 (Fed. Cir. 1989); see also, *Juicy Whip, Inc. v. Orange Band Inc.* et al, 185 F. 3d 1364 (Fed. Cir. 1999) (where an invention designed to deceive customers by imitating another product in order to increase sales satisfied the utility requirement).

As to human tissue and genes, the ruling handed down by the Patents Appeals Board on April 21 1987 (1077 OG 24) maintains that human beings cannot be patented under section 101, because such patenting would be unconstitutional. But, elements isolated from human bodies, including organs, genes, DNA sequences as well as other elements can be patented.

As to ESTs and SNPs, under the new Utility Examination Guideline of the USPTO, if an isolated DNA fragment has a credible, specific and substantial utility, the DNA fragment invention satisfies the requirement of utility and a patent can be granted for such a DNA fragment. Where a new use is discovered for the patented DNA fragment, that new use may qualify for its own process patent. Of course, the latter patent is a dependent patent of the DNA fragment patent.

The first EST patent issued by the USPTO was US Patent No. 5,817,479 which was issued to Incyte Pharmaceuticals, Inc.[134] This elicited q strong reaction on the part of a number of scientists, who criticized what they felt was the excessive ease with which the PTO granted patents, in this case on elements which could only be used as instrument. Many commentators stated that sufficient patentable utility had not been shown when the sole disclosed use of an EST was to identify other nucleic acids whose utility was not known, and the function of the corresponding gene was not known. Some commentators warned that such USPTO examination procedures would result in granting patents based on non-specific and insubstantial utilities, contrary to established case law, and so jeopardize the patenting of whole genes.

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[134] M. S. Tuscan and R. G. Adler, "Patenting of Expressed Sequence Tags in United States", (1999) 4 *Bio Science Law Review* (Oxford: Lawtext Publishing Ltd.) 175, at 178.

In general, the USPTO conferred very extensive protection on the patenting of genes, with exceptions granted only for ' laws of nature, physical phenomena or abstract ideas'. It should be noted that early U.S. patents on biotech inventions often included seemingly broad, "prophetic," claims. During the past ten years, however, the courts have gradually narrowed the scope of biotech patents. In *Amgen Inc v. Chugai Pharmaceutical Co. Ltd. and Genetics Institute*,[135] the ruling prevented a company from getting very broad-based claims on all DNA sequences that code for a protein or analogs of that protein. Nevertheless, we will see that the USPTO's policy is still more lenient with regard to the scope of patents and standards than other countries.

ii. Europe

In most European countries, although not all, patenting decisions are broadly governed by the provisions of the European Patent Convention (EPC). Decisions about patentability under the EPC are made by the European Patent Office (EPO). Since the EPC was written before the advent of the recombinant DNA technology in 1973, the EPO welcomed the reference point that the E.U. Directive provided by laying down clear set of rules in 1998. The European Patent Organization amended the Implementing Regulations of the EPC (which is an international Convention independent of the European Union) by introducing new rules, taking effect from September 1, 1999, to ensure that its interpretation is brought into line with the provisions of the Directive.

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[135] *Amgen Inc v. Chugai Pharmaceutical Co. Ltd. and Genetics Institute*, 927 F. 2d 1200, 18 U.S.P.Q. 2d 1016 (Fed. Cir. 1991).

In line with the American case of *Chakrabarty*, the EPO granted a patent for the first microorganism in 1981. Within the same year, the company HOECHST AG applied - presumably for the first time in Europe[136] - for a patent (EP0034306) containing a human gene.[137] The EPO conducted the same patentability analysis as for every patent application and granted the patent in 1987.

On July 14th 1989, the Examining Division of the EPO, rejected in the first instance the patenting of the Harvard Mouse. It invoked the principle that animal varieties could not be patented, by way of application of Article 53b of the EPC. The applicant filed an appeal. The Board of Appeal overturned the Decision of the Examining Division (OJ EPO 1992, 58) and returned the application for further prosecution with the finding that animals *per se* were not excluded from patentability by the EPC prohibition on the patenting of animal varieties. As a result of that reassessment, the Examining Division decided that the Harvard Mouse was patentable, at least partly on the basis that granting the patent would not offend against the ethical exclusion in Article 53(a) of the EPC.

Before the Directive, the existing legal framework did not allow the patentability of human genetic materials in the European Community countries. The Directive has dramatically changed that approach and has led to the granting of a number of patents on human genes. It ensures free circulation of patented biotechnological products harmonizing the national legal system of each Member State, thereby guaranteeing compliance with the EPC, the TRIPs and the Convention on Biological Diversity.

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[136] Christoph Then, "Gene, Monopole and Life Industry" (October 26 2002), online: Greenpeace http://<www.greanpeace.org.>

[137] It is Interferon.

Exceptions to Patentability

Generally, excluded from patentability are inventions that are contrary to law and *ordre public* or *morality* as well as processes for human cloning for reproductive purposes and for modifying the germ-line genetic identity of human beings, as well as the use of human embryos.[138]

According to Article 53(a) EPC, no European patents may be granted for inventions which are contrary to *"ordre public"* or *"morality"*. Even though the EPC deals with this Article in numerous cases, only the so-called PGS decision[139] contains a definition of the terms. Interestingly, the Directive addresses the question of *''ordre public"* and *"morality"* in article 6[140] and does provide a non-exhaustive list of the inventions that are excluded from patentability. It does not define the terms however, article 27(2) of TRIPS, on the other hand, explains in past which kind of prescriptions belong to *"ordre public"* and *"morality"*, including protection of life or health of humans, animals or plants or to avoid serious prejudice to the environment. In summary, article 53(a) EPC does not appear to be an extraordinarily restrictive patentability requirement.[141] Nevertheless, it is surprising that the EPO never considered it necessary to discuss ethical considerations comprehensively with regard to claims on human genes. Only the

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[138] See article 53 of the EPC and article 6 of the E.U. Directive.

[139] *T356/93 Plant Genetic Systems*, OJ EPO 1995, 545. It defined that inventions the exploitation of which is not conformity with the conventionally accepted standards of conduct pertaining to the culture inherent in European society and civilization are contrary to morality; the concept of the ordre public encompasses also the protection of the environment.

[140] See also article 23(d) of the Implementing Regulations to the EPC; By the way, the proposed Directive's initial version stumbled over the issue of ethics and morals linked to the patenting of human genes and human germ line therapy. In the final draft, the problem concerning patenting of human genes was transferred to the level of the distinction between a discovery and an invention.

[141] H. R. Jaenichen, *The European Patent Office's Case Law On the Patentability of Biotechnological Inventions* (Koln: C. Heymanns, 1997), at 135.

Relaxin decision[142] deals with this issue stating that patents for DNA sequences do not confer on their proprietor any rights whatever to individual human beings.

Furthermore, Article 54(4) states that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not patentable. Conversely, "this provision shall not apply to products, in particular substances or compositions, for use in any of these treatment."

Novelty

It is an established patent practice of the EPO[143] to recognize novelty for a natural substance which has been isolated for the first time and which had no previously recognized existence. Article 5(2) of the Directive confirms this novelty concept of the EPO by providing that "an isolated element 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." Moreover, as reflected in the Relaxin decision,[144] the claimed subject matter of a gene patent is often not genomic DNA but cDNA, a totally artificial construct which does not occur in the human body. This supports the admissibility of gene patents in consideration of the novelty requirement.

The question of the novelty of a partial sequence of a gene or a gene section including the partial sequence can be answered positively, since the partial sequence of the

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[142] *V08/94 Howard Florey Institute/ Relaxin*, OJ EPO 1995, 388.

[143] Part C, Chapter IV.2.3, Guidelines for Examination in the EPO; this novelty concept was already applied by the German Federal Patent Court in 1978. See Naturstoffe, *GRUR* 238 (1978); Menthonthiole, *GRUR* 702 (1978);

[144] Supra note 142.

invention had not been disclosed in its specific form.[145] Neither for that matter is a partial sequence of a gene novelty-destroying as against full-length gene sequences. In addition, even small differences within a DNA sequence are sufficient to confer novelty.[146] Therefore, it can be concluded that the EPO applies the continuously practiced "photographic novelty"[147] approach for DNA sequences as well.[148]

However, problems may arise from the wording of the claims. For example a claim of the type: "DNA, comprising the sequence...." may include sequence variations of the state of the art which could lead to an objection based on lack of novelty.[149] The EPO considers that a DNA claimed in this way cannot posses an unlimited length but a length which is still suitable for the desired purpose.[150] It goes without saying that an application which uses such a language in the claims has to sufficiently disclose its invention to enable necessary delimitations.

Inventive Step

The assessment of inventive step in the EPO is carried out mainly with the help of the so-called "technical problem-and-solution" approach.[151] According to this analysis,

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[145] Andreas Oser, *GRUR Int* 648 (1998)

[146] T886/91 Hepatitis B virus/ Biogen, not yet published in the OJ EPO; The Technical Board of Appeal of the EPO held that "the argument propounded by Appellant V that, in view of the particular nature of the field, small differences in a sequence are not sufficient to confer novelty cannot be accepted by the Board as it is well known that even a change in one amino acid can dramatically change the properties of a protein molecule."

[147] Photographic means "extremely realistic and detailed".

[148] The EPO has used this approach in T886/91 Hepatitis B virus/ Biogen; and in T296/93 HVB antigen production/ Biogen OJ EPO 627 (1995).

[149] Supra note 145; This problem could arise in connection with an EST and a corresponding full-length gene.

[150] EPO, USPTO and Japanese Patent Office. "Trilateral Project 24.1: Report on Comparative Study on Biotechnology Patent Practices", online: <http://www.european-patent-office.gov/tws/sr-3-bio.htm> (2001). To the same result occurs with recital 25 of the Directive 98/44/EC.

[151] The so-called "could-would" approach is another method used by the EPO to judge inventiveness. See T2/83 OJ EPO 265 (1984), T7/ 86 OJ EPO 381 (1988) etc.

inventiveness will heavily rely upon a technical effect that could not have been predicted from the closest prior art. The first granted gene patents were based on a cloning technique in which the protein was first identified, and the gene was found through tracking backward from the protein to identify the responsible gene. Even though the basic principle of the underlying cloning technique was in every gene patent the same, inventiveness was shown by providing technical differences[152] between the approach actually taken by the patentee and the methods disclosed in the prior art. Since genes can be isolated and sequenced routinely with high-speed techniques, the technical contribution to the state of the art depends (in the most cases) not anymore on how the expert could arrive at the claimed DNA, but rather what can be achieved by it. In contrast to sequence analysis, the task of identifying a function is a matter of tremendous complexity and requires specific experiments that are individually tailored to the particular gene.[153] It is usually not obvious to try the combined teaching of prior art documents with a reasonable expectation of success. Hence, the indication of a common function of the claimed DNA sequence is an essential criterion for inventiveness.

These new tendencies regarding patentability of gene sequences were also transposed into the Directive. Recital 23, which should be taken into account when interpreting the Articles of the Directive stipulates that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable

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[152] E.g special probes (length, mixture of oligonucleotides); different hybridization conditions; different mRNA isolation methods, technical differences to overcome difficulties in cloning the gene etc.

[153] These may range from searching for the intracellular location of the gene product, testing expressed proteins for a variety of potential enzymatic functions, attempting to construct knockout mice, attempting to identify human or animal disease states in which the gene is disrupted, or attempting to interfere with the function of the gene though antisense, ribozyme, dsRNA or related technologies. See HUGO Statement on the Patenting of DNA Sequences (1995)

invention. The function of a DNA sequence is in the articles of the Directive is dogmatically tied to the industrial applicability[154] and not to the inventive step. In any event, the relationship is particularly close, since as a rule the indication of the function or effect of the gene sequence can be used to derive the useful application and hence industrial use.

As regards the issue of the guidance provided by the Directive, the question remains whether a gene patent application requires the indication of the real biological function of the claimed gene. Finding the biological function of a gene which enables the commercial production of a therapeutic protein is an achievement that deserves legal protection. However, where no biological function in the body is known, a gene which confers a "normal" allele[155] for good health can mutate to cause disease. This allows its use as a diagnostic probe to accomplish a technical result. This is for example true for BRCA,[156] a gene with unknown biological function but usable in diagnostic kits to screen women susceptible of having breast cancer. However, this leads directly to issues surrounding the patenting of human genes. Is the ''usability'' of this gene enough to get a patent, in the absence of knowledge of what it does? The grant of the European Patent (EP 699754) on BRCA1[157] in January 2001 indicates that the EPO generally accepts patents which disclose genes that can be used as probes to diagnose specific diseases as long as there are no other reasons for rejection. DNA that is useful for diagnosis will enjoy (like every chemical compound product) patent protection. But

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[154] Art.5(3) with the support of Recital 24; Rule 23(3)(e) of Implementation Regulation to the EPC.
[155] B. Alberts, Molecular Biology of the Cell (New York: Garland Science, 2002), at 44. Allele means one of a set of alternative forms of a gene.
[156] Breast Cancer I.
[157] D. Bulter and S. Goodman, "French Researchers Take a Stand Against Cancer Gene Patent" *Nature* (September 2001) 95, at 96.

a subsequent discovery of the real biological function of the corresponding gene is again open to protection for useful applications.

Industrial Application and Utility

The European industrial application requirement as defined in Art (57) EPC can hardly be compared with its US counterpart--the requirement of utility under 35 USC §101. American patent law understands utility to mean usefulness. By way of contrast, Europe, the question whether something is usable involves - among other things - the idea of solving a technical problem, a concept that is decisive for the assessment of inventiveness.

Since 1998, however, the Directive makes it clear that the interpretation of industrial application should also be based on the idea of usefulness. Therefore, Art. 5(3) of the Directive attaches more importance to the industrial application requirement having as a result the gradual approximation towards the utility requirement in US practice.

ESTs(Expressed Sequence Tags)and SNPs(Single Nucleotide Polymorphisms)

ESTs

The Directive makes it clear that ESTs can constitute patentable subject matter by the introduction of explicit references in the Articles to "partial sequence of a gene". Also addressing EST sequences is Art. 5(3) of the Directive which requires the disclosure of an industrial application. In cases where the sequence or partial sequence is used to produce a protein or part of it, the specification of protein structure or the function it

performs is required in order to comply with the industrial application criterion.[158] Presumably the word "used" is directed to the use which confers industrial applicability. Thus, the wording of the Directive leaves open the possibility that, when the use which confers industrial applicability is not the production of a protein or part of a protein, specification of a protein structure or the function it performs is not necessary.

Thus, it seems that the Directive does not exclude a DNA sequence for which no biological function is given from being patented. Yet, Recital 23 of the Directive requires the indication of a function for a DNA sequence to be regarded as contributing to the state of the art.[159] Moreover, patenting of ESTs cannot be looked at in isolation from the patentability of full- length genes.[160] ESTs can have - like full-length genes - unexpected technical effects even though the structure or the function of the corresponding partial protein is unknown. It is for example imaginable that a certain EST can be used to diagnose a specific disease or that it can simplify the distinction of two cancers. Although no EST patents have been granted in Europe so far, it can be assumed that the EPO will accept such patents if they fulfill the rigorous requirements (especially with regard to industrial application and inventive step) of European patent law.

SNPs

In the future, knowledge of SNPs will alter all aspects of medicine. In contrast to ESTs which by their nature encode for partial proteins, SNPs are in regulatory regions, in

[158] Recital 24 of the Directive,
[159] See also Chapter Inventive Step.
[160] See also recital 22 of the Directive.

promoters,[161] rather than in coding regions of the genome. Thus, they can raise slightly different issues of patent law.[162] In any event, to be regarded as a patentable invention (besides all other patent law requirements), a SNP has to show a technical effect that could not have been obviously derived from the closest prior art.

It is unclear how many SNP applications have been filed, but hundreds are believed to be in the queue at the European patent office. Despite controversial, ongoing, public discussions, some of them may stand a good chance of being awarded patents.

iii. Canada

Canada takes an intermediate stance on the patentability of human genetic material. Neither human beings nor their organs are patentable, but products derived from the human body, including cell lines, genes, and DNA sequences are patentable. Biopharmaceutical products obtained via gene therapy are also patentable.

As a member of the WTO and WIPO, Canadian patent law is subject to the provisions of TRIPs and WIPO's patent law treaty. Canada is also less sensitive than the United States about prior publication and therefore the disclosure of partial sequences will not necessarily defeat all subsequent patent rights in genetic material and genetic related inventions. We have seen that the United States Supreme Court ruling that life forms are patentable, has fuelled the growth of the biotech industry.

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[161] Nucleotide sequence in DNA to which RNA polymerase binds to begin transcription. See Alberts, supra note 155, at 44.

[162] The British Group of AIPPI, "Patentability Requirements and Scope of Protection of ESTs, SNPs and Entire Genomes" (2000) 22 *European Intellectual Property Review* 39 (London: Sweet & Maxwell), at 42; For example a complex disease may arise from quantitative, rather than qualitative differences in gene products resulting from a SNP in a promoter region.

In Canada, there have only been a handful of judicial cases dealing with human genetic materials. The Canadian Patent Office has been far less willing to grant patents on life forms. Some Canadian industry representatives have stated that the patenting policies of other nations such as United States, Japan and Europe have more impact on Canadian industry than does Canada's own patenting policy, gives the relatively large size of those systems of its trading partners.[163] Therefore, Canada should work to harmonize patent law and patent procedures internationally so as to enable Canadian industry to take advantage of patents worldwide.

A Canadian patent can only be granted under the Patent Act. It can be obtained for *a product* covering genes and genetic materials, *a process* covering processes of manufacturing having little connection to genetic materials or *a method* covering the use of particular products for particular purposes.

Under the section 2 of Canada's Patent Act, "invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter." A patentable invention must be novel and useful. With regard to living matter, section 12.03.01 of the Manual of Patent Office Practice (MOPOP) provides that inventions for new microbial life forms such as bacteria, yeast, moulds, fungi, actinomycetes, algae, cell lines, viruses and protozoa may be patentable.[164] Being patentable, such inventions must fully satisfy Section 34(1) and all other requirements of the Patent Act. Moreover,

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[163] Canadian Biotechnology Advisor Committee, Patenting of Higher Life Forms (Ottawa: Canadian Biotechnology Advisor Committee, June 2002), at 23.

[164] R. W. Marusyk and A. Athanassiadis, "Patenting of Human Genetic Sequences in Canada", in B.M.Knoppers, eds., *Human DNA: Law and Policy* (The Hague/London/Boston: Kluwer Law International 1997) 343, at 346.

the Canadian Patent Office has expanded the scope of unpatentable subject matter upon reflection of Canadian case law dealing with patentable subject matter. Their express position as stated in the MOPOP reflects the Canadian Patent Office's interpretation of the Patent Act and case law.[165] This position holds that: There is no outright prohibition under statute case law, or in the policy practice of the Canadian Patent Office that would restrict the patentability of human nucleotide sequences or suggesting that such sequences are improper subject matter. [166]

In the case of 'Harvard Mouse', the Commissioner of Patents rejected the patent application at the beginning. On August 3, 2000, the Federal Court of Appeal concluded that a patent ought to be granted on the Harvard mouse. The Court ruled that the wording of Canada's Patent Act, as it currently stands, permits the patentability of genetically altered non-human mammals for use in carcinogenicity studies. On October 2, 2000, the Attorney- General of Canada filed an application seeking leave to appeal the decision to the Supreme Court of Canada. On May 21, 2002, the Supreme Court held a hearing and finally allowed the appeal for the reason of that an animal (in particular mammal) could not be considered to be a "composition of matter" or "manufacture".[167] Higher life forms are still unpatentable in Canada. However, facing with the fact that states have worked diligently to harmonize their patent regime,[168] the Supreme Court of Canada's approach to this case sounds highly discordant note. The more similar Canadian laws and regulations are to those of its major trading partners,

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[165] Ibid., 345.
[166] Ibid., 346.
[167] *Harvard College v. Canada (Commissioner of Patents),* 2002 SCC 76.
[168] A patent for the Harvard Onco-mouse was issued in jurisdictions that cover USA, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and the United Kingdom. A similar patent has been issued in Japan and New Zealand.

the better the prospects of the biotechnology sector in the Canadian economy are believed to be.[169] Therefore, no matter what the Court decides, the Canadian government should consider whether further action is required.

iv. Patenting of Human Genes in China

Article 25 of the Chinese Patent Law (CPL) of 1985 bans the patentability of "medicines or substances derived from the chemical methods". Thus, "microorganisms and genetic substance inventions, bio-product inventions and gene therapy" are not patentable.

But, in 1993, China amended the CPL and deleted the above-mentioned provision and provided that "microorganisms and genetic substance inventions, bio-product inventions" can be patented. The protection on biotechnology inventions in China has basically kept abreast of developed countries.

In 1994, China signed the Patent Cooperation Treaty and became a member state of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in 1995. This led inventors in the field of biotechnology to obtain patents in China. China amended the CPL again on July 1st, 2001, which brought Chinese patent law closer to WTO requirements. While it did not give gene findings (such as ESTs) patent rights, it strengthened the patent rights and simplified the patent examination procedure, as well exerting an active influence over the protection of biotechnological patent.

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[169] Canadian Biotechnology Advisory Committee, supra note 163, at 25.

a. Examination standards for patent applications related to human genetic materials

At present, the CPO examines the application for biotechnology inventions involving human genetic material according to the following:

-The microorganisms and the genetic materials are considered as the subject matter of patentability.

Although there is no specific rule concerning the patenting of microorganisms under the CPL, Article 25 of the Implementing Regulations of CPL and sections 2 (10) of the Examination Guidelines hold that microorganisms are the subject matter of patentability. Microorganisms include actinomyces, bacterium, fungus and virus, as well as animal and plant cell systems, particles, protozoons and algae. Genetic materials, such as genes, DNA, RNA and chromosomes, can be patented like other chemical substances.

Yet, according to Article 25 of CPL, those microorganisms and genetic materials that exist in nature and are not produced by means of any technical processes cannot be patented. Additionally, the isolated or cultured microorganisms or genetic materials must be in accordance with another requirement—the person skilled in the art can repeatedly make and use them according to the specification. Otherwise, failure to satisfy the utility requirement means they are beyond the protection of patent law.

-Bio-products are patentable.

The amended CPL deleted the provision that "medicine and the substance derived from the chemical methods cannot be patented". Thus, bio-products that include vaccines,

antitoxic serums, toxoids and so on are patentable. Moreover, patent applications should be examined in accordance with the relevant standard of chemical substance and medicine set out in the CPL.

As to the new chemical substance obtained by means of microbiology, patent petition must be defined in molecular formulas or structures, the nucleotide sequence of DNA, or the functions and the parameters of the claimed invention; Furthermore, the patent specification must specifically disclose function and at least one production method.

-Methods for surgery, therapy and diagnosis (including stem cell therapy) are unpatentable.

Article 25 (3) of CPL provides that "methods for therapy and diagnosis" cannot be patented. However, the Guide of Examination provides for certain exceptions that are not be considered as methods of therapy and diagnosis. For example, some medicines and medical appliances used for therapy and diagnosis, and methods for determining physiological parameter, can obtain patent protection in China. In practice, the Chinese Patent Office (CPO) has already granted the patent to "methods for ultrasonic flaw detector of blood" in 1988.[170]

b. Utility and scope of the patents

Article 22 of the CPL provides that the invention must meet the criteria of "novelty, creativity and utility". This is essential and the purpose is to avoid granting patents to basic research. But, under the CPL, there is no strict demarcation line between

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[170] Zhang Qinggeng, "The Protection of Biotechnology in China". *Beijing University Law Journal.* (2000) 11, online: CHINAGENE<http://www.chinagenenet.com>

fundamental research and applied research. How to distinguish between the two forms of research is sometimes ambiguous in practice. Although the CPL clearly defines in article 22 that the utility means "can be manufactured, used and produce the active effects". How can we assess if "the active effect" is feasible and credible? No rules, articles or even policy suggestions are found in the current patent law of China.

The patent system is meant to promote technology and economic development. If we were eager to grant the patents to those inventions that fail to meet the criterion of industrial applicability (although it could promote some basic research, such as determining the sequence of gene), it would hinder the development of the biotechnology industry in the long run. However, if the government did not give the appropriate protection, it would render ineffective the exploitation of genetic resources, and so would not benefit the later stage of the development of industrialization of biotechnology.

Article 26 (4) of CPL regulates that "the written description should comply with the specification and describe the scope of patentability." In addition, article 56 provides that the scope of patentability on the invention and the utility model should comply with the written description. The specification and drawing can interpret the claimed patent right. So, the key to the examination of patent applications is to accurately control the scope of patentability on the claimed invention. Determining the scope of claim relates to not only the applicant or patentee's benefits, but also to the direction and the function of the whole patent system. In principle, in order to obtain a patent, only a technological process with complete disclosure, and its application can be fully supported by the specification. Other applications based on subjective assumptions or

on computer calculations and without the experimentation proof of its functions and utilities, will not be granted a patent.

In contrast to the broad patent scope of the U.S.A., China is extremely strict in its examination of gene patent applications. Regarding the patent application involving human genetic material in China, up to the end of 1999, the CPO had received 1,754 patent applications, of which 475 were Chinese applications, and 1,279 applications were foreign applications, coming mainly from the United States, Japan, Germany and Great Britain.[171] No patent has yet been approved. Only if the patent applications possess certain utilities or functions proven by the scientific experiments, will patents be granted.

c. Ownership of biotech patents in China and foreign cooperation

It is very important to determine who holds the ownership of patents derived from Chinese and foreign scientific cooperation in the field of biotechnology. In 1997, Chinese scholars begun to notice that foreign researchers making use of Chinese human genome diversity led to serious intellectual property losses for China.[172] The media reported it as ''[A]larm at foreign companies draining China's gene pool''.[173] These allegations triggered the emergence of Chinese genetic regulations in 1998.

On June 10, 1998, China promulgated the Interim Measure for the Administration of Human Genetic Resources. Article 2 defines human genetic resources as genetic

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[171] Chinese Intellectual Property Office, "Patent Statistics" (2003), online: http://www.sipo.gov.cn/

[172] E.g. Chinese geneticists at the November 1996 Chinese Academy of Sciences meeting at Beijing warned that China faces a gene drain and even foreign theft of Chinese genetic resources by foreigners who take advantage of incomplete Chinese regulations.

[173] See a report from U.S. Embassy Beijing, "Alarm at U.S. Companies Draining China's Gene Pool", (April 1997), online: http://www.usembassy-china.org.cn/English/sandt/generev.htm

material including human organs, tissues, cells, blood specimens, preparation of any types or recombinant DNA constructs, which contain human genes or gene products as well as the information related to such genetic material. Article 3 regulates that whoever is involved in such activities with respect to human genetic material in China must comply with this Measure. Moreover, the article provides that the Chinese research institution shall have priority of access to information about the human genetic resources within the territory of the China. The foreign collaborating institution or individual cannot apply for patent rights or disclose such information without permission. As to the patent rights in collaborative research between China and foreign institutions, article 19 (1) regulates that " a patent shall be jointly applied for by both parties and the consequent patent right shall be owned by both parties." Each party can implement such patents separately in his own country in accordance with the contract. Transfer of such a patent to a third party shall be carried out upon agreement of both parties, and the benefits obtained shall be shared according to their respective contribution. Therefore, in relation to ownership of patent in scientific cooperation between China and foreign countries, it should be noted that:

1) The Chinese institution has the ownership of genetic resources, no one can apply for the patent without its permission.
2) The patent shall be jointly applied for by both parties, and the patent rights shall be jointly shared by both parties.
3) Each party can implement such a patent in their own counties, but cannot transfer it to the third parties without authorization of the other party.

However, this Measure to determine the ownership of gene patents is in conflict with other Chinese law. The Chinese Contract Law (CCL) stipulates that: "unless otherwise agreed by the parties, the right to apply for patents on the invention/innovation resulting from a cooperative development belongs to the parties therein jointly".[174] The CCL is applicable to all contracts including contracts with foreign countries. Obviously, under the CCL, the ownership of patent can be autonomously determined by the interested persons. Only if the interested parties do not agree, would they jointly own the patent. Therefore, according to the CCL, there are three possibilities in practice: 1) the Chinese party owns the patent right; 2) the foreign party owns the patent right; or 3) both parties jointly own it. But under the Measure, there is only one possibility—"jointly own the patent".

It should be understood that China promulgated such special regulations on the intellectual property involving human genetic materials to prevent foreign companies from owning or controlling those genetic resources alone. However, there is a clear defect in the Measure since it excepts the Chinese party from owning the patent right alone.

[174] Article 340 of the Chinese Contract Law, 2001.

VII. A Comparative Study of American and Chinese Biotech Patents

In the past decade, the biotechnology invention patent protection system has been established in different jurisdictions. As the original and the biggest patent registration system for the patenting of genes, judicial practice in the USA undoubtedly has an important theoretical and practical value for others. This section compares the requirements for the patenting of human genetic materials in the USA and China.

i. The Utility Examination Guidelines of the USPTO

According to the 1995 version of the Utility Examination Guidelines, the USPTO uses a two-prong test to determine utility: whether the described utility is credible and specific to a particular purpose. USPTO has also published its new 'Utility Examination Guidelines' in 1999. The Utility Guidelines are applicable to all areas of technology. However, they are particularly relevant in areas of gene-related technologies. Under the new utility guidelines, USPTO moves to a three-prong test for utility: whether the utility of an invention is specific, credible and substantial. In addition, a well-established utility of the invention is always acceptable and easily recognized.

Specific utility

Specific utility means a utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a ''gene probe'' or ''chromosome marker'' would not be considered to be specific in the

absence of the disclosure of a specific DNA target. The use of a protein as an antigen is not a specific utility as essentially all proteins are antigens.

Substantial utility

Substantial utility means a utility that defines a ''real world'' use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a ''real world'' context of use are not substantial utilities. Both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a 'substantial utility' define a 'real world' context of use. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved; a method of treating an unspecified disease or condition; a method of assaying for or identifying a material that itself has no specific, substantial and credible utility; a method of making a material that itself has no specific, substantial and credible utility; and a claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility are not ''substantial utilities''.

Note that 'throw away' utilities do not meet the test for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a 'real world' context of use).[175]

The criterion of substantial utility did not exist in the 1995 version of the Utility Examination Guidelines. The purpose of adding the substantial utility in the new Guidelines is to eliminate ''throw away'' utility.

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[175] USPTO. "Revised Interim Utility Guidelines For Examination of Patent Applications Under 35 U.S.C. § 112 "Writing Description Requirement", 64 Fed. Reg. 71427 (December 21, 1999), online: USPTO<www. uspto.org/web/offices/>.

Credible utility

An assertion is credible unless

(a) the logic underlying the assertion is seriously flawed, or

(b) the facts on which the assertion is based are inconsistent with the logic underlying the assertion.

Credibility of a utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use according to the disclosure of the application and any other evidence of record claimed by the applicant. For example, a perpetual motion machine has no credible utility because no perpetual motion machines would be considered to be currently available.

Well-established utility

An invention has a well-established utility if a person skilled in the art would immediately appreciate why the invention is useful based on the characteristics of the invention and whether the utility is specific, substantial, and credible. ''Well-established utility'' does not encompass any 'throw away' utility that one can dream up for an invention or a non-specific utility that would apply to virtually every member of a general class of materials.

ii. A Comparison of the utility of DNA fragment inventions in the U.S.A. and China

In inventions involving DNA fragments, the utility of ESTs is a highly contentious issue. There is no doubt that an EST can be used to obtain the corresponding full-length

cDNA and the genomic sequence, and an EST can be used as a marker to map the chromosomal region of the gene.[176] But a potential use or a use for the purpose of experimental research is not a specific or substantial utility.

According to the new Utility Examination Guidelines, the view of USPTO now is that an EST whose use is disclosed simply as a 'gene probe' or ''chromosome marker'' would not be considered to have a specific utility. EST is a form of DNA fragment. It satisfies the requirement of utility if a credible, specific and substantial utility of the EST, for example use as a probe to diagnose a specific disease, is disclosed.

China

At present, there is no re-examination board decision or court decision relating to the utility of biotechnology inventions involving human genetic materials. There is no related provision on "utility" in the Examination Guidelines of the CPO. Currently, the CPO is instituting relevant Guidelines. The CPO should use the experiences of the USPTO for reference in the institution on utility of examination guidelines for gene-related inventions.

iii. The novelty of biotech inventions in U.S.A. and China

In the field of biotechnological inventions, the issue of novelty is often combined with the issue of subject matter. The ''Product of Nature'' doctrine creates an important restriction in biotechnology, because biotechnology products and processes may be derived from the duplication of compounds found in living organisms or produced by

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[176] Dr M. Grund and Dr V. Vossius, "Patentability of ESTs under the EPC"(1998) 3 *Bio Science Law Review* (Oxford: Lawtext Publishing) 106, at 109.

naturally occurring animals or plants.[177] If it is accepted that modified micro-organisms and isolated and purified DNA sequences are the result of human intervention and so are patentable subject-matter, naturally, they are ''new'' in the sense of having no previous existence in the state of the art.

The Novelty of DNA Fragment

As noted above, ESTs, SNPs and partial gene sequences, once isolated and characterized and made available to the public (in for example a publicly accessible database, whether or not one needs to pay for access) form a part of the state of the art, in the same way as any other chemical. ESTs, SNPs, partial gene sequences and full-length gene sequences are different chemicals. One chemical is not novelty-destroying as against a different chemical; in the same way, ESTs, SNPs, or partial gene sequences forming a part of the state of the art are not novelty-destroying as against full-length gene sequences. [178] Similarly, a full-length gene sequence is not novelty-destroying as against a section of it, if appropriately claimed.

In the ''Biotechnology Comparative Study on Biotechnology Patent Practices Comparative Study Report''[179] of 2001 by the USPTO, EPO and Japan Patent Office (JPO), there is a posited case. The prior art (X) is a structural gene encoding a functional polypeptide, the whole sequence of which is disclosed. The claimed invention (Y) is a partial DNA fragment of (X). Does the claimed invention (Y) have novelty over the prior art (X)?

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[177] Courtney J. Miller, "Patent Law and Human Genomics" (1997) 26 *The Capital University Law Review*(Oxford: Lawtext Publishing), at 911.
[178] The British Group of AIPPI, supra note 158,at 41.
[179] EPO, JPO, USPTO, supra note 150.

The answer is: an invention that relates to this partial sequence is regarded as being novel when it relates to a partial sequence while has not been disclosed in concrete terms in publicly known literature. [180] It resembles a selection invention. It seems that the DNA fragment is new based on the reason of selection invention. But the invention selecting a DNA fragment from a full-length gene sequence is not a selection invention. The DNA fragment is an isolated compound that is different from the full-length gene compound. Because the DNA fragment and the full-length gene are different compounds, the full-length gene sequence forming part of the state of the art is not novelty-destroying to the DNA fragment. If an invention of a DNA fragment isolated from a full-length gene sequence is considered a selection invention, the DNA fragment invention will become a dependent invention of the full-length gene invention. The DNA fragment invention is not a dependent invention of the full-length gene invention. The two inventions are independent.

China

At present, there is no re-examination board decision or court decision relating to the novelty of gene-related inventions. There is no related provision in the Examination Guidelines of the CPO. But then, as in other countries, if the subject matter issue of a DNA fragment, gene, transgenic plant or animal, and so on is solved subsequently, the novelty issue related is solved.

Moreover, in China, the exception to lack of novelty can be applied to inventions which are exhibited at an international exhibition sponsored or recognized by the Chinese

[180] Ibid., see chapter 2.2 of novelty.

Government, made public at a prescribed academic or technological meeting, and disclosed by any person without the consent of the applicant before the date of filing.[181] Compared with the exception to lack of novelty in US patent law, the scope of the exception to lack of novelty in Chinese patent law is very narrow. So it is more important to take equivalence into account to determine novelty of invention. Then, in order to reduce the possibility that the technical information disclosed by the applicant forms a part of the state of the art in favor of the inventive step in assessing the corresponding patent application, not only identical invention but also a substantially identical invention can be applied to the exception to lack of novelty.

iv. Inventive step of biotech inventions in U.S.A. and China

In Re Bell[182]

Early DNA patent cases focused on the obviousness of the method used to isolate the sequence rather than the obviousness of the sequence itself. *In Re Bell*, the Court of Appeals for the Federal Circuit (CAFC) focused on the structure of a DNA sequence rather than on the method used to obtain the sequence.

In Re Bell, the USPTO reasoned that once a portion of the amino acid sequence is known, the method for isolating DNA sequences encoding a given protein is obvious: simply prepare and utilize nucleotide probes based on the amino acid sequence to isolate the full-length DNA. Thus, the entire nucleotide sequence of the gene would be

[181] Article 24 (2) of the Chinese Patent Law.
[182] *In re Bell*, 991 F.2d 781 782, 26 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1993).

prima facie obvious when the amino acid sequence for that gene could be found in the prior art. The Court commented:

> " [I]t may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. However, because of the degeneracy (redundancy) of the genetic code, there is a vast number of nucleotide sequences that might code for a specific protein."

The Court cautioned that its view was 'not to say that a gene is never rendered obvious when the amino acid sequence of its coded protein is known' but that was not the situation in the case. The art in question suggested use of only a short probe and the applicants apparently had to choose a longer probe in order to obtain the gene in question and thus had taken a step contrary to the prior art teaching. Thus, what the applicants had done was not obvious.[183]

In Re Deuel[184]

In this case, the CAFC stated that the existence of art disclosing a protein and a technique that can be used to determine the DNA sequence coding for that protein does not make obvious the specific claimed DNA sequence coding for that protein. Due to the redundancy of the genetic code, the disclosure of a partial protein sequence does not suggest a particular DNA sequence coding for the protein. The fact that one can conceive a general process in advance for preparing an undefined compound does not mean that a claimed specific compound was precisely envisioned and therefore obvious. The CAFC did state however, that a different result might occur if the prior art

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[183] Iain C. Baillie, J. Richards and J. Gord, " Biotechnology and United States Patent Practice", (July 1996), online: Ladas & Parry <http://www.ladas.com/patents/Biotechnology/Biotechnology.USA.html>
[184] *In re Deuel*, 34 51F 3d 1552, 34 U.S.P.Q. 2d 1210 (Fed. Cir. 1995).

disclosed a small and simple protein so that all DNA coding for that protein would be obvious.[185]

The difference from the principle of assessing inventive step also exists in related comparative studies on biotechnology patents. For example, there is a posited case in the 'Biotechnology Comparative Study on Biotechnology Patent Practices Comparative Study Report' of 2001. The prior art (X) is a structural gene encoding a functional polypeptide, the whole sequence of which is disclosed. The claimed invention (Y) is a partial DNA fragment of X. Does the claimed invention (Y) have inventive step over the prior art (X)?

The USPTO suggests only an assessment of the entire state of the art as well as the information contained in the specification. It does not give an answer as to whether the claimed invention has inventive step or not, because the USPTO holds that patentability shall not be negated by the manner in which the invention was made. It is crucial whether there is a suggestion or incentive to create the claimed invention in the prior art.

China

As with utility and novelty, at present, there is no re-examination board decision or court decision relating to the inventive step of gene-related inventions. There is no related provision in the Examination Guidelines of the CPO.

In 1993, the inventive step criteria in a re-examination board decision of the CPO (No.327) were similar to the inventive step criteria of the Biotechnology Patent Protection Act of United States in 1995. In that decision, the board held that a new germ must be considered to assess the inventive step of a zymolysis process in which

[185] Supra note 181.

the specific germ is used. The new germ is one of the indispensable technical features of the invention. If the new germ is neglected, the process is a conventional technology in the field of microorganism zymolysis. However, because the claimed process includes the use of the new specific germ that is screened out by the inventor and the claimed process has an advantageous effect, the claimed process has an inventive step. In practice, the CPO will probably keep and continue to improve the principle that was established in that decision.

v. The enablement requirement of American patent law

Specification is the core of the patent application. The patent office requires that inventors must provide a high level disclosure to support the utility requirement of the claimed invention in order to enable any person skilled in the art to make and use it, in return for the grant of a limited term of commercial exclusivity. So, the purpose of a specification is to satisfy an important legal requirement. For this reason, the patent law of many countries regulates that specification must be fully, clearly and concisely explained in the claimed invention. This principle is also embodied in the article 29 of the TRIPs.

The 35 U.S.C. Section 112, 1 contains three requirements for patentability: 1) written description; 2) enablement or how to make and use the invention; 3) best mode. Interestingly, it is the issues surrounding "written description" and "enablement" that lie at the core of the landmark biotech patent cases in U.S.A. The inventor must describe the invention, teach how to make and how to use it, and provide the best

known way of practicing the invention. In other words, if a person skilled in the art makes and uses the claimed invention based on undue experimentation, the specification would not be considered as the enablement, since the Section 112 regulates that the claimed invention must enable a person skilled in the art to make and use the invention without undue experimentation as broadly as it is claimed. However, if the term of the specification is feasible, but still needs the necessary experimentation, such specification is also enabling.

Under Section 112, determining what is the necessary experimentation is important in practice. In *re Wands*,[186] the Court set forth a number of factors to be considered when determining whether the specification is sufficiently enabling:

1) the breadth of the claims;
2) the nature of the invention;
3) the state of the prior art;
4) the relative skill of those in the art;
5) the predictability or unpredictability of the art;
6) the amount of direction or guidance presented;
7) the presence or absence of working examples; and
8) the quantity of experimentation necessary.

In the early gene patent applications, these eight factors, to the extent, were ignored so that the scope of gene patent was broad. But today the court trends to narrow the scope of gene patents. Among these eight factors, the level of predictability in the art is the most important for determining whether a specification meets the enablement standard.

[186] *In re Wands*, 858 F.2d 731,737,8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988)

Unlike inventions in the areas of mechanical devices or electrical circuitry, those in the field of biotechnology are often considered as unpredictable because scientists cannot predict what kind of chemical or physical reaction a simple chemical change may result in. As a result, the requirement of predictability in the field of biotechnology is different from that in other scientific areas, and the biotechnology patent claims involving human genetic materials are more likely to be rejected or held invalid than that to inventions in other scientific disciplines.

vi. The enablement requirement under American cases

In general, US Courts have adopted a strict attitude towards the examination standard on biotechnology patent applications. The enablement of gene patents firstly appeared in the ruling of *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd* in 1991.[187] In this case, *Amgen* had sued *Chugai and Genetic Institute* for infringing a claim to a DNA sequence "consisting essentially of a DNA sequence encoding human erythropoietin (EPO)". But the Court judged that it was not enough to know how a compound of unknown structure (in this case, the EPO gene) might be isolated in order to claim the conception; instead, the invention must actually isolate that gene. The Court disagreed that the enablement of the plaintiff's right should have been expanded to all EPO analogues, because the specification only disclosed how to make "gene and a lot of unknown analogues", but not the "EPO analogues". This ruling is a restriction on those who attempt to obtain patent protection for all possible variations in a given DNA sequence. Therefore, even if the inventor could know all possible variations in a given

[187] *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd,* 927 F.2d 1200, 18 U.S.P.Q. 2d 1016 (Fed. Cir.1991)

DNA sequence, he still cannot assert the patent right to all analogues unless he could completely disclose the variations and consequences when encoding the DNA.

The USPTO takes a similar stance. The federal court has confirmed the aforementioned finding in the case of *In re Vaeck* in 1991.[188] In this case, the USPTO rejected the plaintiff's patent application for lacking of enablement. The claims covering gene expression in the broad genus of cyanobacteria were not enabled by a disclosure containing a working example of only a single species of cyanobacteria out of more than 150 different genera of cyanobacteria. The field was unpredictable and cyanobacteria had been poorly studied. It was unreasonable to claim the broad scope of protection because of the narrow disclosure. Therefore, the Federal Court pointed out that unpredictability must satisfy a high level of disclosure to support the enablement requirement. Later, the Court reaffirmed the same standard in other cases.[189]

Moreover, in *In re Wright,* the full-scale of the aforementioned eight factors was applied.[190] In that case, the court held that the plaintiff's right claim was too broad to cover all vaccines for AIDS viruses. In fact, no effective vaccines for AIDS virus were produced after the invention. Therefore, the court concluded it was inappropriate to grant a patent to such an invention without enablement.

To determine whether a patent with broad claims meets the enablement requirement or not, there are six factors that must be considered by US Courts:

1) The quality of required experimentation to obtain a patent: In *Enzo Biochem, Inc. v. Calgene, Inc.*,[191] the Federal Court affirmed the district court's finding that the claims

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[188] *In re Vaeck,* 947 F. 2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)
[189] See fox example, *In re Goodman*, 11 F.3d 1046, 1052, 29 U.S.P.Q. 2d 2010, 2015 (Fed. Cir.1993).
[190] *In re Wright,* 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993)
[191] *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 U.S.P.Q. 2d 1129 (Fed. Cir. 1999).

were invalid as not enabled because undue experimentation was necessary to practice anti-sense technology in cells other than *E. coli*, a prokaryotic organism. Successful anti-sense regulation of three genes in one prokaryote, *E. coli*, did not enable the broad scope of the claims. The inventor had attempted and failed to practice anti-sense technology in yeast or in *E.coli* using alternate genes. The specification could not enable the person skilled in the art to use this patent without undue experimentation. Therefore, such experimentation was not enablement under section 112 because it was only a form of creative experimentation.

2) Whether the unclear specification will cause the undue experimentation: In *Genentech v. Novo Nordisk*,[192] the plaintiff pointed out in the specification that the "human growth hormone (hGH) could be produced by the expression of cleavable fusion protein, and the conjugate protein enzyme was probably the cleavable carrier. Although the plaintiff described the cleavable fusion expression of making the hGH in theory in the specification, the plaintiff's patent specification did not contain sufficient details concerning the practice of the claimed method. It was the unclear specification that made a person skilled in the art fail to practice the claimed invention without undue experimentation.

3) Whether there is unpredictability in the art: *In re Goodman*,[193] the Court held that there was a great unpredictability in the expression of plant DNA recombinant. Goodman's own articles showed a need for extensive experimentation to practice the claimed method for just a few plants, not all plant cells as broadly claimed in the application. As a result, there was unpredictability in such a method for a person skilled

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[192] *Genentech v. Novo Nordisk* , 108 F.3d 1046, 29 U.S.P.Q. 2d 2010 (Fed. Cir. 1993).
[193] *In re Goodman*, 11 F.3d 1046, 1052, 29 U.S.P.Q. 2d 2010, 2015 (Fed. Cir. 1993).

in the art since he could not precisely provide the reasonable result and the variation to public when carrying out the claimed invention.

4) Whether the disclosure of a specification leaves a technical blank which the person skilled in the art will fail to fill up with his knowledge in carrying out the patent: In *Genetech.,* the plaintiff asserted that those skilled in the art of recombinant protein expression and purification would have been able to use the cleavable fusion expression to produce hGH without undue experimentation by using the teachings of the specification along with methods and tools well known in the art. However, the Court held that the mere theoretical interpretation did not meet the enablement disclosure requirement. Also the inventor must precisely describe in detail how to make hGH by using the cleavable fusion expression. The written description did not mean the invention was enablement. If those skilled in the art could not fill up the potential and undisclosed technical blank of the specification, it would not meet the requirement of section 112 §1.

5) Whether the scope of the claimed invention is too broad: In *Enzo Biochem, Inc. v. Calgene, Inc.*, the claims covered a broad range containing any genetic material organisms, capable of being expressed, such as bacteria, yeast, other cellular organisms and even virus. Although the specification provided the application of anti-sense technology in regulating three genes in the prokaryote *E.coli*, the Court pointed out the fact that despite limited disclosure, "the claims at issue are all extraordinary broad, encompassing an infinite number of cell types".[194] So, the Court excluded the idea of a mere germ from constituting enabling disclosure. Again, the broad scope was the reason that the court held the claimed invention invalid.

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[194] See supra note 191, at 14.

6) Whether there is a lack of successful case to practice the patent: The Courts did consider the real world value and practice of the patent both in *Genetech* and in *Enzo. Biochem.* In the former case, the plaintiff had not put his patent into practice until 5 years later following the approval of the patent; in the latter the plaintiff did not have a successful case at all because the inventor failed to use the anti-sense technology in practice.

As biotechnology advances, it has become increasingly routine to probe a cDNA library and clone a gene. As a result, there may be fewer decisions invalidating biotechnology patents under current patent law in the future. It may be possible that the written description requirement will be easier to satisfy in the future as the technology becomes better understood and hence the level of skill and knowledge of one skilled in the art at the time of filing is quite high. Under this circumstance, one should not rely too heavily on patent laws but rather be on the lookout for new case law.

vii. The inspiration for the Chinese biotech patent legislation

The concept of the patentability of human genetic material has been gradually accepted in China. However, this concept is not mentioned in the Chinese Revised Patent Law which only emphasizes the strengthening of patent protection. Chinese legislators have not made the relevant legislative changes. Neither have court decisions. Little research has been accomplished by the Chinese legal academic experts on the patentability of biotech inventions. So, using the US judicial experience and practice for reference is significant for Chinese biotech legislation.

Article 26 of the CPL and the article 18 of the Implementing Regulation of CPL regulate the principle of the specification. In China, ''complete disclosure'' is the essential requirement for the invention patent application. The standard of 'complete disclosure' means that the specification should contain a full, clear, and concise illustration, which would "enable a person skilled in the art to make and use the invention without undue experimentation as broadly as it is claimed." This is similar to the principle of ''best mode'' and ''practice mode'' under the US patent law for determining enablement.

To a certain extent, Chinese patent law has established gene patent protection in principle. In this case, the law should only provide some principles for the issue of the patentability of genes, and the detailed operating rules might be regulated in "Guideline for Examination of Patent Application, in which the article 26 of the CPL and the article 18 of Implementing Regulation could be embodied in the field of patentability of inventions involving human genetic material.[195] As to the detailed regulations, US related judicial experience is obviously valuable to China. In consideration of the public policy issue and conditions in China, the "balance of interests" principle also requires that the written description should strengthen the disclosure.

Since the first patent on EST in 1980, globally gene patent applications have been rising rapidly. Compared with patent applications of 1999, the growth rate was 6000%

[195] Article 26 of the CPL stipulates that the description shall set forth the invention or utility models in a manner sufficiently clear and complete; According to article 18 of the Implementing Regulation, the description shall include technical field, background art, contents of the invention, description of figures, and mode of carrying out the invention or utility model.

by the year to 2000 (up to 3,773,224 gene patent applications).[196] According to statistics of the Chinese Intellectual Property Office, it was estimated that globally, the USA owns 90% and Europe and Japan own 8% of total gene patent applications while other countries share the rest, which is only 2%.[197]

As a developing country, the China scientific and technological level limits patent applications involving human genetic material. They must be strictly examined in order to prevent the board claims from injuring the development of related industry. As one of three factors in the written description, the requirement of enablement should be strengthened. For example, the Japan patent law is very strict with regards to the scope of gene patents. The court interprets the patent application in a narrow sense, but the principle of equity of the injunction [198] in patent-infringement lawsuits is strictly limited in Japan. This policy gives Japan biotech industry a relatively large space when applying for patents. The Japan biotech industry stands in an advantaged position in the gene-war against its American opponent. Additionally, one of the purposes of the US Utility Examination Guideline is to raise the examination standard and apply a stricter approach to biotech patent applications.

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[196] Chinese Intellectual Property Office, supra note 167.
[197] Ibid.,
[198] See article 100 of the Japan Patent Law and the 35 U.S.C. 283, which regulate that the court having jurisdiction of cases may grant injunction in accordance with the principle of equity to prevent the violation of any right secured by patent.

Conclusion

The patent paradigm has been irrevocably placed upon inventions involving human genetic material. Developments in human genetics over the next 20 years and derivative disputes will continue to be played out within the patent regime. The patent debate is an evolutionary process in different stages of development in jurisdictions around the world.

The different cultural, moral and legal concepts governing each country causes different judicial solutions to the issue of the patentability on human genetic materials. While Canada struggles with the concept of the patentability of higher life forms, Europe remains focused on the basic propriety of patents, and the US is attempting to reconcile economic and industry realities within the confines of the traditional patent system. Developing countries have been trying to protect their rich genetic resources from the biopiracy actions of industrialized countries. Our discussion has illustrated how difficult it is to create legal principles of general application which not only retain the qualities of relevance and justice over time, but also harmonize rapid and often unpredictable technological changes in addition to unique moral and social challenges.

During the past 20 years, patent protection of biotechnology inventions has gradually developed and is regarded as the most appropriate way to protect genetic resources. Human genetic material has been categorized within pre-existing subject matter classes. DNA sequences are treated simply as any other complex chemical substance in both national and international patent offices. Patents have been issued over human genes,

human genetic material and other related inventions out of the Canada Patent Office, the European Patent Office and the U.S. Patent Office, often without any special consideration of their origin or social implications. Despite this seemingly established pro-patent practice in the courts and patent offices, the patentability of such invention involving human genetic material remains controversial.[199] Public policy arguments have not been successfully employed to prevent the patenting of human genetic material, but public concern over the ownership of human genetic material is real and is arguably justified.[200] Maybe this concern will influence any modification of the current patent system in the future.

In the patent law of most industrialized countries, the distinction between discovery and invention is gradually being eliminated. The examination standard, however, has been improved by courts and patent offices. As a sequel, the issue of the early so-called "submarine patent applications" has been effectively limited. Companies and patent lawyers cannot obtain the patent unless the claimed invention totally meets the requirement of the three principles of patent law.

Meanwhile, developing countries have adopted the least favorable approach to the patentability of human genetic materials because of the great economic gap between them and industrialized countries. China, India and other developing countries with rich human genetic resources worry about "biopiracy" from developed countries and that the economic discrepancy between both parties will lead to inequitable exploitation of

[199] Caulfield, supra note 71, at 146.
[200] Ibid., 147.

their genetic resources. They hope to adopt a form of protection which differs from the intellectual property right's system, in that it is less exclusive, the pattern of cooperation should be "benefit-sharing". Nevertheless, putting undue emphasis on the protection of genetic resources by maintaining either that "the human genome is the common heritage of humanity" or on "benefit-sharing", is not enough. Rather than emphasizing mere protection, developing countries should further their patent law, strengthen the examination standard and use the experience of industrialized countries as a reference to protect their own invention in the domain of patent law.

The above comparative analysis of the patentability of human genetic materials and the related judicial practice both in international and national jurisdiction leads to the conclusion that it is necessary and feasible for China to adopt legal patent protection for human genetic materials. On the one hand, the pressure of competition in biotechnology industry forces China to grant patents on human genetic material as soon as possible. If China insisted on retaining the old legal concept that human genetic material is not patentable, and does not regulate any practical examination guideline on it, Chinese biotechnology industry would face powerful challenges from their foreign counterparts in the immediate future.

On the other hand, the Chinese patent legislation, in principle, has already opened the door to the patenting on human genetic material. After the first amendment of the CPL in 1993, the chemical substance was formally taken into the patent scope. Genetic material, such as gene, DNA, RNA and chromosome, which belong to bio-chemical

substances, can be patented like other chemical substances. Moreover, in addition to provisions of the CPL related to microorganisms, American experience on the patenting of human genes should be referred to by the CPO. Some statutory provisions and case law must be considered when determining the patentability of a given "genetic invention."

The following are recommendations for Chinese legislation on the patentability of human genetic materials.

1. Some scholars suggest protecting the biotech invention by a special law that differs from patent law. But in practice, only the new plant variety is protected by the special law. Furthermore, some recent important statutes or case law on biotech inventions, both in America and in Europe, are still within the scope of patent law. In general, they adopt a way of combining promulgating the individual act and adjusting the requirement of examination standards to deal with the issue of the patentability of human genetic materials. Therefore, special type protection could be used in the scope of the patent law in China. In short, we advocate the return of patent protection to biotech inventions by way of special legal protection.
2. The distinction between discovery and invention should be reduced; the requirements of patentability on human genetic material should be improved; and the principle that "if patent applications related to human genetic materials meet the substantial requirement of patents, they can be granted the patent" should be established in Chinese patent law. The Chinese legislator could

consider human genetic material as an invention by referring to the regulations of the CPL with respect to microorganisms. In that case, provisions of the E.U Directive and U.S. patent law are also worth referring to.

3. In addition to the three criteria requirements of patent law, the CPO should emphasize the effect of gene function in creativity and be strict with the examination standard in utility. Only if the patent application possesses the certain utilities or functions proven by scientific experimentation, will they be regarded as patentable. In 2002, the United States Patent and Trademark Office (USPTO) issued guidelines on how it applies patent criteria to different types of inventions. These guidelines focus on some of subtle distinctions that the USPTO is called upon to make. Similar interpretative guidelines should be developed in China with the assistance of an expert panel, and the detailed operating rules may be stipulated in the guidelines. The guidelines should be updated on a regular basis and should provide direction to applicants and examiners, notably on:

    (a) the interpretation of the criteria for issuing a patent (i.e., breadth of claims, novelty, utility and non-obviousness) as they relate to biological inventions, and

    (b) the process to be followed by patent applicants and the benchmark time frames for each step, to the extent (if any) that these may differ from other patent applications.

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