

4-1-2006

ESTs under Canadian Patent Law: Useful or Not?

Natalie C. Bellefeuille

Follow this and additional works at: <https://digitalcommons.schulichlaw.dal.ca/cjlt>

Recommended Citation

Bellefeuille, Natalie C. (2006) "ESTs under Canadian Patent Law: Useful or Not?," *Canadian Journal of Law and Technology*: Vol. 5 : No. 2 , Article 2.

Available at: <https://digitalcommons.schulichlaw.dal.ca/cjlt/vol5/iss2/2>

This Article is brought to you for free and open access by the Journals at Schulich Scholars. It has been accepted for inclusion in Canadian Journal of Law and Technology by an authorized editor of Schulich Scholars. For more information, please contact hannah.steeves@dal.ca.

ESTs under Canadian Patent Law: Useful or Not?

Natalie C. Bellefeuille†

Introduction

The Debate

The patentability of human genetic material has given rise to considerable debate around the world.¹ As Kevles notes, “[o]ne of the most controversial issues in biotechnology in the United States and Europe has been the patenting of human DNA sequences and human genes”.² A number of academics and organizations have written on the issue, and arguments both for and against have covered a broad range of concerns of an economic, social, medical, scientific and ethical nature.

Patents have been issued on human genetic material in most jurisdictions.³ Applicants have sought protection for DNA fragments (nucleotide sequences that do not encode full-length genes) including promoter sequences, enhancer sequences, individual exons, complementary DNA (cDNA), expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).⁴ Patent protection has also been sought and granted for full-length gene sequences, synthetic and mutant DNA and gene sequences, amino acid sequences, cloning and expression vectors, methods of transforming genes, and recombinant DNA.⁵ The majority of these patents have been issued by American, European, and Japanese patent offices.⁶

The technical debate as to whether human genetic material meets the requirements for patentability under the law has mainly focused on DNA sequences that do not encode full-length genes, such as ESTs.

What are ESTs?

Double-stranded human DNA contains sequences which code for genes. When genes are expressed, they produce proteins. During a process called transcription, the parts of DNA that encode genes are copied into mRNA. The mRNA present in cells at any given time presents a picture of which genes are being expressed.⁷ Using an enzyme called reverse transcriptase, researchers are able to produce a complementary and more stable copy of the mRNA called cDNA.⁸ ESTs are produced by sequencing a small number of nucleotides at the end of

one of the two cDNA strands: a 5' EST is obtained when the beginning portion of a cDNA is sequenced, whereas a 3' EST is obtained when the ending portion of a cDNA is sequenced.⁹ ESTs thus represent short DNA sequences, the majority of which encode part of a gene, but rarely a full-length gene. As will be discussed in greater detail below, they are generally only useful to researchers as tools to identify the full-length gene, and rarely provide information about the function or location of the gene.

Focus of this Article

A number of patent applications seeking protection over DNA fragments, in particular ESTs, have been filed with the Canadian Intellectual Property Office (CIPO), which is currently faced with the difficult task of determining whether such products are patentable subject-matter and whether they satisfy the requirements under the *Patent Act*.¹⁰ Whatever CIPO ultimately decides, we could expect litigation to arise, calling upon the courts to clarify the issue.¹¹

In the United States, utility is the patentability requirement that has received the most scholarly attention in the context of patenting of biotechnological inventions, because of the debate surrounding the patentability of ESTs.¹² Both courts and the Patents and Trademarks Office (USPTO) have struggled to address criticisms both for and against their patentability. It is still not clear exactly how the USPTO treats applications for EST patents.¹³

The following discussion will examine the utility requirement for patentability in the context of EST patents. Part I will provide background information regarding the utility requirement under patent law and will explain why it has been difficult to apply to ESTs. Part II will briefly examine how other jurisdictions, in particular the United States, have addressed the difficulties associated with applying the current utility requirement to biological materials, in particular ESTs. Part III will look at how Canadian courts have interpreted and applied the utility requirement for patentability, and will suggest that ESTs have sufficient value to the scientific community to satisfy this requirement. In addition, it will examine how the doctrine of sound prediction may

†B.Sc. Biology (Ottawa), B.C.L./LL.B. (McGill), LL.M. Candidate (Law & Technology) (Ottawa). E-mail: nbellefe@hotmail.com. The author wishes to thank Professor Valerie Steeves and Professor Ian Kerr for their ongoing academic support throughout the LL.M. program. © N.C. Bellefeuille

allow patent protection to be extended beyond the simple EST nucleotide sequence. This article will conclude by suggesting two reasons why the utility criterion for patentability has proven difficult to apply to human genetic materials.

The patenting of human genetic materials, including ESTs, raises a number of concerns apart from the question of whether they meet the utility requirement under patent legislation. Not only are there legal concerns in terms of whether such “inventions” are patentable subject-matter and whether they satisfy the requirements of novelty and non-obviousness, but there are also important moral concerns.¹⁴ While all of these issues are clearly related and not completely separable, an examination of their intersection is beyond the scope of this article.

Part I: Utility as a Patentability Requirement

The Utility Requirement

In Canada, an invention is defined as “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”.¹⁵ To meet the utility requirement, an invention must do what the patent claims say it can do.¹⁶ According to the CIPO *Manual of Patent Office Practice (MOPOP)*, the invention must be “operative, controllable and reproducible”.¹⁷ Patent legislation in the United States¹⁸ and Australia¹⁹ similarly require that an invention be “useful” to be patentable.

The *European Patent Convention*, at article 52, sets out the requirements that must be met for a patent to be issued: “Patents shall be granted for any inventions which are *susceptible of industrial application*, which are new and which involve an inventive step”.²⁰ It further states that “an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture”.²¹ Section 29(1) of the *Japan Patent Law* reads “any person who has made an invention which is *industrially applicable* may obtain a patent therefor...”.²² “The word ‘industry’ is interpreted in a broad sense, including mining, agriculture, fishery, transportation, telecommunications, etc., as well as manufacturing”.²³

According to the Nuffield Council on Bioethics report entitled *The Ethics of Patenting DNA*, the expression “susceptible of industrial application” is broader than the term “utility”.²⁴ The report suggests that, in practice because industrial applicability has been construed narrowly, the two standards are analogous.²⁵ This, however, does not appear to be a unanimous position, one source suggesting that, in fact, utility is broader than industrial applicability.²⁶

Difficulties in Applying the Utility Requirement to ESTs

In most jurisdictions, patent legislation has not been significantly amended to reflect advancements in biotechnology. As explained in the Government of Ontario report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, “the current patent system in Canada [is] not...designed to address questions of DNA patenting and the commercialization of the human genome”.²⁷ In the *Harvard Mouse* case, the majority of the Supreme Court of Canada stated that the *Patent Act* is “ill-equipped” to deal with the patenting of higher life forms.²⁸

The *Agreement on Trade-Related Aspects of Intellectual Property Rights* requires that “patent laws [be] applied without discrimination on the basis of technology”.²⁹ This has the status of an international norm.³⁰ Despite the fact that patent legislation is poorly designed to address innovation in the field of biotechnology, such inventions must be considered within the same patent regime as all other inventions.³¹ Courts and patent offices around the world have therefore been faced with the difficult task of interpreting their legislative provisions and developing interpretive guidelines to address the issues raised by biotechnological inventions.³²

Because of exceptional advancements in DNA sequencing techniques that have occurred over the last 10 years, “more DNA sequences have become available without a concomitant understanding of their function”.³³ DNA sequences that arise from these methods often represent short stretches of DNA, such as ESTs. Most ESTs do not provide scientifically useful information regarding the identity or function of the full-length gene.³⁴ Rather, ESTs are generally considered “weak and nonspecific tools for further research” that are generally only useful as probes or chromosomal markers.³⁵ A probe is a “DNA sequence that is used to detect the presence of a complementary sequence by hybridization with a nucleic acid sample”.³⁶ A chromosomal marker is defined as “[a] distinct sequence found on a chromosome that helps identify a particular area of it”.³⁷ While ESTs can be used to isolate the full-length gene, which can then be sequenced and characterized to identify its function, it is the full-length gene which tends to be viewed as the subject of interest and value, not the EST.

The application of the utility requirement to ESTs is problematic because, as Lech explains, any DNA sequence can be used to identify the chromosome from which it originates or to locate the gene to which it relates.³⁸ Similarly, all ESTs can be used as probes or markers to locate the full-length gene, except perhaps for those that are short and only encode a polyA or polyT sequence (short sequence from the 3' end of the EST).³⁹ Thus, use as probes and markers is not specific to ESTs, but applies to almost any nucleotide sequence.

Occasionally, a full-length gene will be encompassed within a single EST, or the DNA sequence of the EST will reveal an important motif or domain, which can allow the function of the gene and/or protein to be predicted.⁴⁰ In addition, ESTs can have very specific uses. As explained in the CBAC Report: “The utilities of nucleotide sequences patented to date include their role in gene regulation, encoding for therapeutic proteins, diagnostic probes, receptors used for identifying molecular targets for therapeutic drug development, immunogens, and gene replacement therapies”.⁴¹ DNA sequences with such functions usually satisfy the utility requirement since they have a specific use apart from that of the full-length gene.

This leads to the question of what type of utility is necessary for ESTs to satisfy the requirement under patent legislation. Is the scientific value of research tools sufficient to meet the utility requirement under the law?

Part II: Response in Other Jurisdictions

United States

Most of the debate regarding the patentability of human genetic material, in particular ESTs, has taken place in the United States. To understand how the utility requirement applies to DNA patents, it is important to examine how the interpretation of the requirement has changed over time.

Prior to 1966, an invention was considered useful if it was not “frivolous or injurious to the well-being, good policy, or sound morals of society”.⁴² The utility requirement was, at this time, described as a *de minimis* standard, as “it [was] seldom a bar to the issue of a given patent. . . [and] all that [was] required [was] a showing that the claimed invention [had] some practical, if attenuated, application or use”.⁴³

In the 1966 decision of *Brenner v. Manson*, the United States Supreme Court replaced the *de minimis* standard for utility with a more demanding requirement.⁴⁴ It found that, to be patentable, an invention had to have “substantial utility. . . [providing a] specific benefit in its currently available form”.⁴⁵ The Court added that an invention was not patentable if it was “only useful in the sense that it may be an object of scientific research”.⁴⁶ It also noted that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion”.⁴⁷

In the 1980 decision of *Diamond v. Chakrabarty*, the United States Supreme Court adopted a very broad definition of what constitutes patentable subject-matter, stating that “anything under the sun that is made by man is eligible for patenting”.⁴⁸ Not long after, the USPTO started issuing patents on DNA sequences.⁴⁹ However, the utility requirement was not applied

evenly.⁵⁰ In 1991, the National Institutes of Health filed patent applications for approximately 2,700 partial DNA sequences, seeking protection not only for the EST sequences, but also for the full-length gene sequences and the proteins derived from these genes.⁵¹ On the basis of *Brenner v. Manson*, the applications were denied as the DNA sequences in question were considered mere research tools that would not satisfy the utility requirement.⁵²

The USPTO, in 1995, issued examination guidelines which imposed a more generous standard for assessing utility. These guidelines required “credible utility”, which could be satisfied if “the assertion of utility was believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided”.⁵³ The guidelines were viewed as a return to the *de minimis* standard.⁵⁴ They did not, however, resolve all of the issues associated with EST patentability.⁵⁵

In 1997, the USPTO announced that from then on it would be granting patents for ESTs, as their utility as probes for locating the corresponding full-length gene was sufficient to meet the requirement under the new guidelines.⁵⁶ It did specify, however, that the patent would not cover the full-length gene unless the EST encompassed the entire gene sequence.⁵⁷ This decision was highly controversial. Only two months later, the USPTO revised its position, stating that “usefulness as a probe alone [will] not qualify an EST as patentable. . . [The] inventor must have some knowledge of the function or utility of the target gene for an EST as a probe to satisfy the legal requirements for patenting”.⁵⁸ Furthermore, “patent applicants must demonstrate a more ‘substantial, real-world utility; not some throwaway utility’”.⁵⁹ Thus, a large number of ESTs would not meet the requirement.⁶⁰ Based on the *Eli Lilly* decision of 1997, the USPTO “refused to grant claims on any nucleotide sequence other than those disclosed in the application even if the type of gene was identified”.⁶¹

In 2001, the USPTO issued revised utility guidelines, according to which an applicant must “assert a specific and substantial utility that a person of ordinary skill in the art to which the invention pertains would consider credible”.⁶² A “specific” utility is one that is not general in nature, but applies to the particular subject-matter claimed,⁶³ whereas, a “substantial” utility requires a real world use (an immediate benefit without the need to conduct further research).⁶⁴ “Credible” requires that the utility be “believable to a person of ordinary skill in the art, based on the totality of evidence and reasoning provided”.⁶⁵ These guidelines have been incorporated into the USPTO, *Manual of Patent Examining Procedure*.⁶⁶

This revised utility requirement represents a return to the *Brenner v. Manson* standard.⁶⁷ A DNA sequence that is useful only as a gene probe or chromosomal marker, will not have a “specific” utility, unless, the par-

ticular gene or chromosome target is also identified.⁶⁸ A DNA fragment will have substantial utility where it allows genes linked to a particular disease to be identified, but not where “it is only useful for studying its own properties”.⁶⁹ The use of ESTs as probes or markers will always be credible, because nucleotide sequences are routinely used for such purposes.⁷⁰

Thus, in the United States, certain ESTs are patentable.⁷¹ According to Demaine & Fellmeth, the USPTO “now routinely grants, and federal courts consistently uphold, patents on newly discovered...DNA fragments”.⁷² While quite a few patents were issued for ESTs belonging to certain gene families prior to the revised utility guidelines, it is not clear how many have been granted by the USPTO since the revised guidelines have been in force.⁷³ According to Human Genome Project Information online, the USPTO has issued only “a few patents for gene fragments”.⁷⁴

A recent Federal Circuit decision has upheld the revised utility guidelines. In *In re Fisher*, the applicant sought patent protection for 5 ESTs that encoded protein fragments in maize plants.⁷⁵ While the structure and function of the full-length genes and proteins were unknown, the applicant argued that this was irrelevant, since the ESTs were useful as research tools, and these uses were distinct from the function of the encoded gene or protein.⁷⁶ The Court found that the ESTs did not meet the requirement under the new utility guidelines. They did not have specific utility, because the utility claimed applied to a broad class of invention (all ESTs and not the specific ESTs that the applicant “invented”).⁷⁷ The ESTs did not have substantial utility, as set out in *Brenner v. Manson*, because they did not provide an immediate benefit to the public in their available form. Rather, further research would be necessary to confirm their “real world use”.⁷⁸

Other Jurisdictions

A number of other jurisdictions, including the United Kingdom, New Zealand and Japan, have endorsed and implemented the current United States’ approach, according to which an invention must have specific, substantial and credible utility.⁷⁹

It is not clear whether this approach has been adopted by the European Patent Office (EPO). Although the *Guidelines for Examination in the European Patent Office (EPO Examination Guidelines)*⁸⁰ do not explicitly require that an invention disclose a specific, substantial and credible utility to be considered “susceptible of industrial application”, according to the *Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Patent Office*, to date, such an approach has been followed by the EPO.⁸¹ With respect to genetic sequences, the *EPO Examination Guidelines* provide that:

A mere nucleic acid sequence without an indication of a function is not a patentable invention ... In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could be that the sequence exhibits a certain transcription promoter activity [for example].⁸²

It does not appear, based on the above passage, that specific, substantial and credible utility is required for DNA patents. It is worth noting that the *EU Biotechnology Directive* requires that “a patent applicant [must] disclose the industrial application of a sequence or partial sequence of a gene”.⁸³

The situation in Australia is also unclear. According to the *Australian Patents for Biological Inventions* fact sheet, a claimed DNA sequence must have a specific utility: “[an applicant] must describe a specific use for the biological material...[and] if the invention relates to a gene, the specification must disclose a specific use for the gene such as its use in the diagnosis or treatment of a specific disease or its use in a specific enzymatic reaction or industrial process”.⁸⁴ Despite the Australian Law Reform Commission’s recommendation, in 2004, that Australia adopt the United States’ approach, to date, it does not appear that such a standard is being applied by the Australian patent office.⁸⁵

Part III: Utility Requirement in Canada

Canada has not yet taken a position as to how it will address the patentability of ESTs, and in particular the question of utility. CIPO has been called upon to develop interpretive guidelines in this respect, but has not yet done so.⁸⁶ An examination of how the utility requirement has evolved over the last century may provide partial answers.

Utility is an Easy Test to Meet

In Canada, the utility requirement is easily met. In 1981, the Supreme Court of Canada adopted the language of *Halsbury’s Laws of England*: “[non-useful] means ‘that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do’”.⁸⁷ A number of older cases also suggest that the utility requirement is not onerous.⁸⁸ For example, a 1928 Exchequer Court decision found that “a definite amount of utility is not required by law to sustain an invention; a slight amount of utility is sufficient”.⁸⁹ The *MOPOP* states that while an invention must have *some purpose*, it need not have any particular purpose unless such a purpose is described in the specification.⁹⁰

Interpretation and Application of the Utility Requirement by Canadian Courts

Utility may be an easy test to meet, but what it means for an invention to be useful, under current patent law, is uncertain. Canadian courts have been inconsistent in their discussions on utility, using such expressions as “industrial value” and “commercial utility” without defining them. Because ESTs are often described as mere research tools that have little or no commercial value, the interpretation of utility will determine whether they satisfy the utility requirement for patentability. For this reason, it is worth briefly reviewing some of the cases in which Canadian courts have interpreted and applied the utility requirement.

In *Re Application of Abitibi Co. [Abitibi]*, the applicant sought a patent for a mixed fungal yeast culture system that could be used to digest effluent from wood pulp mills.⁹¹ The Patent Appeal Board and Commissioner of Patents, in considering whether the patentability requirements were met, stated that an invention could not be “a mere laboratory curiosity whose only possible claim to utility is as starting material for further research”.⁹² The Board seems to have adopted the *Brenner v. Manson* standard according to which mere research tools are unpatentable. The *MOPOP* was subsequently amended to prohibit claims to mere research tools, requiring that inventions have industrial value.⁹³ No other Canadian case has considered, whether an invention useful only as a research tool, meets the utility requirement under patent legislation.

Although the *Abitibi* decision has not been overturned, the short passage on utility has been cited only once by Canadian courts in over 20 years. Justice Binnie, dissenting in the Supreme Court of Canada decision of *Harvard Mouse*, referred to the above passage in the context of his discussion on patentable subject-matter, and without commenting on it.⁹⁴ The *MOPOP* has been amended and no longer prohibits claims on research tools.⁹⁵ On this basis, I would suggest that Canadian patent law has not adopted the reasoning in *Brenner v. Manson*, and that research tools are not unpatentable, *per se*, for lack of utility.

In 1928, in the case of *Prentice v. Dominion Rubber Co. [Prentice]*, the Exchequer Court considered the validity of a patent claiming an improvement in interlocking fastener construction. It found that “[c]ommercial utility is the very essence of a patent; a favourable reception by the purchasing public affords strong evidence of that degree of utility required by law”.⁹⁶ The Court found that the commercial adoption of the invention provided sufficient proof of its utility.⁹⁷

In the 1939 decision of *Northern Electric Co. v. Brown's Theatres Ltd. [Northern Electric]*, the Exchequer Court considered the validity of a patent claiming “an invention for the control of electric currents by and in accordance with variations of light”.⁹⁸ It stated that “[a]n invention to be patentable must confer on the public a

benefit. Utility, as predicated of inventions, means *industrial value*”.⁹⁹ Applying this test to the case at hand, the Court found that the invention lacked utility “because it [was] inoperable for the purpose for which it was designed”.¹⁰⁰ In the Court’s opinion, it was not reasonable to believe that a worker competent in the art, would, at the date of the specification, use the invention as described.¹⁰¹ In fact, the invention in question had never gone into use. The Court, in this case, appears to have adopted a fairly low standard for utility.

These two decisions, both by Maclean P. of the Exchequer Court of Canada, appear inconsistent. Whereas the Court, in *Prentice*, found that the utility requirement for patentability required commercial utility, in *Northern Electric*, it interpreted utility as requiring industrial value. It is unclear whether the Court applied the same standard while simply using different terminology, or whether it applied two different standards for assessing utility, and if so, on what basis.

In *Re Application No. 003,389 of N.V. Organon [Organon]*, the Patent Appeal Board was called upon to determine whether a patent claiming a method of pathological diagnosis satisfied the definition of invention under s. 2(d) of the *Patent Act*, and more specifically whether it was a useful art or process.¹⁰² The Board found that it was, since it was “inherently beneficial to the public...[and had] *utility in practical affairs*...[and] *commercial applications*”.¹⁰³ Because the Board did not address the utility requirement specifically, but rather considered whether the invention was a “useful art or process”, it is unclear whether its findings are relevant to the question of utility, or whether they are relevant to whether an invention is patentable subject-matter.

In the 1981 Supreme Court of Canada decision of *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd. [Consolboard]*, Dickson J., speaking to the validity of two patents, one for wafers and the other for a waferboard, adopted *Halsbury's Laws of England* according to which “*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*”.¹⁰⁴ As the issue in this case was whether the statutory requirement to fully describe the invention in the specification had been met, the Court did not apply the test for utility as explained in *Halsbury's Laws of England*. As such, the binding nature of the Court’s brief discussion on utility is uncertain.¹⁰⁵

In 1989, in *Pioneer Hi Bred Ltd. v. Canada (Commissioner of Patents) [Pioneer]*, the Supreme Court was faced with a patent claiming a new soybean variety developed from cross-breeding.¹⁰⁶ The Court stated that “all inventions are not necessarily patentable, even if they are the work of an inventive genius, they produce a new

industrial result, and are *commercially useful*...”¹⁰⁷ The Court referred to the patentability requirements to explain that even if these requirements are met, failure to comply with the disclosure requirements may render an invention unpatentable. It did not make any findings as to whether the utility requirement was met in the case at hand. It is interesting to note that the Court referred to the *Northern Electric* decision as standing for the proposition that the utility requirement will be satisfied where an invention is “commercially useful”.¹⁰⁸ The *Northern Electric* decision, however, interprets the utility requirement as requiring “*industrial value*”, and does not consider commercial utility.¹⁰⁹

The Patent Appeal Board, in the 1992 decision of *Re McIntyre*, considered the validity of a patent claiming “an apparatus and method for evaluating a patient’s heart function by monitoring the change in arterial pulsations while the patient performs a heart straining maneuver”.¹¹⁰ The patent application had originally been denied for lack of industrial or commercial value, on the basis that because the process claims must be practiced on the body of individuals, they did not describe an industrial process and did not result in a marketable product.¹¹¹ The Patent Appeal Board considered whether the invention was useful:

If diagnostic methods are to be patentable then *commercial value* cannot be assessed as if they are processes for producing milk feedstock. *The test must be that the method, and its results, has value to the community to which it is addressed; that the method be reproducible by anyone skilled in the art; and that some economic benefit can be realized by those who practice the method. We see no reason to doubt that the method claimed in this application will not be useful to the medical community... The method can be worked on a commercial scale that is adequate and reasonable under the circumstances, and which will certainly result in some form of economic benefit for the practitioner.*¹¹²

Interestingly, while the patent examiner seems to have considered whether the invention had either commercial or industrial value,¹¹³ the Board simply considered whether it had commercial value. It did, however, adopt a flexible test for determining whether the utility requirement is met, according to which an invention will have commercial value if it “has value to the community to which it is addressed”.¹¹⁴

The Trial Division of the Federal Court, in the 1995 decision of *Cochlear Corp. v. Cosem Neurostim Ltée* [*Cochlear*], assessed the validity of a patent claiming an “implantable tissue-stimulating prosthesis”.¹¹⁵ It defined utility as requiring that an invention “be operative and have *some commercial value*”.¹¹⁶ After stating that “[t]he utility of a patent may be proven by the reception received from the public”, the Court found that the utility requirement was met as the invention had *commercial success*.¹¹⁷

General Observations Based on the Cases Examined Above

Early Exchequer Court decisions in *Prentice* and *Northern Electric* as well as the Patent Appeal Board decision in *Organon* emphasized the importance of an invention being beneficial to the public.¹¹⁸ The Supreme Court in *Consolboard*, however, adopted *Halsbury’s Laws of England* according to which “it does not matter whether the invention is of any real benefit to the public”.¹¹⁹ Because the Court in that case did not specifically consider whether the utility requirement was met, but rather considered whether the disclosure of the invention in the specification was sufficient, it is unclear whether its discussion on utility is authoritative. The *MOPOP* states, based on the *Organon* decision, that subject-matter “that does not have results beneficial to the public” will not satisfy the utility requirement under s. 2 of the *Patent Act*.¹²⁰ It is worth noting that CIPO has integrated into the *MOPOP* certain aspects of the *Halsbury’s Laws of England* passage adopted by the Supreme Court in *Consolboard*, but not others.¹²¹

Of the cases examined, only *Northern Electric* interpreted “useful” under the legislation as requiring that an invention have “industrial value”.¹²² Other cases do not explain what it means for an invention to be useful, but rather, speak of the requirement being met because of the commercial utility, value or success of the invention. For example, in *Prentice*, the Exchequer Court stated that “a favourable reception by the purchasing public affords strong evidence of that degree of utility required by law”.¹²³ The Federal Court in *Cochlear* similarly found that “[t]he utility of a patent may be proven by the reception received from the public” (i.e. its commercial success).¹²⁴ Therefore, an invention which has commercial success will meet the utility requirement under the law.¹²⁵

Whereas commercial utility, value or success may provide proof of utility, these cases do not state that an invention must meet such a standard to satisfy the utility requirement under the law. The *MOPOP* previously required industrial value for an invention to be considered useful.¹²⁶ This, however, has changed, and the section on utility no longer explicitly requires industrial value.¹²⁷ In fact, it does not require commercial value or commercial utility either. Rather, it simply states, on the basis of the decision in *Consolboard*, that an invention must be “useful for some purpose”.¹²⁸ It should be noted, however, that in its section on subject-matter, the *MOPOP* requires an art, process or manner of manufacture to “produce an essentially economic result in relation to trade, commerce, or industry”.¹²⁹ Not only does this relate to the issue of whether an invention is patentable subject-matter, and not to the question of utility,

but it also does not apply to compositions of matter. Thus, under the *MOPOP*, there is no general requirement that inventions have either commercial utility or industrial value.

An examination of the above cases reveals that the type of utility that is required for inventions to meet the requirement under the law is somewhat ambiguous. Canadian courts have not, to date, required that inventions have a specific, substantial and credible utility, as is required in the United States. Rather, they have used expressions such as “commercial utility”, “commercial success”, “commercial value” and “industrial value”, sometimes interchangeably, and mostly without any explanation of their meaning. Courts have also referred to similar expressions in their examination of whether an invention meets the requirement of inventiveness.¹³⁰ The uncertainty surrounding the meaning of utility as required by the *Patent Act* makes it difficult to ascertain how it would be applied to ESTs, and whether such “inventions” will be found to satisfy the requirement.

Utility of ESTs

The patentability of ESTs raises a number of complex issues, one of which is whether such inventions meet the requirement of utility under patent law. ESTs have been described as having little or no commercial value, because “they do not themselves result in a ‘product’, but rather allow one to continue down the path to a useful end result. . . . It is the gene itself, in its full-length or characterized form, that is potentially useful (in advancing a commercial interest or biological knowledge).”¹³¹ As such, because most ESTs have “no genuine therapeutic or diagnostic value”, their use, as research tools, is considered intermediate.¹³² While providing a means through which commercial products, such as medicines or vaccines, may be developed, ESTs are generally not considered such products themselves.¹³³ ESTs rarely provide specific information regarding the location and function of the full-length gene, and a significant amount of work is needed to isolate the full-length gene and identify its function.¹³⁴ Although most ESTs may serve as probes or markers, their gene or chromosomal target is generally unknown when patent protection is sought.¹³⁵

For the reasons that follow, I would suggest that ESTs meet the current utility requirement under Canadian patent law.

ESTs are important research tools that have a significant value to the scientific community, largely because they “represent a copy of just the interesting part of the genome, that which is expressed”.¹³⁶ A DNA sequence can assist in isolating the full-length gene, which can then be sequenced, characterized and its function identified. Various uses to which the biotechnology industry can put ESTs include using them as diagnostic probes, to construct arrays and perform comparative genomics studies, and for chromosome mapping, tissue typing, and

forensic identification.¹³⁷ The use of ESTs as research tools accelerates research and development, and saves important resources in terms of time and cost. They therefore provide an economic benefit to those who use them, and are of sufficient value to the scientific community to meet the test set out in *Re McIntyre*.¹³⁸

Utility is meant to be an easy test to meet.¹³⁹ As such, it should be flexible enough to take into account the fact that not all inventions are intended to produce marketable products available to the purchasing public. Certain inventions are meant to be used by a particular trade or industry, without necessarily becoming objects of commerce. According to the Supreme Court decision in *Consolboard*, all that is required of an invention is that it “be useful for some purpose”.¹⁴⁰ As such, the use of ESTs as research tools should be sufficient to meet this low standard. In fact, not only do ESTs “have the potential to yield commercial products in the future”,¹⁴¹ but they can also be sold as commercial products, even for their use as research tools.¹⁴² As explained in *The Ethics of Patenting DNA*, “[i]n general, owners of patents on research tools may realize commercial value from their patents either by licensing patents for particular sequences. . . or by applying the knowledge within the institution to programmes aimed at discovering drugs, or other research”.¹⁴³

Therefore, not only are ESTs valuable to the scientific community, and as such can be described as having industrial utility, but they may also have “some” commercial value. If utility truly is an easy test to meet, and if this test is to be applied in a way that takes into account the particular community to which the invention is addressed, then ESTs are of sufficient scientific value to meet the utility requirement under the law. The fact that the full-length gene may be of greater scientific interest and may have greater commercial value than a partial sequence should not take away from the utility of ESTs as research tools. In addition, I would suggest that ESTs are beneficial to the public. While they may not provide a marketable product, they provide an indirect benefit through quicker development and commercialization of medicines, vaccines and diagnostic tests.

The utility requirement for patentability is an easy test to meet. Unfortunately, Canadian courts have not consistently interpreted and applied the requirement. This makes it difficult to know whether ESTs meet the requirement under the law. Despite the uncertainty that surrounds the application of the utility requirement, I suggested, above, that ESTs useful as research tools meet the current test because they have value to the scientific community and are beneficial to the public. As such, they are useful “for some purpose”, as required by the *MOPOP*.

The Doctrine of Sound Prediction

In certain circumstances, the utility requirement can be met even if utility is not demonstrated at the date of

application. A sound prediction of utility can satisfy the requirement under the law.

The doctrine of sound prediction was explained by the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*¹⁴⁴ In that case, the applicant had identified a new use for the known drug, AZT. The Court found that the utility requirement under s. 2 of the *Patent Act* could “either be demonstrated or be a sound prediction based on the information and expertise then available [at the date of application]”.¹⁴⁵ After stating that the doctrine requires more than mere speculation, the Court set out its three components:

- (1) a factual basis for the prediction;
- (2) a sound line of reasoning from which the desired result can be inferred from the factual basis; and
- (3) proper disclosure.¹⁴⁶

The Court found that the doctrine was applicable in that case, as the applicant had “enough information about AZT and its activity against HIV in human cells to make a sound prediction that AZT would be useful in the treatment and prophylaxis of HIV/AIDS in human beings”.¹⁴⁷

The doctrine was first adopted into Canadian Law in *Monsanto Co. v. Canada (Commissioner of Patents)*,¹⁴⁸ based on the English case of *Olin Mathieson Chemical Corp. v. Biorex Laboratories Ltd.*¹⁴⁹ and the Canadian case of *Burton Parsons Chemical Inc. v. Hewlett-Packard (Canada) Ltd.*¹⁵⁰ The findings in *Monsanto* were subsequently applied by the Federal Court of Appeal in *Ciba-Geigy AG v. Commissioner of Patents*, where the Court was faced with an application for new amines useful in the treatment of cancer.¹⁵¹ The applicant had not tested all of the amines before filing his application. The Court stated that “[t]he predictability of a particular result seems to me to be essentially a question of fact, though in some situations it may be a matter of common knowledge”.¹⁵² The doctrine was not applicable in that case, the Court finding that what is chemically predictable may not be pharmacologically predictable.¹⁵³

The case law on sound prediction suggests that a factual basis for a prediction can be supplied by tested compounds, and a sound line of reasoning can be grounded in the known “architecture of chemical compounds”.¹⁵⁴ There will be proper disclosure where a “full, clean and exact description of the nature of the invention and the manner in which it can be practiced” is disclosed.¹⁵⁵

The doctrine, as well as its three requirements, have been incorporated into the *MOPOP*.

If utility of the subject matter which forms the basis of a claim is not apparent or the promised utility of the subject matter is in doubt, then the applicant must have established utility, at the claim date, either by demonstration (i.e. testing the invention and conclusively proving utility) or by sound prediction.¹⁵⁶

The *MOPOP* also confirms that “a lucky guess or mere speculation” will not satisfy the requirements under the doctrine.¹⁵⁷

The doctrine of sound prediction has been applied in a number of cases to chemical compounds, the Supreme Court of Canada stating, in *Monsanto*, that “[w]e are no longer in the days when the architecture of chemical compounds [is] a mystery. By means of modern techniques, chemists are now able to map out in detail the exact composition of every atom in very complex molecules...”¹⁵⁸ To date, the doctrine has not been applied to a case where patent protection was sought for DNA sequences. Nevertheless, given that human genetic material is treated like chemical compounds for the purposes of patent law,¹⁵⁹ the doctrine should be equally applicable to such inventions.

An argument could be made that, in certain circumstances, patent protection could be extended beyond the simple EST sequence to include the full-length gene sequence or amino acid sequence, even if its exact function and location on the human chromosome are unknown. There are situations in which it is possible to make a sound prediction as “to the identity or function of a gene from which an EST has been obtained”.¹⁶⁰

As Resnik explains, “DNA contains information for the primary structure [amino acid sequence] of a protein”.¹⁶¹ This is particularly true of ESTs, since they contain only coding portions of DNA. ESTs which represent the beginning portion of a gene (5' ESTs), indicate the correct reading frame, from which the amino acid sequence can be determined.

An EST, which is generally about 400 to 500 nucleotides in length, is sufficiently long to encode an amino acid domain.¹⁶² A domain is a feature of the three dimensional shape of a protein, usually described in terms of its fold.¹⁶³ Because the conformation of proteins determines their role in the human body, and because different protein domains act in a semi-independent manner, proteins with similar domains usually have functions in common.¹⁶⁴ For example, a particular domain may indicate that the gene product will be a catalytic enzyme.¹⁶⁵

Thus, the amino acid sequence of the resulting protein can be determined based on the DNA sequence of an EST. Occasionally, the amino acid sequence will encode a domain which is typical of a protein having a certain type of function. On this basis, a sound prediction can be made with respect to the function of the protein which is partly encoded by the EST.¹⁶⁶ As evidenced from the Japan Patent Office Examination Guidelines, not all domains reveal a major function of the protein.¹⁶⁷ For example, an EST which encodes a glycosylation domain would not justify a claim for the amino acid sequence, because glycoproteins have a wide range of functions, even though they may also have certain common functions.¹⁶⁸

When ESTs are sequenced, the practice is to enter these sequences into an EST database (dbEST).¹⁶⁹ At this point, one can compare the inputted sequence with those already in the database, allowing a determination of whether the ESTs resemble a known gene, gene family, or category of gene function.¹⁷⁰ I would suggest that this, too, can be the basis of sound prediction.

For the reasons provided above, I would suggest that if a sound prediction can be made of the function of the gene or protein based on the DNA sequence, which reveals information about structure, the utility requirement could be satisfied. The fact that this function may have been identified through a homology search in a computer database is irrelevant to the determination of whether or not the utility requirement is met. The *MOPOP* confirms that sound prediction can be based on the structure of a molecule.¹⁷¹

The United States, Japan and the European Union have acknowledged that the utility requirement can be met where the function of a gene can be inferred from the sequence of a DNA fragment through computer comparisons with other inputted sequences producing high homology.¹⁷² While it is not quite clear what high homology consists of, the Japan Patent Office Examination Guidelines indicate that a 20-30% homology would be insufficient to claim that the DNA fragment for which a patent is being sought has a function similar or akin to another known sequence.¹⁷³

Given that the Supreme Court in *Apotex* warned against confusing sound prediction with speculation,¹⁷⁴ the extent to which the doctrine may be applied to broaden the scope of patent protection for ESTs, is as of yet unclear.

Conclusion

The patenting of human genetic material, in particular ESTs, has been the subject of debate for a number of years. Because most ESTs are useful only as molecular probes or markers for the identification of the corresponding full-length gene, the debate has largely focused on whether ESTs meet the utility requirement for a patent. It is now recognized that “there is no straightforward legal reason to deny patent protection to all ESTs”.¹⁷⁵ The United States, and a number of other jurisdictions, have adopted a similar approach, according to which this requirement will be met where an invention has specific, substantial and credible utility.

A number of applications have been filed with CIPO for patents on ESTs and other human genetic materials. It is not clear whether ESTs meet the utility requirement under Canadian patent law. Court and administrative body decisions have inconsistently described this requirement, referring to such expressions as “commercial utility” and “industrial value”, without providing an explanation of their meaning. ESTs, while arguably having little commercial value, are sufficiently valuable

to the scientific community, as research tools, to be considered “useful” under the law. The extent, to which the doctrine of sound prediction could be applied to allow patents for full-length genes or proteins, where only an EST sequence is disclosed, remains an open question.

Although Canadian courts and CIPO have not adopted the United States approach for assessing the utility of an invention, federal and provincial government reports have been calling upon CIPO to “develop interpretive guidelines for the application of patentability criteria to genetic innovations, similar to those in the United States for applying the utility criterion to [human genetic materials]”.¹⁷⁶ CIPO is currently updating the chapter of the *MOPOP* which deals with the utility requirement for patentability. This may clarify its position regarding the patentability of ESTs, and more specifically, may reveal whether research tools meet this requirement. Regardless of the position adopted by CIPO, we could expect litigation to arise, calling upon the courts to address the issues associated with the patentability of ESTs. Given that two of the leading jurisdictions in patent policy, the United States and Japan,¹⁷⁷ have clearly adopted a common approach, Canadian courts may well decide to endorse this approach as well. Should they decide to do so, only a limited number of ESTs would meet the utility requirement under Canadian patent law.

An examination of the threshold requirement of patentable subject-matter and the patentability requirements of novelty and non-obviousness was beyond the scope of this article, as was a discussion of the moral concerns associated with DNA patenting and the potential impact on research and innovation from allowing patents on research tools such as ESTs.¹⁷⁸ The debate over the patentability of DNA is not limited to the question of utility, and Canadian courts may ultimately decide the issue on the basis of one of the other requirements.

I would like to conclude by suggesting two reasons why the utility criterion for patentability has proven so difficult to apply to human genetic material.

First, there is no consistency in the way in which courts, patent offices and academics describe the kind of utility that is required for biotechnological inventions. Under certain interpretations, a DNA sequence itself must have a function, apart from that of the full-length gene. Under others, something must be known about the full-length gene or protein. For example, the CBAC Report states that “to obtain a patent, the inventor must be able to identify or modify the novel genetic sequence and specify the product of the sequence and how it functions in nature”.¹⁷⁹ Considering that it is possible for a DNA sequence to have a specific function apart from that of the full-length gene, why should the inventor be required to have determined the product of the sequence before applying for a patent?

Secondly, there is significant confusion with respect to the appropriate scope of protection when a patent is

issued for a DNA sequence. It is not clear when knowledge of a DNA sequence should permit patent protection for the full-length gene or protein, and whether a patent for use as a probe or marker should cover all other uses. Usually, an inventor is entitled to protection

over “every use of which his invention is susceptible, whether such use is known or unknown to him”.¹⁸⁰ Not only can an EST have multiple functions, but so can the full-length gene.¹⁸¹

Notes:

¹ Ontario, Ministry of Health and Long Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Toronto: Ministry of Health and Long Term Care, 2002) at 31, online: <http://www.health.gov.on.ca/english/public/pub/ministry_report_s/geneticsrep02/report_e.pdf> [Genetics, Testing & Gene Patenting]. See also Canada, Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Saskatoon: Commission on the Future of Health Care in Canada, 2002) at 209, online: Health Canada <<http://www.hc-sc.gc.ca/english/care/romanow/index1.html>> [Building on Values].

² Daniel J. Kevles & Ari Berkowitz, “The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics” (2001) 67 *Brook. L. Rev.* 233 at 233.

³ See Timothy Caulfield, E. Richard Gold & Mildred K. Cho, “Patenting Human Genetic Material: Refocusing the Debate” (2000) 1 *Nature Reviews Genetics* 227 at 227; Martin Bobrow & Sandy Thomas, “Patents in a Genetic Age” (2001) 409 *Nature* 763 at 763.

⁴ U.K., Nuffield Council on Bioethics, *The Ethics of Patenting DNA: a discussion paper* (London: Nuffield Foundation, 2002) at 25, online: Nuffield Council on Bioethics <<http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf>> [The Ethics of Patenting DNA].

⁵ Austl., Commonwealth, Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC Report No. 99) (Canberra: Australian Government Publishing Service, 2004) at c. 6, s. 6.3, online: Australasian Legal Information Institute <<http://beta.austlii.edu.au/au/other/alc/publications/reports/99/>> [Genes and Ingenuity]. See also *ibid.*

⁶ See “Human Genome Project Information: Genetics and Patenting”, online: Oak Ridge National Laboratory <http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml> [“Human Genome Project Information”]; Lawrence M. Rausch, “International Patenting of Human DNA Sequences” (August 2002) NSF 02-333 National Science Foundation InfoBrief 1 at 1ff.

⁷ Molly A. Holman & Stephen R. Munzer, “Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags” (2000) 85 *Iowa L. Rev.* 735 at 748.

⁸ James D. Watson *et al.*, *Molecular Biology of the Gene* (San Francisco: Pearson/Benjamin Cummings, 2004) at 656.

⁹ “ESTs: Gene Discovery Made Easier”, online: National Center for Biotechnology Information <<http://www.ncbi.nlm.nih.gov/About/primer/est.html>>.

¹⁰ R.S.C. 1985, c. P-4. It is difficult to ascertain, through a database search, exactly how many such applications have been filed, as the terminology used to describe DNA sequences is not consistent.

¹¹ Litigation has taken place in the United States: See *In re Fisher*, 421 F.3d 1365 (Cir. 2005). The issue has not yet been before Canadian courts because CIPO has, to this point, not taken an official position regarding the patentability of ESTs.

¹² Linda J. Demaine & Aaron Xavier Fellmeth, “Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent” (2002) 55 *Stan. L. Rev.* 303 at 364.

¹³ See “The Fate of Gene Patents Under the New Utility Guidelines” (2001) *Duke L. & Tech. Rev.* 0008, online: Duke Law <<http://www.law.duke.edu/journals/dltr/articles/2001dltr0008.html>> [“The Fate of Gene Patents”], where the ambiguities associated with the most recent utility guidelines are discussed in detail.

¹⁴ For a discussion on the various concerns associated with the patentability of DNA, see, for example: *Genetics, Testing & Gene Patenting*, *supra* note 1; *The Ethics of Patenting DNA*, *supra* note 4; *Genes and Ingenuity*, *supra* note 5 at c. 3; Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* (Ottawa: CBAC, 2002), online: Canadian Biotechnology Advisory Committee <<http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html>> [CBAC, 2002 Report]; Canadian Biotechnology Advisory Committee, *Human Genetic*

Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians (Ottawa: CBAC, 2005), online: Canadian Biotechnology Advisory Committee <[http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/CBAC_FINAL-REPORT_English_Oct14-05.pdf/\\$FILE/CBAC_FINAL-REPORT_English_Oct14-05.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/CBAC_FINAL-REPORT_English_Oct14-05.pdf/$FILE/CBAC_FINAL-REPORT_English_Oct14-05.pdf)> [CBAC, 2005 Report]; World Health Organization, *Genetics, genomics and the patenting of DNA: Review of potential implications for health in developing countries* (2005), online: World Health Organization <<http://www.who.int/genomics/en/FullReport.pdf>> [WHO, Patenting of DNA].

¹⁵ Emphasis added. *Patent Act*, *supra*, note 10, s. 2.

¹⁶ Robert T. Hughes, *Patent Legislation and Commentary*, 2005/2006 ed. (Markham, Ont.: LexisNexis Butterworths, 2005) at 9.

¹⁷ Canadian Intellectual Property Office, *Manual of Patent Office Practice*, s. 12.02, online: Industry Canada <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/mopop_dn ld-e.html> [MOPOP].

¹⁸ *Patent Act*, 35 U.S.C. § 101.

¹⁹ *Patents Act 1990* (Cth.), s. 18.

²⁰ Emphasis added. *Convention on the Grant of European Patents*, 5 October 1973, 13 I.L.M. 268, online: European Patent Office <<http://www.european-patent-office.org/legal/epc/e/ma1.html>>.

²¹ *Ibid.*, art. 57.

²² Emphasis added. Japan, *Patent Act*, Law No. 121 (1959), cited in Japan Patent Office, *Examination Guidelines for Patent and Utility Model in Japan*, Part II, ch. 1, online: Japan Patent Office <http://www.jpo.go.jp/quick_e/index_tokkyo.htm> [Japan, Examination Guidelines, Chapter 1].

²³ Japan, *Examination Guidelines*, Chapter 1, *ibid.*

²⁴ *The Ethics of Patenting DNA*, *supra* note 4 at 31. See also Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Aldershot, England: Ashgate, 2005) at 4. A footnote in the *TRIPS Agreement*, *infra* note 29, indicates that member states may consider the two expressions synonymous. See United Nations Conference on Trade and Development & International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development/UNCTAD-ICTSD* (Cambridge: Cambridge University Press, 2005) at 361 [UNCTAD-ICTSD].

²⁵ See *The Ethics of Patenting DNA*, *ibid.*, which states that although industrial applicability is broader than utility, the two expressions are equivalent, as per the English decision in *Chiron v. Murex*, [1996] F.S.R. 153, [1996] R.P.C. 535 (C.A.).

²⁶ See *UNCTAD-ICTSD*, *supra* note 24.

²⁷ *Genetics, Testing & Gene Patenting*, *supra* note 1 at 32.

²⁸ *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 at para. 167 [Harvard Mouse].

²⁹ *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994) 25 Int'l Rev. Ind. Prop & C'right L. 209, art. 27(1) [TRIPS Agreement]. See also CBAC, 2005 Report, *supra* note 14 at 36, n. 95; Donald L. Zuhn, Jr., “DNA Patentability: Shutting the Door to the Utility Requirement” (2001) 34 *J. Marshall L. Rev.* 973 at 996.

³⁰ CBAC, 2005 Report, *ibid.*

³¹ *Ibid.* Note; however, that there are substantial differences in terms of how various member states interpret and apply the patentability requirements. The *TRIPS Agreement*, *supra* note 29, imposes minimum standards for the protection of intellectual property. It has been more effective at reaching procedural harmonization rather than substantive harmonization. The *TRIPS Agreement* only requires that member states make available patents (i.e. that people have the right to obtain a patent) irrespective of the technology: “Availability does not mean, however, that a patent needs to be granted in all circumstances”. Also note that the *EU Biotechnology Directive*, *infra* note 83, does not violate the non-discrimination principle because the *TRIPS Agreement* gives member states flexibility in terms of how they interpret and apply the patentability requirements. It also allows member states, at article 57, to exclude from

- patentability certain inventions in order to protect *ordre public*. See UNCTAD-ICTSD, *supra* note 24 at 362, 370; WHO, *Patenting of DNA*, *supra* note 14 at 16-17.
- ³² See WHO, *Patenting of DNA*, *ibid.* at 16, 36, according to which “there is contention as to whether TRIPS requires countries to grant patents on DNA sequences”.
- ³³ *The Ethics of Patenting DNA*, *supra* note 4 at 31.
- ³⁴ See, for example: “Human Genome Project Information”, *supra* note 6; Holman & Munzer, *supra* note 7 at 749.
- ³⁵ Holman & Munzer, *ibid.* at 758. See also Demaine & Fellmeth, *supra* note 12 at 323; Eileen McMahon, “Nucleic Acid Sequences and Other Naturally Occurring Products: Are They Patentable in Canada?” (1993) 10 C.I.P.R. 11 at 19.
- ³⁶ Bernard R. Glick & Jack J. Pasternak, *Molecular Biotechnology: Principles and Applications of Recombinant DNA*, 2d ed. (Washington, D.C.: ASM Press, 1998) at 651. See also *The Ethics of Patenting DNA*, *supra* note 4 at 91; Watson *et al.*, *supra* note 8 at 651.
- ³⁷ *Biology Online*, s.v. “chromosome marker”, online: Biology-Online.org <http://www.biology-online.org/dictionary/chromosome_marker>.
- ³⁸ Karen F. Lech, “Human Genes Without Functions: Biotechnology Tests the Patent Utility Standard” (1993) 27 Suffolk U.L. Rev. 1631 at 1652. See also Caulfield, Gold & Cho, *supra* note 3 at 229.
- ³⁹ Holman & Munzer, *supra* note 7 at 772.
- ⁴⁰ *Ibid.* at 749.
- ⁴¹ CBAC, *2005 Report*, *supra* note 14 at 7.
- ⁴² *Lowell v. Lewis*, 15 F. Cas. 1018 (Cir. Ct. D. Mass. 1817). See Zuhn, *supra* note 29 at 985-986.
- ⁴³ Zuhn, *ibid.*; Mark Christopher Farrell, “Designer DNA for Humans: Biotech Patent Law Made Interesting for the Average Lawyer” (2000) 35 Gonz. L. Rev. 515 at 526, n. 79.
- ⁴⁴ *Brenner, Commissioner of Patents v. Manson*, 383 U.S. 519 at 534-535 (1966) [*Brenner v. Manson*].
- ⁴⁵ *Ibid.* See Zuhn, *supra* note 29 at 974, n. 12, 986ff.
- ⁴⁶ *Brenner v. Manson*, *supra* note 44 at 535.
- ⁴⁷ *Ibid.* at 536.
- ⁴⁸ *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 447 U.S. 303 at 309 (1980).
- ⁴⁹ See “Human Genome Project Information”, *supra* note 6; Demaine & Fellmeth, *supra* note 12 at 319.
- ⁵⁰ “The Fate of Gene Patents”, *supra* note 13 at para. 8.
- ⁵¹ Holman & Munzer, *supra* note 7 at 750; Zuhn, *supra* note 29 at 978. But see *ibid.* according to which over 20,000 gene sequences were claimed.
- ⁵² See Zuhn, *ibid.* at 982.
- ⁵³ *Utility Examination Guidelines*, 60 Fed. Reg. 36263, 36264 (1995). See “PTO Examination Guidelines on Utility Requirements” (1995) 50 Pat. Trademark & Copyright J. 295 at 303.
- ⁵⁴ Zuhn, *supra* note 29 at 991.
- ⁵⁵ *Ibid.* at 983.
- ⁵⁶ Claire O’Brien, “US decision ‘will not limit gene patents’” (1997) 385 Nature 755. See also Meredith Wadman, “NIH is likely to challenge genetic ‘probe’ patents” (1997) 386 Nature 312.
- ⁵⁷ O’Brien, *ibid.*
- ⁵⁸ Meredith Wadman, “Patent office replies to fears over ESTs” (1997) 386 Nature 747 at 747.
- ⁵⁹ See *Genetics, Testing & Gene Patenting*, *supra* note 1 at 48; Martin Enserink, “Patent Office May Raise The Bar on Gene Claims” (2000) 287 Science 1196 at 1196.
- ⁶⁰ Enserink, *ibid.*
- ⁶¹ *The Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Cir. 1997). See Holman & Munzer, *supra* note 8 at 768-770.
- ⁶² *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (2001). See *Genetics, Testing & Gene Patenting*, *supra* note 1 at 47.
- ⁶³ *Genes and Ingenuity*, *supra* note 5 at c. 6, s. 6.110; *Genetics, Testing & Gene Patenting*, *ibid.*
- ⁶⁴ *Genes and Ingenuity*, *ibid.*; *Genetics, Testing & Gene Patenting*, *ibid.*
- ⁶⁵ *Genes and Ingenuity*, *ibid.*
- ⁶⁶ § 2107 (8th ed. 2001, rev. May 2004). See *In re Fisher*, *supra* note 11 at 1372. The Nuffield Council on Bioethics has expressed concern with the United States approach, suggesting that the term “credible” has been interpreted as meaning “theoretically possible”. See *The Ethics of Patenting DNA*, *supra* note 4 at 31. See also *Genes and Ingenuity*, *ibid.* at c. 6, s. 6.115.
- ⁶⁷ Zuhn, *supra* note 29 at 998. See also “The Fate of Gene Patents”, *supra* note 13 at para. 9.
- ⁶⁸ “The Fate of Gene Patents”, *ibid.* at para. 12.
- ⁶⁹ *Ibid.* at para. 13.
- ⁷⁰ *Ibid.* at para. 14.
- ⁷¹ *Ibid.* at para. 3. See also *Genetics, Testing & Gene Patenting*, *supra* note 1 at 47.
- ⁷² Demaine & Fellmeth, *supra* note 12 at 304.
- ⁷³ Holman & Munzer, *supra* note 7 at 770ff.
- ⁷⁴ “Human Genome Project Information”, *supra* note 6.
- ⁷⁵ *In re Fisher*, *supra* note 11.
- ⁷⁶ *Ibid.*
- ⁷⁷ *Ibid.*
- ⁷⁸ *Ibid.*
- ⁷⁹ See *Genes and Ingenuity*, *supra* note 5 at c. 6, s. 6.114; Japan Patent Office, *Examination of Biotech-related Applications at the Japan Patent Office* (2004), online: The National Academies <http://www7.nationalacademies.org/step/Tamura1_presentation_Bellagio_proteomics.pdf>.
- ⁸⁰ European Patent Office, *Guidelines for Examination in the European Patent Office* (2005), Part C, c. IV, s. 4.5, online: European Patent Office <http://www.european-patent-office.org/legal/gui_lines/pdf_2005/index.html> [EPO, *Examination Guidelines*]. See also *Genes and Ingenuity*, *ibid.*
- ⁸¹ *Genes and Ingenuity*, *ibid.*; U.K., Patent Office, *Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Patent Office* (2005), online: The UK Patent Office <<http://www.patent.gov.uk/patent/reference/biotechguide/biotech.pdf>>.
- ⁸² EPO, *Examination Guidelines*, *supra* note 80. See also *Genes and Ingenuity*, *ibid.* at c. 6, s. 6.113.
- ⁸³ EC, *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, [1998] O.J.L 213/13, art. 5(3) [EU *Biotechnology Directive*]. See also *Genes and Ingenuity*, *ibid.*
- ⁸⁴ IP Australia, *Australian Patents for Biological Inventions: Fact Sheet*, online: Australian Government: IP Australia <<http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf>>.
- ⁸⁵ *Genes and Ingenuity*, *supra* note 5 at c. 6, s. 6.142.
- ⁸⁶ CBAC, *2005 Report*, *supra* note 14 at 37. See also *Genetics, Testing & Gene Patenting*, *supra* note 1 at 47; CBAC, *2002 Report*, *supra* note 14 at 21. Note, however, that CIPO is currently updating the chapter of the MOPOP which deals with the utility requirement. See *MOPOP*, *supra* note 17.
- ⁸⁷ *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 525 [*Consolboard*].
- ⁸⁸ McMahon, *supra* note 35 at 20.
- ⁸⁹ *Prentice v. Dominion Rubber Co.*, [1928] Ex. C.R. 196 at 199 [*Prentice*]. See also *Wandscheer et al. v. Sicard Ltd.* (1947), [1948] S.C.R. 1.
- ⁹⁰ *MOPOP*, *supra* note 17, s. 12.03.
- ⁹¹ *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 at 83 (Patent Appeal Board and Commissioner of Patents) [*Abitibi*].
- ⁹² *Ibid.* at 91.
- ⁹³ McMahon, *supra* note 35 at 19; *MOPOP*, *supra* note 17, s. 12.03.
- ⁹⁴ *Harvard Mouse*, *supra* note 28 at para. 31.
- ⁹⁵ It is not clear exactly when the *MOPOP* was amended in this fashion.
- ⁹⁶ Emphasis added. *Prentice*, *supra* note 89.
- ⁹⁷ *Ibid.*
- ⁹⁸ *Northern Electric Co. v. Brown's Theatres Ltd.* (1939), [1940] Ex. C.R. 36 at 53 [*Northern Electric*, Exchequer Ct]. This case was affirmed by the

Supreme Court of Canada, who did not comment on the validity of the claims: [1941] S.C.R. 224. See McMahon, *supra* note 35 at 19.

⁹⁹ Emphasis added. *Northern Electric*, Exchequer Ct, *ibid.* at 56.

¹⁰⁰ *Ibid.*

¹⁰¹ *Ibid.* at 57.

¹⁰² *Re Application No. 003,389 of N.V. Organon* (1973), 15 C.P.R. (2d) 253 at 256 [*Organon*].

¹⁰³ *Ibid.* at 258-259.

¹⁰⁴ Emphasis added. *Consolboard*, *supra* note 87 at 525.

¹⁰⁵ The only decision identified, which refers to the Supreme Court of Canada's adoption of the *Halsbury's Laws of England* passage on utility in *Consolboard*, is *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2005] F.C. 1205 at para. 69 (T.D.).

¹⁰⁶ [1989] 1 S.C.R. 1623 at 1626 [*Pioneer*].

¹⁰⁷ Emphasis added. *Ibid.* at 1636-1637.

¹⁰⁸ *Ibid.*

¹⁰⁹ Emphasis added. *Northern Electric*, Exchequer Ct, *supra* note 98 at 56.

¹¹⁰ *Re McIntyre* (sub nom. *Re Application for Patent of McIntyre*), (1992), 53 C.P.R. (3d) 532 at 533 [*McIntyre*].

¹¹¹ *Ibid.* at 534.

¹¹² Emphasis added. *Ibid.* at 536-537.

¹¹³ *Ibid.* at 534.

¹¹⁴ *Ibid.* at 536.

¹¹⁵ *Cochlear Corp. v. Cosem Neurostim Ltée* (1995), 64 C.P.R. (3d) 10 at 13-14 [*Cochlear*].

¹¹⁶ Emphasis added. *Ibid.* at 33.

¹¹⁷ *Ibid.* at 35.

¹¹⁸ *Prentice*, *supra* note 89 at 199; *Northern Electric*, Exchequer Ct, *supra* note 98 at 56; *Organon*, *supra* note 102 at 258.

¹¹⁹ *Consolboard*, *supra* note 87 at 525.

¹²⁰ *MOPOP*, *supra* note 17, s. 12.03.

¹²¹ While an invention must be "useful for some purpose but not any particular purpose...", an invention must produce results which are beneficial to the public to meet the utility requirement. See *ibid.*

¹²² *Northern Electric*, Exchequer Ct, *supra* note 98 at 56.

¹²³ *Prentice*, *supra* note 89 at 199.

¹²⁴ *Cochlear*, *supra* note 115 at 33.

¹²⁵ See also *Jamb Sets Ltd. v. Carlton* (1963), [1964] Ex. C.R. 377 at para. 39 aff'd (1965), 46 C.P.R. 192 (S.C.C.); *McPhar Engineering Co. v. Sharpe Instruments*, [1956-1960] Ex. C.R. 467 at para. 53, 35 C.P.R. 105.

¹²⁶ See McMahon, *supra* note 35 at 19, 21.

¹²⁷ *MOPOP*, *supra* note 17, s. 12.03.

¹²⁸ *Ibid.*

¹²⁹ *Ibid.*, s. 12.02.01.

¹³⁰ For example, "practical utility" and "commercial success" provide evidence of an inventive step, because they indicate that there was a need for the invention. They are not, however, determinative to the issue of inventiveness. See *Diversified Products Corp. v. Tye-Sil Corp. Ltd.* (1991), 35 C.P.R. (3d) 350 at 367 (F.C.A.). See also *Samuel Parkes & Co. Ltd. v. Cocker Bros. Ltd.* (1929), 46 R.P.C. 241; *R. v. Uhlemann Optical Co.* (1949), [1950] Ex. C.R. 142, aff'd (1951), [1952] 1 S.C.R. 143; *R. v. American Optical Co.*, [1950] Ex. C.R. 344; *Emmanuel Simard & Fils (1983) Inc. v. Raydan Manufacturing Ltd.* (2005), 41 C.P.R. (4th) 385 (F.C.T.D.); *Kramer v. Lawn Furniture Inc.* (1974), 13 C.P.R. (2d) 231 (F.C.T.D.), aff'd (1979), 43 C.P.R. (2d) 231 (F.C.T.D.); *Wright v. Brake Service Ltd.*, [1926] S.C.R. 434.

¹³¹ Holman & Munzer, *supra* note 7 at 749-750. See also *The Ethics of Patenting DNA*, *supra* note 4 at 47; Zuhn, *supra* note 29 at 178.

¹³² Bobrow & Thomas, *supra* note 3 at 763; Holman & Munzer, *ibid.* at 749. Note that s. 12.05 of the *MOPOP* lists examples of subject-matter that lack utility, or that are not recognized as statutory subject-matter: *MOPOP*, *supra* note 17. One such example is an "intermediate transitory product with no inherent commercial use per se". This is based on the Commissioner of Patents decision in *Re Application 298,822 to Babcock & Wilcox Company* (1981) (now patent 1,116,380) C.D. No. 821,

online: CIPO <http://patents1.ic.gc.ca/details_comdec?comdec_number=821&-n=0&-p=0&-t=0&-l=E>, according to which: "usefulness in further processing is implied in the definition of expression 'intermediate product', but such usefulness does not necessarily imply patentability. A further usefulness must be inherent in the intermediary product..." This decision has not been cited by Canadian courts and it is not clear whether it relates to the issue of utility or subject-matter.

¹³³ *The Ethics of Patenting DNA*, *supra* note 4 at 56.

¹³⁴ Holman & Munzer, *supra* note 7 at 750.

¹³⁵ In fact, according to Zuhn, *supra* note 29 at 982, even their use as probes and markers is sometimes unclear. See also *Genetics, Testing & Gene Patenting*, *supra* note 2 at 35.

¹³⁶ "ESTs: Gene Discoveries Made Easier", *supra* note 9.

¹³⁷ See Kevles & Berkowitz, *supra* note 2 at 236; Zuhn, *supra* note 29 at 978-979; McMahon, *supra* note 35 at 19; John J. Doll, "The Patenting of DNA" (1998) 280 *Science* 689 at 689; Stefan Lorkowski & Paul Cullen, eds., *Analysing Gene Expression: a handbook of methods: possibilities and pitfalls*, (Weinheim, N.Y.: Wiley-VCH, 2003) vol. 2 at 770.

¹³⁸ *McIntyre*, *supra* note 110 at 536-537.

¹³⁹ See *supra* notes 87-90 and accompanying text.

¹⁴⁰ *MOPOP*, *supra* note 17, s. 12.03; *Consolboard*, *supra* note 87 at 525.

¹⁴¹ *The Ethics of Patenting DNA*, *supra* note 4 at 56.

¹⁴² Holman & Munzer, *supra* note 7 at 760.

¹⁴³ *The Ethics of Patenting DNA*, *supra* note 4 at 57.

¹⁴⁴ [2002] 4 S.C.R. 153 [*Apotex*].

¹⁴⁵ *Ibid.* at 180.

¹⁴⁶ *Ibid.* at 186-187.

¹⁴⁷ *Ibid.* at 180.

¹⁴⁸ [1979] 2 S.C.R. 1108 [*Monsanto*].

¹⁴⁹ [1970] R.P.C. 157 (Ch.D.).

¹⁵⁰ [1976] 1 S.C.R. 555.

¹⁵¹ (1982), 65 C.P.R. (2d) 73, 42 N.R. 587.

¹⁵² *Ibid.* at 77.

¹⁵³ *Ibid.*

¹⁵⁴ *Apotex*, *supra* note 144 at 186.

¹⁵⁵ *Ibid.*

¹⁵⁶ *MOPOP*, *supra* note 17, s. 12.03.01.

¹⁵⁷ *Ibid.*

¹⁵⁸ *Monsanto*, *supra* note 148 at 1119.

¹⁵⁹ See *MOPOP*, *supra* note 17, s. 12.02; Lori B. Andrews, "Genes and Patent Policy: Rethinking Intellectual Property Rights" (2002) 3 *Nature Reviews Genetics* 803 at 803.

¹⁶⁰ Holman & Munzer, *supra* note 7 at 749.

¹⁶¹ David B. Resnik, *Owning the Genome: A Moral Analysis of DNA Patenting* (Albany: State University of New York Press, 2004) at 19.

¹⁶² Holman & Munzer, *supra* note 7 at 749.

¹⁶³ Gerald Karp & Peter van de Geer, *Cell and Molecular Biology: Concepts and Experiments*, 4th ed. (Hoboken, NJ.: John Wiley, 2005) at 60.

¹⁶⁴ See *ibid.* at 55, 57, 61.

¹⁶⁵ See *ibid.* at 60.

¹⁶⁶ Holman & Munzer, *supra* note 7 at 749.

¹⁶⁷ Japan Patent Office, *Examination Guidelines for Patent and Utility Model in Japan*, Part VII, c. 2 at 39, online: Japan Patent Office <http://www.jpo.go.jp/quick_e/index_tokkyo.htm> [Japan, *Examination Guidelines*, Chapter 2].

¹⁶⁸ *Ibid.*

¹⁶⁹ Glick & Pasternak, *supra* note 36 at 535.

¹⁷⁰ *Ibid.* at 535, 537. See also Lorkowski & Cullen, *supra* note 137 at 772.

¹⁷¹ *MOPOP*, *supra* note 17, s. 12.03.01, which speaks of "structure-activity relationship".

¹⁷² See Japan, *Examination Guidelines*, Chapter 2, *supra* note 167 at 39-40.

¹⁷³ *Ibid.*

¹⁷⁴ *Apotex*, *supra* note 144 at 185-186.

¹⁷⁵ Holman & Munzer, *supra* note 7 at 765.

¹⁷⁶ CBAC, *2005 Report*, *supra* note 14 at 37. See also *Genetics, Testing & Gene Patenting*, *supra* note 1 at 47; CBAC, *2002 Report*, *supra* note 14.

¹⁷⁷ WHO, *Patenting of DNA*, *supra* note 14 at 15.

¹⁷⁸ For a discussion on the patenting of research tools, see Rebecca Eisenberg, "Patenting Research Tools and the Law" in *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington, D.C.: National Academic Press, 1997) at c. 2, online: <<http://stills.nap.edu/html/property/2.html#2>>. For a discussion on the potential impact of DNA patenting on research and innovation, see, for example: *The Ethics*

of Patenting DNA, *supra* note 4; WHO, *Patenting of DNA*, *supra* note 14; Michael A. Heller & Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 *Science* 698, online: *Science*, AAAS <<http://www.sciencemag.org/cgi/content/full/280/5364/698>>; Donald J. Willison & Stuart M. MacLeod, "Patenting of genetic material: Are the benefits to society being realized" (2002) 167 *Can. Med. Assoc. J.* 259, online: *CMAJ* <<http://www.cmaj.ca/cgi/reprint/167/3/259>>.

¹⁷⁹ CBAC, *2005 Report*, *supra* note 14 at 7.

¹⁸⁰ Zuhn, *supra* note 29 at 992.

¹⁸¹ Farrell, *supra* note 43 at 528.