A STUDY OF ISSUES RELATING TO THE PATENTABILITY OF BIOTECHNOLOGICAL SUBJECT MATTER

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EXECUTIVE SUMMARY

Biotechnology is an important area of research, development and commercial activity. The prospects for commercial development in this area are considerable especially considering that so many sectors of the economy are affected by it. *Chapter 1* of the Report provides an overview of this situation and discusses the fact that Canada is currently well positioned to be a leader in biotechnology. It goes on to suggest that the patent system which helped to fuel the growth of the field may not be the best means by which to sustain the growth. This is explained as being due to a number of fundamental aspects of biotechnological subject matter which make it different from all other fields of technology. Consequently, the Report queries whether the patent system is the appropriate vehicle for securing intellectual property rights. A summary of objectives for the Report is provided which serve to focus the scope of the Report to the issues of "invention", "non-obviousness" and "novelty" as they relate to the patentability of biotechnological subject matter.

In order to set the stage for subsequent discussion, in *Chapter 2* "biotechnology" is broken down into three basic categories of subject matter which are encompassed by the term. These are the bio-matter itself which includes parts of biotechnology; methods and processes for making bio-matter; and, the uses of bio-matter of biotechnology. The chapter provides a brief review of basic biology and genetics in respect of the broad divisions of biotechnology in order to assist the reader in understanding the nature of the subject matter which is at the heart of the issue of invention in biotechnology.

Chapter 3 of the Report provides a discussion of the "concept" of invention from a somewhat philosophical perspective with a view to considering whether the subject matter of biotechnology can, at any level, be considered an invention. The discussion provided in the chapter is based on the perceptions and perspectives of the author drawing on a background in the medical sciences and patent law to analyze the issue. A discussion in relation to creation and discovery as those concepts relate to invention is provided with a conclusion that invention is a sub-set or separate class which shares features of both creation and discovery. One of the key elements proposed as a distinguishing feature of invention over creations and discoveries is the element of utility or applicability. It is concluded that invention is very much a subjective assessment and that there is nothing unusual or different about the subject matter of biotechnology which would result in a finding that there could not be biotechnological invention.

A more pragmatic and substantive analysis of the question of invention in biotechnology is presented in *Chapter 4* where the Report provides discussion on the elements of patentable invention as this concept is understood in Canadian practice. An overview of the philosophical basis for the patent system is first provided with the preliminary recitation of the current definition of "invention" as found in the Canadian *Patent Act*. The Report then considers whether biotechnology subject matter fits within the scope of the legislative definition highlighting in particular, exceptions to proper subject matter including methods of medical treatment, human beings and higher life forms.

In respect of higher life forms, the enumerated categories contained in the *Patent Act* which describe the "proper subject matter" of statutory invention are discussed with particular attention to the terms "manufacture" and "composition of matter." In this part, discussion is provided with respect to the scope of patent protection which may be available in respect of biotechnological subject matter with an example of a higher life form highlighted. Related issues such as the problem of progeny are discussed with specific reference to the potential for infringement by progeny and the problems of infringement analysis under the doctrine of equivalents.

The Report then turns to the questions of statutory invention which necessarily flow once proper subject matter has been found. These questions are contained in the elements of "novelty", "utility" and "obviousness." Each of these elements is discussed briefly with an overview of the current Canadian position or standards in respect of their evaluation or assessment. The Report then examines whether biotechnological invention fits within those standards, with an emphasis on those aspects which are of particular concern in biotechnology. The Report concludes that there is nothing about biotechnology that requires a review of the standard of utility as applied in Canada. Further the Report concludes that the only unusual aspect of biotechnology in respect of analysis of the element of novelty is in respect of products of nature. Consequently, issues relating to the "product of nature" doctrine are discussed in greater detail.

Arising from the determination of non-obviousness, the chapter provides consideration of the "worth a try" doctrine and *desideratum* inventions are considered as they are stated to be intermingled with the analysis of the "worth a try" doctrine. Following this is a consideration of the "technicians skilled in the art." The discussion under this heading quickly focuses on the expertise of Examiners in the Patent Office as it is these individuals who are called upon daily to assess this element of the test for non-obviousness.

The Report concludes in this chapter that with respect to invention in biotechnology the "skilled technician" is likely to be a Ph.D. researcher and may more likely be a composite research team. This is a direct result of the complexity of the subject matter of biotechnology. The Report also concludes that the mere complexity of biotechnological subject matter should not be the basis upon which a change is sought or brought to the standard of non-obviousness.

Chapter 5 is the final chapter and it presents the recommendations of the Report. In this chapter the Report indicates that there are three outstanding issues which, arguably, are preventing Canada from being a world leader with respect to providing rights to innovators in biotechnology. Namely, the question of patentability of higher life forms; the patentability of products of nature; and the problems with progeny.

The Report recommends that higher life forms be patentable and recommends amendments to the *Patent Act*, in order to achieve this result. As a consequence of this recommendation, the Report provides a farmer's exemption with respect to the potential problems with progeny. Also introduced is a proposal to limit patentability of higher life forms to non-human subject matter.

The Report also recommends that the current Canadian standards applied in the assessment of novelty and non-obviousness are acceptable and need not be changed in order to accommodate biotechnological innovation.

Finally, the Report recommends that in order to further encourage the biotechnology industry in Canada, a separate piece of legislation should be enacted in order to encourage research and development with respect to "products of nature."

CHAPTER ONE
INTRODUCTION AND OVERVIEW

As the beginning of the next millennium approaches, Canada is uniquely positioned in the world to participate in the biotechnological revolution which has taken place over the last thirty years. Developments in biotechnology have effectively stolen the spotlight of technological advance from the industrial revolution which began this century. Although the proposal for DNA structure by Watson and Crick took place in the 1950's, modern day biotechnology really began in the early 1970's when techniques for transformation of *Escherichia coli*, cutting and joining DNA molecules, and monitoring the cutting and joining reactions, became possible. From this time forward it became possible to create recombinant DNA. With these techniques it became possible to cut a gene from the DNA of one organism, to recombine it in a test-tube with the DNA of a host organism, and to reintroduce it into a host.[1]

Canada is uniquely positioned to participate in the biotechnological revolution because its industries, particularly its resource industries such as agriculture, fisheries, and pulp and paper, offer enormous challenges and opportunities in connection with biotechnology.[2] The potential for economic growth and development in industries with applications in biotechnology, such as in the agricultural sector, is considerable:

> "It has been estimated that with hardier wheat varieties [grown in the Prairie provinces], there could be up to an eight-fold increase in the acreage of winter wheat planted. Winter wheat offers a number of advantages, related to soil conservation, as well as drought and salination problems, over spring wheat, which it would replace. The net incremental value to farmers of these advantages [brought about through genetic engineering of wheat for a hardier variety], assuming only a four-fold increase in the acreage of winter wheat, could be up to $50 million annually. The seed industry would also benefit by increased revenues of $1.5 to $2

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1 This is carried out by way of a vector (which is a DNA molecule that could be moved between cells and is functional in different cells - common types of vectors are plasmids (circular pieces of DNA often exchanged by bacteria - and viruses)). The recombinant gene, once in the cells of the host organism, if correctly transferred, conferred the gene's characteristic trait on the host organism. Indeed, Dr. Hebert Boyer, a research scientist at the University of California made critical contributions to this work and in 1976, with Robert Swanson founded a biotechnology company called Genentech. See R.W. Old and S.B. Primrose, "Principles of Gene Manipulation: An Introduction to Genetic Engineering" Fifth Ed. (Oxford: Blackwell Scientific Publications, 1994), Chapter 1.

2 National Biotechnology Advisory Committee, "National Biotechnology Business Strategy: Capturing Competitive Advantage for Canada, Fifth Report" (Ottawa: Industry, Science and Technology Canada, 1991) at 37-38; Science Council of Canada Summary of Report 38, Seeds of Renewal: Biotechnology and Canada's Resource Industries (Ottawa, 1985).

million annually. Another example is canola, a high-value ($1.5 billion) high-quality oilseed crop where a large research effort is underway."[3]

"Biotechnology" encompasses many disciplines and broadly speaking may be defined as the synergistic union of the biological life sciences and the technologically based industrial arts:

"Biotechnology is a blend of two basic concepts. The first is *Biology*, a very expansive field of study which encompasses all plants, animals, reptiles, amphibians (i.e., all complex, multi-organ, multi-cellular life-forms) as well as all organisms, microorganisms and unicellular entities, in other words, it is the science of life. The second is *Technology* and it can be defined as: "a practical or industrial art ... application of science"."[4]

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[3] National Biotechnology Advisory Committee, *Fifth Report: National Biotechnology Business Strategy: Capturing Competitive Advantage for Canada*, (Ottawa: Supply and Services, Canada, November 1991) (Chairperson: W.A. Cochrane), at page 34-35. As an agricultural example from the U.S.:

> "Gen Pharm International is a small biotechnology company located in Mountainview, California. Gen Pharm produced Herman, the world's first transgenic bull. This bull carries a gene for production in cow milk of human lactoferrin. Lactoferrin is an orally active protein produced naturally in human milk which has antibacterial iron transport and other important properties...The market for human lactoferrin, ...lies in providing protection to populations particularly at risk for bacterial infections of the gastrointestinal tract...The infant formula market alone totals $5 billion worldwide,..."
>
> [Seltzer, R. "First Transgenic Bull Sires Transgenic Calves" Chemical and Engineering News, February 14, 1994 at pg 30.]

The large research effort in respect of canola has recently yielded a variety with marked tolerance to commercial herbicides, see *infra*, note 14.

[4] J.R. Rudolph, "Regulation of the Products of Biotechnology Under the Canadian Environmental Protection Act: Any Impetus for Innovation?" (1993) 10 C.I.P.R. 317 at 318. Following are illustrations of other definitions given to biotechnology:

The Organization for Economic Cooperation and Development (OECD) has indicated that biotechnology includes:

> "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses"
>
> [taken from C.A. Franklin, "Modern Biotechnology: A review of Current Regulatory Status and Identification of Research and Regulatory Needs" (1988) 4 Toxicology and Industrial Health 91 at 91.]

and the National Research Council of Canada has defined it as:

> "The application of science and engineering to the direct use of cells from plants or animals, or micro-organisms, in their natural or modified forms, for the production of goods or the provision of services."
>
> [taken from M.A. Valiante and P.R. Muldoon "Biotechnology and the Environment: A Regulatory Proposal" (1985) 23 Osgoode Hall L.J. 359 at 364-365.]

The products of biotechnology include such things as living micro-organisms, cell cultures, and proteins such as t-PA or insulin, and as such, "...it has been with us since the first nameless biotechnologist discovered that fermentation did interesting things to grape juice."[5]

Investment in the promised "fruits" of biotechnology has been considerable. The kind of investment which has taken place in biotechnology has been, in fact, unprecedented, and arguably, so too has the rate of innovation.[6] There is little disagreement among experts and observers of the biotechnology industry that strong intellectual property rights in biotechnology are of critical importance to the continued growth of the industry. Arguably, significant investment to date in biotechnology has been attributable in large part to the patent system which first officially started to allow patents for living matter such as microorganisms in 1980, but for non-viable products, since the beginning of the modern biotechnology era (circa 1972):

> "Biotechnology is an evolving industry, particularly dependant on patent protection. Recent advances in the field have led to breakthrough technology (such as gene therapy) and raised expectations. Expectations fuel investment and increased innovation; precisely what the patent system is designed to encourage."[7]

However, the investment-return cycle of economy in biotechnology has been unprecedented, and, may ultimately be unsupportable. Indeed, in recent years there has been considerable reorganization within the industry as the smaller players drop out or merge with larger biotech firms who themselves are forming alliances with pharmaceutical firms.[8] Furthermore, it is not clear that patent rights will be adequate to maintain and foster continued growth in biotechnology. The production of many of the products of biotechnology rely, for the most part, on the use of what is now standard methodology. For example, it is a standard technique to splice the gene coding for a protein of interest into bacterial plasmid vectors for production of a recombinant protein.[9] Such standard methodology, which was new, unobvious and patentable twenty years ago, is no longer patentable today.[10] Notwithstanding the fact that jurisdictions such

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5 P. W. Grubb, "Patents in Biotechnology" Swiss Biotech v. 4: page 12 (1986) at 12.

6 R. Magnaval, "New Biotechnologies - A Financial Venture Without Industrial Strategy: Opinion" Industrial Biotechnology v. 8: page 34.

7 J. Cubert, "U.S. Patent Policy and Biotechnology: Growing Pains on the cutting Edge" (1995) JPTOS 77 at 174.

8 See *supra*, note 6.

9 See *supra*, note 7 at 158.

10 This situation is not unique to biotechnology insofar as all areas of technology advance such that what was unobvious early on in the development of the technology becomes obvious with time. The issue is whether this situation is uniquely detrimental to the biotechnology industry because so many of the products, or prospective products are, arguably, not novel, e.g.: recombinant versions of naturally occurring proteins. However, as discussed *infra*, under *Desideratum* Inventions (See Chapter 4) there is still room for invention given that in biotechnology

as the United States, Europe and Japan now allow patents to issue for almost any living entity, the rapid pace of development taking place in biotechnology appears to have created a perception that in Canada and the United States, the fast pace is exceeding the ability of the patent system to provide sufficient intellectual property rights.[11] The public perception in Canada is well illustrated by the comments of the Honourable Willard Estey who had the following to say as part of his "Opening Remarks" at Wilfred Laurier's Chancellor's Symposium on International Trade:

> "Canada won't allow us to patent that mouse...we need to bring our laws up to date to deal with the revolution in genetic engineering."[12]

Indeed, it is appropriate to raise the question of whether the patent system is the correct vehicle with which to confer intellectual property rights.

Some very basic characteristics of the subject matter of biotechnology set biotechnology apart from all other technology and thereby highlight this issue. The first is that unlike anything else, some of the subject matter is living. This issue has been acknowledged and considered in the Canadian Patent Office ("CIPO") and as a result patents are available in Canada for unicellular organisms. However, patents are not available for higher life forms. Higher life forms are those life forms which are multicellular complex entities whose identity is characterized and identified on the basis of the multicellular composite which makes up the organism. Are higher life forms not patentable because they can not be the subject of inventions? Or is it a moral/ethical issue?

A further feature of invention in biotechnology which distinguishes it from other fields of technology, and which flows from the fact that some of the subject matter is alive is the fact that living organisms are *self-replicating*.[13] This means that once biomatter is patented and one acquires certain types of this patented bio subject matter, mere ownership may result in the "reproduction" of the patented matter. Does this constitute an infringement under the current regime of the traditional making, selling, manufacturing of the invention, which are the sole rights of the

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what may appear to be standard and straightforward is not necessarily.

11 A.S. Viksnins, "*AmGen, Inc. v United States International Trade Commission*: Designer Jeans Don't Fit" (1991) 76 Minnesota Law Review 161; L. Maher, "The Patent Environment: Domestic and European Community Frameworks for Biotechnology" (1992) 33 Jurimetrics Journal 67; and J. Cubert, "U.S. Patent Policy and Biotechnology: Growing Pains on the cutting Edge" (1995) JPTOS 77.

12 Paraphrased from a speech delivered in Toronto on June 14, 1995. Similar comments can be found in learned papers on the subject of patents and biotechnology. For example, an article entitled "Limited Protection for Proteins" by C. Collard published in the special edition of the Canadian Intellectual Property Review (C.P.I.R.) on Biotechnology, at volume 10 No.1, page 25 states at page 32:

"The Canadian patent laws need to be updated to deal specifically with the unique problems encountered in biotechnology."

13 J.D. Morrow, "Application of Patent Law to Biotechnology Subject Matter" 6 C.I.P.R. 34 (1989).

inventor? The patent system, arguably isn't presently able to deal with this situation. How does one deal with a patented living organism which is bred by the purchaser? Can the purchaser breed the invention without infringing a patentee's rights?

A further difference arises from the fact that the subject matter of many products of biotechnology is incredibly complex, particularly where the subject-matter is a living organism. Indeed, because they have not been constructed by man, such subject matter truly is a "black box" and therefore virtually impossible to describe. Complete disclosure of an invention is a fundamental requirement in order to obtain patent protection. In all other technologies, every aspect of the elements of invention are known.[14] In jurisdictions which allow for the patenting of biotechnology a concession to this fundamental requirement is made, namely, allowing for the deposit of samples of the patented subject matter. Such deposits are part of the "complete description" of the invention and the deposit is said to "supplement" the complete description.[15]

A further feature of invention in biotechnology which distinguishes it from other fields of technology, and which flows from the fact that the subject matter is so complex, relates to the fundamental requirement that all patentable invention must be non-obvious. This assessment is made by a mythical "technician skilled in the art." Invention in biotechnology typically draws on a number of discrete fields of technology. This makes identification of the "skilled technician" challenging and leads to the concern that the "technician" may not be properly identified.

A further complicating factor peculiar to biotechnology, arises in respect of the fundamental requirement that all patentable invention must be new. This is a problem in biotechnology because the object of much effort in biotechnology industries is to produce synthetic versions of substances which exist in nature. If the substance exists in nature, arguably a synthetic version is not "new."

Such fundamental issues raise the following question:

If biotechnology industries are to continue to grow, do the means for acquisition, and the very nature of a bundle of patent rights for advances in the biotechnology field need to be redefined?

In providing an answer to this question it must be decided whether the patent system is the appropriate vehicle to provide rights to innovators in biotechnology. If the patent system is the correct vehicle, then it must be decided whether, and if so how much the present system needs to be adjusted to "fit" biotechnology. As already alluded to *supra*, it is clear that in view of the complexity of the subject matter of biotechnology, some modification of the patent system has already occurred in order to provide a "fit." If the patent system turns out to not be the right

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14 *Id.*

15 As discussed *infra*, this is currently the practice in Canada in respect of microorganisms, although it is about to change to official practice. (See Chapter 4, *infra*, under non-obviousness.)

system, then what are the alternatives? It is these issues which provided the impetus for the present report.

This Report works from the premise that biotechnology and the industries it has spawned are important to Canada. Further, in order for growth and prosperity to continue in biotechnology certain rights should be provided, and these are arguably best provided by the federal government. From this premise this Report considers key issues concerning the patentability of biotechnological invention and makes certain recommendations based on those considerations.

In particular, the present Report provides consideration, discussion and recommendations about whether the subject matter of biotechnology can be an invention for the purposes of granting a patent. In order to provide the reader with some perspective and understanding in order to appreciate the issues involved in this analysis, the Report begins by providing a background, or primer on the subject matter of biotechnology. For those who are acquainted with the basics of the technology this primer can be by-passed.

The report then examines the very essence of the concept of invention. This is a fundamental, conceptual, somewhat philosophical analysis which is provided in order to assist in appreciating the elements of invention.

With a conceptual framework in mind, the Report examines the statutory requirements for invention as found in the *Patent Act* of Canada. Issues challenging the analysis of, and, intimately intertwined with, the definition of invention, namely non-obviousness, novelty and utility, as they relate to biotechnology are discussed. Arising from this discussion the Report provides conclusions, and directions that should be taken by Industry Canada with respect to the definition of "invention" in the *Patent Act* and the standards of non-obviousness and novelty as they relate to biotechnology.

CHAPTER TWO
SUBJECT MATTER OF BIOTECHNOLOGY

In order to decide whether the subject matter of biotechnology is patentable, or at least susceptible to patent protection, it is essential to understand what it is that makes up the subject-matter of biotechnology.

> "Broadly defined, biotechnology may be considered as the production of useful products from living micro-organisms and cell cultures, and as such it has been with us since the first nameless biotechnologist discovered that fermentation did interesting things to grape juice."[16]

Notwithstanding this broad definition, today biotechnology is most closely identified with work involving changes to the genetic make-up of an organism, the so-called "genetic engineering". As a result of this engineering, new and improved drugs have been constructed. These include human insulin, interferons, vaccines, and treatments for a host of human afflictions such as septic shock, anemia, diabetes, AIDS, cancer, hepatitis, and heart attack. Biotechnology is also the area of human endeavour which has simultaneously produced controversy and modified higher life forms like the Harvard and Dupont mice, and, modified not so high life forms such as microorganisms for use in environmental areas such as oil spill cleanup technology.[17]

Clearly the term "biotechnology" covers many things, but broadly speaking (and from a patentability point of view) it can be said that in biotechnology, there are three types of subject matter and these are:

(1) the bio-matter itself which includes the products of biotechnology;
(2) the methods and processes of making the bio-matter and/or the products[18], and;
(3) the uses of the bio-matter or the products of biotechnology.

The following is a brief introduction to each of these types of biotechnology-related subject-matter and definitions of terms which are peculiar to biotechnology.

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16 P.W. Grubb, "Patents in Biotechnology" Swiss Biotech v. 4: page 12 (1986) at 12. See also, *supra*, Chapter 1, Note 4.

17 L. Maher, "The Patent Environment: Domestic and European Community Frameworks for Biotechnology" (1992) 33 Jurimetrics Journal 67 E.C. Biotech, Patent Framework; GATT At 68 and 69.

18 This includes products in the form of starting materials and intermediates used in the method(s) and/or process(es).

A. Bio-matter Itself

Bio-matter is a term broad enough in scope to capture all "products" related to biotechnology. Compounds and organisms *per se* are what constitute bio-matter. Within this category, there are two main groups of "products": living and non-living.

Non-living Bio-matter

Examples of this kind of bio-matter are, amino acids, peptides, proteins, fats and fatty acids, and nucleic acids. These kinds of compounds are better recognized when referred to by their more commonly known names of antibodies, hormones, enzymes, antibiotics, steroids, cholesterol, HLDL, VLDL, and DNA molecules. Although complex, they are all really just chemical compounds.

For example, amino acids are chemical compounds composed of carbon, nitrogen, hydrogen and oxygen in various combinations to give 20 naturally occurring amino acids. Amino acids combine together to form peptides and proteins. A peptide is a short string of amino acids typically fewer than 10. A chain of amino acids of a length greater than 10 or so amino acids is referred to as a protein. Because of the chemical and electrical properties of the constituent amino acids, proteins fold and bend into various conformations and are not found as straight chains of amino acids. All cells and viruses contain proteins so that no matter what definition of living systems is used, proteins are said to be ubiquitous. A protein is also referred to as a poly-peptide and there is no universally acceptable distinction between this term and the term protein.[19]

Fats and fatty acids are sub-classes of a general group known as lipids. They lack a common structural feature (the proteins of course having amino acids as their basic structural components). The most abundant naturally occurring lipids are the fatty acids, which, for example, are found in milk, waxes and various kinds of oils. Fats and fatty acids are typically found as significant components in the walls of cells.

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[19] Many biotech patents are directed to specific proteins and the DNA which codes for the protein, for example U.S. Patent No. 5,403,926 relates to an oncoprotein specific for hepatocellular carcinomas and a nucleotide sequence that codes for such a protein. The typical claiming language of such patents in respect of claims for the gene is "a pure [or substantially pure] nucleotide sequence comprising the nucleotide sequence substantially as shown in SEQ. ID NO.#". Given that the best way to identify a particular nucleotide sequence is to actually list it, a practice (which is an official requirement in many countries such as the U.S. - it will soon have official status here as well with the proclamation of Bill S-17. See Chapter 4 *infra*, Non-obviousness.) has arisen using sequence identification numbers ("SEQ. ID NO.). A variation on the "pure sequence" is "an isolated" sequence. This kind of language is used to deal with novelty objections. See Chapter 4, *infra*, "Products of Nature."

Nucleic acids are the basic building blocks of genetic materials.[20] There are two major types of nucleic acids namely DNA (deoxyribonucleic acid) and RNA (ribonucleic acid). DNA and RNA are both composed of a type of sugar known as a pentose, a molecule of phosphoric acid and nucleotides which are chemical compounds having a nitrogen-containing base. The pentose, which is ribose, is oxygenated in RNA while in DNA it is deoxygenated. DNA and RNA are also distinguished on the basis of the nucleotides which comprise these nucleic acids. There are four different nucleotides which serve as major components of DNA and these are known as cytosine, adenine, guanine and thymine, while RNA contains the same cytosine, adenine and guanine, but uracil as opposed to thymine. A base pair is the combination of any two of the four bases which are characteristic of DNA.

The ability of organisms to pass on traits from one generation to the next lies in the genetic information contained in the chromosomes. Chromosomes are made up of, *inter alia*, genes which in turn consist of DNA. It is the DNA that stores the complete genetic information required to specify the structure of all proteins of the organism and to determine the individuality of the organism. All of the genetic material which defines an organism is known as the genome of the organism. This genetic material is typically found in a differentiated organelle known as the nucleus of a cell, however, less sophisticated cells such as bacterial cells have their genome generally in the cytoplasm.

DNA is ultimately responsible for the synthesis of proteins but as already stated, DNA is contained in the nucleus. Most protein synthesis occurs in the body of the cell (the "cytoplasm") outside the nucleus but inside the cell wall of the cell. Messengers composed of RNA known as messenger RNA (mRNA) act as couriers between the DNA, where the message specifying the component to be constructed is received, and the sites of protein synthesis (usually on a ribosome), where the message is interpreted and the protein synthesized. The content of the message contained in the RNA directs the order in which amino acids are put together to create a protein.

The "message" of the RNA is a sequence of three nucleotides called a codon and one codon codes for one amino acid. It should be appreciated then, that the source for the message is the corresponding three nucleotides of the nuclear DNA. Since there are 64 possible codons and only 20 natural amino acids, most amino acids are specified by more than one codon. Degeneracy of the genetic code is where more than one codon specifies a particular amino acid. However, there are some amino acids which are coded for by only one codon. These codons are unique codons.

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[20] See generally: M. L. Gravelle "Biotechnology - An Overview", CIPR, Volume 10, 1993, pages 1-10 or for a more technical approach see for example, K. Drlica, "Understanding DNA and Gene Cloning: A Guide for the Curious" (John Wiley & Sons, Inc.: Toronto, 1992).

Enzymes are a type of protein which perform a specific function in terms of breaking down, or building other proteins and chemical compounds[21]. Typically, one can distinguish between the name of a non-enzymatic protein and the name of an enzyme by the suffix "ase". A peptidase is a protein which has enzymatic activity on peptides. Restriction enzymes are enzymes capable of severing bonds between bases in DNA and RNA at specific locations. These locations are "recognized" by the enzyme because of the chemical conformation of the constituents of the DNA and RNA. Restriction enzymes and ligases (joining enzymes) are very useful "tools" of recombinant DNA technology.[22]

What distinguishes these chemical compounds from the chemical compounds we think of when speaking to chemists, is that all of these chemical compounds are part of living entities. In the normal course, none of these "products" are considered to be "living" bio-matter. Most of biotechnology is currently directed at producing these non-living products.[23]

Somewhere between non-living and living matter are viruses. A virus is a tiny infective particle composed of protein and nucleic acids (the same kind of materials that DNA and RNA are made of). Outside of a living entity viruses do not demonstrate any of the qualities of living things, however, once in a living organism, viruses are able to move and invade cells, and take over the genetic manufacturing aspects of a cell and reproduce themselves. It is this ability to penetrate a cell and direct the genetic manufacturing that is at the heart of modern-day biotechnology. Consequently viruses are utilized and are referred to in recombinant DNA technology as vectors, i.e., a means by which a gene of interest is transported into the genome of the target organism.

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21 One of the earliest cases in Canada which was concerned with a biotech product is the case of *Continental Soya Co. Ltd. v. J.R. Short Milling Co. (Canada) Ltd.* (1942) 2 CPR (1) (S.C.C.) where it was held that claims to a specific enzyme found in soya bean flour were permissible.

22 It was Cohen and Boyer who obtained patents on the use of restriction enzymes to make recombinant DNA; and W.D. Noonan, "Patenting Medical and Surgical Procedures" Journal of the Patent and Trademark Office Society, vol 77 8: 651 at 657).

23 Biotechnology news items are typically concerned with this type of subject-matter. For example recent announcements of significance include the first cloning of the RNA component of telomerase, an enzyme which appears to play a role in stopping the molecular clock of aging by maintaining the length of telomeres (a component of genes) allowing cancer cells to proliferate indefinitely (Canadian Biotech News, Vol. 4, No. 36 at 3); the discovery of the "Bak" gene (Bcl-2-homologous antagonist/killer) which is believed to be a gene responsible for the control of the death of heart muscle cells during a heart attack (Canadian Biotech News, Vol. 4, No. 19 at 4); and the gene on Chromosome 1 which plays a key role in Alzheimer's disease (Canadian Biotech News, Vol. 4, No. 33 at 3), all of which are reported in learned scientific journals but which are also most likely the subject of patent applications.

Living Bio-matter

Beyond the structural non-living components of living organisms is the primary living entity called a cell. The smallest, wholly viable units of life are cells: They are also the smallest reproducible units of life, and it is this aspect of reproducibility which is completely unique to invention in biotechnology.

Cells come in all different shapes and sizes and have differing capacities for independent survival. Microbes, for example, are unicellular organisms capable of living in the environment. Indeed they are found in the environment and are often a part of inventions[24] which are maintained as biologically pure isolates from soil. On the other hand, human, animal or plant cell lines existing as individual cells isolated from the whole organism are completely dependent on laboratory generated medium and culture conditions for survival. Examples of classes of these cell lines are hybridomas, mutant cells, biologically pure cells, and transformed cells.

Microorganisms[25] are a large and diverse group of organisms consisting of only one cell or cell clusters of prokaryotic or eucaryotic cells. Examples of eukaryotic organisms are algae, fungi, molds and yeasts. An example of prokaryotes is bacteria. An important distinction between single cells or cell clusters which are microorganisms, and single cells or cell clusters which are not microorganisms, is that microbial cells are able to live alone in nature: single animal or plant cells or cell clusters are unable to exist by themselves in nature and can only be successful in either a specialized environment such as a culture system (typically created by man in the laboratory) or

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24 Certain groups of naturally occurring microbes can produce valuable antibiotics. Such cells are typically found after directed prospecting of soil samples. For example, in *Re: Bergy* the antibiotic lincomycin and the pure culture of the microorganism Streptomyces vellosus which produced it were the subjects of the invention. The cells were "found" after laborious sifting through soil samples in a tropical location (In *Re: Bergy*, 201 USPQ 352).

25 Arguably the most celebrated decision in the short history of patenting products of modern biotechnology, *Diamond v. Chakrabarty*, 206 USPQ 193 (1980), related to microorganisms. The application asserted 36 claims related to Chakrabarty's bacterium containing two stable energy-generating plasmids. Each of the plasmids was capable of providing a separate hydrocarbon degradative pathway. In essence, Chakrabarty had developed a genetically engineered bacterium which is capable of breaking down multiple components of crude oil. In the patent application Chakrabarty had three types of claims including process claims for the method of producing the bacteria, claims for an inoculum including the bacterium and claims to the bacterium themselves. The critical issue in the case was whether a claim to a bacteria was permissible under the *Patent Act* of the United States. The decision dramatically changed the direction of patent law in the United States by holding that such claims are permissible. Following on the heels of the Chakrabarty decision was a Canadian decision also in respect of a microorganism namely a microbial culture system composed of different forms of fungi (*Application of Abitibi Company* (1982) 62 CPR (2d) 81 (PAB)). Indeed, in this case the Chakrabarty decision was of persuasive value in allowing the Patent Appeal Board to find that yeast culture is proper subject matter for patent protection in Canada. The decision extended to all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics (at page 89 of the decision). Subsequent to this decision another application came before the Patent Appeal Board, namely, *Re: Application for Patent of Connaught Laboratories* (1982) 82 CPR (2d) 32 in which the Board allowed claims for bovine cells. Arguably this is the highest type of life form for which patent protection has been allowed in Canada.

as part of a multicellular organism such as a plant or animal.[26] The so-called "higher life forms" are complex multicellular organisms such as simple plants[27] or oysters[28], for example, which contain thousands or hundreds of thousands of cells. The human, which is a complex multicellular organism, has been estimated to contain at least 10^{14} cells.

B. Methods and Processes of Making Products of Biotechnology

The next aspect of this discussion of subject matter of biotechnology has to do with the methods of making products of biotechnology. This, of course, includes those processes for producing plants and animals which require significant technical intervention by man or are "a product of human ingenuity having a distinctive name, character and use."[29] It also includes methods and processes for the creation of products of cells such as hormones, enzymes and the like. The more commonly known types of processes which are included under the rubric of biotechnology are fermentation processes, chemical and diagnostic processes as well as methods of treating human or animal bodies and methods of controlling pests.[30]

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26 Thomas D. Brock and Michael T. Madigan, "Biology of Microorganisms", 5th Edition (Prentice Hall: Toronto, 1988).

27 Patents for plants are not available in Canada, however, they are available in the United States, even though two Acts specifically for plants and plant varieties (the Plant Patent Act 35 USC 161 and the Plant Varieties Protection Act 7 USC 2321). The landmark decision on this point is *Ex Parte Hibberd* 227 USPQ 443 (1985) where claims to a corn plant and its seeds were allowed.

28 Polyploid oysters are the subject of patent protection in the U.S. after the decision in *Ex Parte Allen* 2 USPQ (2d) 1425 (1987) where it was held that the issue of whether subject matter is living matter is not controlling on the question of whether the claims to the polyploid oysters are drawn to patentable subject matter.

29 *Diamond v. Chakrabarty*, supra, at 197. In *Pioneer Hi-Bred ltd. v. Commissioner of Patents*(1989), 25 C.P.R. (3d) 257 (S.C.C.) at 264-265 the Court discusses the likelihood of patentability for such inventions, although the Court does not rule on this point.

30 In Canada, connected with the question of methods of making products of biotechnology is the issue of old *Patent Act* versus new *Patent Act* cases. Prior to November 19, 1987 ("Old Act" cases), in the case of inventions which related to naturally occurring substances as prepared or produced by or significantly derived from microbiological processes and which inventions were intended for food or medicine, arguably, it was possible to obtain a claim for the resulting food or medicine itself. It is arguable because prior to 1987, only foods or medicines prepared by chemical processes were unpatentable subject matter. Thus, is a microbiological process a "chemical" process? In any event, after November 19, 1987 ("New Act" cases), for a food or medicine that was prepared or produced or significantly derived from a microbiological process, it was only possible to obtain a claim for that food or medicine when it was prepared or produced or significantly derived from the microbiological process of manufacture, where that process could be particularly described or claimed. This was by virtue of the wording of subsection 39(1). This subsection was abolished in 1991 by virtue of subsection 39(1.1). Consequently, for the period from November 19, 1987 to November 19, 1991, there was a bar with respect to the ability to obtain patents in respect of this kind of subject matter. However, in respect of the method of manufacture itself, i.e., by chemical or microbiological process there was, and is no bar in respect of this type of subject matter, assuming the more significant questions in respect of the patentability, eg. novelty and obviousness., were satisfied.

It is probably this area of the subject matter of biotechnology which has raised the greatest number of questions because the techniques which are available in modern day biotechnology provide the potential for creation of genetically altered biomatter itself. In the early to mid 1980's, researchers were altering mice, hamsters, rats, hogs, poultry, cattle, sheep and fish through genetic techniques creating transgenic animals. Understanding how to transfer genetic information from one organism to another allows for modification of the recipient organism to improve the characteristics of the recipient such that it may be used to perform particular functions, or, the mere transference of superior genetic qualities provides a better genetically altered organism.[31] The use of bacterial, yeast or sub-cultures as factories for the production of high quality pharmaceuticals such as human insulin, interferon, and growth hormones for use in the treatment of human disease is the best understood approach to altering a recipient organism to provide a means by which various gene products can be actively produced in significant quantities. These techniques are best known as recombinant DNA techniques:

> "A variety of techniques, mostly developed from early bacterial research, can now be used to insert genes from one animal to another. These techniques are known by a number of exotic names, such as micro-injection, cell fusion, electroporation, and transformation...
>
> The techniques for introducing a foreign gene into a bacterium and achieving normal expression and function [occurs through the use of]...bacterial enzymes, known as restriction enzymes [which] have the ability to recognize specific, short sequences of DNA (between 4 and 12 nucleotide base pairs in length) and cut the DNA molecule where these sites occur. Over 400 restriction enzymes are known, and are capable of cutting DNA molecules at over 100 different recognition sequences. Using these enzymes, it is possible to extract an entire gene that has been identified in the heredity material of an organism. These genes can be linked with the DNA carrier molecule called a vector which is then inserted into a bacterium...
>
> Inserting a gene from one animal into another animal is more complicated than insertion into bacteria and, at present, less precise. The cells of animals generally do not carry plasmids or DNA molecules which can be used to transport genetic material between different cells. To compensate for this lack of a convenient delivery vehicle, researchers inject highly purified copies of the gene of interest directly into the fertilized animal's egg shortly thereafter the fertilized egg is surgically implanted into the female's reproductive

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[31] For example, the gene for naturally occurring BtCryIA(B) an insect toxin, has been successfully transferred to corn which enables the plants to produce an insecticidal protein which is similar to the naturally occurring version (Canadian Biotech News, Vol. 4, No. 33 at page 4); and two strains of canola which were treated with genes extracted from yeast culture demonstrate a marked tolerance to certain popular commercial herbicides (Canadian Biotech News, Vol. 4, No. 29 at page 6).

tract. This injection process is quite delicate, and only a small fraction of the injected eggs survive. Even fewer express the inserted gene."[32]

The methods and processes of manufacture in biotechnology are distinguished from other fields of subject matter in that most of the actual process is carried out by something other than man. The "work" is done by a living organism, eg., a bacterial cell, or a biological compound, eg., an enzyme.[33] The method is really more of a recipe for success in preparation of the product. In many respects, this is very similar for processes of manufacture of chemicals. The inventor simply identifies the correct combination, sequence, conditions, etc., but the intrinsic properties of the chemicals are responsible for the product.

C. Methods of Use or Uses

Finally, there are inventions which deal with what is done with the products of biotechnology, which of course includes all bio-matter. In this respect, the only kinds of limitations on this subject matter, in some jurisdictions, have to do with whether a process or method involving the product of biotechnology, (or any other technology for that matter) involves treating a living

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[32] The report of the committee on Judiciary: Staff Report of the sub-committee on Courts, Civil Liberties and the Administration of Justice Accompanying the Transgenic Animal Patent Reform Act report 100-88 of the House of Representatives, 100th Congress 2nd session, dated August 26, 1988 in: "Animal patents: The legal, economic and social issues" Ed. William Lesser (MacMillan Publishers Limited: New York, 1989) pages 185-265 at pp. 207-209. The quoted text provides in very broad brush important features of recombinant DNA techniques. Perhaps the most reported application of genetic engineering techniques were those used by Philip Leder and Timothy Stewart at Harvard University to produce a transgenic mouse which was the subject of the first U.S. Patent covering non-human mammals. The "Harvard Mouse," also known as the "Oncomouse" was "created" by viral transfection of a mouse embryo where the virus contained the foreign DNA which was inserted into the mouse cell genome (see U.S. Patent 4,736,866). The number of articles and books devoted to providing detail in respect of the techniques of genetic engineering is legion. A very few examples, which are in no way recommendations, are: M.D. Trevan *et al.* "Biotechnology: The Biological Principals" (Taylor and Francis: New York, 1987); K.E. Davies "Genome Analysis: A Practical Approach" (IRL Press: Washington, 1988); K. Drlica "Understanding DNA and Gene Cloning: A Guide for the Curious" (John Wiley & Sons, Inc.: New York, 1992); H.R. Bungay and G. Belfort "Advanced Biochemical Engineering" (John Wiley & Sons: New York, 1987); R.W. Old and S.B. Primrose, "Principles of Gene Manipulation: An Introduction to Genetic Engineering: 5th Ed. (Blackwell Scientific Publications: Oxford, 1994); and V. Moses and R.E. Cape "Biotechnology: The Science and The Business" (Harwood Academic Publishers: New York, 1991). Also, an excellent overview may be found in the English Court of Appeal decision *Genentech Inc.'s Patent*, at pages 159 to 169 of R.P.C.[1989].

[33] For example, in U.S. Patent No. 5,411,732 which is entitled "Preparation of Fused Proteins, Antibodies and Processes Therefore", a process for preparing antibodies specific for an amino acid sequence is disclosed. The claims are directed to a process for preparing polyclonal antibodies and comprises the steps of immunizing a mammal with a fused protein comprising the particular amino acid sequence. Needless to say, the immune system of the mammal which is "immunized" is the element which produces the polyclonal antibody. A further step is the introduction of a cloned or synthetic DNA segment into a prokaryotic expression vector, however, this process also takes place by virtue of intrinsic properties of the DNA segment and the approach used to introduce the segment.

human being or animal by surgery or therapy. In such cases, "method" claims may not be allowed in some jurisdictions, including Canada.[34] However, in Canada, "methods of use" or "use" claims are now more commonly acceptable at the Canadian Patent Office if they are acceptably worded.[35]

These three aspects then, in very brief overview, are what biotechnology is, and what it is all about. Having provided a broad framework for understanding what biotechnology is, the concept of invention will next be examined.

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34 *Tennessee Eastman v. The Commissioner of Patents*, [1974] S.C.R. at 111. The patent laws of the European Patent Convention (EPC Article 52(4)), Japan and a number of other jurisdictions throughout the world refuse to allow patent protection for methods of medical treatment of the human body (W.D. Noonan, "Patenting Medical and Surgical Procedures" JPTOS, vol 77 no. 8 651 at 664 (1995)).

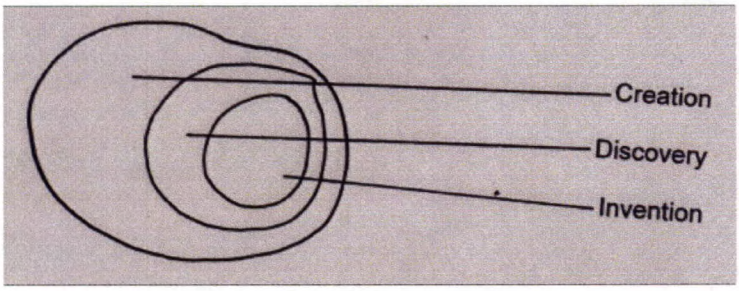
35 *Manual of Patent Office Procedure ("MOPOP")*. See also K.R. Britt, "Method of Use Claims in Biotechnology" (1993) 10 C.I.P.R. 101 as well as *Shell Oil Co. v. Commissioner of Patents*(1982), 67 C.P.R. (2d) 1 (S.C.C.) and *Re Application for Patent of Wayne State University* (1988), 22 C.P.R. (3d) 407 (PAB).

CHAPTER THREE
ON THE NATURE OF INVENTION

A. Introduction

The subject matter of biotechnology is complex. Many of the products and processes of biotechnology appear in nature, and so, with such origins those products and processes are somewhat familiar to most people notwithstanding their complexity. Indeed, it is the fact that the subject matter of biotechnology is derived from nature that one may question whether there can ever be invention in biotechnology. In other words, people can identify with mushrooms, and genetically altered tomatoes, or furry creatures like the Harvard Mouse. Such familiar subject matter compels the observer on the street to query whether one can "invent" something like a Harvard Mouse, let alone whether such things can be patented. In order to discuss this question in the context of patentable invention, this chapter briefly explores the concept of invention and through it an attempt is made to give the concept some definition and clarity. In this regard, three propositions are put forward and serve as focal points for understanding the concept.[36]

The first proposal put forward here is that invention can be distinguished from creation, and from discovery, although it shares features of both. Using a Venn diagram this can be illustrated as follows:



The second proposal is that discovery and invention are observer-centred realities and that this brings to the analysis a significant bias. This theme will be developed through the chapter and is highlighted in the sections titled: "Invention as a Result"; "Avenues to Invention"; and "Discovery and Invention."

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[36] This portion of the report is not intended to be a rigorous philosophical analysis of invention. Rather, it is intended simply to explore the concept with a view to raising issues and questions which are arguably important considerations in assessing the patentability of the subject matter of biotechnology.

Finally, the third proposal is that the sine qua non of invention is utility. As developed below, utility, which itself is observer-centred, is defined as having a purpose beyond the mere existence of the item under consideration. The basis for this proposition is presented below under the heading "Invention as a Result" and is elaborated upon throughout the remainder of the chapter.

The analysis is begun by providing a conceptual framework for invention which is developed through the next four sections. It is from this analysis that creation and discovery are subsequently distinguished.

B. Invention

Invention is a concept which is both active and static in that it is both a process and a result. In other words, it is quite correct to state that invention results in invention, or an inventor invents invention. As such, and broadly speaking, invention may be thought of as a process and a product, both of which are concerned with the same matter but which are separate and distinct.[37] Arguably, however, it is not until one has an invention that it can be stated that the process which resulted in the invention was in fact "invention." Following this argument to its conclusion, it is the "end

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[37] It has been suggested that part of the problem in the longstanding battle to understand this word "invention" has been related to the linguistic context in which the word is used:

> "We call an inventive manufacture an "invention," but in talking of a ripe apple we do not refer to a "ripeness," nor in talking of a resilient metal do we talk of a "resiliency" - we call it a "spring."
>
> Thus, it is that great confusion is caused not merely by the creation of a fictitious entity invention out of a Quality by a purely linguistic operation; but also by using the same word when referring to the Thing or Act (the manufacture) without which that quality could not otherwise exist. Using mathematical notation to illustrate [what we can refer to as a] process of linguistic evolution, we may write:
>
> (inventive)(manufacture) =manufacture + inventiveness
> =manufacture + invention
> =invention
>
> In all discussions of an "invention" in the past there has been no conscious distinction made between Things, Acts and Qualities. Until this distinction is realized, we can make no progress. Once the distinction is made, it is clear that we are fundamentally concerned with a Quality, the quality of inventiveness and that has nowhere been defined either in Statute Law or at Common Law. Nor is it capable of an acceptable definition because the quality of inventiveness is a man-made concept which has evolved purely as a useful and empirical expedient in industrial life."
>
> [E. Williamson, "The Linguistic Basis of Patent Law" (1943) 25 J.P.O.S. 852 at 869.]

These comments are equally applicable to the word and concept of "discovery" which, like "invention" also suffers in the English usage from being both a dynamic and a static: The scientist discovers a discovery.

product" therefore which facilitates recognition of the existence of invention.[38] Indeed, it was not until PROZAC™ was created and the experiments and clinical trials were complete that it was clear what the dimensions were of this pharmaceutical. In mechanical terms, it was not clear that the work of Alexander Graham Bell was inventive until it resulted in the production of the telephone; it was at that point that it became clear that something had been invented.

Yet, this discussion is merely "about" invention, it does not say what it is. It is something about penicillin and about the Harvard Mouse; it is something about a microbial culture system which Abitibi patented that **is** invention. But what? Maclean, J., speaking in the Exchequer Court said,[39] it is an "impalpable something."[40] This short answer implies that there is no short answer to this question because the determination of whether something is an invention is complex. The present discussion begins an exploration of the concept by first analyzing invention as a result followed by an analysis of the elements of the process of invention.

C. Invention as a Result

Invention can be defined as the identifiable result of an amalgam of mental and physical processes (which are discussed further, infra) of an inventor. How is the result which is an invention different from a result of the mental and physical processes of an artist or an author? It is proposed that an invention does not exist unless two fundamental requirements are fulfilled. These are: 1) that it be new and 2) that it has a purpose beyond the mere purpose of existence for

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38 Of course where the invention is a method or a use the "product" aspect of the invention is more readily captured in the concept of a "result" and consequently, when I use the word "product" it is my intent to include this understanding.

39 *Crosley Radio v. G.* 193 Ex. C.R. 190 at 197.

40 Examples of other views are: One neuroscientist, when asked what invention meant to him responded:

> "Anything which improves the quality of life."

A patent examiner explained that invention is:

> "...a creation from the mind,... which is tangible, and can be tested... that is new and useful,... and would not have been obvious."

While a medical doctor/research scientist said that invention is:

> "Something practical.., doing things in a different way... saving time, money or both...less sophisticated intellectual action than discovery."
> [Interviews with research scientists]

All of which points to a practicality or utility that does not exist in respect of discovery. Discovery becomes an invention when its utility becomes clear. An invention, on the other hand can never become a discovery, thus discovery always precedes invention.

the sake of existence. Inventions do something. They have some level of value. The concepts of purpose, "doing something", "having some level of value", are all ethnocentric value laden expressions and terms.

Invention reflects, or embodies, basic, background knowledge combined with some recognition and understanding of value, purpose or applicability of the subject matter. The purpose, value or applicability is defined here as utility. As just stated, the level of utility is merely that which is beyond existence for the sake of existence. To illustrate, a piece of stone exists. Where one is found on a road it has no (apparent) purpose beyond mere existence. If the stone is broken into two pieces, nothing has been invented for neither piece either separately or together has any value. However, for the person who first hits the stones together and noticed a spark, the creation of the spark itself is invention. At this level, the work of an artist to create a work of art which serves only to give pleasure to those who consider the work, can be considered invention. Such work can also be considered a creation. In such examples, invention and creation have identity. The further recognition that hitting the stones together next to a few twigs of wood so as to ignite the wood was an invention. Although is this invention, if it had already been known that striking two stones together created sparks, actually an invention? If this was known, then the hitting of the stones is merely repetition, not invention. Indeed, invention is very much an observer-centred concept and from an observer-centred perspective, the same invention may be made in different parts of the world at different times, and each will be an invention until the existence of a version of it is known by others, and even though conditions may exist to suggest that the invention is obvious, the creation of this obvious invention does not mean it is not an invention. It just means that it is an obvious invention. By this I mean, in its broadest sense, invention can be obvious and still be invention.[41]

Newness is a quality which is a fundamental requirement of invention. As discussed, when something is not new it is a repetition of that which already is known. However, that is not to say that every repetition of something which has been known is not itself new. It is just that it is known. What is known defines what is an invention and what is not. As such, the evaluation of invention is inescapably subjective.

Is it necessary for invention to be tangible? In its broadest sense, probably not. All inventions, as discussed *infra*, start as an idea, the "invention of the mind", and it is not until the idea is tried, based on the experience, understanding, knowledge, expectations, and belief of the inventor in the way something works or should work or could work, that the physical embodiment of the invention is made. In fact, the tangible "invention" is really only the physical expression of the intangible, always precedential, invention of the mind.

Notwithstanding this analysis, it is, strictly speaking, a "method" or "process" invention, *per se*, which can never be tangible; it is the physical elements which allow the process or method to be carried out.

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41 Clearly this is not the case in respect of patentable invention as will be seen in the discussion, *infra*.

In summary, does an invention exist if what is formulated has no utility? As outlined above, probably not. Without utility one has a discovery, or an idea or a creation. One does not have an invention. As discussed infra, at the heart of invention through the plotted course process is the search for something which has utility in the setting under consideration.

D. Invention as a Process

As the word "process" connotes, this is the dynamic aspect of invention and as with all processes it constitutes a continuum. As discussed, infra, broadly speaking, there are two avenues to invention, namely serendipity and the plotted course or "prospect" avenue. It is possible to take snapshot views of the process and define what appear to be constitutive elements. It is suggested here that regardless of the avenue there are at least three important elements to the "inventive" process. Inevitably there has to be a starting point in invention, and thus the first, and the necessary forerunner to the second element, is the facultative process. This is the process which moves to a focussed thought and thereby achieves the starting point for a second active process. This second "active" process merely relates to the physical, or actual carrying out of the steps or thoughts conceived in the first process. The third aspect which is superimposed on the active process may be thought of as a monitoring and integrating process. As the inventor carries out the steps which have been suggested by the facultative process information about the subject matter under consideration passes to the inventor through observation. This information is integrated with the beginning concepts, the form of integration ranging from refining the approach and expectations concerning the result to rejection as not relevant. This process is, of course, iterative, with the number of iterations dependant upon how well-formed the first thoughts are.

The facultative process[42] can range from a threshold thought or proposition (which is sufficient to initiate action in a directed manner), to a complete, defined theory. In the case of an invention arrived at through serendipity, the facultative process is closer to the complete and defined theory, the difference being that this complete and definite theory is arrived at by luck or circumstance rather than as a result of many iterative steps in the previously discussed process of invention. Regardless of whether it occurs at the threshold level or at the conclusion of much thinking and second and third step interaction to result in a complete defined theory, the result is

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[42] It is proposed that the facultative process is composed of elements which allow it to occur. These are elements which include the acquisition of basic, background knowledge which is combined with some recognition and/or integration along with understanding of the value of the subject matter.

Foundational knowledge is essential and it consists of the information about a particular discipline, and/or about all disciplines and areas of human endeavour. The broader the foundation, i.e., the more information from as many disciplines as possible, the more adept will the mind be at discovery, creation and/or invention. However, a computer can be provided with all knowledge known to humanity, but without the faculties of recognition and integration, the knowledge is meaningless. Recognition occurs at stages and to varying degrees. There is the mere understanding and recognition of the information itself. A next level is recognition of place, i.e., where the information belongs in relation to other information. A further level is recognition of relationships between information and integration as to the place where this belongs.

an "ah ha, that's it!" in the mind of the inventor - and so too for those who are informed of the concept, and this has been termed as the process of bisociation[43]

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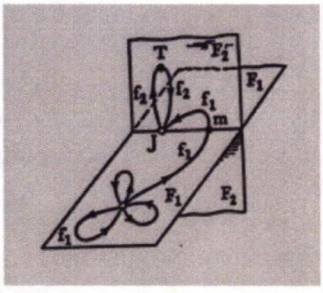
[43] The process of bisociation, as it has been described by Arthur Koestler in his book "Insight and Outlook: An Inquiry into the Common Foundations of Science, Art and Social Ethics" (The MacMillan Company: New York, 1949), is fundamental to the processes of discovery and invention and helps to understand where this "ah ha" originates. At the end of the bisociation process, once the junctional nexus has been created, there is a conceptual invention or discovery as the case may be. As already suggested, there may be a number of such junctional nexus along the path to a final invention. However, at each step, the process is similar.

The process of bisociation is the simultaneous connection of two association complexes which are suggested to be habitually incompatible. Koestler suggests that habitually incompatible does not mean logically incompatible, rather that the association of thought processes is regulated not by logic but by habits of thought acquired by past experience, i.e., the foundational knowledge. After a concept has become "bisociated" with two previously independent unassociated occurrences, these cease to be "independent". A given bisociate connection becomes, after a few repetitions, if not at once, transformed into an ordinary association and is incorporated into the realm of normal mental processes and concomitantly expands foundational knowledge.

The following, which is adapted from Koestler, and is found at 253-254 of his text, illustrates the principles of bisociation:

Figure 1



Referring to Figure 1, F1 is the original field of a problem for which a solution is sought. F2 is the field of habitual association of contexts of a different field of information. M stands for many missed opportunities for connecting the two fields on previous occasions; f2 is an actual thought train within the context of F2 and J is the junctional link which affects the bisociation of the two fields. The junction may be a verbal concept or it may equally be a visual percept or any similar link. The essential point is that at the critical moment both fields, F1 and F2 are simultaneously active in the inventor's mind though on different levels of consciousness. Although Koestler suggests two "fields", it is quite reasonable, and likely probable that a number, if not many fields may be operating simultaneously. The key is the bi, or tri or quadsociation at a junctional link which defines the invention in concept.

The following provides an excellent illustration of bisociation in which the result is, in the realm of the individual chimpanzee whom is the subject of the observations, an invention:

"[A young chimpanzee has not yet made the acquaintance of other animals but remains isolated in a cage.] A small stick is introduced into her cage; she scrapes the ground with it, pushes the banana skins together in a heap and then carelessly drops the stick at a distance of about 3/4s of a metre from the bars. Ten minutes later, food is placed

At the threshold level, the inventor recognizes that work in a certain area may provide a useful result and thinks to carry out work in that respect. Subsequent to this there is further, more focussed thought which brings about refined work in a particular arena. For example, there is no question that society wants to prevent cancer. Indeed, a method, product or process which achieves this result will be a great invention. However, one cannot set such broad objectives and simply expect to find such an invention. The process consists of many discoveries, insights, perceptions or small steps along the way: the recognition of the value and meaning of the genetic code; the role of vectors in transferring genetic information; the value of endonucleases; and so on (and of course all of the steps required to reach each of those stages), all of which, for example, brought us to the Leder patent which covers the Harvard Mouse (which itself is a step along the path to understanding and "curing" cancer), each step and practicality thereof being a discovery and/or invention itself.

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outside the cage beyond her reach. She grasps at it, vainly of course, and then begins the characteristic complaint of the chimpanzee .... thus, between lamentations and entreaties, some time passes until - about seven minutes after the fruit has been exhibited to her - she suddenly casts a look at the stick, ceases her moaning, seizes the stick, stretches it out of the cage, and succeeds, though somewhat clumsily, in drawing the bananas within arms length.....

It is obvious that [the young chimpanzee's] accomplishment was not obtained by the trial-and-error method, nor by conditionary reflex. For her behaviour, from the moment her eyes fell on the stick, was unwavering purposeful; she did not stumble on the solution by poking about aimlessly with the stick beyond the bars, but seized the stick, carried it to the bars, stretched it out of the cage, and placed it behind the banana.....

The process which led [the chimpanzee] to her discovery may be summed up as follows. The animal had acquired in her earlier experiences two independent patterns of behaviour. Behaviour within the framework of the first field F1 is exemplified in the various forms of straining to reach the banana. The second operative pattern F2 is the habit of scraping the ground with a stick and pushing things about with it. It should be noted that in this aimless occupation, the stick is not yet used as an "implement"; it is a playful exercise comparable to a kitten's playing with a ball of wool. To throw, push, or roll things about is a common animal pattern; a significant discovery of the chimpanzee is the use of the stick for a definite, useful purpose. It becomes an "implement" or "tool" precisely when it is for the first time used to serve as a means towards a given end.

The bisociative act occurred at the moment [the chimpanzee's] eyes fell on the stick while her mind was set on the banana.... The junction, "stick" may have given as a visual, or occulo motor or kinaesthetic experience linking the two fields together. We also find, again, the factor of a blockage of F1 [the banana being out of reach]; the creative stress resulting from it, expressed in disoriented behaviour (howling and lamenting); and the trigger action of apparent chance (the presence of the stick within visual range just at the right moment)...
Finally, we notice that the Eureka Process does not consist in inventing something new out of nothing, but in bringing together of the hitherto unconnected. Nothing is created that was not already there, in the outside world and its mental reflection. Likewise, the so-called "revolutions" in thought consist not in destruction but in synthesis; in connecting the hitherto unconnected."

[A. Koestler, "Insight and Outlook: An Inquiry into the Common Foundations of Science, Art and Social Ethics" (The MacMillan Company: New York, 1949) at 256-258.]

As suggested by this example and in the comments of Koestler, it is the search for a solution to a problem which sparks and drives the process.

E. Avenues to Invention

Broadly speaking, I would propose that there are two avenues to invention. Within those two avenues, there are, again broadly speaking, two types of invention.

The first avenue to invention is akin to the discovery by serendipity[44]. This occurs when it "hits" you that something will work in a certain way to give a certain result. This type of invention "comes" to an inventor "out of the blue", typically when working on something totally unrelated to a main course of work. The recognition of the value of penicillin as an antibiotic is a good example of an invention arrived at through serendipity. With respect to this avenue, the invention can be minimal, or it can be truly insightful and pioneering.

The second avenue to invention is the plotted course. This is where one gathers background information recognizing that there is value in pursuing a particular line of work (based on an understanding of what has gone on before[45]). There are at least two aspects to this type of inventive process. The first is where the inventor charts a course toward a given result, not knowing for sure how to get there, but setting out in any event.[46] The nature of the objective is variable: from the "known" end product to the end product which is something no-one else has thought of. Along the way to the objective, inventions may be created from the work in getting there. Banting and Best knew that the pancreas of mammals served a useful purpose in treating diabetes and ultimately isolated insulin.

The second is the so-called "prospecting" for invention. Good examples of this kind of invention are those relying on ethnobotany to find new pharmaceuticals.[47] Ethnobotany is the study of direct interrelations between humans and plants; the study of indigenous plant use. From this type of study, and in recognition that the human condition is the common denominator, the potential exists to find new medicines to treat human ailments. This of course quickly turns the discussion to the issue of novelty. If a little known people in South America has been using a particular type of organic material to treat a common ailment, how new is this? It quickly becomes clear that the newness of anything is really observer centred, and for the purposes of patenting societies, is based on the knowledge of that society. As such, this means that on the scale of a

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44 If the events which lead to the invention are reproducible then such invention may be patentable. However, it is the chance invention, which is not easily reproducible which is not likely to be patentable. This was one of the problems encountered by Pioneer Hi-bred in its application for a patent - see the reasons of Lamer, J (as he was then) at page 263 of the *Hi-bred* decision ((1989), 25 C.P.R. (3d) 257 (S.C.C.)).

45 Needless to say, serendipity is achieved with an understanding of what has gone on before, it just isn't as apparent. As will be seen below, without this knowledge of what has "gone on before" invention is not possible.

46 This is the same as the followers in the invention of new antibiotics as discussed in *Farbewerke Hoechst A.G. V. Halocarbon (Ontario) Ltd.* (1979), 42 C.P.R. (2d) 145, *infra*, Chapter 4.

47 See for examples: C. Joyce,"Prospectors for Tropical Medicines" (1991) New Scientist October 19, at 36-40; and M.J. Plotkin, "The Healing Forest" (1990) The Futurist January-February, at 9-14.

society, the "objective standard of novelty" is really subjective. These comments apply equally to non-obviousness. It is inherent in the non-obviousness inquiry that these issues have been taken into account given the difficulty courts have with respect to deciding what it is that the person skilled in the art knows.

Returning to the "prospecting" process of invention, once the inventor locates (discovers) a people and a remedy, the process evolves to the "plotted course" type of process of invention. Indeed, the plotted course approach to invention is taken in industry today:

> "Originally, industry relied on the chance discoveries of gifted individuals working at random, their choice of problems being guided by their interests, backgrounds, abilities and the prospect they saw of making a profit from their activities. Modern research is planned to fit specific needs. A large element of unpredictability and discovery and in the value of discoveries in monetary terms, can no longer be permitted. [The so-called discovery and invention of serendipity] In the 20th century industry saw that it could no longer rely on random discoveries and it turned to the accumulation of new knowledge. The science of invention was perfected and research discoveries were largely tailored to specific business or industrial requirements."[48]

However, an invention, whether *achieved* by prospecting or plotting, or *occasioned upon* by serendipity is still a matter of a concept. In the plotting or prospecting mode, one does not plot aimlessly (and if one does so we refer to the invention as being one arrived at by serendipity). Typically, the plotter or prospector starts with some sense, theory or idea about what they are doing. Thus, it is the concept which is the starting point and the tangible aspect which is the result. For example, notwithstanding the invention which existed leading to the understanding that antibodies recognize other proteins, it was clearly desirable to have a uniform population of antibodies, all of which would recognize the same epitope of the same protein (monoclonal antibodies). Further, the need to quantify certain proteins in solution which exist in very low concentration led to the recognition that utilizing antibodies could provide the means to do so (kits which test for pregnancy are based on these principles).

F. Creation and Invention

Creation[49] is similar to invention and indeed shares many elements of invention, but it can be distinguished from invention. Like invention, a creation in its physical sense can be discovered. For example, on the assumption that living organisms were created through a process of evolution,

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48 T.S. Harding "Exploitation of the Creators" at 386-387.

49 The word creation suffers the same type of linguistic difficulties that are encountered by invention. See footnote 37 for further discussion.

those unknown to humans can be discovered. Creation however, is not similar to discovery. Also, as with invention, a discovery cannot be invented and discovery cannot be created. Thus, it is proposed that all invention is creation, i.e., that invention is merely a subset of creation,[50] and as such, there is a spectrum of creation: from its most basic simplistic meaning which can be thought of as the mere bringing of something (whether tangible such as a recombinant protein[51], or intangible such as a thought) into existence, to its most provocative where something fundamental is brought into existence. Invention is further up the scale from mundane creation but the form of creation which is a grand scale kind of creation I would argue is much more than invention, and, is fundamentally separate from invention.[52] Further, creation, at its more mundane level can result in something known and as such serves to distinguish it further from invention. For example, a

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50 See Venn diagram at beginning of Chapter.

51 For products of biotechnology which are not living,eg., proteins, nucleic acids, fatty acids, etc. the concept of creation fits well in that they can be made from their substituent amino acids or even elemental parts. It is when the concept moves into the category of living matter that we encounter a situation where humans are unable to create. We can create a modified life form, but we cannot create that modified life form itself *per se*. We must depend upon the underlying biological processes in order to "create". As such, the creative element is removed from us. In all other aspects of invention, we can create. This, at first blush, is a fundamental difference between biotechnology and all other technologies of invention. In many respects this may be a fundamental distinction between products of biotechnology and all other types of products in that the living products are truly fundamental creations, which, as proposed here, are different from inventions.

52 This type of creation was well described by Bronowski (J. Bronowski, "The Experience of Creation" at 97-98):

> "Christopher Columbus discovered the West Indies, and Alexander Graham Bell invented the telephone. We do not call their achievements creations because they are not personal enough. The West Indies were there all the time; and as for the telephone, we feel that Bell's ingenious thought was somehow not fundamental. The groundwork was there, and if not Bell then someone else would have stumbled on the telephone almost as accidently as on the West Indies.
>
> By contrast, we feel that *Othello* is genuinely a creation. This is not because *Othello* came out of a clear sky; it did not. There were Elizabethan dramatists before William Shakespeare, and without them he could not have written as he did. Yet within their tradition *Othello* remains profoundly personal; and though every element in the play has been a theme of other poets, we know that the amalgam of these elements is Shakespeare's; we feel the presence of his single mind. The Elizabethan drama would have gone on without Shakespeare, but no one else would have written *Othello*...
>
> A fact is discovered, a theory is invented; is any theory ever deep enough for it to be truly called a creation? Most scientists would answer: no! Science, they would say, engages only part of the mind - the rational intellect - but creation must engage the whole mind. Science demands none of that ground swell of emotion, none of the rich bottom of personality, which fills out the work of art...
>
> Creation consists in finding unity, finding likenesses, finding pattern...
>
> Nature herself is chaos; she is full of infinite variety without order. But if you see her with inner vision, a creative mind (whether a poetic mind like Charles Baudelaire's or a scientific mind like Isaac Newton's), there comes a moment when many different aspects suddenly crystallize in a single unity. You have found a key; you have found a clue; you have found the path which organizes the material. You have found what Coleridge called "unity in variety." That is the moment of creation."

printer's press "creates" copies of a book. According to our broad understanding of invention outlined above, when the first book was created it was, arguably, an invention. The copies which are now made by the printing press are not themselves inventions, although, strictly speaking, they are creations.

G. Discovery and Invention

The process of invention is unquestionably similar to the process of discovery. When asked what this process is, from a scientific perspective, the following type of answer was given by life scientists:

> "There is an element of process to it in as much as I think we get ourselves, in the greater thinking of things, we get ourselves into trained thought which is supported by experimental evidence that we gather as the months go by and the years go by and it does kind of push you into a kind of direction - your research does tend to be evolved in a direction. Sometimes your research appears to be headless but other times it does seem to have a head and a direction. It's a purely relative thing I think...I am speaking for myself, I think I am making discoveries all the time and many of these discoveries are small footsteps. Something incremental. But I think there are discoveries going on all the time. It's just a question of the harder you work the more discoveries you'll make and one day you will hit the jackpot. You'll create information which a lot people are interested in as opposed to just you. So I think this is a relative term..."

Discovery is like invention in that it can be a process or it can be the result. It is also amenable to the same type of linguistic analysis as invention.[53] Two broad classifications of both the process and the results which are discovery are (1) discovery by serendipity; and (2) the discovery which results from a chosen course of endeavour.[54] As with invention, discovery can occur along a chosen course of endeavour and that often times discoveries along this path are made serendipitously.

Invention is, however, to be understood as distinguishable from discovery, even though they may be co-terminus in some cases.

In Popper's work entitled The Logic of Scientific Discovery he describes the avenue to the end product that no-one else has thought of - the "theory":

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[53] See note 37, *supra.*

[54] One research scientist suggested that all scientific discovery could be categorized as one or the other - from the Interviews of Research Scientists, 1995.

"The theoretician puts certain definite questions to the experimenter, and the latter, by his experiments, tries to elicit a decisive answer to these questions, and to no others. All of their questions he tries hard to answer. (Here the relative independence of sub-systems of a theory may be important.) Thus, he makes his test with respect to this one question "....as sensitive as possible, but as insensitive as possible with respect to all other associated questions. ...Part of this work consists of screening off all possible sources of error." But it is a mistake to suppose that the experimenter proceeds in this way "in order to lighten the task of theoretician", or perhaps in order to furnish the theoretician with a basis for inductive generalizations. On the contrary, the theoretician must long before have done his work, or at least what is the most important part of his work: He must have formulated his question as sharply as possible. Thus, it is he who shows the experimenter the way. But even the experimenter is not in the main engaged in making exact observations; his work, too, is largely of a theoretical kind. Theory dominates the experimental work from its initial planning up to the finishing touches in the laboratory."

This can be summarized as follows:

"A scientist, whether theorist or experimenter, puts forward statements or systems of statements, and tests them step by step. In the field of the empirical sciences, more particularly, he constructs hypothesis, or systems of theories, and tests them against experience by observation and experiment."[55]

In accordance with these thoughts, the invention is the end product, which, according to Popper, is the theory to be tested, the hypothesis or system which represents a result. The objective may be fairly broad but the goal must be, as Popper states "...formulated...as sharply as possible." For example, in the mid 1980's it was a goal of the researchers at Genetech Inc. to be able to express desired heterologous proteins (polypeptides) in a bacterial host under the control of a homologous regulon, in a recoverable form. However, it was only with sharply defined theories about how to achieve this result that sufficient experimentation resulted in an approach which requires that the heterologous DNA insert should be in a proper reading frame with the homologous regulon in the plasmid for the transformation of a suitable bacterial host and, importantly, that the DNA must code for a polypeptide not degradable by proteolytic enzymes. At the time of the invention, there was no known way to achieve this result. Thus, drawing from this example, it may be said that invention is a way of doing something for which at the time the invention does not exist, there is no way of doing. The inventor then, conceives of the way, or means of achieving the desired result, which itself may be an invention. Concerning the "invention" aspect Popper had the following to say:

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[55] K. R. Popper, "The Logic of Scientific Discovery" (Basic Books, Inc.: New York, 1961) at 27.

> "The initial stage, the act of conceiving or inventing a theory, seems to me neither to call for logical analysis nor to be susceptible of it. The question how it happens that a new idea occurs to a man - whether it is a musical theme, a dramatic conflict or a scientific theory - may be of great interest to empirical psychology; but it is irrelevant to the logical analysis of scientific knowledge. This latter is concerned with questions of fact (Kant's *quid facti*?), but only with questions of *justification or validity* (Kant's *quid juris*?). Its questions are of the following kind. Can a statement be justified? and if so, how? Is it testable? Is it logically dependent on certain other statements? or does it perhaps contradict them? ...Accordingly, I shall distinguish sharply between the process of conceiving a new idea, and the methods and results of examining it logically."[56]

The scientific process then, according to Popper, cannot be used to "invent":

> "However, my view of the matter, for what it is worth, is that there is no such thing as a logical method of having new ideas, or a logical restriction of this process. My view may be expressed by saying that every discovery contains "any rational element", or "a creative intuition"...

In a similar way, Einstein speaks of "..... the search for those highly universal...laws from which a picture of the world can be obtained by pure deduction. There is no logical path, "he says", leading to these...laws. They can only be reached by intuition, based upon something like an intellectual love ("if einfühlung") of the objects of experience".[57]

Even though Popper's work is entitled the "Logic of Discovery" I would suggest that the process about which he speaks, the "creative" process is the first level of the same process for invention. Indeed, much of discovery is the same as invention, yet discovery is not synonymous with invention, although it is true that one can discover an invention, and that therefore the "discovery" is the "invention" and they are, in such cases, co-terminus. Thus, discovery is a broader concept and encompasses invention in this sense but invention is also many discoveries which allow for the arrival at invention, and clearly one cannot invent a discovery. It is this reality which helps distinguish between discovery and invention. Certainly it is correct to say that one can discover something useful and that will be a discovery, and consequently one can discover an invention, but it is equally true that a discovery may not necessarily be an invention. As such, discovery encompasses more than just invention. Thus, it may be said, and what flows from what has just been stated, is that discovery is a basic element of all invention. Indeed, it may be

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56 K.R. Popper *Ibid*

57 K.R. Popper *Ibid*

discovered that something works in a certain useful way, as did the plasmids which Chakrabarty inserted into *Pseudomonas* bacterium, and this discovery is discovery of the invention.[58]

Of course, implicit in the concept of discovery is an element of newness, i.e., the requirement that what is discovered has not been known before.[59] Otherwise, it is re-discovery (if that is ever possible) or simply finding that which was known (assuming it was not easily retrievable from the first site of discovery).

Finally, insofar as it is possible to discover the obvious, so too is invention possible in respect of the obvious. Such "discovery" may not be of major significance, (and so too may the invention which arises from such discovery). However, it is discovery nonetheless.

H. What Does "Invention" Mean - A Synthesis

In summary, an invention is something which is new and is both the process of, and the result of, the bi-, tri-, multisociation of previous discovery (which forms the relevant background) which has a purpose, or some level of value or does something. Put simply, it is new and has utility. At a more industrial level, utility is thought of as providing a solution to some existing problem. Although this puts the overall requirement higher (more in line with patentable invention), it is yet a further perspective on the issue of utility and is a convenient way of thinking about the elements of invention. These themes or elements of invention are applicable to all fields of human endeavour. Indeed, it is a fundamental requirement that the human mind deal with these issues in providing a solution which helps characterize the process and result as being "invention." Therefore, looking to the knowledge, discovery, integration/bisociation and solutions in biotechnology, it is clear that there are inventions in biotechnology. Surely the ability to create recombinant DNA is one of the great inventions in biotechnology in this century. To take as a practical example, the development of a basic, new, innovative technique in biotechnology is that of the polymerase chain reaction (PCR) which is a powerful technique of molecular biology that can be used to enhance the sensitivity of various assays including, for example, pre-natal diagnosis of known molecular defects. The problem in the field of DNA detection was that the target nucleic

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[58] A related issue with respect to discovery and invention is whether the isolation and purification of a micro-organism with unique features and properties is truly an invention under Canadian practice or is merely a discovery. The *In Re: Bergy* case ((1979), 201 U.S.P.Q. 352 (C.C.P.A.)) is a good example of this situation where the subject matter of the invention is really a discovery in that researchers devoted a considerable period of time searching through soil samples and methodically screened the various micro-organisms found in those cultures. It can be said that it was more a matter of discovery than that of invention which led to the researchers to obtain the Bergy patent, but the discovery of the micro-organisms was really only a part of the invention. The invention was in recognizing that the isolated and purified version of the microorganism was able to produce the desired antibiotic.

[59] This is not to say that the subject of discovery needs to be new. As has been suggested, the discovery of a fossil is the discovery of something quite old in fact, and as such, on one level is not novel. However, since all of these terms are observer-centred, the newness of the fossil comes in the fact that it was previously not **known** by humans. As such it is a discovery.

acid sequence typically was only a small portion of the DNA or RNA in question, so it was difficult to detect its presence using non-isotopically labelled or unlabelled probes. Much effort had been expended in attempting to increase the sensitivity of probe detection systems and up until the development of the PCR technique little research had been conducted on amplifying the target sequence. Indeed, the invention of PCR lay in its ability to amplify the target sequence so that it would be present in quantities sufficient to be readily detectible using methods which existed at the time of PCR's invention. The sensitivity of PCR allows the detection of infectious disease agents which are present at very low levels.

Consequently this problem existed in the field of DNA detection at the time Dr. Mullis conceived of his solution. In fact, Mullis describes his conception of the invention as follows:

> "Drivin' up to Mendocino thinkin' about this stuff, and I hit Cloverdale and I thought what if the [primers] that got extended could bind to the other primer... and I stopped the car... I immediately knew you could do it several times. You see, no-one ever did that in biochemistry. In biochemistry you do it once and that's it. And you could do it with just an enzyme and deoxynucleoside triphosphates, which are cheap, soluble and legal... I couldn't figure out why it wouldn't work, but I knew it couldn't because I hadn't heard of it..."[60]

Mullis is a molecular biologist who was working at Cetus Corporation and was a chemist and head of the DNA synthesis group at Cetus at the time he conceived of this invention. All aspects of the invention were known at the time Mullis conceived of PCR. It simply was that no one had thought to bring the components together in this way to achieve this result. Its utility has proved to be greater than conceived by Mullis and is poignant example of the bisociative processes involved in invention. The basic patents in respect of PCR (U.S. Patent Nos. 4,683,195; 4,683,202; and 4,800,159) are for processes for amplifying nucleic acid sequences as well as the detection and/or cloning of nucleic acid sequences.[61]

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[60] E. Daniell, "Polymerase Chain Reaction: Development of a Novel Technology in a Corporate Environment" In: Biotechnology: The Science and The Business, Ed V. Moses and R.E. Cape (Harwood Academic Publishers: New York, 1991) Chapter 11 at 147.

[61] There are innumerable examples in biotechnology which can serve the purpose of asserting that all types of subject matter of biotechnology are susceptible to being considered invention as described here, Abitibi's yeast (see Chapter 4, Enumerated Categories of Statutory Invention), Chakrabarty's bacteria (see Chapter 4, Enumerated Categories of Statutory Invention) Mullis' Polymerase chain reaction, as well as Pioneer Hi-bred's soybean seeds (see Chapter 4, page 50 ff.).

From an economic perspective[62] invention may be thought of as providing the owner of such a thing with a commercial advantage over others. If it is an invention which is patentable then the owner of the invention, upon obtaining a patent, has the right to prevent others from practising the invention.

If the invention is not patentable, so long as the invention is able to be maintained in secrecy, the holder of the invention will be able to maintain the competitive and technical advantage of the invention over his competitors. However, it is becoming increasingly difficult to maintain secrecy in biotechnology. Although there is a perception that society is dealing with "black box" technology in respect of biotechnology, the fact is that the box's lid is quickly opening to let significant light in. The "black box" is typically the micro-organism or whole organism which is providing the product or process of biotechnology, or, is itself the product of biotechnology. It is now true that in situations where a micro-biological invention is used, it is possible for reverse engineering to determine the basis upon which the invention operates. For

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62 Is there an economic element to invention? From a strictly definitional perspective, the answer is no. Invention can exist without any economic element. However, economics are intimately associated with invention, during the process and once it exists. This aspect is tied up with the concept of utility. It is, of course, from the element of utility that the economic consequences of invention flow. Put simply, no one is willing to invest money in a curiosity. However, something which has a practical benefit is a different matter. Furthermore, the degree of economic interest in an invention is directly proportional to the number of people who are directly impacted by the invention. It is for these kinds of reasons that "commercial success" has only ever been elevated to the level of a "secondary consideration" when the issue of invention has been judicially considered. However, this is not to say that economics is not a consideration in respect of invention and the inventive process:

"Once knowledge is acquired it has a zero cost of production; that is, the marginal cost of producing acquired knowledge is zero. The fact that one person is using it does not preclude someone else from using it; it is not a scarce resource. Therefore, once something has been invented the only cost to produce it is the cost of manufacturing it; the knowledge of how to produce it, how it works and so forth costs nothing further. If this knowledge is not somehow protected from competing firms acquiring it at zero cost, then a competitive market will force prices down to a level where only normal profits are earned by each firm, including the inventing firm. While all firms face the same costs given that the invention has been invented, the inventing firm has also paid the large fixed costs of research and development for discovering the knowledge imbedded in the product. Consequently, this firm is suffering substantial losses in the long run because it is unable to recoup its initial investment. Given this prospect, a firm considering developing a new product will have two choices. Its first choice is to do nothing at all. Unless the firm can be assured of covering its research and development costs it will not invent and society will suffer tremendous losses. The obvious loss is the loss of the invention and the benefit derived from it. The more serious loss, however, is the loss of the knowledge and technology imbedded in the invention. Without this knowledge, future developments will be thwarted and the gains to society from technological advancement will be foregone.

The second choice is to keep the invention a secret to prevent competitors from exploiting it. For example, a firm that developed a product or process that reduces the cost of producing what it manufactures may use the innovation for its own manufacturing purposes without disclosing it, thereby keeping its competitors from benefitting from the cost saving innovation. Secrecy would of course cause society to forego the gains that disclosure provides."

M.S. Hart, "Getting Back to Basics: Reinventing Patent Law for Economic Efficiency" Intellectual Property Journal v. 8: 217 (1994) at 220-221.

example, a review of the Leder patent[63] indicates that the desirable traits of the "Harvard Mouse" arise from insertion of the *myc* gene into the mouse's genome. Had the patent not been obtained, today, the purchaser of the Harvard Mouse would be able to isolate cells from the mouse and through various analytical techniques available to those skilled in the art, be able to determine the nature of the changes to the mouse's genes and be able to synthetically produce the appropriate DNA insert which was used to create the Harvard Mouse. It would then simply be a matter of following the same type of procedure, which today is a standard procedure, in order to arrive at a reverse engineered version of the Harvard Mouse.[64] This would appear to be fundamentally true for all aspects of biotechnological invention. So long as the source material is available either through sale or through deposit, it should be possible to reverse engineer.

The "flip side" of this situation is that the Harvard Mouse contains all of the information desired by the end user and because the mouse can reproduce, a theoretically endless supply of mice is available. Consequently, the inventor is no longer needed and thus, his "economic advantage" is lost.[65]

Thus, in order to benefit the inventor, and in view of the societal and economic benefits associated with developments in biotechnology it is proposed to be appropriate to provide the inventor with some rights to allow for the maintenance of commercial advantage. Having determined that there can be invention in the subject matter of biotechnology, in order to determine if patent rights are applicable, we now turn to the statutory definition of invention as contained in the *Patent Act*.

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63 United States Patent no. 4,736,866 "Transgenic Non-human mammals" April 12, 1988.

64 There are those who would argue that, but for the publishing of the patent, the technique would not be known. In view of the sharing of information which occurs in the scientific community, and particularly given the objective in mind, i.e., of creating a transgenic mouse with an activated oncogene, the techniques would be known.

65 The opportunities to provide a reward to the inventor through licensing is beyond the discussion of the scope of this paper. The reader is referred to articles such as J.D. Morrow, "Biotechnology Licensing" (1993) 10/1 CIPR 277, for this kind of discussion.

CHAPTER 4
PATENTABLE INVENTION

The statutory definition of invention as found in the Canadian *Patent Act* creates a subset of invention within the set established under the discussion of the concept of invention as developed above. The statutory definition of invention, in comparison with the concept of invention, is a narrower view of what is invention. The question addressed below is whether, and if so to what extent, this narrowing impacts on the ability to find whether biotechnological subject matter fits the definition of statutory invention. As part of the analysis we will examine whether biotechnology can be accommodated within judicial interpretation of the elements of statutory invention or if modification is necessary to accommodate biotechnology. As part of the discussion, a number of critical issues which are peculiar to biotechnology in respect of patentability will be canvassed.

A. The *Quid Pro Quo* of a Patent

Today in Canada the grant of a patent provides the patentee with the exclusive rights of "making, constructing and using the invention and selling it to others"[66] for twenty years from the date of filing of the application. In practical terms, this amounts to approximately seventeen years which is a considerable length of time[67]. However, it is understood that the work involved to "generate" an invention is also a significant undertaking[68] deserving of a significant reward if the knowledge behind the invention is to be shared[69].

It is essential to appreciate this *quid pro quo* as it is at the heart of, and heavily influences, the definition and determination of patentable inventions. It is a restriction, or fettering on interpretation which does not exist when considering the concept of invention *per se*. Most

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66 The *Patent Act*, R.S.C. 1985 (3rd Supp. C. 33, s.42.) as amended.

67 This is based on the assumption that it will take approximately 3 years to marshall the application through the Patent Office, i.e., prosecution time is on average 3 years. In respect of complex biotechnological subject matter, this is often a longer period of time. Indeed in some cases it can take as long as 5 to 8 years.

68 Many inventions such as eyeglasses and the clock have taken effectively centuries to become completely crystallized into useful products. A.W. Deller, *Deller's Walker on Patents*, vol 1 2nd Ed. (New York: Baker, Voorhis, 1964) c. 1.

69 This sentiment was outlined by Maclean, J., In *Canadian Gypsum Co. v. Gypsum, Lime & Alabastine Can, Ltd.* [1931] Ex. C.R. 180:

> "The design of the patent law is to reward those who make some substantial discovery or invention which adds to our knowledge and makes a step in advance in the useful arts. If there is no novelty there can of course be no inventive ingenuity, but if there is novelty in the sense required in the law of patents, it must be the product of original thought or inventive skill."

industrially developed countries have some form of patent legislation in place. The purpose of such legislation is for the most part a universally shared theme. This theme was effectively conveyed in the following comment and in the context of the United States:[70]

> The purpose of United States patent law is to promote progress in science and technology. The scientific and technological progress sought to be promoted is achieved through the continuous discovery of new scientific principles and technical know-how, as well as through the continued development of new products and processes employing such discoveries.

The reward provided by the state provides the patentee with a right to prevent others from practising the invention (the *"quid"*).[71] Without the ability to enforce the patent, the "invention" is subject to examination[72] and reproduction by others, at will, with limited recourse available to the owner of the patent. In effect, the inventor ends up competing with himself. The result: there is no incentive to discuss or publish the idea/invention[73]. The patent provides the inventor with protection from such competition on a national basis and the inventor gets a chance to profit from the time and effort which went into making the invention; that is the cost to the State. The reward for the State is technology, knowledge, insight, understanding and, most importantly, the sum of

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70 T.I. Nguti, "Patent Law: Doctrinal Stability - A Research and Development Definition of Invention is Key" (1986) 20 Val. U.L. Rev. 59 (footnotes excluded).

71 "A patent is, after all, the grant of a powerful monopoly right provided by the state to the inventor". G.F. Henderson, "An Introduction to Patent Law" In: Patent Law of Canada, G.F. Henderson *et al.* eds. (Carswell: Toronto, 1994) at page 9.

72 In most countries, except for example the United States, the ability to examine occurs at least as early as 18 months after the first filing. At this time the application is "laid open" for public inspection (section 10, *Patent Act*).

73 At this point one is led into a discussion concerning the free exchange of ideas which is claimed to exist in the scientific community, a place where there "is" free exchange of ideas. The notion of withholding knowledge and insight is rejected. In fact, scientists will argue that the patent system actually impedes progress because of the tendency to withhold information until the patent issues...or so the argument goes. The fact is, however, that it is rare to find a scientist who is willing to share their ideas unless they have already been published; but isn't publishing part of that free exchange? In a word, no. Publishing ideas in scientific journals provides the reward system of the scientific community. Without publication there are no financial rewards (grants), i.e., publish or perish. In effect, the system is entirely analogous to the patent system: if a scientific advance, i.e. invention, is shared with the scientific community by publication, the analogy for a patentable invention is it is shared with the State. The scientist has an increased probability of winning grant money to continue research, while in the patent form the inventor has increased the probability of making a profit and continuing a chosen discipline. In broad terms: not all scientific work is published, only that which is new and useful. Indeed, not all inventions are patented, only those which are new and useful. Counter-balanced with this view is the fact that today more research scientists are communicating their inventions to research technology transfer offices in their institutions wherein the invention is in theory quickly evaluated and a decision is made with respect to whether an application for a patent is to be filed. Of course, once the application is filed, the scientist is free to publish the invention at will. Because of the potential for economic rewards to academic institutions there is an increasing change in philosophy directing research scientists towards patenting as the means to justify and maintain their position in the institution.

these, the ability to advance (the *"quo"*). This statement is, of course, premised on the belief that such an ability to advance is good for the Canadian public. A related issue is whether the *Patent Act* should be used to promote progress in areas of scientific research which are deemed not to be in the public's interest. Indeed, there are those who would argue that it is inappropriate to allow for the patenting of higher life forms and consequently that the *Patent Act* should not be a vehicle to encourage such activities.[74] Notwithstanding such views, it may be fairly stated that the purpose of all patent systems throughout the world is the promotion of progress in science and technology. As already stated, these are key elements in the consideration of any subject matter and whether such subject matter qualifies as a statutory invention, and it is from this perspective that we turn to an examination of the statutory definition of invention.

Statutory Invention

The word "invention" is defined by the Canadian *Patent Act* at section 2 as follows:

> **"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.

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[74] Indeed, it may be argued that the *Patent Act* is a tool by which undesirable social public policy is implemented, for example, the encouragement of scientists to unfairly take advantage of people in under-developed countries. The push for new inventions arising from the study of ethnobotany and the subsequent exploitation of indigenous peoples is arguably being fuelled by the patent system. For an example of such concern see an article entitled "Indigenous Person from Papua New Guinea claimed in U.S. Government Patent" published on the Internet by Fringeware Daily http://fringeware.com/HTML/ online.html#digest, on October 16, 1995, as forwarded by Mariman Batlivala (narib@sj.unisys.com) which concerns U.S. Patent No 5,397,696 "Papua New Guinea Human T-Lymphotrophic Virus". In accordance with this argument is the fact that not all types of invention can be patented and consequently, the *Patent Act* serves as a vehicle for promoting those "new and useful arts, processes, machines, manufactures or compositions of matter" which society deems appropriate. Indeed, some would argue that the *Patent Act* is a useful forum for shaping societal mores. In this respect the *Patent Act* has, since its inception in Canada, explicitly identified subject-matter which could not be patented. In particular, a patent could not be obtained for an invention that had "an illicit object in view" or for any mere scientific principle or abstract theorem. Although the limitation with respect to inventions having an illicit object in view was removed in 1994 (*Patent Act*, R.S.C. 1985, c. P-4, s.27(3), as amended), as discussed below, case law makes it very clear that certain subject matter, beyond the mere scientific principle or abstract theorem, is not patentable subject matter. Consequently, notwithstanding the argument which has been put forward by some to suggest that a patent act is not the proper forum to put forward social ethical policy, there is considerable precedent for specifically excluding types of subject matter under the *Patent Act*. The real question is whether it is appropriate to do so, and where the line should be drawn with respect to what can be patented and what cannot. A more significant discussion of such ethical and moral issues is beyond the scope of this report. However, the reader is referred to the following papers as well as the bibliography for further reading: S.R. Avisar, "The Ethics of Biotechnology - The Argument in Favour of Patents" (1993) 10 Can. Intell. Prop. Rev. 209; J.F. Barshear, "Inoculum or Perilous Parasite? Encouraging Genetic Research through Patent Grants: A Call for Regulation and Debate" (1981) 18(2) San Diego Law Review 263; S. Chong, "The Relevancy of Ethical Concerns in the Patenting of Life Forms" (1993) 10 Can. Intell. Prop. Rev. 189.

Thus, the "elements" of patentable "invention" under Canadian law are as follows:

1. the subject-matter must be one of:
   an art,
   process,
   machine,
   manufacture or
   composition of matter;

2. newness or novelty; and

3. it must be useful.

A fourth element, which is not yet explicit from the statute,[75] is the analysis, or requirement of non-obviousness, or inventive step. Non-obviousness has been judicially imported into this "statutory" definition of invention and is assessed by an examination of the subject-matter on the basis of an objective standard which involves a determination by a worker skilled in the relevant art.[76]

DOES BIOTECHNOLOGY FIT?: Proper Subject-matter

Before something can be considered as patentable a preliminary determination must be made with respect to the propriety of the subject matter, i.e., is it an "art", "process", "machine", "manufacture", or "composition of matter"? This first step in the analysis of patentable invention clearly distinguishes statutory invention from the conceptual approach to invention, the latter being entirely uninfluenced by the nature of the subject matter.

Two aspects of biotechnology which are currently not proper subject matter in Canada and, as discussed below, in a number of other jurisdictions, are methods of medical treatment, and human beings and body parts.[77] In addition, as discussed infra under the heading of "Enumerated Categories of Statutory Invention", higher life forms are not proper subject matter in Canada.

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75 However, as discussed *infra*, under "New, Useful and Unobvious - C. non-obviousness", the statute has been amended to include a non-obviousness analysis. The new section is yet to be proclaimed in force.

76 See discussion, *infra*, under "New, Useful and Unobvious", the heading of Non-obviousness.

77 By body parts what is meant is that genes, proteins or cells in their natural state in the human body are not patentable. Notwithstanding this, when such elements are isolated from the human body they are in fact patentable and simply because of their human origin have not been held to be unpatentable in Canada.

A. Methods of Medical Treatment

In Canada, where a biotechnological process or method, or a process or method involving a product of biotechnology (or any other technology for that matter) involves treating a living human being or animal by surgery or therapy, claims to such "methods" may be construed as methods of medical treatment and may not be allowed.[78] This is the case notwithstanding the fact that there is nothing which explicitly relates to this point in the statute.

This is to be contrasted with the United States. Although the U.S. statute is also silent on the issue of methods of medical treatment and at one time, like in Canada, patents were not available for medical therapeutic and diagnostic methods, however, according to current caselaw no such bar exists.[79]

In Japan, legislation specifically indicates that methods of medical treatment for human beings are excluded from patentable subject matter. The basis for this legislation is a policy to allow doctors to practice without concern about infringing patents. As is the case in Canada, only treatment methods are excluded, products including medical devices and pharmaceutical compounds are patentable subject matter.[80]

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78 The leading decision in Canada on this point is *Tennessee Eastman v. The Commissioner of Patents*, [1974] S.C.R. at 111. However, "methods of use" or "use" claims are now more commonly acceptable at the Canadian Patent Office if they are acceptably worded: *Manual of Patent Office Procedure.* See also K.R. Britt, "Method of Use Claims in Biotechnology" (1993) 10 CIPR 101 as well as *Shell Oil Co. v. Commissioner of Patents* (1982), 67 C.P.R. (2d) 1 (S.C.C.) and *Re Application for Patent of Wayne State University* (1988), 22 C.P.R. (3d) 407 (PAB).

79 D.S. Chisum, "Patenting Living Subject Matter, DNA sequences encoding proteins, Gene Therapy and Therapeutic Methods under United States Law" presented at Patenting Living Organisms Including Human Genes AIPPI, Montreal, June 27, 1995; and (W.D. Noonan, "Patenting Medical and Surgical Procedures" JPTOS, vol 77 no. 8 651 at 664 (1995)) While such claims are currently acceptable there is a movement underway to make such patents unavailable (BNA's Patent, Trademark & Copyright Journal, vol. 50, No. 1250, p. 737 (1995)).

80 "Examination Practice for Chemical and Biotechnological Inventions in Japan", Japanese Patent Office, December, 1994.

This same bar to patentability exists in Europe, by statute,[81] and the basis for the bar is, in both Canada and Europe, similar to that in Japan. This legislation in Japan and Europe, and through caselaw in Canada, is very value laden and this is difficult to reconcile with those who suggest that the *Patent Act* is not the correct vehicle for making ethical and moral decisions. Without this moral gloss on proper subject matter, processes of biotechnology which are to be classified as "methods of medical treatment" would otherwise be patentable.

B. Human Beings

Directly tied to this area of nonpatentable subject matter is the question of the patentability of any subject matter relating to humans. Indeed, the question of the patentability of humans or human body parts is an excellent example of how limiting the scope of subject matter which can or cannot be patented, can help define social policy in a country:

> "In legislation attempts have been made to introduce specific exclusionary provisions into the patent system in order to draw a more precise borderline between ethically permissible and unacceptable inventive subject matter. For example, the Transgenic Animals Patent Bill which was submitted to the U.S. Congress several years ago, contained an *expressis verbis* prohibition on the patenting of human beings. A corresponding provision was recently anchored in the Australian Patents Act of 1990 [Section 18(2) of the Act reads: "Human beings, and the biological processes for their generation, are not patentable inventions"]. When in Europe, the EC Commission's original draft Directive on the Protection of Biotechnological Inventions was submitted to the Parliament, a number of reservations [on this matter] were expressed. The amended proposal now lays down in Article 2(3) that

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[81] Article 52 of the EPC, paragraph 4 provides:

> *(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions for use in any of these methods.*

One commentator on the European provision stated the following:

> "...[A]rticle 52 (4) which excludes methods for treatment of the human or animal body by surgery, therapy and diagnostic methods... [is] to keep the medical practitioner away from the patent activities and to avoid doctors being sued for patent infringement. Although the article is not in dispute at present, sometimes the opinion is voiced that it is superfluous..." "The effect of this, though, is not too wide, only the methods which are applied on the human or animal body directly are excluded. In modern bio-technology, for example, somatic gene therapies, the process of administrating gene constructs, may be a therapeutic method, but the products being administered may still be protectable under existing law."

[C. Gugerell, "Bio-technology patenting - the current practice of the European Patent Office" The Genetic Engineer and Bio-Technologist v. 14, p. 195 - 200 (1994) at 197.]

> neither the human body nor parts of the human body as such are patentable. [As already stated the Directive was not passed by the European Parliament in early 1995]"[82]

In Canada there is no provision in the *Patent Act* which speaks to this issue. There is also no caselaw aside from the method of medical treatment cases. Further, there is no caselaw or patent legislation in respect to the patentability of humans or their parts. This is also true in the United States although the United States Constitution forbids exclusive property rights in a human being.[83] Arguably, this is also the case in Canada under the *Charter of Rights and Freedoms*.

The current position of the Canadian Patent Office is that patents will not be allowed for subject matter which is multicellular, and this inherently includes whole human beings and body parts. What this means in terms of patents for humans however, is that patent applications directed to human subject matter which is not multicellular, i.e., human DNA sequences, cell lines and hybridomas can be filed.[84] As a part of those applications, relevant, biological material deriving from the human body such as isolated cell lines, may be deposited. Many opponents to the patenting of higher life forms are of the view that allowing patents for even simple "higher" life forms will put us on the slippery slope to patenting human beings.[85] Although, if the concern of

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82 R. Moufang "Patenting of Human Genes, Cells and Parts of the Body? - The Ethical Dimensions of Patent Law" IIC v. 25: 487 (1994) at 489.

83 See United States Patent and Trade-marks Office Policy Statement dated 4\7\87 on the Patentability of Animals.

84 This is true also in other jurisdictions such as in Europe. (R. Moufang, "Patenting of Human Genes, Cells and Parts of the Body? - The Ethical Dimension of Patent Law" IIC v. 25: 487 (1994) at 509.) However, in his article R. Moufang suggests that certain inventions derived from human beings constitute questionable subject matter even though the subject matter is unicellular in nature:

> "A prominent example is the patenting of human germ cells, which meets with fundamental ethical reservations: the closer the application of methods of reproductive biology (artificial insemination and fertilization) becomes interwoven with commercial interests, the more the current bio-ethnical problems in this field will become aggravated unnecessarily...In addition, patent applications claiming embryonic cell lines or fetal tissue also appear extremely dubious. Research carried out on embryos and their use for medical purposes already touch upon the very boundaries of ethically tolerable behaviour,..."

85 This was the suggestion outlined in Farfan's article "Patentability of life forms" Canadian Computer Law Reporter v. 5: 138 (1988) at 138. Although Farfan does not appear to advocate or reject the argument, it is indeed an argument made by those who oppose the patenting of higher life forms. Although it is possible that patents may be sought for humans or human parts, this is most unlikely.

> "Animals for which patents are likely to be sought are food-yielding animals capable of producing meat, milk, eggs, and other animal products more efficiently, animals that produce pharmaceutical compounds, particularly for human use such as transgenic sheep capable of synthesizing factor IX (important in treating hemophiliacs) and the production of tissue plasminogen activator (TPA) (used to treat humans to minimize heart attacks). Other transgenic animals will be produced as models for studying human diseases. One such strain of mice useful as a model in cancer studies is the Harvard Mouse."

opponents to the patenting of higher life forms was that patenting human beings or their parts is unacceptable, Canada could simply decide not to allow patents for human beings, and this can be categorically set forth in the *Patent Act* as has been done in Australia.[86] But the concern of those who are opposed to patenting higher life forms extends beyond humans. They are opposed to patents for cows, mice, plants, i.e., higher life forms. Indeed, the current policy of the CIPO reflects these concerns: improper as patentable subject matter is anything which is multicellular. These preliminary impediments to patentability are policy decisions of the CIPO and likely have their roots in a narrow interpretation of the enumerated categories of statutory invention. How we have arrived at this point will now be discussed.

C. Enumerated Categories of Statutory Invention

As outlined in the section dealing with the "Subject Matter of Biotechnology" there are three main categories of subject matter in biotechnology and they are: the biomatter itself; methods and processes of biotechnology; and methods of use and uses of biotechnology. There is no argument that biotechnological methods, processes and uses can easily be included under the headings of art[87] or process[88] as appropriate, subject to the "method of medical treatment" caveat.

[Foote, R.H. "The Technology and Costs of Deposits" In: "Animal Patents: The Legal, Economic and Social Issues", Ed. Lesser, W. H. (MacMillan Publishers Limited: New York, N.Y., 1989) pg. 48 at 48.]

86 The wording in the Australian Patent Act is as follows:

> **"Patentable Inventions**
>
> 18. (1) Subject to subsection (2), a patentable invention is an invention...
> (2) Human beings, and the biological processes for their generation are not patentable inventions."

87 It is well settled in Canada that "art" is an act or series of acts which are carried out by some physical agent in respect of, or on some particular physical agent and producing in this object some change either of character or of condition and as such, can be considered as the means of achieving a particular result (*Lawson v. Commissioner of Patents*, (1970) 62 C.P.R. 101 at 109 (Ex.Ch.)).

88 An interpretation of the word "process" may be found in the words of Audette, J. in *Grissinger v. Victor Talking Machine*, even though there was no reference to it as such:

> "...a principle cannot be the subject of a patent, and a claim to every mode or means of carrying this principle into effect would amount to a claim to a principle, for it was said in Neilson v. Harford, 1 Web. Pat. Cas. 295, that there is no difference between a principle to be carried into effect in any way you will and claiming the principle itself. A patent may be granted for a principle coupled with a mode of carrying out this principle into effect, and it may be carried into effect under several patents operating in different ways and by different means."
>
> [[1929] Ex.C.R. 24, affirmed [1931] S.C.R. 144.]

From this, it is clear that a process is a principle coupled with a mode of carrying this principle into effect..." but that

Indeed, even in respect of the most controversial subject matter, namely plants and animals, or any other higher life forms, the Patent Office has indicated that processes for producing plants and animals which "require significant technical intervention by man"[89] are proper subject matter and may be patentable if the other criteria of patentability are fulfilled.[90]

It is equally clear that none of the different subject matters of biotechnology can, in any aspect, be included in the "machine" category.[91] Consequently, in respect of the products *per se*, a key issue has been, and still is in respect of higher life forms, whether such products of biotechnology fit within the terms "manufacture and/or composition of matter" in light of how these words have been construed by Canadian Courts.

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a principle, *per se*, is not proper subject matter. This conclusion is buttressed by the words of Supreme Court Justice Martland, J. who stated at page 141 of the *Ciba* decision (*Commissioner of Patents v. CIBA Ltd.* (1959), 30 C.P.R. 135 (S.C.C.):

> "This interpretation of process was confirmed in *Tennessee Eastman Co. v. Commissioner of Patents* (1972), 8 C.P.R. (2d) 202 at 206 (S.C.C.)): "A process implies the application of a method to a material or materials."

and by Maclean, J. who stated: "...there is that kind of invention which is to be found in some particular new method of applying a well known principle." (*Canadian Radio Patents Ltd. v. Hobbs Hardware Co.*, [1929] Ex.C.R. 238) Certainly there are many methods and processes used in biotechnology which are consequently capable of fitting into this category of invention just as much as the processes of any other technology (See the discussion in Chapter 2 "Subject Matter of Biotechnology" under the heading Methods and Processes of Making Products of Biotechnology for example, of the types of processes germane to Biotechnology.).

89 This is in line with the decision in *Pioneer Hi-bred Ltd. v. Commissioner of Patents*, (1989), 25 C.P.R. (3d) 257(S.C.C.). In the *Hi-bred* decision the Supreme Court of Canada distinguished between processes for producing plants which do and do not require significant technical intervention by man. The Court was concerned that traditional forms of cross-breeding of plants did not constitute sufficient intervention whereas new techniques of biotechnology, i.e., genetic engineering were potentially worthy of patent protection. The notion of "intervention by the hand of man" is also consistent with the broad notion of patentable subject matter taken in the U.S.

90 Manual of Patent Office Procedure (MOPOP) Ottawa-Hull, 1990.

91 The word "machine" is probably the most straightforward. This word is of such universal and common understanding that there has been little need to pursue the inquiry beyond the definition used in early English cases such as *Morgan v. Seward*:

> The embodiment in mechanism of any function or mode of operation designed to accomplish a particular effect...every mechanical device or combination of mechanical powers and devices that perform some function and produce a new result.
>
> [(1837), 1 Web.Pat.Cas. 187.]

From the perspective of biotechnology, this aspect of the definition has little relevance.

Manufacture and Composition of Matter

The term "manufacture" has not been well defined in Canadian jurisprudence and is often used in conjunction with "composition of matter". Manufacture has been used in a manner by which it is possible to infer the meaning to be attributed to it, for example, as per Maclean, J. in *Hosiers Ltd. v. Penmans Ltd.* stated:[92]

> "If a product is known to the trade, its production by a new process or new instruments cannot make it new. A manufacture is not new and patentable until the creative act in which it originated, is distinct from that required to invent the process or apparatus by which it is made."

From this statement "manufacture" is meant to be an end product, i.e., a manufacture - a result from a process of creation which presumably involves input from a human. The Concise Oxford dictionary provides support for this conclusion based on its definition of manufacture: "making of articles by physical labour or machinery..."[93] The word "manufacture," like discovery and invention, can mean the process or it can mean the result and this duality complicates the understanding.

In Canada, reliance on British case law for interpretation has introduced some complications in understanding definitions, for example, some British decisions go so far as to suggest that the word "manufacture" is synonymous with invention[94] and often the analysis is tied up with the notion

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92 [1925] Ex.C.R. 93.

93 Concise Oxford Dictionary, (Clarendon Press: Oxford, 1985).

94 See H. Fox, "The Canadian Law and Practice relating to Letters Patent for Inventions", 4th ed. (Toronto: Carswell, 1969) at 19

of "manner of manufacture".[95] Unfortunately this blurring of concepts takes the inquiry a step further from ultimately answering the question of "invention."

However, in the British case of *Re Application of Compagnies Reunies des Glaces & Verres* (1931), 48 R.P.C. 185 at 188, "manufacture" was succinctly defined as "a manner of adapting natural materials by the hands of man or by man-made devices or machinery." This definition, particularly with respect to human involvement, is in accordance with the definition used in the Canadian decision in *Application of Abitibi Co.*[96] where the Commissioner of Patents stated through the Patent Appeal Board:

> "...Chakrabarty's invention is patentable because it is a non-naturally occurring manufacture or composition of matter - "a product of human's ingenuity having a distinctive name, character and use"."

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95 For an example in Canadian case law see: *Re Application of Pallos* (1978), 1 C.P.R. (3d) 334 where the Patent Appeal Board states at 337:

> "To begin with, we are not satisfied that fruit, seed and other growing crops per se, are not the result of a process which is a manner of manufacture even though the hand of man may have been involved in planting and cultivating them...On the other hand, we have come to the conclusion that a process of coating a seed may properly be viewed as a manner of manufacture. Where the coating is novel, the result of the process -"the coated seed" - is, by virtue of the novel coating, a novel article or composition of matter. What we would then have is a new result produced by the hand of man." [Emphasis added]

Further, in England the Patent Act defines invention as meaning "any manner of new manufacture..." and this expression finds its origin in the Statute of Monopolies (1624). The English cases are not always consistent in their attempts to adopt this expression to the development to typical advances. In such cases it is considered that these words of the English statute express the same ideas as the categories found in Section 2(d) of the Canadian statute. The categories of subject matter in Section 2(d) find their origins in the early United States patent statutes, a difference being that process is an enumerated category in Canada while it is understood in the United States that process is included in the broad expression "process". Indeed it is a defined term which encompasses the word "art" (see 35 U.S.C. 100). Confusion will inevitably arise when one tries to equate "manner of new manufacture" in the English statute with the categories "art, process, machine, manufacture and composition of matter" as used in the Canadian Act. The English expression must include the concepts of utility and novelty as well as inventive step whereas the concepts appear to be outside the categories of the Canadian statute. On the basis of this distinction, it has been suggested that the rejection of claims for an application of professional skill has a different basis in England than in Canada and consequently such decision must be carefully considered. (Editorial note - *Lawson v. Commissioner of Patents* (1970), 62 C.P.R. 101 at 102-103.)

96 (1982), 62 C.P.R. (2d) 81 (P.A.B.) at 87 which is an adoption of the definition offered by the United States Supreme Court in *Diamond v. Chakrabarty* (1980), 206 U.S.P.Q. 193.

The *Abitibi* decision was concerned with the patentability of a microbial culture system and represented the first decision in Canada allowing claims[97] in a patent to living matter. Indeed, it supports the view that these words, "manufacture", and "composition of matter", encompass living matter. As may be noted from the above quote, the Patent Appeal Board came to its decision relying to a certain extent on the *Chakrabarty* decision, which was a decision of the United States Supreme Court.

Prior to 1980 there had been no court decisions on the patentability of life forms, *per se*. In the United States, patents for such subject matter were simply not allowed.[98] However, in 1980 Chakrabarty's claims for life forms *per se* were allowed by the United States Supreme Court. As a consequence, the name Chakrabarty[99] became a commonplace name in the biotech patent field. The facts of the case were straight-forward: Chakrabarty had developed genetically engineered bacterium capable of breaking down multiple components of crude oil. In the patent application he had made 3 types of claims including process claims for the method producing the bacterium, claims for an inoculum (the mixture which would be applied to an oil site) including the bacterium and claims to the bacterium. The claims to the process and methods had been allowed by the examiner. The critical issue in the case was whether a claim to bacteria was permissible under U.S. patent law.

The case ended up in the United States Supreme Court which looked to the definition of what a patentable invention is under U.S. patent law. The Court found that a bacterium which had been genetically engineered could be considered a "manufacture" as well as a "composition of matter" as those terms appeared in the U.S. statute. The critical message delivered by the Court was that so long as sufficient input by man was involved in the "invention", the subject-matter could satisfy these elements of the definition of invention.

Returning to the Canadian *Abitibi* decision, the only reservation expressed by the Patent Appeal Board with respect to the patentability of living matter was in respect of higher life forms where the concern expressed was the **ability of those reading a disclosure to such an invention to be able to replicate the invention**. They did not express any concern that the words "manufacture" or "composition of matter" were not broad enough to capture this subject matter. However, when the issue of higher life forms as proper subject matter came before the Federal Court of Appeal in the Canadian decision of Pioneer Hi-bred:

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97 A claim is the way in which a patentee, i.e., holder of patent rights, stakes out their territory with respect to what is covered under the patent and therefore the subject-matter of which only the patentee is allowed to practice or authorize practice versus what is not.

98 In Canada, one of the earliest cases concerning the patentability of life forms *per se* was *Re Application No. 086,556* (1975), C.P.R. (2d) 56 (PAB)(now Canadian patent no. 999,546 issued 76/11/09). In the decision claims for a human liver cell line *per se* were not allowed because the cells had been produced by random mutation which was held to be a non-repeatable fortuitous event. Method of use claims were allowed.

99 *Diamond v. Chakrabarty*, (1980) 206 U.S.P.Q. 193.

"Marceau J., in a separate judgment rejected the appellant's argument that the words "manufacture" and "composition of matter" found in s. 2 applied to the new soy bean strain. He stated:

> I have not been convinced. Even if those definitions were held to be applicable to a micro-organism obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. Such a plant cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means."[100]

This use of terminology relating to "...a combination of two or more substances united by chemical or mechanical means" reflects Mr. Justice Marceau's understanding of the expression "composition of matter" which appears to flow from early Canadian decisions such as that of Idington, J. who stated:[101]

> "Our Statute provides for a patent issuing to 'any person who has invented any new and useful...manufacture or composition of matter...' It is admitted the composition need not be a chemical, but may be a mechanical one."

and the notion of a combination of chemicals, as in composition of chemicals as was used in *Chipman Chemicals Ltd. v. Fairview Chemical Co.*[102] However, Marceau, J. states at page 495 of the [Pioneer Hi-bred Federal Court of Appeal] judgment:[103]

> "I am prepared to accept that the Canadian patent legislation does not support the assumption that life forms are definitely not patentable."

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100 R.W. Marusyk "The Patentability of New Plant Life Forms in Canada" Can. Bus. L.J. v. 16: 333 (1990) at 337 and for the statement of Mr. Justice Marceau: *Pioneer Hi-bred v. Commissioner of Patents* (1987), 14 CPR (3d) 491 at 496.

101 *Electric Fireproofing Co. of Can. v. Electric Fireproofing Co.* (1909), 43 S.C.R. 182.

102 [1932] Ex.C.R. 107 at 115.

103 *Pioneer Hi-bred v. Commissioner of Patents* (1987), 14 CPR (3d) 491 at 495.

This double negative is in contrast with His Lordship's earlier remarks and consequently it is not clear that the words "manufacture" and "composition of matter" encompass living matter.[104] Undoubtably they do, but unfortunately:

> "The Supreme Court of Canada declined to address the question as to whether this soybean variety could be regarded as an "invention" within the meaning of s.2 of the Patent Act."[105]

There is no higher authority on the point of whether higher life forms are unpatentable. The policy of the Canadian Patent Office, as reflected in the Canadian Manual of Patent Office Procedure (MOPOP) is that plants and animals i.e., higher life forms are **not** patentable subject matter. However, this apparent bar to living matter as proper subject matter does not extend to **all** living subject matter. Indeed, as provided by The *Abitibi* decision, the Patent Office has stated that inventions for new microbes such as bacteria, yeast, molds, fungi, actinomycetes, algae, cell lines, viruses and protozoa may be patentable[106]. Note that the distinction between this patentable subject matter and that of plants and animals is that the former are unicellular while the latter are multi-cellular complex integrated organisms, or "higher life forms". Note however, as indicated above, the Patent Office does indicate that processes for producing **plants and animals** which "require significant technical intervention by man" may be patentable. This, of course, invokes the *Chakrabarty* element of human intervention which is the *sine qua non* of "manufacture" and "composition of matter". Finally, as outlined above, where a process or method involving a product of biotechnology, (or any other technology for that matter) involves treating a living human being or animal by surgery or therapy, claims to such "methods" may not be allowed.[107] Although not explicit, it is reasonably apparent that the words "manufacture" and "composition of matter" of the Canadian *Patent Act* can include all life forms of biotechnology, as has been found in the United States.

The position of the Patent Office in respect of higher life forms is divergent from the impressions of Patent examiners and Patent Agents practising in the field of biotechnology: namely that the words "manufacture" and composition of matter" in the *Patent Act* are broad enough to include all living subject matter. The Patent Agents, as did the Commissioner in *Abitibi*, could see no reason for drawing a line on the applicability of the definition to "higher" life forms. Indeed,

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104 It is possible that His Lordship's remarks were confined to a plant variety produced by cross-breeding techniques. The issue of plant varieties and animal varieties is very much debated in the European Patent Office, and at the time of this decision, the draft Plant Breeders' Rights Act was receiving Parliamentary attention. His Lordship may have also found it objectionable to grant a patent in respect of a product of cross-breeding which, in the view of the Supreme Court lacked significant intervention by humans. It was more of a result obtained from "letting nature take its course" (even though it was being guided by humans).

105 R.W. Marusyk "The Patentability of New Plant Life Forms in Canada" Can. Bus. L.J. v. 16: 333 (1990) at 339.

106 *Manual of Patent Office Procedure* (MOPOP).

107 See discussion, *supra*, under "Methods of Medical Treatment".

it is a conclusion of this Report that all subject matter of biotechnology, including higher life forms, "fit" into the enumerated categories of the definition of invention and consequently, from the perspective of proper subject matter, are patentable.

D. Scope of Patents for Higher Life forms

The real issue with respect to patents for higher life forms is, if a claim is directed to a genetically modified "higher" life form, can it be said, or is it possible that such a claim exceeds the scope of the invention by going further than the protection to which the inventor is entitled?[108] Stated differently, is a claim to a higher life form directed to the improvement alone such that it is not embracing that which on a fair construction of the specification is in the public domain?[109] The debate concerning this issue became acutely focused as of April 12, 1988, the date when U.S. Patent No. 4,736,866 issued for the Harvard Mouse (the "Leder Patent"). This patent provides an excellent example for discussion of this issue. Claim number 1 of the patent claims:

> 1. A transgenic non-human mammal all of whose cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

This is now the classic example of a claim directed to a genetically modified higher life form. This broad patent also includes claims to any non-human animal into which "any oncogene or effective sequence thereof" has been introduced. Notwithstanding that the disclosure portion of the specification only describes experiments and results conducted in the mouse in respect of the *myc* gene (one of a number of so-called "oncogenes"), and lists thirty-three additional oncogenes and mentions that primates such as the Rhesus monkey could also serve as a trans-genic animal, this claim includes all mammals (except humans) and all oncogenes, and all future generations of the animal containing those oncogenes.[110]

Two key questions arise from this example. The first is a reformulation of the issue as stated at the beginning of this section in the light of this patent: Are the claims of the Leder patent, as exemplified by claim 1, directed to the invention alone or do they embrace that which, on a fair construction of the specification, is within the public domain. In other words, is the patentee entitled to a patent for an entire mouse? The second question which arises from claim 1 of Leder is whether the inventor is entitled to a patent on any transgenic non-human mammal. A related

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[108] MOPOP §8.05.01.

[109] Paraphrased to "inventions" from H.G. Fox "The Canadian Law Practice relating to Letters Patent for Inventions", 4th ed. (Toronto: Carswell, 1969) at 49.

[110] W. Booth "Animals of Invention" Science v. 240: 718 (1988).

issue is whether in respect of each mammal, should descendants be covered by the claim? We will now examine these questions.

Essence of Invention

It is certainly a part of Canadian law that a truly meritorious, so-called pioneering invention deserves broad coverage[111] and this has historically been the case in respect of pharmaceutical cases. Yet, there is a limitation which relates to the specification; there must be support for the claim in the specification, even when it is given a "reasonable view". With respect to the Leder Patent, there are two aspects to this question. The first relates to the subject matter actually described in the specification and the second, whether there can ever be sufficient support in a specification to claim an **entire** animal. This of course relates to the question of the essence of the invention; this is central to the interpretation of the claims.

Interpreting or construing claims[112] must be done without reference to other documents and:

> "...in construing the claims in a patent recourse to the remainder of the specification is (a) permissible only to assist in understanding the terms used in the claims; (b) unnecessary where the words of the claim are plain and unambiguous; and (c) improper to vary the scope or ambit of the claims."[113]

or in other words, the specification must be construed as a whole.[114] It is with these elements in mind that the claims must be given a purposive construction through the eyes of a skilled addressee, and not a purely literal one such as the meticulous verbal analysis so often used by lawyers.[115] They are not to be construed upon what the inventor thought, or what others who merely observed what

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111 "Where the language of the specification, upon a reasonable view of it can be so read as to afford the inventor protection for that which he has actually in good faith invented, the Court, as a rule, will endeavour to give effect to that construction [of the claims]...The patent should be approached "with a judicial anxiety to support a really useful invention."

Consolboard Inc. v. MacMillan Bloedel (1981), 56 C.P.R.(2d) 145 at 156-157 (S.C.C.) quoting *Western Electric Co. et al. v. Baldwin Int'l Radio of Canada Ltd.*,[1934] S.C.R. 570 at 574.

112 An excellent discussion of these issues can be found in "The Art of Claiming and Reading a Claim" by William L. Hayhurst, Q.C. may be found at Chapter 8 of "Patent Law of Canada" G.F. Henderson *et al.* eds. (Toronto: Carswell, 1994) at page 177.

113 *Beecham Canada Ltd. v. Procter & Gamble Co.* (1982), 61 C.P.R. (2d) 1 at 11 (F.C.A.).

114 *Metalliflex Ltd. v. Rodi & Wienenberger A.G.* (1960), 35 C.P.R. 49 at 53 (S.C.C.).

115 Beecham Canada Ltd. v. Procter & Gamble Co. (1982), 61 C.P.R. (2d) 1 at 10 (F.C.A.).

is in use may have thought.[116] Further, many practitioners would agree that a patent's claims should not be limited in scope to just what the examples are in the disclosure - this would make it an easy thing for engineering around the patent.[117]

With this understanding in mind, is the scope of claim 1 of the Leder patent of such breadth in scope that it claims what is in the public domain? To address this question we must attempt to define the essence of the invention and then determine if the claims cover more than this. From the claims (exemplified by claim 1) it may be seen that the essential feature, "the invention" is the mammal containing the activated oncogene. It is not clear from the claim what is meant by "activated" and thus to understand what is meant by this word we may turn to the specification for clarification. At the first paragraph of the "Summary of Invention" an "activated" oncogene sequence is defined as an oncogene which when incorporated into the genome of the animal, increases the probability of development of neoplasms. Text from later in the disclosure supports this view as it states that:

> "The animals of the invention can be used to test a material suspected of being a carcinogen by exposing the animal to the material and determining neoplastic growth as an indicator of carcinogenicity...
> ...The animals of the invention can also be used as tester animals for materials, e.g. antioxidants such as beta-carotene or Vitamin E, thought to confer protection against the development of neoplasms...
>
> ...The animals of the invention can also be used as a source of cells for cell culture."[118] [underlining added]

This is the "utility" of the invention. The novelty resides in the oncogene in the mammal, not the mammal or oncogene on their own. On its most basic level, the situation is analogous to the new use of an old compound as discussed in the *Shell Oil* decision.[119] There, the inventor had taken an old known compound and found a new use for it in regulating plant growth. The patentee was allowed claims to the compound in a composition for this specific "new use". Claim 1 of the allowed patent application stated:

> "a plant growth regulant composition comprising a compound of the formula...together with an adjuvant therefore."

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116 W. L. Hayhurst, "The Art of Claiming and Reading a Claim" In: Henderson, G.F., *et al.*, eds."Patent Law of Canada" (Toronto: Carswell, 1994) at 195.

117 T. Roberts "Broad Claims for Biotechnological Inventions : Opinion" EIPR v. 9: 371 (1994).

118 U.S. Patent No. 4,736,866.

119 See discussion, *infra*, "Product of Nature Doctrine".

In exactly the same manner, Leder took a known compound *myc* gene and inserted it into a "known composition" - a mouse. As disclosed in the "Background to Invention" of the Leder patent, there was nothing new in the concept of transgenic mammals. What was new and inventive here was the "new product", whereby the invention resided in the usefulness of the "old" compound in this "old" setting, i.e., significantly enhancing the susceptibility of the mouse to cancer. Indeed, Leder's claims are so circumscribed: an "activated" sequence is required.

> "In general the most directly effective way of protecting the host which has been modified to include new information is to claim that host, and that is the point at which genetic engineering and the development of patent law with respect to micro-organisms is [at present in Canada.]"[120]

The "new information" referred to in the above quotation is not new *per se*. What is new is its environment. This is the point of invention in the Leder patent; The incorporation of an oncogene into the genome of a mammal produces a "new" mammal has unique, desirable traits which give society a benefit. There is no doubt that of the millions of cells which comprise the Harvard mouse there may be the perception that some aspects are not part of the "invention" However, each and every one of those cells contains the activated oncogene sequence. Each cell has been altered. It is the oncogene, in the environment of normal cells, all of which *in situ*, give the new makeup of the mouse, and it is this new mouse, which by virtue of the oncogene, is more susceptible to carcinogens than is a mouse which does not possess such a gene. Therein lies the value. The "product" which has the utility is the mouse. The invention is the mouse. None of the elements, separately gives the value of the mouse. The oncogene by itself is old, known and of little value *per se*. The mouse by itself is just a mouse - clearly subject matter in the public domain. However, the amalgam of the oncogene in the mouse such that the oncogene is activated and provides the mouse with a predisposition to cancer, was not in the public domain at the date of invention. It requires the context of a cell, and most meaningful is the context of the cell in a whole organism. Thus, a claim to the whole animal covers the invention.

However, it is possible to give the patentee the ability to prevent infringement without allowing a claim for the organism/ higher life form itself, although claiming the life form is simply easier, and in the end, from the perspective of rights of a patentee to prevent infringement, amounts to the same thing. If a claim to the gene alone is allowed, then the patentee in this case would have the most powerful right. Anything incorporating the gene would be an infringement. This is similar to the pharmaceutical patent which claims the active ingredient in a medicine. Regardless of what setting the active ingredient appears in, if it doesn't originate from the patentee or an authorized user, it infringes. The problem in biotechnology is that unlike newly synthesized chemical compounds, DNA exists in nature and is not novel, consequently a claim to the gene itself

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120 R. Perry "What is a Patentable Biotechnological Invention?" Biotech 84: The proceedings of Biotech '84 Europe v. 1: 45 (1984) at 53.

is likely not possible.[121] However, if the gene were claimed in a given context which provides utility, is there any difference in the ability of a patentee to stop infringement? Turning back to the Leder patent as an example, there is no difference in the ability of the patentee of the following claim to prevent infringement than there is for Leder:

1. In a transgenic non-human mammal, or an ancestor of said mammal, a recombinant activated oncogene sequence said sequence introduced at an embryonic stage, such that all of said mammal's, or an ancestor of said mammal's, cells and somatic cells contain said sequence.

This is analogous to the "second generation" claim for known pharmaceuticals, or the "new use" for a known substance which was the subject matter in the *Shell Oil* decision. In each case, the pharmaceutical, or chemical or gene is not new and a *per se* claim is not possible. However, anyone using the pharmaceutical, chemical or gene in the setting of the claim will infringe. In the case of the Leder patent and hypothetical claim 1 above, this is really no different than the limitation Leder has introduced in that claim 1 is restricted to non-human mammals. In many respects the difference between the Leder claim and the hypothetical "gene" claim is only cosmetic. More importantly, the effect is the same from an infringement perspective, i.e., the patentee has an equivalent ability to prevent infringement of the invention. Although the claim is directed only to the sequence, it is the sequence with the condition of a particular environment. All transgenic non-human mammals, or their ancestors, containing a recombinant activated oncogene sequence will infringe. All of the same issues of progeny and equivalents discussed below still exist. Thus, it is not necessary to claim the animal *per se* and still provide the patentee with equivalent protection for the invention. *De facto*, though, this type of claim amounts to the same thing as the claim to the non-human mammals. Consequently, the question of patenting higher life forms still resides in the issues of morality, ethics and economics - not whether sufficient patent protection is available, if claims are not allowed to the entity *per se*.

Mere Aggregation?

Could it be said that a claim to the whole animal, is not allowable because the inventive matter is claimed in association with other elements, i.e., the rest of the animal, and it is clear that there is no invention in the aggregation so resulting apart from the inventive matter itself?[122] The answer to this question is no. As discussed already, the invention is the organism with this special

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121 If it is altered DNA which gives some new property then we are really back into the arena of a new compound as in the chemical arts, this would have the proper novelty, and a claim for the novel sequence, *per se*, should be possible. As already stated, this is the most powerful claim as it allows the holder of such a claim to prevent use in any setting.

122 MOPOP §8.05.02.

feature. The organism is merely another organism without it, and it requires the entire organism to give proper expression to the feature.

Sound Prediction?

The second question raised *supra*, in respect of the Leder example is whether the inventor is entitled to a patent on any transgenic non-human mammal. This question relates to the problem of sufficiency of disclosure. A claim will be held to be invalid if there is no support for it in the disclosure of the patent. As already discussed, the ability to properly describe invention in biotechnology is complex when the subject matter is a living entity. Indeed, a required element of patentability which does not flow from the definition of invention, is the necessity of sufficiently disclosing the invention. In Canada an applicant for a patent shall: "Correctly and fully describe the invention and its operation or use as contemplated by the inventor."[123] In the United States a similar requirement is made of applicants insofar as the specification must contain a written description of the invention and of the manner and process of making and using it in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....[124] Consequently, if an applicant for a patent is unable to fulfil these requirements, notwithstanding the fact that the subject matter may be an invention in every other respect, it will not be a patentable invention. The lack of sufficiency of description, i.e., sufficiency of disclosure, was the stated problem in the *Pioneer Hi-bred* decision.[125]

This disclosure problem is usually overcome by a practice of filing a deposit of the invention in an international depositary. In all jurisdictions where the biotechnological subject matter is a life form, the deposit of the life form is treated as part of the disclosure process. An international treaty known as the Budapest Treaty[126] provides the framework within which a depositary may be recognized as an international depositary authority for the purposes of a patent procedure. Indeed, concomitant with the application made by Abitibi for its fungal culture, it

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123 *Patent Act*, supra, s. 34(1)(a).

124 35 U.S.C. 112.

125 In the United States this was the basis for an initial rejection of the application in Ex Parte Hibberd (1985), 227 U.S.P.Q. 443 wherein it was found that evidence demonstrating that the subject matter of the claims had been placed in a depository which was not a recognized depository in combination with evidence suggesting that the depository was not required to supply samples to anyone seeking such samples supported a rejection for insufficiency of disclosure under 35 U.S. 112.

126 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms (1977).*

provided samples of the culture to an international depositary authority notwithstanding the fact that Canada wasn't, and still isn't a member of the Treaty.[127]

Some would argue that the depositary is a concession to the subject matter of biotechnology which amounts to a softening of patentability requirements and leads to a less well defined patent system. Whether such a deposit is sufficient is an arguable point, particularly with respect to higher life forms. However, what is a well established practice in the United States will be part of the Canadian statute once amendments which have been made to the *Patent Act* are proclaimed in force.[128]

Returning to the issue of sufficiency in support of broad claims, with one notable exception, the subject matter of biotechnology, beyond the level of simple molecular chemical structures such as amino acids and nucleic acids, raises problems with respect to predictability (and therefore scope of claims) that have not generally been encountered in respect of other types of subject matter. In the mechanical, electrical, computer, etc. arts it is possible to predict, with considerable certainty, the effect of variants to an invention and consequently clearly identify the scope of a claim in respect of modifications to an invention. The exception is that just mentioned, chemistry. During its early stages of development chemistry shared many of the "predictability" problems currently faced by the subject matter of biotechnology. Indeed, in the 1930s, when the preparation of chemical products was not as predictable as it is today, this situation was recognized by the Canadian Courts where in the *Chipman Chemicals Ltd. v. Fairview Chemical Co. Ltd.* decision it was said: "There is no prevision in chemistry."[129] The situation has changed since that time and with the advent of techniques such as nuclear magnetic resonance (NMR), high pressure liquid

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127 Indeed, it is an unofficial practice at the CIPO to deposit microorganisms in support of an applicant's disclosure. This practice will become official with the proclamation into force of bill S-17. See discussion at footnote next, *infra*.

128 Amendments to the Canadian *Patent Act* which were part of Bill S-17 have been enacted but as yet have not been proclaimed in force. This section of the Act is awaiting proclamation which will occur when new rules have been adopted which rules will govern patent procedure in connection with the making of deposits and filing applications in respect of DNA and protein sequences. Clause 41 of Bill S-17 provides the following new section for the *Patent Act*:

> "38.1(1) Where a specification refers to a deposit of biological matter and the deposit is in accordance with the regulations, the deposit shall be considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, the deposit shall be taken into consideration in determining whether the specification complies with that subsection."

Subsection 27(3) is the section which provides the requirement for a detailed written disclosure of the invention. For further discussion of the topic of disclosure see the following: K.P. Kaminski, "Disclosure of Information in a Computer-Readable Form for Biotechnology Inventions" (1993) 10 C.I.P. Rev. 93; T. Orlhac, "Les Specificites de L'Invention Dans Le Domain de la Biotechnologie" (1993) 10 C.I.P. Rev. 57; J.C. Robinson, "Canadian Disclosure Requirements for Biotechnology Inventions" (1993) 10 C.I.P. Rev. 69; and B.G. Kingwell, "Functional Language and Finger Prints" (1993) 10 C.I.P. Rev. 87.

129 [1932] Ex. C.R. 107 at 115.

chromatography (HPLC), and x-ray crystallography, the structure and function of chemical compounds are much better understood, to the point where the behaviour of chemicals is quite predictable. As such, if the development of a new chemical compound is an invention, related chemicals can be claimed based on this predictability. Typically chemical compounds in pharmaceutical patents are claimed specifically, i.e., fluoxetine hydrochloride,[130] and by general formulas which include the specific compound and others. Indeed the claims of most patents conceming pharmaceuticals are based on the discovery of a handful of compounds, but in the main claims actually use formulae which relate to those compounds and perhaps hundreds or thousands more. This is based on the principle that they share equivalent properties. Such claims have been held to be acceptable in the chemical arts on the basis of a holding in the *Monsanto* decision.[131] In this decision the Commissioner of Patents had rejected product claims in an application for a patent for new chemical compounds. One of the claims rejected covered 126 species when details in the disclosure related to only 3 which had been tested. The Supreme Court of Canada reversed the Commissioner stating that the Commissioner could not refuse a patent because an inventor had not tested and proved all its claimed applications. The Court found that there was no evidence to demonstrate that the prediction of utility for every compound claimed was not sound and reasonable. The same kind of extrapolation is often made in patent applications in respect of the subject matter of biotechnology. However, because there are situations where there really is no prevision in biotechnology, such claims are not allowed. However, many products of biotechnology are simply chemical compounds and as such are susceptible of prevision. In such cases the argument of predictability is available, and the scope of the claims is correspondingly wider.[132]

However, where an invention in biotechnology is found to work in a mammalian model such as the mouse, can it be said that it will predictably work in all mammals? Patent agents argue *Monsanto*, i.e., predictability, saying that because, for example, results from experiments detailed in the disclosure suggest the same should occur in other organisms, that their results are predictable thereby justifying broad claims. Notwithstanding such arguments, the current view in the CIPO as gleaned from patent practitioners is that without experimental support, such claims cannot be justified. In other words, there is currently no prevision in such complex systems. In the disclosure

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130 Actually, Canadian Letters Patent 1,051,034 has claims known as "product-by-process" claims. Under Canadian practice at the time the patent issued, claims to the medicine itself were not permissible. See the discussion of the related problem in respect of products by microbiological processes as discussed in Chapter 2 at footnote 30. Today however, claims to the product itself now are permissible.

131 *Monsanto Co. v. Commissioner of Patents* (1979), 42 C.P.R. (2d) 161 (S.C.C.).

132 Notwithstanding this, even in respect of proteins, patent agents will make the argument that the effect of changes to the basic structure of a protein, even as minor as changing one amino acid, are not predictable. Indeed, while most molecular biologists can simply and easily state what would appear to be an elegant solution to a particular problem in biotechnology, the same people would also agree that reducing that "obvious" solution to practise is often extraordinarily difficult, being fraught with unexpected problems along the way (M. Paver, "A Tale of Two Rodents, or a Rodent with Two Tails: Europe Grapples with Patenting Animals" Patent World, June (1993) 29 at 31.). Such arguments are also often made in respect of inventions which are the subject of obviousness rejections. See discussion below under the heading "*Desideratum* Inventions".

of the Leder patent only the mouse model is described in detail. While there is nothing to suggest the approach disclosed in the patent would not work in other mammals, there is no data to support the claim that it would.[133] Consequently, Canadian examiners would likely tend to refuse claims of scope as broad as the Leder patent arguing that biotechnology, unlike chemistry, is still too much of a black box to be able to safely argue sound prediction. On this basis it is quite unlikely that claims as broad as exist in the Leder patent could be obtained in Canada.

A related question, as raised above, is whether it is appropriate for claims to cover descendants. Clearly it is predictable that the invention extends to descendants and are therefore on this basis necessary, and should be included in the scope of a claim. In fact, if it did not then the entire issue of reproduction of the invention could defeat the validity of a patent. What the question raises is the issue of infringement by progeny. This is because in order to obtain a patent, an invention must be reproducible. In the case of the mouse, the descendants are reproductions of the invention.

Do these issues take the subject matter of biotechnology outside of the framework of a workable fit in patent law? Probably not. This is because this issue of predictability relates only to the issue of scope. As such, there must be an underlying patentable invention before the issue is raised.[134] In a similar respect, the problematic issue arising from the reproducibility of the "invention" is concerned with infringement and patentability. This issue is discussed further below.

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133 In Europe, however, the Board of Appeals found that the invention was sufficiently disclosed to support claims to mammals in general (see *Onco-mouse/Harvard* (1990) T 19/90 (Decision of Technical Board of Appeal 3.3.2 at 3.0-3.9). Although it may turn out that this is problematic for the Leder patent. In a recent decision of the U.S. District Court for the Southern District of Indiana (*Regents of the University of California v. Eli Lilly and Co.* DC SInd, No. MDL 912, 12/11/95) the court found that the isolation and characterization of proinsulin cDNA from one member of a genus is not sufficient to support claims to the insulin cDNA of thousands of other species from that genus. The patent at issue only described rat insulin cDNA, while the claims were drawn to the genera of vertebrates and mammals to the human species. See "Human Insulin Patent is Invalid for Inadequate Written Description" in BNA's Patent, Trademark & Copyright Journal V. 51 No. 1260 (1996).

134 In addition, the similarity in experience with the subject matter of chemistry is striking. Indeed, in an extreme view the subject matter of biotechnology and chemistry is identical - or in time will be understood as identical. This view is premised on the perception that biological systems are really nothing more than extremely complex mixtures of chemicals, and when viewed on the molecular level, this is correct. Indeed the "activity" of biological systems in certain respects is driven by chemical functionality. As such, it will only be a matter of time before prevision will be more of a reality in all aspects of biotechnology.

The Problem of Progeny

Even if the claims do encompass the higher life form itself, should they include within their scope, as suggested above, future generations of the genetically altered organism?[135] The problem relates to the theory of exhaustion of patent rights. It is understood in patent law that a patentee has the right to make, construct, use and sell the patented invention. However, it is also understood that once the invention is sold, any rights the patentee had are exhausted at the point of sale. But some organisms are self-reproducing, (asexual reproduction) and breeding or otherwise reproducing a patented organism amounts to copying, or "making" the invention. Where the organism is patented, such activity may arguably amount to an infringement of the patent rights if the activity occurred without the consent of the patent holder. In the situation where farmers are using patented, reproducible biomatter, monitoring the "infringing activity" will be difficult as each farmer has the potential to be an infringer. Consequently, the normal rules of infringement under the *Patent Act* do not "fit" for this type of invention. In the United States, the problem has been addressed in respect of plants covered by the Plant Variety Protection Act. Under that legislation a farmer has the right to replant seeds harvested from a protected variety.[136] However, where the seeds are being protected under the Patent Act, there is no provision for these situations. Furthermore, there is no "Animal Variety Protection Act", so problems arise animal inventions.

To date, no definitive answer has been worked out in any jurisdiction where patents are allowed for higher life forms and the need for an answer is great in view of the potential for significant economic impact in allowing claims of such scope. This is underlined in an article by Robert P. Merges and Richard R. Nelson[137] who, through the use of historical studies, suggest that where a court grants broad patent scope to ground breaking, or so-called "pioneering" inventions the progress in several industries is slowed. Merges and Nelson suggest that patent scope affects progress in each industry differently and that it depends upon the nature of the technology involved, the manner in which technical advances in the industry relate to each other, and the extent to which firms licence technologies to each other.[138] Indeed, if broad scope is to be given to patents in biotechnology, as is well illustrated in the farming example, there may be considerable difficulty in monitoring and enforcing such rights.

There are three basic approaches to dealing with the potential for infringement which may arise in respect of inventions which reproduce or are bred.

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135 Arguably, the Leder patent didn't even have to refer to ancestors. The mere statement "A non-human mammal with the activated sequence..." includes within its scope all generations containing this trait.

136 J.H. Barton "Patenting Life" Scientific American, v. 264: 40 (1991) at 43. Such exemption, although not explicit, does exist under the *Plant Breeders' Rights Act* of Canada.

137 "On the Complex Economics of Patent Scope" Columbia Law Review v. 9E: 839 (1990).

138 Y. Ko "An Economic Analysis of Biotechnology Patent Protection" The Yale Law Journal, v. 102: 777 (1992) at 782-783.

The first is to do nothing except trust that the judiciary, when confronted with a case alleging infringement in such circumstances, will come to the conclusion that the farmer who breeds to maintain the stock is not an infringer:

> Some have assumed that the sale of a patented animal "exhausts" all patent rights in it, freeing the purchaser to use the animal for any purpose, including the production of additional animals (progeny) which may themselves satisfy the recitations of the patent claims. A more recent analysis, however, shows that propagation of any patented life form from a purchased embodiment, be it animal or otherwise, may avoid infringement of the patent only to the extent that the propagation is necessary to maintain that quantity of the life form necessary for its continued use *as intended*, under what the law refers to as an "implied license... the implied license accompanying the purchase of a patented animal would be delimited by the nature of the intended use of the animal. To the extent that the intended use entails periodic breeding, say, to build up and sustain the herd, the sale price of the animal could reflect the patent owner's expectation of a cumulative adverse effect such as "maintenance" reproduction may have on his potential market share.[139]"

The second approach to dealing with this situation is to have the patentee adopt a more rigorous licensing strategy, where appropriate, in order to ensure the appropriate reward to the patentee. An approach to this problem has been suggested:

> Alternatively, the farmer/purchaser and the patent owner/seller may negotiate the sort of arrangement... where a payment is made for each offspring. Exacting a per unit royalty in this manner is only one of the ways that a patent owner can be compensated, and need not (indeed, surely will not) be employed where to do so renders the patented animal non-competitive with accepted life forms."[140]

Even if this is an approach to the problem of progeny, there is a question that an "equivalents" determination may not be available in respect of higher life forms. This is discussed further below in respect of "Infringement and the Doctrine of Equivalents".

The third is to amend the *Patent Act* to provide a so-called "farmer's exemption". It is not clear that an amendment to the *Patent Act* would be sufficient (or even possible) to solve the problem for each case of patented, reproducible biomatter, given the vastly different types of subject matter which make up biotechnology. Each subject matter will raise different concerns. For example, the sale of patented brewer's yeast is meaningless unless the yeast can be allowed to reproduce during the brewing process. Equally, sales of patented livestock for the purpose of

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139 S.A. Bent "Issues and Prospects in the U.S.A." In "Animal Patents: The Legal, Economic and Social Issues", Ed. Lesser, W.H. (MacMillan Publishers Limited: New York, N.Y., 1989) pg 5 at pg 13.

140 *Id.*

fattening them are less likely to include an assumption that the animals will be bred or reproduced.[141]

Infringement and the Doctrine of Equivalents

> "The patent holder's exclusive right to exploit products or processes within the scope of his patent grants him economic power. ...[C]ourts analyze infringement in three steps. First, courts examine the claims, as described above to ascertain the scope of a patent. "Literal" infringement results if the alleged infringing matter falls within the scope of the claims as properly construed. Even if an accused product or process does not literally infringe the claim, it may still infringe under the "doctrine of equivalents". Under this judicially created doctrine, a product or process, though it does not fall within the literal language of the patent claims, may infringe if it "forms substantially the same overall function or work in substantially the same way, to obtain substantially the same overall result as the claimed invention." [142]

This analysis is equally applicable in Canada. The formulation of the test under the doctrine of equivalents in the United States is not significantly different from the purposive approach taken in Canada and the United Kingdom. Consequently, it is arguable that the same results should be achieved. Indeed, similar results were achieved in the *Genentech* cases in both the United States and the U.K. in the consideration of infringement[143] However, the *Genentech* case was about a protein, t-PA, which is really just a complex chemical compound.

How does this analysis stand up when the subject matter is one which is alleged to infringe the Leder patent? Let us assume a researcher has found a way to manipulate the genes of a rabbit to generate oncogenes, and that it is no longer necessary to introduce these homologous genes at the embryonic stage. What are the essential elements of the Leder invention in such a case?

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141 J.H. Barton "Patenting Life" Scientific American, v. 264: 40 (1991) at 43. Although, in Europe there was such concern about this issue, Article 13 of the EPC was amended to provide that farmers may use for purposes of multiplication or propagation on their own farm the seeds obtained from crops cultivated on their own farms using seeds protected by patents. In the same manner, livestock which are the subject of patent protection can be used for multiplication/propagation by farmers so long as it is on their own farms in order to renew stock. The "own farm" wording is intended to avoid abuse by co-operatives (J. Thurston, "Recent EC Developments in Biotechnology" [1993] 6 EIPR 187 at 188.)

142 Y. Ko "An Economic Analysis of Biotechnology Patent Protection" The Yale Law Journal, v. 102: 777 (1992) at 780-781.

143 The key difference being that the English Court found the patent invalid for lack of invention.

Arguably they are:

1. transgenic
2. non-human mammal
3. all of whose cells and somatic cells
4. embryonic stage

When does the embryonic stage end? What does transgenic really mean? What if all of the cells of the rabbits do not contain the oncogene? How many cells don't have to contain the gene before it is no longer in the realm of "all"? With respect to purposive construction (i.e., substantially the same *function* in substantially the same *way* to achieve the same *result* as the patented invention analysis) isn't the whole point of the invention to have a model which is highly susceptible to cancer? On this level of analysis isn't it arguable that anything that achieves that result is within the "scope" of the claims and therefore infringing? This latter interpretation is probably too broad for it is merely a restatement of the problem which Leder solved. However it is not clear where the answer lies in respect of this problem. This fact situation presents significant issues which will, no doubt be difficult to answer. However, there are always equivalents, regardless of the field of technology, and there will always be pioneering inventions which make those that follow in a field of technology appear as though they are not equivalents. The appropriate experts would be found and their opinions rendered to a Court of law and a determination would be made to determine if the transgenic rabbit is the equivalent of the invention.

In conclusion, the subject matter of biotechnology, including higher life forms, does "fit" within the "enumerated categories" of invention. Namely, biotechnology can be considered as a manufacture or composition of matter. In respect of such inventions it is appropriate for claims to include within their scope the entire life form where the life form is in fact and in law the invention. The only significant issue of concern which arises from these conclusions and assuming that the invention is patentable, is the problem of progeny and how to deal with infringement by a descendant of a patented invention. It is recommended that a farmer's exemption be introduced to insure that infringement is not an issue in respect of proper use of a patented life form by farmers. This exemption is discussed further in Chapter five under the heading "Problems with Progeny"

Thus, on the assumption that one has proper subject matter we now turn to the remaining aspects of the definition of statutory invention.

NEW, USEFUL AND UNOBVIOUS - DOES BIOTECHNOLOGY FIT?: Specific Issues of Patentability

The remaining elements of statutory invention which must be considered are whether the subject matter has novelty, is useful and is unobvious. There are separate considerations in respect of each of these remaining elements and these will now be discussed. However, what is set out below provides only a brief overview of the guiding principles by which these elements are

assessed regardless of the subject matter. Under each heading specific issues peculiar to biotechnology will be discussed in detail.

A. Utility

According to the *Patent Act* definition of invention utility is the last mentioned element. It requires that the subject matter under consideration must be useful i.e., it must have utility. Case law supports the view that inventions, which are the subject of a patent, are, *prima facie*, presumed to be useful.[144] This accords with the definition of invention given above in the discussion of the concept of invention, however, the question in patent law is if mere utility/applicability is enough. Arguably it is enough. Indeed, Canadian caselaw suggests that there must simply be some practical utility, if not a commercial aspect. In the words of Mr. Justice Dickson (as he was then) in *Consulboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*,[145] quoting with approval from an authoritative British legal reference material (Halsbury):

> "...the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested....[I]t is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice."

Inherent in this analysis though is the feature of public utility, having a purpose or a usefulness for society. It is quite unlikely that a patent could be obtained for subject-matter which is of little use or the use is of very limited benefit. This relates to the purpose of a patent system. An advance in technology, for the benefit of society, is impossible if there is no utility. This, too is in agreement with the concept of invention considered above, wherein it was concluded that utility is an essential ingredient in defining invention. However, arguably the standard of utility is higher under the statutory definition than it is under the conceptual discussion in Chapter 3 where for utility all that was required is a purpose beyond the mere purpose of existence for the sake of existence. Although it has never been the subject of a Canadian decision, this point is well illustrated by the decision of the United States Patent Office in refusing the National Institutes of Health's (NIH) patent application for "fragments" of DNA.[146] Under the conceptual analysis of invention, the

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144 *Unipak Cartons Ltd. v. Crown Zellerbach Canada Ltd.* (1960, 20 Fox Pat C. 1 (Ex. Ct) at 34; and *Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd.* (1972), 8 C.P.R. (2d) 6 (F.C.T.D.).

145 (1981), 56 C.P.R. (2d) 145 (S.C.C.) at 160.

146 The so-called Venter Patent Application which is continuation-in-part June 20, 1991 of NIH as cited in (1992), 11 Biotech. L.R. 1324; and the rejection of the claims in the application as provided in Office action dated August 20, 1992 of the USPTO to the representatives of the NIH - see E. McMahon, Nucleic Acid Sequences and other

fragments could be used in further research and could therefore fulfil the applicability/ usefulness criterion but, when one considers the bisociative aspect, which in respect of the fragments is weak if present at all, the fragments seem more to fall into the category of discovery. Notwithstanding this difference in standards, in principle, this element does not distinguish statutory invention from the broad concept of invention. In conclusion, in Canada there is nothing unusual about the subject-matter of biotechnology to affect or change the outcome of the utility inquiry.[147]

Naturally Occurring Products: Are they Patentable in Canada? (1993) 10 C.I.P.R. 11. A technique had been developed or isolating and identifying portions of the human genome. The result of this technology was pieces of DNA from the Hayman genome whose function was not understood at the date of filing the patent applications

147 Under U.S. practise in respect of biotechnology subject matter the standard of utility has been extremely high. In fact so much debate was engendered by the practise of the U.S.P.T.O. Public Hearings on Patent Protection for Biotechnological Inventions were held on October 17, 1994 in San Diego, California. With the Supreme Court's ruling in *Diamond v. Chakrabarty* the patent system was faced with enormous challenges.

> "...while Section 101 of Title 35 requires patentable inventions to be "new and useful", the application of this "practical utility" requirement in biotechnology remain[ed] unclear. Courts have interpreted the Section 101 "utility" requirement to mean a patentable invention must be "operative". However, the meaning of this requirement and the related enablement requirement at Section 112 is uncertain in the area of biotechnology. Whether the patent law requires evidence that a therapeutically related invention is safe and effective in humans is also not fully determined."
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> ["Biotech Industry Blasts PTO at San Diego Hearing", BNA's Patent, Trademark & Copyright Journal, Volume 48: 677 (1994) at 677.]

Indeed, with respect to many biotechnology-based inventions which were to be used in the treatment of human beings, they were held not to be "inventions" for the purposes of patenting because the applicant had not demonstrated that the subject matter actually worked, and were therefore not useful. The biotechnology examiners were requiring Phase III clinical trial data before they were "convinced" that utility existed. Phase III means that significant preliminary testing in clinical trials had taken place to get to Phase III. Phase III itself is a thorough experimental\clinical investigation of the value of a drug substance. The basis for this position arose from an interpretation of case law which interpreted the utility requirements of 35 U.S.C. 101 to require that an invention be operative to possess utility. See, e.g., *Raytheon Co. v. Roper Corp.*, 220 U.S.P.Q. 592 (Fed. Cir. 1983); *Stiftung v. Renishaw PLC* ... 20 U.S.P.Q. 2d 1094 (Fed. Cir. 1991); *In Re Gazave...* 154 U.S.P.Q. 92 (C.C.P.A. 1967); *In Re Chilowsky...* 108 U.S.P.Q. 321 (C.C.P.A. 1956). Second, because 35 U.S.C. 112, requires that an inventor provide a disclosure of the invention that will enable a person of skill in the art to make and use the claimed invention, the examiners interpreted this as requiring a disclosure proving operability, otherwise they would reject the invention as being insufficiently disclosed as to be enabling. Following the hearings, the USPTO recognized there was a problem and has amended its policy on utility in respect of inventions in biotechnology. See the discussion in Stinson, S., "New rules ease bio-tech patent requirements". Chem. & Eng. News, January 1995, p. 7-8 (Utility) (1995) where it is stated: "The new guidelines shift PTO's policy for compliance with this "utility" requirement from an approach that doubts whether an invention works, to one that assumes the invention works, at most there are sound reasons to suspect otherwise."

B. Novelty

As provided in the statutory definition, to be an invention, the subject matter cannot have been previously known. A test which is often applied at this stage of inquiry is whether the invention is new or novel,[148] i.e., the invention must not have been anticipated,

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[148] For a good discussion of the novelty requirements see H.G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions, 4th ed. (Toronto: Carswell, 1969) c. 4 and for anticipation see page 128ff of the text; also R.E. Dimock "Patent Anticipation or What's New, Patent Act" In: Patent Law of Canada Eds. G.F. Henderson *et al.* (Carswell: Toronto, 1994) at 101.

i) Legislation

27. - Who may obtain patents

(1) Subject to this section, any inventor or legal representative of an inventor of an invention may, on presentation to the Commissioner of a petition setting out the facts (in this Act be termed the filing of the application) and on compliance with all other requirements of the Act, obtain a patent granting to the applicant an exclusive property in the invention unless

(a) in the case of an application to which Section 28 applies,

(i) an application for a patent describing the same invention was filed in Canada by any other person before the priority date of the application, or

(ii) an application for a patent describing the same invention and to which Section 28 applies is filed in Canada by any other person at any time and the priority date of that application precedes the priority date of the application;

(b) in the case of any other application,

(i) an application for a patent describing the same invention was filed in Canada by any other person before the filing of the application, or

(ii) an application for a patent describing the same invention and to which Section 28 applies is filed in Canada by any other person after the filing of the application and the priority date of that application precedes the date of filing of the application;

(c) the invention was, before the date of filing of the application or before the priority date of the application, if any, disclosed by a person other than a person referred to in paragraph (d) in such a manner that it became available to the public in Canada or elsewhere; or

(d) the invention was, more than one year before the date of filing of the application, disclosed by the applicant or a by a person who obtained knowledge of the invention, directly or indirectly, from the applicant, in such a manner that it became available to the public in Canada or elsewhere.

This is the current state of the legislation at the date of writing. As mentioned above, Bill S-17 introduced a number of amendments one of which included amending this novelty provision. This section 27 will be repealed when the

e.g, described in any patent or in any publication.[149] Applicants for patents in Canada are faced

amendments come into force and replaced with a new section 27 which is concerned with content of the specification. New section 28 will be concerned with novelty, and as discussed *supra*, non-obviousness. The section as presently enacted, but which is not yet in force, is as follows:

28.2 - Subject-matter of Claim Must not be Previously Disclosed

(1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed

(a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;

(b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;

(c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or

(d) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if

(i) the co-pending application is filed by

(A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or

(B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada and application for a patent disclosing the subject-matter defined by the claim,

(ii) filing date of the previously regularly filed application is before the claim date of the pending application,

(iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and

(iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.

The main effect of the amendments is to better define the time at which applications are made. Under the old sections there was some confusion between the filing date of an application in another country and which was being relied upon as a priority date, and the date of filing the application in Canada. The introduction of the "claim date" is intended to clarify this situation. In addition, as the Canadian statute is presently framed, the novelty inquiry is in respect of the "invention". The new section purportedly modifies this to "the subject-matter defined by a claim in an application". Whether this modification will impact significantly on the nature of the novelty inquiry will remain to be seen.

with the requirement that the subject-matter must not have become available to the public, in Canada or elsewhere, more than one year prior to the date of first filing of the application.[150] The

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[149] Canadian jurisprudence established the test (or standard) for novelty in the *Reeves Brothers* case ((1978), 43 C.P.R (2nd) 145 at 157 (Fed. T.D.)) which held that the following criteria were required in order to find anticipation, or lack of novelty, in a published document:

1. Give an exact prior description;
2. Give directions which will inevitably result in something within the claims;
3. Give clear and unmistakeable directions;
4. Give information which for the purpose of practical utility is equal to that given by the subject patent;
5. Convey information so that a person grappling with the same problem must be able to say "that gives me what I wish";
6. Give information to a person of ordinary knowledge so that he must at once perceive the invention;
7. In the absence of explicit directions, teach an "inevitable" result which "can only be proved by experiments"; and
8. Satisfy all of these tests in a single document without making a mosaic.

This would apply in respect of all published literature which, of course, includes patents and patent applications. The test was interpreted as requiring that all of the above 8 aspects be met before anticipation existed in the prior art. In essence, the invention had to exist or the invention had to have been precisely described. Consequently, from 1978 until the Court of Appeal in the *Tye-Sil* case modified this approach, it could be said that the standard of novelty was low, i.e., very little had to be "new", and the standard for anticipation, which is the opposite view of novelty, was very high. Notwithstanding the comments on the *Reeves Brothers* standard in the *Tye-Sil* ((1991), 35 C.P.R. (3rd) 350 at 361 (Fed. C.A.)) decision, which arguably softened the requirements under *Reeves Brothers*, from a practical perspective for one to find an anticipation, a prior publication still must detail something which is the same as the invention. This is not surprising considering the words of the statute which state: "the invention was...disclosed...". This too means that any prior art reference which is not a printed document, but is a physical embodiment, must be the same as the invention. Indeed, at the CPO, the *Reeves Brother's* test, as modified by *Tye-sil*, has been distilled into a simple question of "Is it the same?" which is asked when evaluating the prior art in respect of applications in biotechnology.

[150] In almost every other country worldwide which has a patent system, except for Mexico, the United States and Japan, absolute novelty is required, where any showing or disclosure prior to filing is sufficient to negate any possibility of obtaining a patent. In the United States the "world" is a somewhat smaller place than it is under Canadian practise. There, as in Canada, publication of the invention anywhere in the world will render the invention not novel. However, public use or sale is restricted to the United States, i.e., so long as the invention has not been disclosed anywhere in the United States it may be considered new, notwithstanding that it may have been publically available in another country. 35 U.S.C. 102 states:

> "A person shall be entitled to a patent unless - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described

importance of the question of novelty in biotechnology is unparalleled because of the fact that some of the subject matter is found in nature. This aspect of the novelty inquiry is addressed in greater detail below under the heading "Product of Nature Doctrine".

Availability to the Public

It is one thing to be an anticipatory document, but if it is not available to the public, then it will not destroy the novelty in an invention. The European statute adds a further element to this aspect of novelty: it requires at Article 54(1) that the invention does not "form part of the state of art", or in other words, the prior art must be in the same field of art as the invention. As discussed below, this is probably a distinction without much of a difference.

In Canada there have been no decisions interpreting what is meant by "available to the public". Consequently, the closest jurisprudence relates to what amounts to a "publication". In order to be a publication it has been held that a document must be generally available without restriction, to members of the public, and the persons receiving the information must have no special relationship with the author.[151] In Europe, the expression is "made available to the public" and in view of this interpretation from *Xerox* it is likely that the approach taken here will be the same as that in Europe. Consequently, the elaborations on this point, set out under the consideration of the European legislation, will probably apply equally to interpretation here.

In order to be considered novel the subject matter of an invention must not have become available to the public. This aspect of novelty is probably the most critical aspect of the inquiry with respect to biotechnology, as it will be difficult to decide if, as has been decided in Europe, that a gene sequence, which was known to be contained in the genetic information contained in a "gene bank" was "publically available". The European Patent Office (EP0) held that it was not (T301/87). The same question arises in respect of new bacteria isolated from soil samples, and so on.

The answer to this issue is arguably answerable only on a case by case basis. For example, if it was generally understood that soil in a particular region was a likely source of bacteria with desirable traits, and access to this region was unrestricted then novelty would likely be destroyed in such circumstances. However, if, as is usually the case, the bacterium isolated was unknown, and its desirable properties did not become apparent until isolated and cultured, then in such

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> in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States,..."

Prior to 1989, the Canadian statute was similarly limited with respect to novelty to disclosures in public in Canada. However, with the amendments to the Canadian *Patent Act* which came into effect in 1989 disclosure anywhere in the world was sufficient to destroy the novelty or newness of an invention which was the subject of a patent application.

151 *Xerox of Canada Ltd. v. IBM Canada Ltd.* (1977), 33 C.P.R. (2d) 24 (F.C.T.D.) at 85.

circumstances, novelty would be preserved. This was the finding in the U.S. decision *In re Bergy*.[152]

With respect to the genetic sequence from the "gene bank", it is likely that the same result would be found here. In many ways, as was analogized by the EPO, the gene bank is similar to the soil sample. If the value of the gene "hidden within" was not realized until isolated and identified, then the "invention" really cannot be said to have been "available to the public".

Product of Nature Doctrine

Regardless of the subject matter of biotechnology under consideration, i.e., whether it is a monoclonal antibody, a bacterium, a plant or an animal, a special kind of consideration arises which does not enter into the picture with respect to other subject matter, and this is that often the invention has a counterpart which occurs in nature. In such cases how can there be novelty? In all jurisdictions which are faced with applications for patents in respect of the products of biotechnology, this fundamental issue must be addressed in order to determine whether the application may proceed. This issue is well illustrated by the following quote:

> "...DNA is a polymer which is a natural product, and most, but not all, sequences of interest in DNA are present somewhere in nature. It is worth recognizing explicitly that most of what recombinant DNA methodology is doing at the present time is taking genes out of one genetic context in nature where, at least for our immediate purposes, they are not directly useful to us, and putting them in another genetic context where they are more useful. To what extent the Patent Office and the Courts will hold that a pre-existing sequence of base pairs which has been isolated and amplified by gene splicing methods is a "product of nature" and therefore not patentable remains to be determined"[153]

While this example is limited to DNA, the same problem is true for any other product of biotechnology which amounts to a synthetic version of the product which "occurs in nature". In many ways the issue is fundamentally the same as the distinction between discovery and invention and it is tied in with the issue of obviousness, i.e., is the purification and isolation or preparation of a "naturally occurring" substance obvious. In fact, where the "product of nature" has already been discovered, the issue really is not "product of nature", it is obviousness.

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152 (1979), 201 U.S.P.Q. 352 (C.C.P.A.).

153 Jackson, "Patenting of Genes: Ground Rules in ASM, Forum on Patentability of Micro-organisms 17 (1981) at 25 In: Cooper, I.P., "Biotechnology in the Law - 1995 Revision" v. 1 (Clark, Bordman, Callaghan: New York, N.Y., 1995) at page 3-12.

The classic distinction between a "discovery" and an "invention" may be found in the judgment of Buckley J. in *Reynolds v. Herbert Smith & Co., Ltd.*[154], who stated at p. 126:

> "Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result."

The "original" Canadian biotechnology case which addressed the "product of nature" doctrine and incorporated the above-noted distinction between invention and discovery was *Continental Soya Co. Ltd. v. J. R. Short Milling Co. Ltd.*[155] This case concerned the patentability of an enzyme which occurred naturally in soya beans. Duff, C.J.C. cited with approval, the words of Lord Justice Luxmmoor, H. Fletcher Moulton and A. W. Bowyer in the treatise on Patents and Inventions, 24 Hals. (2d), para. 1123, p. 591, at page 4 of the decision:

> "The difference between discovery and invention has been frequently emphasised [sic], and it has been laid down that a patent cannot be obtained for a discovery in the strict sense. If, however, the patented article or process has not been anticipated, so that the effect of the claims is not to prevent anything being done which has been done or proposed previously, the discovery which led to the patentee devising a process or apparatus may well supply the necessary elements of invention required to support a patent. This is certainly the case if it can be shown that, apart from the discovery, there would have been no apparent reason for making the variation in the former practice."

Duff C.J.C. then went on to agree with the President of the Exchequer Court (Mr. Justice MacLean) in the lower court decision who stated in respect of the same matter:[156]

> "I think Haas undoubtedly made an important discovery, and as a result of substantial and original research and experimental work he has disclosed a process or processes, or means, for translating his discovery into practical and useful ends, something that was not, I think done before. (The production of a flour bleaching agent from vegetable material for the use in the production of bread)."

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154 (1902), 20 R.P.C. 123 (Ch. D.). In that case the patentee had claims only for an article made of commonly available materials. The invention involved a strip of canvas with a piece of india rubber attached to it, to be used for wrapping around damaged tires in order to make a repair.

155 (1943), 2 C.P.R. 1 (S.C.C.).

156 *Continental Soya Co. Ltd. v. J.R. Short Milling Co. Ltd.* [1940] 4 D.L.R. 579 at 597-598.

The critical feature of this case is that, for naturally occurring products, where the isolated and purified product is for a use that is new and inventive, the isolated and purified product, for that use, is patentable, the product *per se* is not. Therefore, even if something is discovered in nature, and is therefore entirely "new", without some practical application or minimal utility, it is not an invention.[157]

In many respects, the principles underlying the "product of nature" doctrine as applied to biotechnology cases are the same as the "old known compounds" doctrine in respect of chemical cases. In these cases the invention was found to exist within the application of the compounds. The classic example is found in the discussion of inventiveness in *Re May & Baker & Ciba Ltd.*[158] which was followed by Martland J. in *Commissioner of Patents v. Ciba Ltd.*[159] In the judgment in *Re May & Baker*, Jenkins J. stated at p. 279:

> "[T]here is no inventive step, no element of discovery, merely by making new substances by known methods out of known materials. ...Assuming that the substances produced do possess some previously undiscovered useful quality, for example some remarkable value as a drug, then although the methods are known and the materials are known yet the application of those to those materials to produce those new substances may amount to a true invention, because of the discovery that those particular known materials when combined by those methods do not merely produce those new substances but produce, in the shape of those new substances, drugs of remarkable value."

This reasoning was applied by Madame Justice Wilson in the *Shell Oil* case which involved the recognition by the inventor that the mixing of certain known compounds with an adjuvant created a product which was particularly useful, and previously unknown, for the regulation of plant growth. Wilson J. held:[160]

> "This is not a case where the inventive ingenuity is alleged to lie in the combination; the combination is simply the means of realizing on the new discovery potential of the compounds. This is a case where the inventive ingenuity is in the discovery of the new use and no further inventive step is required in the application of the compounds to that, i.e., in the preparation of the appropriate compositions."

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157 This is as discussed in Chapter 3 where invention is defined as something which is new and has some element of usefulness or utility. In the *Continental Soya Co. Ltd.* case the isolated enzyme was interesting and of value as a discovery. However, it was the fact that enzyme could be used to bleach flour that constituted the invention.

158 (1948), 65 R.P.C. 255

159 (1959), 30 C.P.R. 135 at p. 383.

160 *Shell Oil v. Commissioner of Patents* (1982), 67 C.P.R. (2d) 1 (S.C.C.) at 11.

Finally, in the Supreme Court decision in *Pioneer Hi-bred v. The Commissioner of Patents*[161] Lamer J., at page 267 of the decision, confirmed this approach in the context of the biotechnological subject matter which was before him when he discussed the importance of an enabling disclosure and that through a sufficient disclosure it should be possible to distinguish between the discovery of a theoretical principle or product occurring in nature and an invention which requires human activity for its development:

> "This distinction is crucial in the field of patents, since only the latter is an invention within the meaning of the Act, unless the former is associated with a new method of implementation giving a new and unique result. (Gerrard Wire Tying Machines Co. v. Cary Manufacturing Co., [1926] Ex. C.R. 170)" [Emphasis added]

Thus, to simply discover a product which exists in nature without any further activity would not be patentable. At this point the "product of nature" doctrine would be applied and a claim for such a product would, in all certainty, be rejected. Although, as indicated by the patent agents and examiners who were interviewed, this is not a difficult rejection to overcome. The isolation and purification of the product may be enough to bring it into the realm of the patentable. However, a claim to the isolated and purified product with nothing further would also likely be rejected. It would likely require the combination of this isolation and purification in combination with utility for the product that would justify a claim to the product.

Standard of Novelty Assessment in CIPO

It is in the light of these principles that novelty of biotechnological subject matter is assessed in the Canadian Patent Office (CIPO).[162] Regardless of the nature of the subject matter of the application, when an application is received by the CIPO it is classified by classifiers and directed to an examiner having expertise in the subject matter. The examiners have biological, biochemical, chemical, etc. backgrounds, many having a Ph.D. in the particular area of science. The classifiers have the same type of qualifications as examiners and receive the same training as examiners. Where subject matter presents difficulty in terms of classification, i.e., a number of fields of technology are involved, in order to ensure that the classifications are as accurate as possible a number of classifiers consult to determine the appropriate classification.[163]

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161 (1989), 25 C.P.R. (3d) 257 (S.C.C.).

162 The information in this section is drawn from the MOPOP and from an interview with Examiners at the Canadian Patent Office.

163 See Appendix "A" which is a form setting out the classification scheme used at the CIPO in connection with biotechnology cases.

Once an examiner receives an application for examination an initial assessment is made with respect to the subject matter. If it falls under any one of the heads of non-patentable subject matter, i.e., an application claiming a higher life form, a formalities objection is issued. As an example, we will assume that the application under consideration is for a recombinant version of human transferrin. Transferrin is a plasma protein important for its role in delivering iron to the haemoglobin of maturing red blood cells. We will assume that the vector for synthesis of the protein is a bacterium, consequently, the recombinant version will not be glycosylated.

The prior art in respect of this application is gathered from a number of sources. The first is through a Rule 40 request[164] which can produce significant art, especially if U.S. and PCT applications have been made. In addition, manual and computer searches are conducted in the CIPO. Finally, commercially available Patent databases are searched.[165] The examiner will both direct and conduct the searches. In the course of conducting the searches the novelty sections of the *Patent Act* (sections 27 and 28) are taken into consideration to determine which art is available for comparison and which is not.[166]

Once the relevant prior art has been gathered, each piece of art is reviewed by the examiner apart from the other prior art, but in conjunction with the application. With respect to the issue of novelty, the assessment is usually made by the original examiner on the case, unless the technology is unclear or the prior art reference under consideration is close and a second opinion is required to assess whether it is an anticipation. Clearly, the formal academic training received by the examiner will have an impact on the perspective of this review. In our example, an examiner with a background in molecular biology will bring a different understanding to the application for recombinant transferrin than will an examiner with a chemistry background. Consequently, the second opinion will be from another examiner of biotechnology cases. More frequently it is during evaluation of the issue of non-obviousness that consultation between a number of examiners will occur. A prior art reference will be cited as anticipatory if it is deemed by the examiner to be "the same" as the subject matter of the application.[167] The examiners keep abreast of Canadian judicial decisions which impact upon this analysis.

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164 Rule 40 of the *Patent Rules* SOR 78-673 as amended, allows an examiner to require of the applicant any information which the applicant has in the way of prior art, and related documents, cited against corresponding applications in other countries, in any proceedings which relate to those applications such as interferences in the United States.

165 The examiners indicated that currently, the patent databases known as "Orbit" and "STA" are routinely searched.

166 Prior art references are considered as "not available" for citation of they are not available to the public, for example, if not available from a library or other publically accessible reference location. The standard suggested in the MOPOP is whether the reference is "readily available" (see paragraph 11.06).

167 Although the MOPOP discusses novelty together with utility (see for example part 11.01) it is clear form the interview with the examiners that novelty is a separate inquiry. With respect to the standard for novelty, the MOPOP paraphrases the test from *Reeves Brothers* and indicates that anticipation can only be found in one reference (see paragraph 11.02.01.01).

This approach to assessing novelty is the same for all fields of technology, i.e., the approach is no different for applications in biotechnology. Thus, to simply discover a product which exists in nature without any further activity would not be patentable as it would be considered a "product of nature". This type of rejection is particularly well known in the chemical field which shares many similarities to the biotechnology field. However, the problem, is particularly acute in biotechnology, because of the fact that the biotechnology field devotes a great deal of resources to the production of synthetic "products of nature", eg. growth hormone, insulin, t-PA, and our example of transferrin, with no ability to prevent duplication once the path to synthetic production is achieved.[168]

Therefore, one can expect known and previously isolated "products of nature" to be non-patentable by themselves. It will only be the inventive process to produce them which will be available for protection. However, as just discussed, the techniques are typically standard so there is arguably little chance of a new process being invented. In any event, if one did come up with a new process, there would probably be little incentive to obtain a patent for it. To do so one would require disclosing the improved process. If maintained as a trade secret it may confer a greater competitive advantage on the owner of the information. In addition, it is very difficult to prove infringement of a process claim for a product due to the likelihood that the "infringer" will not be using the identical process. As such, the case would be based on the Doctrine of Equivalents which is a harder case to meet than a case of literal infringement. Finally, where a patent exists on the "isolated and purified" product of nature, the inventor of the new and improved process could not practice the process without infringing that product.

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[168] The situation is very analogous the situation faced by Hoffman-La Roche in the case of *F. Hoffman-La Roche & Co. Ltd. v. Commissioner of Patents* (1955), 23 C.P.R. 1 (S.C.C.). In that case, a novel method of making an aldehyde had been invented. The applicant tried to claim the aldehyde when made by the novel process. The Supreme Court of Canada would only allow claims to the inventive process, it would not allow the product-by-process claims. The aldehyde, it reasoned, was a well known compound and could not be made an invention merely by association with the inventive process. Indeed, this was the basis of the decision of the English Court of Appeal in its invalidation of all of the claims of the Genetech patent in *Genentech's Patent* notwithstanding the considerable time, money and effort which went into producing the Genetech t-PA. Although this decision was in respect of a European patent it was from an English perspective and consequently will be influential in any Canadian decisions concerning the same subject matter. This is of course the complicating factor in biotechnology: in many cases most of the techniques for producing synthetic versions of products of nature are standard, well known techniques that allow anyone with a specific object in mind (product of nature) to achieve the result. At least these products appear to be straight forward to produce. See the discussion *infra*, under *desideratum* inventions. The problem is that to undertake this kind of work requires considerable financial resources.

In summary, with respect to the availability of claims to proteins or cell cultures, such as an antibiotic and cell culture isolated from soil samples,[169] which are an "isolated and pure form of what was found in nature", under Canadian practice such claims should be available where the protein is isolated "from nature" for the first time if the protein was unknown (no prior art) and consequently its desirable properties did not become apparent until isolated. However, claims to recombinant versions of the naturally occurring forms which had previously been isolated and purified, may not be able to overcome the "product of nature" doctrine, even if claimed as a highly purified form.[170]

In the EPO the situation is much the same. The requirement that the invention must be new does not mean that a micro-organism, enzyme or other natural product cannot be patented because it already exists in nature, i.e., is a "product of nature". If the micro-organism or natural product has never previously been isolated and/or characterized, then the isolated and purified "product" may be patentable, as was done *In Re Bergy*.[171] However in Decision T 205/83 (EPH Chapter 103)[172] a known product will not necessarily acquire novelty simply because it has been prepared in a purer form. As in Canada and the U.K (as reflected in the *Genetech* case), there must be something more.[173] In conclusion it is clear that the Product of Nature doctrine imposes problems for the "fit" of biotechnology into statutory invention. Many products of biotechnology will not be patentable as a result. In fact, where a natural substance is first isolated and purified and

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169 A decision in the United States by the Court of Customs and Patent Appeals, *In Re Bergy,* was among the first which wrestled with the question of whether a product found in nature could be considered new for the purposes of patenting. The case related to an antibiotic known as lincomycin as well as to the micro-organisms which produced the antibiotic. The claims were worded in a manner which did not refer to the micro-organisms as they were originally found; rather, the claims recited a "biologically pure culture" of the specific micro-organism. Evidence provided to the Court indicated that a biologically pure culture (such as the one at issue) is a well defined product of a microbiologist which is capable of producing a particular antibiotic under controlled fermentation conditions. There was also evidence that the soil source in which the micro-organism was discovered is a complex microbial environment which could not be used to produce a desired product under any known fermentation conditions. The Court held that because a biologically pure culture does not exist in nature, this constituted sufficient novelty for the purposes of a patent. This was the result, notwithstanding the fact that the micro-organisms which are the subject of Bergy's patent were found in soil samples, and, the only thing which distinguishes those micro-organisms from Bergy's micro-organisms was the fact that Bergy's micro-organisms had been purified and maintained in a laboratory culture setting.

170 While there is no caselaw on the point, some Patent Agent practitioners who prosecute applications for biotechnological subject matter before the Canadian Patent Office have indicated some difficulty in obtaining such claims. However, where the chosen vector, such as bacterium, provides a recombinant version of the native form of protein which is different, eg. unglycosylated, claims to the purified recombinant, unglycosylated form may be allowed.

171 Austin, H."Bio-Technology Patent Law: A European Perspective" The Genetic Engineer and Bio-Technologist v. 10, p. 15 (1990).

172 As cited in "Biological Inventions" In: "European Patents Handbook (2nd) Edn Rel 20 1995 at 18/11.

173 Austin, H."Bio-Technology Patent Law: A European Perspective" The Genetic Engineer and Bio-Technologist v. 10, p. 15 (1990).

patented, the hard work and resources devoted to creating a synthetic version will likely not be patentable as a product *per se*. In fact, the synthetic version will not be practised since the resulting product would infringe. This is a clear disincentive to biotech firms worldwide. Is this situation any different from the experience with pharmaceutical compounds? It is concluded that it is. In biotechnology a product of nature is just that. It is something that already existed. The inventor has discovered it, or isolated it and recognized its value. The inventor does not create it. The value of products of nature is often readily apparent because they perform some functions *in situ* which gives insight to their value. Pharmaceuticals on the other hand are synthesized *de novo* by the inventor and as such the value is attributable to the inventor who designs or "builds in" the functionality and utility. This is a fundamental distinction and as such the patent system does not extend rights to biotech firms who devote significant resources to producing synthetic versions of products of nature.

C. Non-obviousness

An important consideration and the one which, by itself or in conjunction with issues relating to novelty, is more likely to hamper making a finding that there is patentable invention is the consideration of non-obviousness. As indicated above, this element of invention is derived from the judiciary[174] and in spite of many formulations used by our courts when dealing with the different aspects of the question of "invention", it is clear that they are searching for an answer to the issue of obviousness. Many Canadian decisions also refer to inventiveness, or, the so-called "inventive

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[174] To date, Canada does not have any legislative language concerning the concept of non-obviousness. This is about to change with the introduction into the *Patent Act* of section 28.3 which is, at the time of this writing, enacted but not yet proclaimed in force. The section states:

> **28.3 - Invention must not be Obvious**
> The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to:
>
> (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

These amendments were part of an omnibus intellectual property improvement bill known as Bill S-17. These amendments are now found at S.C. 1993, c. 15. The coming into force of this section and other sections of this Improvement Act is dependent upon the completion of a significant overhaul of the Patent Rules. It was the consensus of those Patent agents and Examiners interviewed and asked for their opinion on this section that it is unlikely that section 28.3 will have much of an impact on the general interpretation and application of the concept in the analysis of invention.

step"[175]. However, the analysis inevitably returns to whether the invention was obvious.This is hardly surprising. Obviousness, after all, is intimately related to the issue of novelty or newness because if something is obvious then it is not likely to be considered to be new. Yet, something can be new in the literal sense of the word even though it was obvious because it was never actually produced in a tangible form before. But as the Courts have correctly interpreted, this is not the type of "new" contemplated by Parliament which is willing to exchange a 17-20 year right to prevent others from practising an invention for the knowledge behind the "new" subject matter. The newness that the *Patent Act* seeks to protect must be imbued with this further quality which has been formulated by the Canadian judiciary into the concept of non-obviousness.

The test, for non-obviousness in Canada was well formulated by the Federal Court of Appeal in *Beloit Canada Ltd. v. Valmet OY.*[176] at p 294, by Mr. Justice Hugessen.[177] His Lordship said as follows:

> "The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in light of the state of the art and of common general knowledge

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175 For an excellent discussions of the "Inventive Step" see J. Bochnovic,"Invention/Inventive Step/Obviousness" In: "Patent Law of Canada" G.F. Henderson et al. eds. (Carswell: Toronto, 1994) at p.41; and J. Bochnovic, "The Inventive Step" IIC Studies Volume 5 (IIC Publications: Basel, 1982).

176 (1986) 8 C.P.R. (3d) 289

177 This test has been formulated in many ways over the years, the most famous formulation being that of Sir Stafford Cripps as counsel in *Sharpe & Dohme Inc. v. Boots Pure Drug Coy Ld.* (1928), 45 R.P.C. 153 at 163:

> "Was it obvious to any skilled chemist in the state of chemical knowledge existing at the date of the patent that he could manufacture valuable therapeutic agents by making the higher resorcinol ny use of the condensation and reduction process described. If the answer is "No" the patent is valid, if "Yes" the patent is invalid."

This formulation of the test, and others were quoted with approval by Mr. Justice Pigeon speaking for the majority of the Supreme court of Canada in *Farbewerke Hoechst A/G v. Halocarbon (Ontario) Ltd.* (1979), 42 C.P.R. (2d) 145 at 156 (S.C.C.). In addition to the formulation of Mr. Justice Hugessen set out in the text, the test has also been well formulated by Mr. justice Urie in *Beecham Canada Ltd. v. Procter & Gamble Co.*(1982), 61 C.P.R. (2d) 1 at 27 (F.C.A.) and by Mr. Justice Stone in *Reading & Bates Construction Co. v. Baker Resources Corp.*(1987), 18 C.P.R. (3d) 181 at 188 (F.C.A.). See generally "Hughes and Woodley on Patents" by R.T. Hughes and J.H. Woodley issue 1995,(Markham: Butterworths, 1984-1995) at §11; Bochnovic, J. "Invention/Inventive Step/Obviousness" In: "Patent Law of Canada" Henderson G.F. *et al.* eds. (Toronto: Carswell, 1994) at 41; and Fox, H.G. "The Canadian Law and Practice relating to Letters Patent for Inventions", 4th ed., (Toronto: Carswell, 1969) at 69.

as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy."

Thus the question which must be answered in considering whether there is invention is whether the skilled technician[178] with "the state of the art and of common general knowledge[179] as at the claimed date of invention"[180] is able "...[to] come directly and without difficulty to the solution[181] taught by the patent."

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178 This concept is intended to capture that person who has sufficient grasp of the information, "knowledge" of an art so as to be able to appreciate the nature of the invention which they are considering.

> "Thus, it becomes obvious that the expression, "ordinary workman skilled in the art:, must be construed differently for different classes of patents. A complex chemical patent would necessarily require high technical skill in order to be put into use, while a small improvement patent would require very few directions in order to be capable of comprehension by an ordinary workman. The specification is, therefore, addressed not to the public generally, many of who may be ignorant of the subject-matter of the patent, but only to those skilful men [and women] who possess sufficient knowledge to render them capable of appreciating the nature of the invention. And this skill must be taken to mean skill and knowledge incidental to that particular art to which the invention relates, for a mechanic may be ordinarily skilled and competent in one branch of industry and not in another." [Footnotes not included]
>
> from Fox at page 184.

179 The common general knowledge is to be distinguished from the "public knowledge" as a broader level of inquiry. The distinction between public knowledge and common knowledge is that the former is any information which is available to the public, regardless of who has seen it:

> "[As]...pointed out by Lindley L.J. in *Savage v. Harris*[(1896), 13 R.P.C. 364 at 367.]: "It is admitted that his specification was published in this country and was a matter of public knowledge and public property, although very likely not of common knowledge, the difference between the two being obvious. There may be a publication that is quite sufficient to invalidate a subsequent patent, and there may be very few people who knew of that publication, so that you cannot say that the publication is a matter of common knowledge, however truly you may say it is a matter of public knowledge."
>
> from Fox at page 103-104.

The latter is that information which is a part of the knowledge generally well known by those skilled in an art, and has been held to include that information which such a skilled person would be able to find in a reasonable diligent search (*Procter & Gamble v. Kimberly-Clark Ltd.*, (1991) 40 C.P.R. (3d) 1 (F.C.T.D.) at 45-48 per Teitelbaum J.).

180 After S-17 is proclaimed, this enquiry will be as of the "claim date". S-17 is the Omnibus Intellectual Property Improvement Bill referred to above with respect to the footnote concerning Section 28.3 and non-obviousness.

181 Though easy to state, this concept is difficult in application. In essence, the skilled technician, charged with the common general knowledge, must be able to perceive the invention, which must be plain and obvious. It is said to be a very low standard. The "worth a try" doctrine has been suggested as an element of this analysis, however as discussed below, that doctrine has been held to put the standard too high.

Invention in biotechnology has arguably been more susceptible to attacks on the basis of obviousness given the underlining perceptions that many of the products are "products of nature" and because many procedures and methods which are used to prepare products of nature have become fairly standard and well known. Intermixed with these problems is the fact that the examiners concerning biotechnology cases are usually highly academically trained and consequently arguably taking a more sophisticated view to addressing this issue. Consequently the report will now examine these three closely related issues which are of concern with respect to addressing the non-obviousness inquiry.

The Worth a Try Doctrine

The inquiry relating to the obviousness of an invention is closely associated with the question of predictability in so far as it concerns questions of whether the "invention" was "worth a try" based on the prior art available to one who is skilled in the art. Notwithstanding that the "reasonable predictability" assessment is employed to help delineate the scope of a patentable invention,[182] it is an inevitable part of the obviousness assessment to determine whether in fact it can be said that the predictability question, if answered in the affirmative, confirms that the invention is obvious and was "worth a try." If something was worth a try, then the result is arguably predictable, i.e., the result is expected, or obvious.

In the U.K. the standard of obviousness on this point is that the skilled person would have thought that the invention was "well worth trying in order to see whether it would have beneficial results."[183] It has been stated differently in respect of a research group but amounts to the same test: [Would the research group] have been directly led to try the idea [invention] in the expectation that it might well produce a useful result."[184]

In the United States, the formulation of the Courts is put in the words "would it have been obvious to try." This conclusion by a court on the issue of obviousness must only be arrived at where the prior art clearly indicates that it would, in fact, be obvious to try. This has also been

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182 As discussed *supra*, predictability is directed to whether a claim in a patent is too broad. In other words, based on the prior art, and from the perspective of the person skilled in the art, would the disputed subject matter which is the subject of a claim have been predictably included in the scope of the claim? It has been held by the Supreme Court of Canada in *Monsanto c. v. Commissioner of Patents* (1979), 42 C.P.R. (2d) 161 at 174, that so long as it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so.

183 *Johns-Manville Corporation's Patent* [1967] R.P.C. 479 cited with approval by the English Court of Appeal in *Genentech Inc's Patent* [1989] R.P.C. 147 (C.A.) as quoted in M. Paver "A Tale of Two Rodents, or a Rodent with two tails: Europe grapples with patenting animals." Patent World June 1993, p. 29 at page 31.

184 *Olin Mathieson Chemical Corporation v. Biorex Laboratories* [1970] R.P.C. 157 cited with approval by the English Court of Appeal in *Genentech, supra*, as cited in M. Paver, "A Tale of Two Rodents, or a Rodent with two tails: Europe grapples with patenting animals." Patent World June 1993, p. 29 at 31.

formulated as a "reasonable expectation of success"[185] From the decision *In Re Wright* (1988)[186] the Federal Circuit reversed a decision of the Board of Patent Appeals and Interferences holding "the question is whether what the inventor did would have been obvious to one of ordinary skill in the art attempting to solve the problem upon which the inventor was working."[187] In other words, an invention is patentable, or non-obvious unless the prior art suggests the actual result which is claimed in the invention. This approach is in most respects, except for the specific wording, quite similar to the English test.[188] The key feature is that the idea to be tried must lead to a useful result. Notwithstanding this approach, the "obvious to try" doctrine had caused considerable trouble for invention in biotechnology in the United States because patents were refused for DNA sequences coding for amino acid sequence where the protein amino acid sequence had been published. On this basis the U.S. PTO would issue a rejection on the basis that creating the corresponding DNA would have been obvious or "worth a try". Even where only a partial amino acid sequence was available.[189]

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185 *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd* 927 F.2d 1200 (Fed. Cir.) at 1209 (1991).

186 6 U.S.P.Q. (2d) 1959 (1988) (C.C.P.A.).

187 K.R. Adamo, "The Power of Suggestion (Teaching, Reason or Motivation) and Combined-Reference Obviousness: Part I" Patent World, July/August 1993, page 29 at 37-38.

188 However, even though the standard may appear to be similar, significantly different results can arise out of similar facts. The case to consider in this respect is *Genentech, Inc. v. Welcome Foundation, Ltd.*, 14 U.S.P.Q. 2d 1363 (P.N.A.). The critical issue was determining the scope of Genentech's patents [one patent described a method to isolate and purify tissue-type plasminogen activator (t-PA) from cultured human melanoma cells and included a claim to the resulting purified t-PA and the second patent described the use of genetic engineering techniques to produce a recombinant t-PA]. The Genentech products were two-fold: one with a single amino acid substitution at position 245 and a second which was short two domains found in the naturally occurring protein.

The court construed the term "human plasminogen activator" restrictively and concluded that the term could only refer to human t-PA or naturally occurring variance of human t-PA. Consequently neither protein produced by Welcome Foundation literally infringed. The court then looked at the question of substantial infringement under the doctrine of equivalents. The Delaware Federal District Court decided in respect of this issue that a critical question was whether the patented t-PA and the accused's variance produced the cleavage of plasminogen to plasmin in the same way. The issue was decided by a jury which returned a verdict against Welcome.

In the United Kingdom with the same facts, it was held that the Welcome variant which contained a single amino acid substitution was an infringing version however the further modified form of t-PA was held not to infringe. This is because the entire patent of Genentech's was held to be invalid on the basis of being obvious and not having an inventive step in that the product was well known and it would have been worth a try to produce t-PA.

189 Given the state of technology, arguably the entire gene would be obvious or at least "worth a try" to produce because routine procedures should allow an investigator to design probes based on the published amino acid sequence to extract the relevant gene sequence from a DNA library.

Traditionally, in the United States, a gene has been considered a new chemical compound and the test to decide whether a new compound is obvious is based on: a. the structure of the new compound in comparison with similar compounds previously uncovered; and b. a review of the prior art which is searched for suggestions or any hint or direction of how to create the new compound. In other words, did literature in the prior art made it "worth a try." In chemistry cases where both of these elements are found the Patent Office would find the compound under

In Canada, this doctrine is tied to the aspect of the obviousness inquiry discussed above which relates to being led "directly and without difficulty to the solution." The leading case in Canada on this doctrine is *Farbewerke Hoechst A/G v. Halocarbon (Ontario) Ltd.*[190] where Mr. Justice Pigeon speaking for the majority of the Supreme Court of Canada first quoted from the trial level decision where it was held that the defence urged by the defendant, that carrying out the patented process was "worth a try" in the light of the prior art, failed. He then quoted Mr. Justice Jackett of the Federal Court of Appeal who overturned the trial judge on this point. Jackett, C.J. stated:

> "I do not think that the learned trial Judge's assumption is correct as a universal rule. I would not hazard a definition of what is involved in the requirement of "inventive ingenuity" but, as it seems to me, the requirement of "inventive ingenuity" is not met in the circumstance of the claim in question where the "state of the art" points to a process and all that the alleged inventor has done is ascertain whether or not the process will work successfully."[191]

In response to this, Mr. Justice Pigeon stated the Canadian position on this doctrine:

> "In my view this statement of the requirement of inventive ingenuity puts it much too high. Very few inventions are unexpected discoveries. Practically all research work is done by looking in directions where the "state of the art" points. On that basis and with hindsight, it could be said in most cases that there was no inventive ingenuity in the new development

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consideration to be obvious. It was purportedly on this basis that the USPTO denied claims to DNA sequences in two U.S. decisions, *In Re Bell*(90991 F. 2d 781 (Fed.Cir. 1993)) and *Ex Parte Deuel*(This decision went from the Patent Appeals Board to the Federal Circuit and those decisions are reported at 33 U.S.P.Q. 2d 1445 and 34 U.S.P.Q. 2d 1210, respectively).

When the case came before the Court *In re Bell* it was held that, in respect of biotechnological inventions, the Patent Board had taken a view quite different from the traditional chemical test. It was the Court's view that the Board had incorrectly compared the DNA sequence and the amino acid sequence and imposed techniques for using one sequence to obtain the other as the link between the compounds. The Court stated that DNA and proteins are different chemical compounds which cannot be compared. The Court ultimately found in favour of Bell.

In Re Deuel followed *In Re Bell.* Notwithstanding the Federal Circuit's decision *In re Bell*, the Board again found obviousness in a DNA sequence based on previously available amino acid sequence information, and a "method of cloning" reference which suggested a way to isolate from a DNA library the gene which was the subject of the case. The Federal Circuit rejected the USPTO's views and stated that the proper test is the traditional structural test for new compounds. The Court found that in light of the redundancy of the genetic code one could not have conceived of the natural DNA sequences from published protein sequences. It stated that no particular one of [the enormous number of possible] DNAs can be obvious unless there is something in prior art to lead to the particular DNA.

190 (1979), 42 C.P.R. (2d) 145 at 155 (S.C.C.).

191 *Id.*

> because everyone would then see how the previous accomplishments pointed the way. The discovery of penicillin was, of course, a major development, a great invention. After that, a number of workers went looking for other antibiotics methodically testing whole families of various micro-organisms other than *penicillium notatum.* This research work was rewarded by the discovery of a number of antibiotics such as chlormycetin...as mentioned in *American Cyanamid Co. v. Berk Pharmaceuticals Ltd.*,[1976] R.P.C. 231, where Whitford, J., said (at p.257): "A patient searcher is as much entitled to the benefits of a monopoly as someone who hits upon an invention by some lucky chance or inspiration". I cannot imagine patents obtained for antibiotics and for various processes for their production being successfully challenged on the basis that the discovery of penicillin pointed the way and there was no inventive ingenuity in the search for other antibiotics and in the testing and the development of processes."

His Lordship then went on to quote various formulations of the test of obviousness.[192] Consequently, diligent, "sweat of the brow" work in a directed manner is likely not to be viewed as obvious in Canada. It is the view of this author that of the three approaches, namely, the U.S.'s "would it have been obvious to try"; the U.K.'s "was it well worth trying in order to see if it would have beneficial results"; and the Canadians "to come directly and without difficulty to the solution", the Canadian view is the most sensible. It is also least likely to do harm to biotechnological inventions seeking patent protection while recognizing that certain inventions will be obvious where the prior art leads directly to the invention. This view also recognizes that other inventions, which while seemingly obvious, such as *desideratum* inventions, are likely to be considered as non-obvious.

Desideratum Inventions

Inextricably linked with the "worth a try", "obvious to try" assessment are so-called *desideratum* inventions. These are the inventions where it is clear that a certain product or process or method is desired, and the route to achieving the result is also fairly straightforward, or at least appears to be. For example, in respect of research directed toward developing proteins, the research project typically begins with the discovery that a particular protein performs some desirable function. Understanding how this protein functions requires scientists to extract the target protein

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[192] It is noteworthy that at the trial level on the reference back from the Supreme Court, the trial Judge (Mr. Justice Collier) found obviousness on the basis of the invention having been "worth a try". See *Hoechst v. Halocarbon* (1983), 74 C.P.R. (2d) 95 at 99 (F.C.T.D.). Although, it is arguable that the context of use of the "worth a try" doctrine by the trial Judge was as no more than a restatement of "was it obvious or very plain". Indeed, in the "first' trial decision Collier, J. was well aware of the importance of not elevating the "worth a try" approach - he stated at p. 125 of the decision:

> "as cautioned by Urie, J., [of the Court of Appeal], I have endeavoured to temper my view of the "worth a try" approach;..."

from a natural source. Subsequently, once the target protein has been purified, a next step is isolating the gene that expresses this protein and placing that gene in a suitable environment so as to allow for the production of the protein in large quantities. [193] While all of these steps seem fairly straightforward, as one commentator has suggested, in biotechnology the technology is simple in theory, but the elegant simplicity of concept hides "a mass of uncertainties and practical hurdles which need to be overcome before success can be achieved."[194]

Earlier, the ethnobotanical approach to invention was discussed and such an approach can arguably be classified as a *desideratum*, although, such "inventions" are also, equally, not as easy to achieve. This is particularly true in cases where the approach to invention is "prospecting." In many respects this approach is really no different from the one described by Mr. Justice Pigeon, which was quoted *supra*. Indeed, these kinds of difficulties have been recognized in U.S. decisions. For example in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*[195] the court held that "...until [the scientist] had a complete mental conception of a purified and isolated DNA sequence encoding EPO [erythropoietin] and a *method* for its preparation...all he had was an *objective* to make an invention" not an invention. Getting to the result may be an enormous task with much invention along the way.[196]

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193 Y. Ko "An Economic Analysis of Biotechnology Patent Protection" The Yale Law Journal, v. 102: 777 (1992) at 784.

194 M. Paver, "A Tale of Two Rodents, or a Rodent with two tails: Europe grapples with patenting animals." Patent World June 1993, p. 29 at 31. Indeed, as discussed in M. Vicente, "*Introduction: A Simple Expression? Complexities of Genetic Regulation in Micro-organisms*", World Journal of Microbiology and Biotechnoloy Volume 9 401 (1993) extreme complexity is involved in "gene expression". Vicente argues that the complexity creates endless opportunities for invention. His view is that as knowledge increases about how cells and bio matter work, the opportunities for invention increase with them. This fits with the general impression that as information about a subject becomes known the questions and problems and solutions to those problems become possible. In the end, invention in biotechnology is not really any different than it is with any other area of scientific endeavour where there is great complexity in the subject matter.

195 927 F.2d 1200 (Fed. Cir.) 112 S.Ct. (1991), as cited in B. C. Cannon, "Toward a Clear Standard of Obviousness For Biotechnology Patents" [1994] Cornell L. Rev. 735 at 755.

196 Consequently, is a scientific discovery which is made according to this type of research program truly an invention worthy of patent protection? The answer is probably yes. This is because in biotechnology as in any other field of endeavour, inventors work with the known to create the new and unobvious:

> "Future products from Protein Polymer will be designed by plugging various combinations of the 20 naturally occurring amino acids into 4 generic frames sketched by company researchers to resemble natural protein structures. The targets are silk, elastin (found in skin and other elastic organs), collagen (the fibrous component of skin and connective tissue) and keratin (which makes up nails and hair). The structures built by the company may or may not completely reflect their natural role models. ...others painstakingly characterizing the natural proteins first, then improving variation on those themes. For instance, Dan W. Urry, Director of the Laboratory of Molecular Biophysics at the University of Alabama at Birmingham, has spent the past 20 years studying the flexible but resilient elastin protein. Now he has designed a collection of elastin-like polypeptides based on 5 amino acids. The chains naturally fold (or contract) in response to increases in temperature; Urry has also tailored them to react to concentrations of chemicals and changes in pressure.

On the other hand, notwithstanding the enormity of the work and effort involved in creating some products in biotechnology, it is still possible that the end result is viewed as nothing more than a goal achieved by known means, even though the means is difficult. This was the case in the recent British decision of *Biogen Inc. v. Medeva Plc.*[197] This was a decision of the Court of Appeal in the Patents Court in connection with the question of whether claims in an issued British patent to recombinant DNA molecules for hepatitis B virus (HBV) were valid and infringed. The facts in the case are complex because of the nature of the subject matter but in essence, the claims were directed to recombinant DNA molecules characterized by DNA sequences coding for polypeptides displaying HBV antigen specificity. At trial it was held that the claims were not obvious (this was the main defence put forward by the defendant). The Court held that the difference between the prior art and the inventive concept was the idea or decision to express a polypeptide displaying HBV antigen specificity in a suitable host, and concluded that the defendant had not established that the invention was obvious. Part of the analysis concerned the problem of clearly identifying what information was actually available at the time of invention. This is a constant problem for inventions in biotechnology where the science advances so rapidly.

In the Court of Appeal it was held that the invention was obvious and that "a commercial decision to pursue an identified goal by known means" was not an invention. To spend time and money upon a project where others would have regarded the odds against success as too long to

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Potential applications for such materials abound, particularly if they can be programmed to disintegrate on cue. For instance, abdominal surgery requires a physician to cut through and later stitch separately five layers of tissue. To prevent the layers from knitting together as they heal, a doctor might separate them with sheets of polymers, which would then gradually dissolve. Because Urry's polymers convert one form of energy into another (such as chemical into mechanical energy), they could also be considered a type of micro machine. A visiting navy official recently suggested Urry consider using his polymers as minuscule spheres for delivering drugs to disease sites in the body. "Within a few hours, I put together the basis for another patent application."

E. Corcoran "Charlotte's Patent: Spider Webs and Other Proteins Inspire Engineers" Scientific American, April 1992: 138 at 140.

197 [1995] R.P.C. 25 (C.A.).

justify the investment required was a matter of business judgment and not inventive activity.[198] This decision is under appeal to the House of Lords.[199]

It is concluded that this situation is peculiar to biotechnology. Such considerations tend not to arise for other fields of technology, i.e., what appears at first blush to be a simple, obviously desirable result, is not so simple. Indeed, as will be seen from the discussion below concerning examiner's expertise, it is concluded this expertise which, in part, contributes to finding inventions in biotechnology "worth a try" or *desideratum*. However, as will be seen it is concluded that it is the complexity of the subject matter which contributes to these difficulties, but that this should not result in amending the standard of non-obviousness specifically for invention in the field of biotechnology.

Examiners Expertise - The Technician Skilled in the Art

Ultimately someone has to decide whether an invention is simply *desideratum*, or clearly "worth a try," or non-obvious, but who? Someone has to apply the Canadian test for the technician skilled in the art "...having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right."[200] Needless to say, this in itself is a somewhat subjective assessment in that not all will agree upon who the appropriate expert is depending on the subject matter. As mentioned above, the technicians skilled in the art can be a composite person and this has been acknowledged.[201] Perhaps the best arena for

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198 It was also held by the Court of Appeal that the main claims to the product had been drafted in terms wide enough to cover both core and surface antigens and in any host whether bacterial or non-bacterial. This relates back to the discussion, supra, concerning the scope of claims and "sound prediction". In biotechnology, it is difficult to extrapolate results in one host or species to other varieties of hosts or species. The underlying science is simply not well enough understood yet. The Court of Appeal applied the same standard as required in all fields of technology, namely that the disclosure had to be wide enough to enable the man skilled in the art to perform the claimed invention across its full width, and not, in the instant case, just by reference to one type of antigen or one type of host. The plaintiff was unable to make that disclosure and that showed it was seeking to claim an invention to which it was not entitled. The question of sufficiency of the specification was to be assessed by reference to the state of the art at the date of filing of the application. Consequently, if there was insufficient prior art to allow for such prediction, the claims would fail for insufficiency of disclosure and inherently unsound prediction.

199 Interestingly, and illustrative of the fact that this is universally never a clear cut issue, the same facts in the European system also resulted in an issued European patent. Also like the British Court of Appeal, in opposition before the Opposition division, the patent was revoked. However, on appeal to the Technical Board of Appeal, the decision of the Opposition division was set aside and the Patent allowed to stand (EPO T 296/93 *Biogen Inc.*). It will be interesting to see if the House of Lords agrees with theTechnical Board of Appeal.

200 *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 at 294 (F.C.A.).

201 According to Fox at 185-186, it may be necessary to call in more than one person to make up this "skilled technician." In support of this he cited *Orsam lamp Works Ltd. v. Popes Electric Lamp Co. Ltd.*:

"...it may well be necessary to call in aid more than one art. Some of the directions contained in a specification may

the assessment of the skilled person in the art, and the determination to be made by that person, is when a patent comes under the microscope of litigation. However, while it may be clear and obvious to a court, with an invention fully diagrammed and explained by a host of experts in the field, to combine references to come to the conclusion that an invention is obvious, this is not the situation in the patent office. In day to day practice, it is the examiner at the patent office, usually by themselves (occasionally with discussions with one or two others) who must decide what the skilled technician would conclude in the light of the common general knowledge (also as decided upon by the examiner), and make a determination either to reject claims on the basis of obviousness, or allow them as being non-obvious. The examiner is required to review a variety of fields of technology in making an assessment in respect of any field of technology and this is particularly so in respect of biotechnology. Often these fields of information will be unrelated to their expertise and will consequently impact on the judgement call. Imposed on this situation in biotechnology is the fact that knowledge in the field is expanding rapidly:

> "The scope of patent protection available for any technology varies inversely with the advancement of the state of the technology. For example, in 1974, Cohen and Boyer received a basic patent to recombinant DNA technology. (U.S. Patent No. 4,468,464 and U.S. Patent No. 4,740,470). As the state of the art in biotechnology has developed, it has become increasingly difficult to obtain patent protection. Rising to the challenge of protecting emerging technologies requires recognition that as the field becomes more crowded, innovations become incremental and the scope of protection becomes narrower...when a technology develops rapidly, it is more difficult to view invention through the eyes of one of ordinary skill in the art at the time the invention was made as 35 U.S.C. ¶103 requires. As a result, the novelty and non-obviousness that can result from application of "old" processes to patentable products may be difficult to recognize."[202]

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have to be carried out by skilled mechanics, others by competent chemists. In such cases, the mechanic and chemist must be assumed to co-operate for the purpose in view, each making good any deficiency in the other's technical equipment."[173]

[173] See also ***Burns & Russell of Canada Ltd. v. Day & Campbell Ltd.*** **(1965), 31 Fox Pat. C. 36 at 48."**

202 J. Culbert, "U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge" (1995) 77 (2) J.P.T.O.S. 151, at 154-155. This comment is from the perspective of the United States however it is universally recognized (although not necessarily commented upon universally) as can be seen in the following comment by P.W. Grubb speaking from the European perspective:

> "It is also extremely difficult in this field to decide whether any particular patent or application is invalid for lack of inventive step. Inventive step must be judged in the light of the state of the art at the priority date, and in this field the rate of progress is so rapid that what was truly inventive 3 or 4 years ago may very easily appear commonplace and obvious by today's standards."
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> P.W. Grubb "Patents in Biotechnology" Swiss Biotech Vol. 4: pg 12 at pg 15 (1986).

In view of these considerations, does the subject matter of biotechnology necessitate a different approach with respect to determining the skilled technician? In other words is this aspect of the non-obviousness inquiry different from other fields of technology? Certainly in coping with the challenges of assessing non-obviousness in biotechnology there have been differences in the Patent Office. In order to deal with the subject matter patent offices have specifically hired graduates of graduate schools with specific training in respect of some of the more common disciplines in respect of biotechnology, for example, Ph.D.s in molecular biology and genetics. Arguably, part of the impetus for this approach was a concern that without advanced training, examiners might be inclined to find all subject matter non-obvious. However, notwithstanding this approach to examiners with advanced academic training it is not uncommon for an examiner with a Ph.D. in biochemistry to be called upon to review an invention dealing with subject matter with which the Examiner is not intimately familiar, eg. molecular biology. Further, even the classification of "molecular biology" means that a number of disciplines are involved in assessing the subject. Indeed, much research is conducted in research teams where the expertise of a number of scientists with different (yet within the field of "biotechnology") disciplinary backgrounds come together to work on research problems. Where the subject matter is basic chemistry, physics, mechanics, electrical engineering, or other such subject matter, identification of the appropriate expert is arguably more straight forward. Consequently, it may fairly be stated that biotechnology is different. It is highly complex.

Imposed on this situation is the fact that the level of analysis of such biotechnology examiners is considerably different and arguably more sophisticated than would be the case where a basic chemist or biologist was called upon to review the inventions under consideration. This will, of course, alter the extent of the prior art search. A skilled technician in the art who has a Ph.D. will, generally, know to consult more widely and more rigorously than will a skilled technician with a B.Sc.. As such, the perspective of what is the common general knowledge as assessed by examiners with graduate training will be broader and more detailed leading to a tendency to suggest that all invention is obvious. In addition, a lack of sufficient understanding of subject matter can also cause an individual to miss important detail which, if properly understood, as those skilled technicians in the particular art would, makes it clear that something is non-obvious. Consequently, where the subject matter is particularly complex, both views can lead to obviousness rejections. Needless to say, the subject matter of biotechnology is complex. Indeed, this situation of excessive objections based on obviousness was addressed in the United States in hearings held to consider altering the standard of obviousness for invention in biotechnology where it was generally agreed that the general standard of non-obviousness is both appropriate and workable and that it should be applied consistently across all areas of technology.[203]

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[203] Prior to the implementation of section 103 in the United States in 1952, the standard for patentability of an invention was whether there was "invention"(Witherspoon, J.F., ed.,"Nonobviousness - The ultimate Condition of Patentability" (Washington: The Bureau of National Affairs Inc., 1978)). Section 103, which states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

In the light of the foregoing it is worthwhile restating the Canadian test for assessing obviousness:

> "The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy."
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> *Beloit Canada Ltd. v. Valmet OY* (1986) 8 C.P.R. (3d) 289 at p 294, by Mr. Justice Hugessen.

Mr. Justice Hugessen's comment is completely accurate: It is a very difficult test to satisfy. Obviousness is not easy to find. It is also true that it is a difficult test to apply. Which turns this discussion to the question: Is there a need to provide a more comprehensive definition for the standard of non-obviousness with respect to invention in biotechnology? The answer is no. In the light of the preceding discussion, it is clear that a reason a change might be considered is that the

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> ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made...

35 U.S.C.103 - Conditions for patentability; nonobvious subject matter

was interpreted by the Supreme Court of the U.S. in what has been considered the leading decision on the question of obviousness in the United States *Graham v. John Deere* 383 U.S. 1 (1966) (U.S.S.C.). There was considerable grumbling in the United States over the application of the standard of non-obviousness as set forth in that decision in the USPTO by examiners in biotechnology. On July 20, 1994 a public hearing on the standard of non-obviousness was held.

> "Many witnesses accuse the PTO of applying a stricter standard of non-obviousness for biotech patents than for other types of inventions. The "reasonable person in the field" for non-obviousness purposes is a genius, while that person is an idiot when it comes to evaluating an invention's workability or enablement under 35 USC 112, they complain.
>
> They observe that new examiners just out of grad school are using today's scientific knowledge in hindsight to find obviousness in pending patent applications that were filed years ago when the field was new and the claimed discoveries were not at all obvious. Others suggested that veteran examiners with less current training in science are reluctant to issue patents in an emerging field where the parameters are uncertain and unfamiliar to them."

"Biotech Industry Blasts PTO at San Diego Hearing", BNA's Patent, Trademark & Copyright Journal, Volume 48: 677 (1994) at 678. The transcript is available through the United State Patents and Trade-mark Office and is entitled "In the Matter of: Public Hearing on the Standard of Non-obviousness" held Wednesday, July 20, 1994.

subject matter of biotechnology is complex. However, complexity is not a reason to change the standard. What is required is a heightened awareness that, because of the complexity of the subject matter, the assessment, under the time honoured standard, must be carefully conducted with attention to the complicating aspects. Thus, if the following factors are borne in mind when conducting the assessment, namely:

I The skilled technician is likely a Ph.D. researcher, and may more likely be a composite of a research team;

II The particular fields which impact on the invention are clearly and properly identified and reasonable, diligent searches are conducted in those fields identified; and

III The field is advancing rapidly therefore care must be taken to properly consider the state of the art at the time of application, i.e., cautious regard must be given to the possibility of judging in hindsight;

it is likely that the issue of non-obviousness will be properly resolved.[204]

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[204] The same cannot be said in the United States where the law has taken a turn for the worse. In particular the *In Re Durden* case stood in the way of inventors in biotechnology from claiming known processes when used to prepare new, non-obvious products. The case stands for the proposition that the existence of a patentable starting matter or end-product does not make an obvious process non-obvious, and therefore patentable. In the case, the Federal Circuit rejected Durden's process claims as obvious because another inventor had already described the process in a patent, even though Durden used a different starting material and created a different end-product (for further discussion see Viksnins, A.S. "Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit" Minnesota Law Review of v. 76: at 161).

> "Unfortunately, the PTO has bodily applied the holding in *In Re Durden* to biotechnology reducing the availability of process patenting where *Durden* has even been used to reject process claims in the non-chemical arts. However, biotechnology has been especially susceptible to *Durden* rejections. The unpredictability inherent in biotechnology has led to more stringent standards for other aspects of patentability such as conception of gene." (Viksnins, A.S. "Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit" Minnesota Law Review of v. 76: at 157-158

Illustrative of this is the *Amgen* case where the company Amgen owned a patent which was a product patent covering certain DNA sequences, vectors and wholesales used to make recombinant erythropoietin (EPO). Amgen sued a company named Chugai under United States patent law for infringement of this patent based on Chugai's importation of EPO product which was manufactured off shore. The court held that importation of a non-patented product notwithstanding the fact that the intermediates were patented would not constitute infringement. Furthermore, because the process involved could not be patented notwithstanding the fact that it was used to produce new intermediates which themselves were patentable it was not possible to sue on the basis of importation of a product which was produced by a patented process.

These two decisions posed considerable problems for the biotechnology industry wherein the end products are typically not novel notwithstanding the fact that intermediate products may be. It was proposed that Section 103 of Title 35 be amended to expand the definition of non-obviousness, and this is exactly what happened. Bill S 1111 was passed prohibiting obviousness rejections of process patent applications for biotechnological processes "using

Finally, a factor militating against changing the standard is the fact that despite the complexity, the growth of information and understanding of the science is advancing and removing the mystery associated with the complexity. Biological systems are much better understood today than they were 30 years ago. This is reminiscent of the evolving comprehension and disappearance of the mystery of chemistry as understanding advanced in that field of technology. Consequently, obviousness rejections in biotechnology, which may have been occurring more often than in respect of other areas of invention, particularly so in the United States, are less likely as time progresses. In addition, as the science is better understood and becomes more familiar, examiners will become better at applying time honoured approaches to the analysis of non-obviousness.

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or resulting in a composition of matter" that is novel and non-obvious if: (1) the product and process are in the same application and have the same filing date; and (2) the product and process claims were owned by the same person when they were invented. ("Senate Passes Biotech Process Patent Bill" BNA's Patent, Trademark & Copyright Journal, (1995) vol. 50 at 633.) President Clinton has signed this bill into law.

This kind of problem has not occurred in Canada and is unlikely to do so. In Canada, claims for a process which is limited to the production of a new, useful and non-obvious product are allowable (MOPOP 10.02.01.) Judicial support for this can be found in the *Shell Oil* decision where it was held that claims to an old compound are allowable if limited to a new, useful and non-obvious use.

CHAPTER FIVE
CONCLUSIONS AND DIRECTIONS

A. Introduction

The United States is viewed by many as a world leader in the biotechnology industry. The patent rights it provides to the industry are arguably the most advanced in the world. Sharing such an extensive border with the United States inevitably results in Canada being influenced by developments south of that border. Indeed, with respect to defining our patent system, and in particular concerning the patentability of biotechnology, our system is in many ways similar to that in the United States.

Yet, in many respects, the U.S. system is less accommodating to biotechnology than in Canada. For example, a considerable debate arose in the United States over utility requirements imposed by the Group 180 examiners[205] in respect of biotechnology patent applications. Many biotechnology-based inventions with clinical applications were held not to be patentable because the applicants had not demonstrated that the subject matter worked in a clinical setting, and were therefore not useful. Indeed, the biotechnology examiners were requiring Phase III clinical trial data before they were "convinced" that utility existed.[206]

As such, it may be said that the Canadian patent system is also one of the leading systems for advancing the rights of the biotechnology industry. Indeed, in the light of the preceding chapters of discussion, it is a conclusion of this Report that there are, arguably, only three significant issues outstanding in Canada which need to be resolved before this country can take its place as the world leader with respect to providing patent rights to innovators in biotechnology. These issues are:

1. The question of the patentability of higher life forms;
2. The patentability of "products of nature"; and
3. The problems with progeny.

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[205] Group 180 examiners are those who consider patent applications wherein the subject matter is classified as biotechnology.

[206] For further discussion see Chapter 4, and the footnotes associated with the section concerning *Utility*.

B. Summary

As discussed below, it is a recommendation of this report that in order to deal with the issue of the patentability of higher life forms, an amendment to the *Patent Act* is required to ensure that patents can issue in respect of higher life form inventions.

It is also concluded that the present form of the *Patent Act* is acceptably drafted with respect to the important issues of novelty and non-obviousness and that the present standards for review of these elements are also acceptable. In particular, there is no need to create a more comprehensive definition of non-obviousness either through legislative or administrative options so as to redefine the standard of non-obviousness to accommodate biotechnological innovations.

The report also recommends that there is no need to create a more comprehensive definition of novelty in the *Patent Act* either through legislative or administrative options so as to redefine the standard of novelty in biotechnological innovations. However, the report does recommend the creation of a new statute in order to address the problems associated with obtaining patent protection for useful "products of nature" which have been prepared after much effort and expenditure of capital investment.

It is concluded that "tinkering" with the *Patent Act* is not the appropriate route to resolution of this issue:

> "Legislative tinkering with the definition of non-obviousness [or novelty] for one particular industry threatens the basic structure of the patent laws. The entire patent law scheme depends upon consistent, objective determinations of non-obviousness [or novelty] based on the expertise of the United States Patent Office [or any patent office]. A decision to alter definitional requirements not only would undermine competence in the objectivity of the patent system, but also would discourage new experimentation and innovation in areas other than the narrow areas covered by the congressionally [or by Parliament] altered definition of non-obviousness [or novelty]. Inventors would be more inclined to work in areas where there was a possibility of acquiring a patent than in non-patentable areas. If an inventor is unsure whether she will be able to patent her technology, she may prefer to keep it secret or not go through the expensive and time-consuming process of pursuing a patent application. This defeats the constitutional [and philosophical] goal of encouraging the useful arts and patents. Predictability, fairness and incentives for innovation would [likely] suffer."[207]

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[207] A.S. Viksnins, "Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit" Minnesota Law Review of v. 76: 161 at 182-183.

Finally, although not an issue directly related to the issues of invention, non-obviousness or novelty, in view of the recommendation to allow patents to issue in respect of higher life forms, the report recommends amending the *Patent Act* in order to specifically address issues arising from the "problems with progeny" as they relate to farmers.

C. The Patentability of Higher Life forms

In this report we have discussed the issues of proper subject matter, novelty, utility and non-obviousness. In order for there to be a patentable invention, a first requirement is proper subject matter. As such, the subject matter of biotechnology must be capable of being interpreted as "fitting" within the scope of the categories of subject matter as set forth in the *Patent Act*. As already concluded, *supra*, the words found in the Canadian definition of "invention" are sufficiently broad to include not only the subject matter of biotechnology, but, for all intents and purposes, any subject matter which exists and has some element of human input. The United States Supreme Court did not put it too high when it stated that the definition of invention as found in the U.S. Patent Act, which incorporates much the same wording as in the Canadian Act, encompasses "anything under the sun" which has input from the hand of man.

Also as discussed *supra*, the current position of the Canadian Patent Office is that patents will not be allowed for subject matter which is multicellular, i.e., a higher life form. Yet, it is arguable that the only reservation by the Commissioner of Patents from allowing patents for higher life forms was expressed by the Patent Appeal Board in *Abitibi*,[208] namely, the concern about the ability of those reading a disclosure to such an invention to be able to replicate the invention.[209] This is clearly a different concern from the concern about whether the subject matter of higher life forms fits within the definition of "invention". Assuming deposits as a supplement to disclosure are enough to overcome this problem, there is no indication that the Commissioner is concerned that the words "manufacture" or "composition of matter" are not broad enough to capture this subject matter. Furthermore, the Supreme Court of Canada in the *Pioneer Hi-bred* decision[210] has left the matter open. Even the most contentious piece of Canadian jurisprudence on the subject, the Federal Court of Appeal decision in *Pioneer*,[211] does not exclude the possibility that the *Patent Act* encompasses as proper subject matter, "life forms".[212] Yet, patents for higher life forms have

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208 (1982), 62 C.P.R. (2d) 81 (P.A.B.).

209 Concerning the ability of a person reading a disclosure to such an invention to be able to replicate the invention, techniques in biotechnology have advanced to the point where it should possible, in the same way that *Abitibi* was able to produce its microorganism *en masse*, to faithfully reproduce whole organisms and, as such, this should not be a bar to patentability today.

210 (1989), 25 C.P.R. (3d) 257 (S.C.C.).

211 (1987), 14 C.P.R. (3d) 491 (F.C.A.).

212 At page 495 of the decision.

not issued in Canada. It is this situation which must be corrected with, at a minimum, a policy note from the Canadian Patent Office indicating that, assuming there is sufficiency of disclosure, the propriety of subject matter is not an obstacle to patent issuance in respect of inventions dealing with higher life forms. However, in view of the possibility that future Courts may override the policy, and/or, narrowly interpret the definition of "invention" so as to exclude this subject matter, it is recommended that an amendment should be introduced to ensure that there is no question about this issue.

"Manufacture or Composition of Matter"

It is recommended that section 2 of the *Patent Act* be amended to include the following:

2. **Definitions.** - In this Act, except as otherwise provided,...

> **"manufacture or composition of matter".** - "manufacture or composition of matter" includes biological material, including plants and animals, as well as parts of plants and animals.

The wording here is intended to clarify that higher life forms may be patentable. "Manufacture or composition of matter" have been chosen as the appropriate elements of invention based on their clear identification through caselaw discussed *supra*, as the terms most closely associated with this subject matter. By highlighting these terms and merely specifying what is **included** within the meaning of the words, no harm is done to the jurisprudence which has developed thus far concerning their legal interpretation. This modification also keeps this clearly identified aspect of meaning within the required framework of the "new and useful" elements of the definition of "invention". It is optional as to whether it should include a limitation with respect to "plant varieties" so as to avoid the possibility of plant breeders' rights and patent rights coexisting. With the amendment suggested, this is a possibility. If overlap is not acceptable then the wording should be:

2. **Definitions.** - In this Act, except as otherwise provided,...

> **"manufacture or composition of matter".** - "manufacture or composition of matter" includes biological material, including plants and animals, as well as parts of plants and animals, except plant varieties, as "plant varieties" is defined in the *Plant Breeders' Rights Act.*

These amendments do not conflict with Canada's international obligations under the North American Free Trade Agreement ("NAFTA"). All that the amendments achieve is clarification. They do not run afoul Article 1709(1) which requires that each Party must make patents available in all fields of technology.[213]

Human Beings are Not Patentable

With this amendment in place the scope of patentable subject matter will inherently include whole human beings and body parts. In order to address concerns about the patentability of human beings Canada could further amend the *Patent Act* so as not to allow patents for human beings.[214]

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213 North American Free Trade Agreement, Article 1709(1)

214 Although arguably the Canadian *Charter of Rights and Freedoms* is available to ensure such is not a possibility. In particular, section 7 of the *Charter* provides:

> *Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.*

Support for the argument that section 7 could prevent the possibility of a patent issuing in respect of a human, or human body part may be found in the decision of *R v. Morgentaler (No. 2)* [1988] 1 S.C.R. 30 where Wilson J., one of the 5 majority judges, found, amongst other deprivations, a deprivation of liberty in the loss of a woman's control over the termination of her pregnancy. In examining the concept of liberty Wilson J. said at p. 164:

> The Charter and the right to individual liberty guaranteed under it are inexorably tied to the concept of human dignity. Professor Neil MacCormick, *Legal Right and Social Democracy: Essays in Legal and Political Philosophy*, speaks of liberty as a "condition of human self-respect and of that contentment which resides in the ability to pursue one's own conception of a full and rewarding life" (p. 39). He said at p. 41:
>
> > "*To be able to decide what to do and how to do it*, to carry out one's own decisions and accept their consequences, seems to me essential to one's self-respect as a human being, and essential to the possibility of that contentment. Such self-respect and self contentment are in my judgment fundamental goods for human beings, the worth of life itself being on condition of having to strive for them. If a person were deliberately denied the opportunity for self-respect and that contentment, he would suffer deprivation of his essential humanity."

Wilson J. then continued:

> Indeed, as the Chief Justice pointed out in *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295, belief about human worth and dignity "are the *sine qua non* of the political tradition underlying the Charter". I would conclude, therefore, that the right to liberty contained in section 7 guarantees to every individual a degree of personal autonomy over important decisions intimately affecting their private lives.

In order to find that a section 7 *Charter* right had been contravened arguably there would have to be evidence that the grant of a patent had in some way diminished the freedom of the individual. Where such evidence exists, the grant of such a patent would have been contrary to section 7.

This is not a novel approach to this subject given that specific wording concerning the non-patentability of human beings has been adopted in the Australian Patent Act, and legislation concerning this issue has been the subject of much debate in Europe. Indeed, it is recommended that an amendment to the Canadian *Patent Act* track the language suggested in the draft European Parliament and Council of Ministers for a Directive on the legal protection of biotechnological inventions (the first "Directive").[215] The amendment would be in respect of the definition of invention so that it includes the following:

> 2. **Definitions.** - In this Act, except as otherwise provided,...
>
> **"invention".** - ...
>
> "For clarification, "invention" does not include:
>
> (a) the human body or parts of the human body in their natural state, except subject matter isolated from the human body or otherwise produced by means of a technical process;
>
> (b) processes for modifying the genetic identity of the human body contrary to the dignity of humans;
>
> (c) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without substantial benefit to man or animal, and animals resulting from such processes."

The Directive is an appropriate choice of source for such wording based on the fact that Europe has been wrestling with this problem for a considerable period of time, and that the first Directive was intended to reflect the European position on this issue.[216] As a result of considerable debate, the first Directive, (which was defeated) had been through a number of iterations in order to find wording which was acceptable to competing interests concerning this issue. However, this Report does not recommend merely following the wording of the Directive, rather, the recommended amendments "borrow" from both the first and recent Directive. Indeed, the wording

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[215] First proposed in Doc. COM (88) 196. See (1989) 20 IIC 55 for the Directive and see the next note for further references concerning the fate of the Directive.

[216] As indicated *supra*, in the Report, the European Directive was rejected by a co-decision procedure of the European Parliament on March 1, 1995. For further discussion see Rothley, "Why Parliament Must Think Again About Biotechnological Protection" (1995) 26 IIC 668; R. Stephen Crespi, "*The European Biotechnology Patent Directive is Dead*", Trends in Biotechnology Volume 13 No. 5 at 162, 1995; S. Hassler, "European Patent Legislation: A Missed Opportunity" (1995) 13(4) Bio\Technology 305; and J. Straus, "Patenting Human Genes in Europe - Past Developments and Prospects for the Future (1995) 26 IIC 920.

suggested above does not use the wording of *Article 3* of the most recent version of the Directive.[217] *Article 3*, essentially provides that human beings and parts thereof are not patentable. Rather, the wording suggested here borrowed from both the first and most recent versions of the Directive, provides a clearer, simpler indication that "patenting" human beings, *per se*, is not allowed, while allowing for patents in respect of subject matter such as human cell lines, proteins and nucleic acid sequences derived from human material, when created by non-natural, or "technical" means.

A further difference between the first Directive, the wording suggested above, and the new Directive, is the specific exclusion found in the new Directive, namely "methods of human treatment involving germ line therapy" are not patentable.[218] Such wording did not appear in the first Directive and is not suggested for the amendment to the Canadian *Patent Act*. The basis for this position is twofold. Firstly, because the "method of treatment" aspect is already well entrenched in Canadian jurisprudence as not being patentable specific wording is probably not necessary.[219] Secondly, the new Directive's restriction arguably disallows patents in respect of potentially important areas such as subject matter for modifying the genetic identity of the human body. This might imply, for example, that certain processes which alter the genetic identity of an

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[217] Recently, fresh wording has been suggested for a new Directive and in respect of the patentability of human beings the wording is as follows:

Article 3

1. The human body and its elements in their natural state shall not be considered patentable inventions.

2. Notwithstanding paragraph 1, the subject-matter of an invention capable of industrial application which relates to an element isolated from the human body or otherwise produced by means of a technical process shall be patentable, even if the structure of that element is identical to that of a natural element.

Article 9

1. Inventions shall be considered unpatentable where exploitation would be contrary to public policy or morality, provided that exploitation is not deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following shall be considered unpatentable:

   (a) methods of human treatment involving germ line therapy;

   (b) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and animals resulting from such processes, insofar as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued.

[218] Although this wording is, in many respects, similar to the wording of its predecessor, the wording of the new Directive is somewhat more restrictive, the intention being to avoid the possibility for allowing patents on isolated human genes, and in particular, human gene therapy (see J. Straus, "Patenting Human Genes in Europe - Past Developments and Prospects for the Future (1995) 26 IIC 920).

[219] See the section *supra*, in Chapter 4, concerning "Methods of Medical Treatment."

individual who, but for an appropriately altered genetic identity, stood to inherit a dominant disease-causing gene, such as for example polycystic kidney disease, would not be patentable. Under the wording suggested in this Report, such processes could be patented, assuming that such alteration would not be considered as a modification contrary to the dignity of humans. Indeed, for issues which are so value-laden, as germ line therapy is, the "contrary to the dignity of humans" wording provides a mechanism for preventing patents in this area where they are deemed by society to be objectionable.

With respect to Canada's international obligations under the North American Free Trade Agreement ("NAFTA"), this amendment does not conflict, especially in view of the exemption from patent protection available to the members of NAFTA in respect of certain subject matter in order to protect the *ordre public* or morality of the country.[220]

Problems with Progeny

With the patentability of higher life forms comes the problem of controlling infringement by propagating material. Notwithstanding the possibility of licensing relationships and other creative approaches to dealing with this problem of infringing progeny, it is recommended that the *Patent Act* be amended to provide farmers with a defence to infringement according to the following specific legislative terms:

> "Patent rights shall not be infringed where, through the sale of patented propagating material to a farmer, or with the patent holder's consent implies authorization, the farmer uses the patented propagating material and the product of his harvest for further reproduction or propagation by him on his own farm."

Such amendment would avoid the problems of restricting farmers in the production of food materials for market, and burdening the small farmer with extensive licenses (which might arguably drive the small farmer out of business), and ensures that abuses such as through co-operatives do not take place.[221]

Finally, such an amendment to the *Patent Act* would not conflict with Canada's international obligations under NAFTA.

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220 North American Free Trade Agreement, Article 1709(2).

221 Co-operatives consist of a number of farms banded together wherein the produce of one marketer may be exchanged for those of another.

D. Novelty and Invention in Biotechnology

It is a recommendation of this report that there is no need to create a more comprehensive definition of novelty in the *Patent Act* either through legislative or administrative options so as to redefine the standard for determination of novelty in biotechnological innovations.

The present definition of novelty is very acceptable and indeed is very favourable to prospective patentees in all fields of technology, including biotechnology. The matter of whether to change the standard arises in relation to biotechnology only with respect to synthesis of naturally occurring substances, the so-called "products of nature," which are already known.[222] Other modifications to "products of nature," such as the introduction of new amino acid sequences into a known protein, or the absence of a glycan structure on a synthetic version of a naturally occurring glycoprotein, would probably give rise to so-called second generation use or compounds[223], and thereby be patentable.[224] The problem really only arises in respect of the applicant who has, through considerable time, money and effort, developed a process for synthesizing a known "product of nature."[225]

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222 For the purposes of the following discussion, products of nature can be classified as "known" and "new." Known products of nature are those which have been isolated and characterized. New products of nature are those just isolated, and not previously known. Once a new product of nature is published, including in patent art, it becomes known. Further, products of nature isolated from nature are referred to herein as "natural" products of nature. Products of nature produced through significant human intervention, eg., by recombinant DNA techniques, are referred to herein as "synthetic" products of nature. As such there will be situations where a synthetic version may exist in respect of known products of nature, and there may be synthetic versions of new products of nature.

223 The expression "second generation compound" is intended to mean those naturally occurring substances which have been modified in order to confer some property, feature or characteristic which distinguishes it from the natural or "first generation" of the substance.

224 As discussed, *supra*, in Canada, it is even possible to obtain claims to a "product of nature" produced by recombinant means where the only difference between the recombinant version and the natural version is the presence of a glycan. As such, Canada is a very favourable jurisdiction in which to obtain patent protection for such products. Whether such patents would withstand the scrutiny of the Courts (in view of decisions like *Genentech's Patent*) remains to be seen.

The question of the patentability of second use, or second generation proteins is always subject to the following caveat, notwithstanding the newness:

> "[Speaking of second "use" pharmaceuticals, or products of biotechnology] The invention is unpatentable if when compared with what is already known "in the public domain", it will be obvious to someone knowledgable in field of invention, the mythical person who is "skilled in the art".
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> Austin, H."Bio-Technology Patent Law: A European Perspective" The Genetic Engineer and Bio-Technologist v. 10, p. 15 (1990).

225 "There are a number of roadblocks to achieving this end including the difficulty of isolating the target protein; the search for the gene which expresses the desired protein - this involves searching DNA libraries with a probe which may be a DNA fragment from other animal species or a synthetic construct from the amino acid sequence of the naturally-derived protein; once the gene is isolated the researcher may explore ways to modify the sequence to

Are such products novel? Even if the synthetic version is identical to the naturally occurring product? Strictly speaking, every time the synthetic substance is made it is new, i.e., each and every molecule, as it is synthesized is new (not novel). The first synthetic version of a "new" naturally occurring substance is also new (and novel). But is a synthetic version of a "known" naturally occurring substance "new" for the purposes of obtaining a patent. According to current practice, and under the current standard of novelty in Canada, the answer is no. A synthetic version of a "known" substance, which synthetic substance, but for the fact that it is synthetic is identical to the "known" product of nature, is viewed as being "known" and consequently not patentable. This is problematic especially if one has spent considerable time, money and effort to develop a process (even if patentable) for producing a synthetic version of a known product of nature,[226] it is likely not possible to commercialize it without entering into a cross-licence with the patentee who has claims to the product itself.[227] Consequently, on the assumption that other

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produce a protein with one or more variations in its amino acid structure. These new proteins are known as "second generation" proteins and the variations may enhance potency, resistance to degradation or other desirable qualities. Because the relationship between structure and function in proteins is still not completely understood this relationship remains unpredictable and consequently the creation of an improved "second generation" protein may be as daunting a task as producing the first generation protein."

Y. Ko, "An Economic Analysis of Biotechnology Patent Protection" The Yale Law Journal, v. 102: 777 (1992) at 784-785.

The inference from this author is that because so much work is involved in generating a recombinant "second generation" protein some rights should flow to the creator. However as mentioned *supra*, it is important to distinguish between true second generation proteins and proteins which have been synthesized to replicate the protein found in nature. The true second generation protein will have some new and desirable feature which makes it better than the native or synthetically modeled protein which copies the natural protein. As such, according to the traditional rules of patent law, such proteins would not likely be obvious and should be accorded patent protection.

226 Where an inventor is able to recognize the utility of a previously unknown, or "new" product of nature, and that inventor also finds a way of synthesizing the "new" product of nature, unrestricted product claims would probably be available, as opposed to being fettered with the "purified isolated" limitations. However, according to the analysis presented *infra*, claims would be limited in scope to that which is truly invented, i.e., the natural product of nature and the synthetic product of nature when produced by a described process.

227 Otherwise, the manufacturer of the recombinant version is likely to be sued:

> "In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, [66 F. Supp. 1379 (N.D. Cal. 1987)] Scripps charged Genentech with infringement of its patent on Factor VIII:C, a protein that activates the blood clotting mechanism. ...the Scripps patent included both product and product by process claims. [The product claims were "a human VIII: C preparation having a potency in the range of 134 to 1172 units per ml and being substantially free of VIII:RP"; and claim 25: "a human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma."] ...Although Genentech manufactured its factor of VIII:C by recombinant techniques, Genentech was accused of infringement on both the product and product-by-process claims. [The issue in this case was whether a patent claim obtained on the basis of isolating and purifying the natural protein was infringed when the same protein was produced by recombinant means - the court refused to read a limitation, as suggested by Genentech that the asserted product claims must be interpreted to apply solely to Factor VIII:C derived directly from human blood plasma and that the filtering process was also a necessary

approaches to patentability are not available,[228] for reasons set out below, it is a recommendation of this Report that a new Act should be brought into force providing certain limited rights to the innovators of processes for synthesizing such products. This is as opposed to amending the *Patent Act* in order to directly or indirectly modify the standard for novelty with respect to products of biotechnology which are products of nature.

Amending the Act and Dilution of the Standard of Novelty

It would not be appropriate to attempt to amend the *Patent Act* or modify how novelty is determined in order to provide rights to those who develop new and useful processes resulting in synthetic versions of known products of nature because to do so would dilute the meaning of "new" as set out in the definition of "invention." Invariably, regardless of how an amendment may be sought to allow patents for the subject matter of the synthetic product of nature, the definition of "new" would have to be softened. For example one approach might be to allow claims to the product when made by the novel process. However, such amendments would invariably require enactment of a section or sections similar in nature to old section 39(1) of the *Patent Act*.[229] However, section 39(1) and its predecessors applied in respect of patentable "new" substances, which were a food or medicine. Without section 39(1) such substances would have been patentable *per se*. In other words, the "product by process" legislation prevented an applicant from obtaining a patent on a product which was otherwise patentable, i.e., new, useful and non-obvious.

The result of implementing a similar type of section for products of biotechnology which are synthetic versions of products of nature would be to provide the ability to claim a synthetic "product of nature" which is known. Such an amendment would arguably dilute the *Patent Act* by requiring, in effect, that synthetic versions of known products of nature be considered as "new."

> limitation, into the claims.] ...the trial court focused on the fact that recombinant Factor VIII:C is structurally and functionally the same as Scripps' plasma-derived Factor VIII:C. ...on appeal the Federal Circuit likewise refused to construe the product claims to include the inherent process limitation."
>
> "Genentech raised the defence that the recombinant product was so far changed in principle that it did not infringe Scripps' product claims by virtue of the "reverse doctrine of equivalence" however this argument also was unsuccessful."
>
> Ko, Y."An Economic Analysis of Biotechnology Patent Protection" The Yale Law Journal, v. 102: 777 (1992) at 788.

228 Such avenues to patentability for so-called "products of nature" include claims to products isolated and purified from a soil sample, etc.

229 Section 39(1) and its forerunners, including when it was better known as section 41(1), related to substances intended for food or medicine and in effect allowed patents for new substances which were, or were intended for food or medicine only when claimed by the processes of their manufacture. For a brief discussion of the history of these provisions see: Jennifer Morton, "Pharmaceutical Patents and Bill C-91: The Historical Perspective: C.I.P.R. 10(1) 145 (1993).

This would be contrary to a clear line of Canadian and British jurisprudence on the subject, beginning in Canada with the *Hoffman-La Roche*[230] decision where it was held by Mr. Justice Rand:

> "...[T]he mere need for means of protecting the monopoly cannot justify the extension of the statutory language beyond what it can fairly bear. The definition clause [for invention] furnishes no warrant for treating a well-known substance as being a "new and useful...composition of matter" because it has been produced by a certain process. The assumption is that the product of different processes is identical and no such constructive attribute can render the substance itself either new or useful."

In respect of the "product by process" provisions of the *Patent Act* His Lordship further stated:

> "This again seems to confirm the view that both substance and process are to be new. **But at least the substance must be new**, and no inference can be drawn from it of a process dependent product claim where the product is old."

This is precisely the situation where one attempts to obtain claims to amino acids and nucleic acids, which are found in nature, have previously been isolated and identified, but which have been manufactured by a new and useful process.

As an alternative, it has been suggested to amend the *Patent Act* to limit patents for all "products of nature" to only process patents.[231] However this approach to amendment, as well as the "product by process" approach would arguably run afoul of NAFTA Article 1709(1). In the case of the latter it may be perceived that such amendment allowed patent protection to be biased in favour of the field of biotechnology, while in the case of the former, such amendment could be perceived as taking rights away from patentees.

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230 *Hoffman-LaRoche v. Commissioner of Patents* (1955), 23 C.P.R. 1 (S.C.C.) at 4 and 5. This was a case where the applicant Hoffman-LaRoche had developed a new and useful process to manufacture an old, well-known compound, aldehyde. The applicant sought to obtain claims to the product produced by the patentable process, even though the product was old.

231 Michael S. Greenfield, "Recombinant DNA Technology: A Science Struggling with the Patent Law" Stanford Law Review 44:1052 (1992). Greenfield ultimately recommends limiting the scope of all patent protection for "products of nature" to process patents only. It is arguable that such an approach is overly restrictive in that the true pioneer who sets the stage for subsequent recombinant production of a given "product of nature" is denied the benefit that would be awarded to the counterpart in other fields of technology. This raises potential problems with respect to compliance with obligations under NAFTA. It is likely that Greenfield was not considering NAFTA at the time of writing his article given the timing of NAFTA implementation in the U.S.

The Products of Biotechnology Act

In order to avoid such dilutional problems, and yet provide incentive to innovators of new and useful processes for the synthesis of known products of nature, a new Act, called the "Products of Biotechnology Act" (the "PBA") should be enacted. The concept of specific legislation to address specific socio-economic concerns is not new. In particular, with respect to promoting the biotechnology industry Canada has implemented the *Plant Breeders' Rights Act* and in the United States there is the *Plant Variety Protection Act*. Further, in non-biotechnology fields there are *suis generis* pieces of legislation such as the integrated circuit topography Acts both in Canada and the United States.

The Act would provide limited right's to those who develop new, non-obvious and useful methods and processes of manufacturing known "products of nature." In other words, an application in respect of a "new" "product of nature" would not be allowed. Such applications would be made under the *Patent Act*.

The term of protection would be less than that of a patent, perhaps no more than 10 years, and should extend from the date of application, with priority on the basis of first to file.

The rights conferred by the PBA would be the exclusive rights to the manufacture, sale and use of the protected product when manufactured by the process(es) claimed. Further, and importantly, the holder of rights under the PBA would be able to produce the "product of nature" made pursuant to their claimed processes free of concern about patent infringement and would be provided with a *prima facie* presumption of infringement in respect of others manufacturing the same "product of nature."

An applicant for protection under the PBA would not be precluded from applying for protection of the process(es) under the *Patent Act* and *vice versa*. However, an applicant would not be entitled to obtain sequential terms of protection, and to ensure this could not occur, an application for a patent would be deemed to start the term under the PBA. The *Patent Act* would require amendment to indicate that an application for the same subject matter under the PBA is deemed to start the twenty year term under the *Patent Act*.

Clearly, those who make an application for a "new" "product of nature" under the *Patent Act* will be entitled to claims to an isolated, purified form of the product. However, where a patent issues in respect of such products, the patentee would arguably be able to sue applicants who are protected under the PBA for infringement where the products are the same. In order to overcome this potential problem, the scope of claims for those "new" products of nature should be limited to that which the inventor has truly invented. The basis for this proposition is that products of nature are intrinsically, fundamentally different from chemical compounds synthesized by a human.

In order to illustrate the distinction being made here, take an example from chemistry. In the chemical arts the inventor is entitled to protect a new and useful compound which is designed, fashioned, and created by the inventor. For such inventions, the inventor should be entitled to protect the product regardless of how it is made. The inventor is responsible for the functionality, having "built it into" the product.

Products of nature on the other hand, have been designed by nature. The inventor discovers the functionality and recognizes the utility, but is not responsible for imbuing the product with these qualities. As such, these inventors should only be entitled to protect those products, i.e., that which they have invented -pure products of nature. Where the inventor takes that product of nature and modifies it to enhance its features, or to incorporate new useful features, we are back to the inventor who creates a product, and protection should be available for such products, regardless of how made.

Arguably, patents which have issued thus far with claims to products of nature *per se* should only be effective in preventing the manufacture, use or sale of the product of nature. They should not allow the patentee to prevent the manufacture use or sale of synthetic versions of products of nature. The only case where synthetic products of nature should be challenged is where the patentee suspects the patented process has been infringed by the process for making the impugned synthetic product of nature.

How does this interpretation stand up to the doctrine of sound prediction? If the basic tenet that an inventor is only entitled to that which is invented is maintained, then it can co-exist with the present doctrine. It is important to recall that this doctrine has been developed most recently through the chemical arts where the inventor is responsible for the design and intended functionality of the compounds which are synthesized, and as such the inventor is entitled to claim the compound created and those which fall within the bounds of reasonable predictability. However, products of nature have not been designed by inventors and accordingly should not be treated in the same manner. Products of nature are fundamentally different from chemical inventions in that nature has built the intrinsic properties into the product. In order to ensure that the scope of claims is limited to just the products of nature, i.e., the scope is limited to the "invention," as required by Rule 25 of the *Patent Rules*, it is suggested that immediately following Rule 25, the following Rule be introduced:

RULE 25.1 For disclosures which describe a product of nature, claims will be allowed only in respect of each embodiment of the product of nature described.

In the case of an application for a patent for a "new" product of nature this rule will limit the scope to just that natural product of nature. Further, where a synthetic version of the new product of nature is created, the rule will also have the effect of limiting the scope to the synthetic version as produced by the process described in the disclosure.

How does this amendment stand up with respect to infringement and the doctrine of equivalents? Clearly a synthetic version of a product of nature could be considered as equivalent. However, if the invention is the natural product of nature then arguably, the only appropriate equivalents are those which are also natural products of nature. For example, depending upon the circumstances, a precursor to insulin, called proinsulin could be considered an equivalent. In order to ensure this is clear, section 55 is suggested to be amended as follows:

> **s. 55.3** In an action for infringement of a patent where the invention relates to a product of nature, chemical equivalents do not include products of nature synthesized by technical processes.

"Technical processes" is meant to ensure that products of nature which are synthesized as a result of significant human intervention, eg, through recombinant techniques, are not considered equivalent and therefore do not infringe a claim directed to a natural product of nature.

According to this view, products covered by the PBA could not infringe claims of a patent for a product of nature.

However, also according to this view, products covered by the PBA could infringe claims of a patent for a product of nature where the patent claimed the product of nature and a synthetic version of the product of nature when made by a specific process. The infringement would occur where the synthetic version covered under the PBA is produced by the same process, substantially the same process, or by an equivalent process. This situation would only arise where the inventor isolates a product of nature, and before disclosing it develops a process, or processes for synthesizing the product of nature. However, in accordance with suggested Rule 25.1 the claims in such a patent would only include within their scope the product of nature when isolated and purified, and each synthetic product of nature, when made by a given process. As such, the inventor is awarded patent rights only in respect of that which is truly invented.

Finally, the PBA would provide a reverse onus in respect of the same product, similar to that provided at section 55.1 of the *Patent Act*, by stating:

> **Burden of proof for protected process.** - In an action for infringement of a protected process for obtaining a product produced by the protected process, any product that is the same as the aforementioned product shall, in the absence of proof to the contrary, be considered to have been produced by the protected process.

The amendments to the *Patent Act* suggested arguably do not conflict with Canada's international obligations under NAFTA, and the enactment of a Products of Biotechnology Act would not likely run afoul the provisions of NAFTA.[232] Indeed, such an Act would be consistent with Article 1702.[233]

E. Non-obviousness in Biotechnology

The present form of the *Patent Act*, assuming the anticipated amendment under Bill S-17 which introduces specific language on non-obviousness comes into force, is acceptably drafted with respect to the issue of non-obviousness. The present standard for review of non-obviousness is also acceptable as it is presently applied by the Patent Office and Canadian courts. It is the recommendation of the Report that nothing be done to the definition of non-obviousness either through legislative or administrative options so as to attempt to redefine the standard of non-obviousness. As it presently exists, it adequately accommodates biotechnological innovations.

Biotechnology itself can be thought of as an invention of the human mind insofar as it brings together concepts from many different fields to provide new applications of various subject matter. Who is the person skilled in the art to assess the non-obviousness of invention in a field that draws upon so many disciplines? Indeed, it is this complexity of subject matter which presents the appearance of requiring a different standard. As an example, it is likely that no one thought of using bacteria to metabolize various fractions from an oil spill until Dr. Chakrabarty recognized this possibility and engineered Pseudomonas strains of bacterium to do just this. However, as can be gleaned from Popper's comments discussed *supra*, this is the process of invention in all sciences. Much of invention involves drawing information from a variety of related, and sometimes unrelated sources or fields of knowledge in order to invent.

Does the standard of non-obviousness shift? Since the beginning of the biotechnology revolution in the early 1970s to date, the judicial criteria by which obviousness is assessed have remained largely unchanged. As outlined in the discussion of how obviousness is analyzed, the critical factors arguably are, at the claim date (or date of invention):

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232 An argument may be made, however, that patentees with claims to the original isolated purified product of nature are disadvantaged by PBA legislation in so far as they would not be fully able to prevent others from manufacturing their claimed product, at least where the others are using a new, non-obvious, useful process. This would arguably be contrary to Article 1709(5)(a). In response, it may be said that Article 1709(6) provides support for any such derogation of rights in that the PBA represents a limited exception to the exclusive rights conferred by the patent and that this exception does not unreasonably conflict with the normal exploitation of the patent, nor would it unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of the PBA rights holder.

233 Article 1702 of NAFTA states:

> "A Party may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement."

1. the skilled technician; and
2. the common general knowledge.

There have been refinements and restatements of these elements, such as the reasonable diligent search and the "worth a try" analysis. However, the test, and the approach by the judiciary to the test, has remained substantially the same over the last 30 years. It is from this frame of reference that the invention must be obvious. In practical terms, since there must be an assessment made by a human being, who better to make the assessment than the one who is skilled in the art having regard to the common general knowledge? The problem is that this assessment, regardless of how it is phrased - non-obviousness, inventive step, etc. - is ultimately a subjective test wrapped in objective language. As the frame of reference changes, so too does the result.

In biotechnology, as in all fields of technology which advance, the information concerning the technology increases with time. Indeed, as the information increases, sub-technologies emerge, and the information within that sub-technology then increases. In the biotechnology field, this increase has been exponential. For example, at the turn of the 19th century it was possible to know everything there was to know about the biology of the human being. As the century progressed so too did knowledge. The disciplines of chemistry, mathematics, and physics were well established, but biochemistry, physiology, genetics, immunology, neurology, enzymology, haematology, gastroenterology, to name but a few, became disciplines unto themselves. Within each of these there are further, numerous subdivisions. Consequently, the skilled technician at the turn of the century, who was called upon to answer the inquiry of obviousness knew only a fraction of what that same technician would know today. Indeed, the "diligent search" of 1900 would turn up very little compared to the computer assisted search of today. Arguably, everything invented in the 19th century would be obvious from the perspective of the common general knowledge of 1996. So too, as the knowledge base expands, the field of inquiry narrows. The obviousness inquiry for an invention in the neurosciences would not necessarily include a review of literature in enzymology (unless something in the disclosure suggested it should). Is this any different for any other technology? It would appear not. In the computer sciences there are numerous subspecialties. The overly broad headings of chemistry and physics have been subdivided many times as knowledge increased in respect of certain aspects of each discipline. So too in these fields of inquiry has the search been necessarily narrowed to the sub-discipline, as there is just too much information within all of, say, chemistry, for the skilled technician to know as the common general knowledge.

Thus, the standard itself remains unchanged, and the result need not be changed. As discussed *supra*, what has made it appear to shift is the level of sophistication of the examiners and their ability to conduct and consider what is a reasonable diligent search. In Canada and the United States, in respect of biotechnology, the examiners have significant academic training, moreso than their counterparts in other fields of technology. Consequently obviousness may be more appropriately assessed by these examiners: They have a better grasp of what is the common general knowledge relevant to the invention than their counterparts in different fields. The challenge in biotechnology is not related to assessing and revising the standard of non-obviousness itself. The standard as it is works well enough. Rather, the challenge is ensuring that the level of inquiry with respect to the "common general knowledge" is appropriate. Returning to the discussion from the

"concept of invention" chapter, it is the frame of reference which changes as knowledge increases. Put another way, it is the "art" and the "common general knowledge" which change, not the standard. Given that the assessment of what is properly part of the "common general knowledge" is itself subjective, it is not possible to provide guidelines beyond what the court has already suggested, i.e., possibly the information which a reasonably skilled person would be able to find in a reasonable diligent search,[234] which itself is an objective test, but very subjective in application.

F. Conclusions

As stated at the beginning of this Report, some very basic characteristics of the subject matter of biotechnology set it apart from all other technology and as such raised the following question:

> *If biotechnology industries are to continue to grow, do the means for acquisition, and the very nature of a bundle of patent rights for advances in the biotechnology field, need to be redefined?*

This Report concludes that there can be invention pertaining to the subject matter of biotechnology, and further, that such subject matter can be proper subject matter, and assuming the remaining requirements of patentability are fulfilled, can be patentable invention. Indeed it is a conclusion of this Report that the patent system continues to be an important, integral part of the delivery of proprietary rights in respect of invention in biotechnology, and further, that the bundle of patent rights which are available for invention in biotechnology need not be redefined.

Although not explicitly discussed in the Report, it is concluded that, notwithstanding the fact that living organisms are *self-replicating*, the patent system is an adequate vehicle to enforce proprietary claims subject to the "farmers' exemption" discussed *supra*.

In jurisdictions which allow for the patenting of biotechnology a concession to the disclosure requirement is made, namely, allowing for the deposit of samples of the patented subject matter. Such deposits are part of the "complete description" of the invention and the deposit is said to "supplement" the complete description. It is concluded that this is a workable solution and arguably does no harm to the underlying philosophy of the patent system.

It is also concluded, as discussed *supra*, that with respect to the inquiry concerning non-obviousness the challenge in evaluating invention in biotechnology is ensuring that the level of inquiry with respect to the "common general knowledge" is appropriate.

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[234] As suggested by Teitelbaum, J. in *Procter & Gamble v. Kimberly-Clark Ltd.* (1991) 40 C.P.R. (3d) 1 (F.C.T.D.) at 45-48.

It is a requirement that all patentable invention must be new. The novelty requirement poses a significant hurdle to obtaining proprietary rights in those sectors of the biotechnology industry concerned with synthesis of products of nature. It is concluded that inventions premised on products of nature are fundamentally different from all other invention. Biotechnology and the industries it has spawned are important to Canada, and in order for growth and prosperity to continue in biotechnology concerning products of nature, it is concluded that certain rights should be provided, and these are arguably best provided by the Federal Government through the vehicle of the Products of Biotechnology Act.

It is concluded that if the substance of the recommendations of this Report are adopted such action will help to ensure that as the beginning of the next millennium approaches, Canada will be uniquely positioned in the world as a leader in providing intellectual property rights to innovation in biotechnology and may thereby more actively participate in the biotechnological revolution which has taken place over the last thirty years.

APPENDIX "A"
BIOTECHNOLOGY: DEFINITION IN THE CIPO

Inventions related to biotechnology would include claims to:

1. Processes defining any technique that uses:

   living organisms, parts of organisms, or substances from these organisms to make or modify products, to improve plants and animals, or to develop microorganisms for specific uses.

   > These processes include recent technologies such as: recombinant DNA, cell fusion including hybridoma, and bioprocesses, and "old" technologies such as: extraction and purification of substances from biological sources, the use of microorganisms for brewing and baking, and selective breeding in agriculture and animal husbandry.

2. Products produced by these processes.

3. Methods of using the above products.

4. Proteins produced by these processes and further modified by chemical processes are considered biotech products.

5. Compositions containing these products.

6. Apparatuses used in preparing or testing these products.

Class 195 Microbiochemistry. This includes cell fusion, genetic engineering, preparation of organic compounds (including proteins) using either an enzyme or cell to catalyze the reaction; and the apparatus used.

C12 Biochemistry; beer; spirits; wine; vinegar; microbiology; enzymology; mutation or genetic engineering.

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530 Peptides; Proteins
C07K Peptides; Proteins.

This includes the proteins themselves and non-microbiological processes of preparing them, such as extracting from natural sources and chemical synthesis.

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167 103-103.9 Medicines; Proteinaceous Materials

A61K 37/* Medicinal preparations containing proteinaceous materials, or derivatives thereof.

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177 104-118 and 286-291 Medicines; Animal and Plant Extracts

A61K 35/12-35/84 Medicinal preparations containing materials from animals, birds, microorganisms and plants.

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167 129-140 Medicines; Antigens (vaccines) Sera (antibodies)
A61K 39/* Medicinal preparations containing antigens or antibodies.

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167 37-45 Antigen-Antibody Testing (Diagnostics)

G01N 33/50-33/98 Chemical analysis of biological material, including immunoassays and biospecific binding assays.

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150 8.5-14 Testing involving enzymes, microbes or DNA probes. Testing involving pathology (Diagnostics).

In the IPC this is already included under C12 above i.e. C12Q Measuring or testing processes involving enzymes or microorganisms; and under G01N Chemical analysis of biological material.

167-5.1 Pesticides; Microorganisms, Enzymes, Animal Extracts.
167-5.3 Pesticides; Plant Extracts
71-4.5 Plant Growth Regulators; Treating plants with microbes or enzymes

A01N 63/* and 65/* Biocides or plant growth regulators containing microorganisms, enzymes, plant material or animal material.

Applications for new breeds of vertebrates and invertebrates in the Canadian scheme are classified for the most part among other subject matter in class 195-1.36, Modified Eucaryotic Cells.

A01K 67/07 New breeds of vertebrates
A01K 67/033 New breeds of invertebrates

47-4 Plant Husbandry; Propagation. Applications for new plants in the Canadian scheme have been classified here and among other subject matter in 195-1.36, Modified Eucaryotic Cells.

A01H New Plants or processes for obtaining them; Plant Reproduction by tissue culture techniques.

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362 1-25 Microbiological treatment of sewage.

C02F 3/* Biological treatment of water, waste water or sewage.
C02F 11/02 and 11/04 Biological treatment of sludge.

53-18 Metallurgy; Bacterial treatment

C22B 3/18 Extraction of metal compounds from ores with the aid of microorganisms or enzymes.

Methods of oil recovery or oil spill clean up using microorganisms are classified in class 195 in the Canadian scheme.

E21B 43/22 Methods of hydrocarbon recovery using bacterial activity.

Biosensors are classified in class 195 in the Canadian scheme.

G01N 27/327 Biochemical electrodes.

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